The VIOLA Study

Validating **I**ndividualized breast cancer screening by **O**ffering a new **L**ink in **A**ccess

Protocol Identifying Number: Pro00053749

Principal Investigator: Anna Daily, Ph.D.

Funded by: Namida Lab, Inc.

Version Number: v.0.4

10 May 2021

Table of Contents

List of Abbreviations

AE	Adverse Event
CFR	Code of Federal Regulations
CIOMS	Council for International Organizations of Medical Science
CLIA	Clinical Laboratory Improvement Amendments
CMP	Clinical Monitoring Plan
CMS	Centers for Medicare and Medicaid Services
CRF	Case Report Form
CRO	Contract Research Organization
DCC	Data Coordinating Center
DHHS	Department of Health and Human Services
DSMB	Data Safety Monitoring Board
eCRF	Electronic Case Report Forms
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Amendments Act of 2007
FFR	Federal Financial Report
GCP	Good Clinical Practice
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
GWAS	Genome-Wide Association Studies
HIPAA	Health Insurance Portability and Accountability Act
IB	Investigator's Brochure
ICH	International Conference on Harmonization
ICH E6	International Conference on Harmonization Guidance for Industry, Good Clinical Practice: Consolidated Guidance
ICMJE	International Committee of Medical Journal Editors
IDE	Investigational Device Exemption
IND	Investigational New Drug Application
IRB	Investigational Review Board
ISO	International Organization for Standardization
MedDRA	Medical Dictionary for Regulatory Activities
MOP	Manual of Procedures
MSDS	Material Safety Data Sheet
NIH	National Institutes of Health
NIH IC	NIH Institute & Center
OHRP	Office for Human Research Protections
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SMC	Safety Monitoring Committee
SOP	Standard Operating Procedure
UP	Unanticipated Problem
US	United States

Statement of Compliance

The VIOLA Study will be carried out in accordance with Good Clinical Practice (GCP) as required by the following:

- US Code of Federal Regulations applicable to clinical studies (45 CFR 46)
- ICH GCP E6
- Completion of Human Subjects Protection Training

Protocol Summary

Title: Validating Individualized breast cancer screening by Offering a new Link in Access

Short Title: The VIOLA Study

Précis: The VIOLA Study is a Clinical Utility Study to investigate the useability of Melody®, a tear-based screening assay for breast cancer developed and validated by Namida Lab, Inc., a high complexity CLIA certified lab.

The VIOLA Study will have multiple study sites, with a minimum participation of 205 women who are 40 to 74 years of age, at average risk for developing breast cancer, asymptomatic, and have no concerns or breast abnormalities.

Melody® consists of two parts: tear sample collection and clinical lab assay. Participants will have a tear sample collected at a study site. The clinical lab assay, Melody®, will be performed at Namida Lab, Inc. The results of the Melody® assay will be returned to the site clinician to be discussed with the participant.

Objectives: Primary Objective: Investigate the clinical utility of Melody® in federally qualified health centers in populations with historically low compliance rates with screening mammography.

Secondary Objective: Assess how incorporating Melody® into a primary care provider setting affects participation and confidence in the current breast health continuum of care.

Endpoint: Primary endpoint: The VIOLA Study is designed to quantify the relationship between two variables: an exposure and an outcome, by utilizing different study sites and recruiting from a diverse population.

Secondary endpoint: Quantifying the relationship between Melody® and increased participation in breast health care offers the clinical utility evidence required for adoption into the Standard of Care.

Population: Women ages 40-74 years old, at average risk for developing breast cancer

Number of Sites: 3+ sites

Study Agent: Melody® is a tear-based, high complexity lab-developed test. Melody® has been developed, validated, and will only be run by Namida Lab, Inc. as a tool in breast cancer screening.

Study Duration: 6-12 months

Participant Duration: Six months

Schematic of Study Design

The VIOLA Study: Validating Individualized breast cancer screening
by Offering a new Link in Access

Define – Month 1-6 Study Design/Site Enrollment

Recruit and consent study sites
Establish study site principal investigator and study agreement consent
On-board and train study site personnel
Define study site opportunity/channels for study participant recruitment
Create study site materials from approved IRB submission

Measure – Month 5-11 Participant Recruitment/Enrollment (Study Intervention)

Total participants (205 minimum)
Recruit potential participants by inclusion/exclusion criteria
Participant downloads the Namida Lab, Inc. mobile app if they have access to a device
Obtain informed consent from the study participant
Obtain participant's history/demographics from surveys/questionnaires
Sample Collection – Site-specific: Sample may be collected as a walk-in or scheduled appointment

Analyze – Month 5-11 Baseline Assessments/Study Intervention

Study participant tear sample sent to Namida Lab, Inc.
Namida Lab, Inc. conducts Melody® assay on participant samples
Namida Lab, Inc. returns Melody® assay results to the study site investigator/clinician/personnel
Study site clinician and Namida Lab, Inc. review Melody® assay results, if requested
Study site clinician and study participant review Melody® assay results

Improve – Month 5-11 Follow-Up (Assessments of Study Endpoints/Safety)

Study participant completes exit survey/questionnaire
Study site personnel completes exit survey/questionnaire
Namida Lab, Inc. distributes compensation to study participants
Ongoing data analysis at Namida Lab, Inc.

Control – Month 12 End of Study Assessment

Namida Lab, Inc. completes all data analysis from study site personnel and participants
Namida Lab, Inc. closes sites/study

**Appendix A: Visual Diagram of Study Schematic*

1. Key Roles

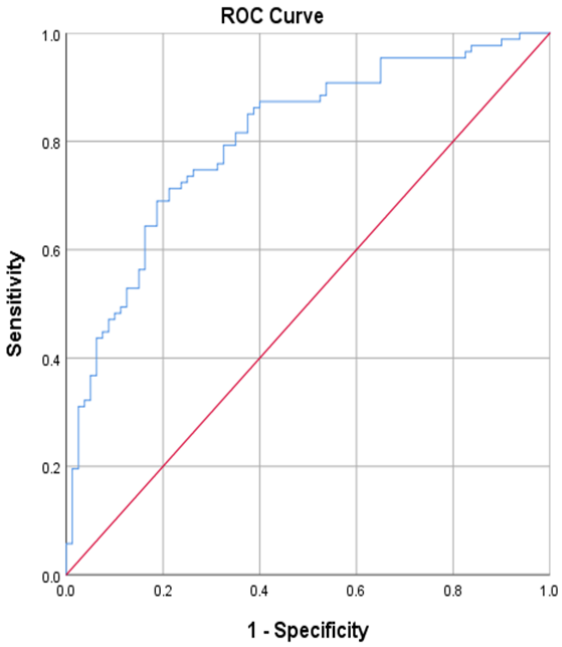
Anna Daily, Ph.D.
VP of Product Development & Innovation
Principal Investigator
Namida Lab, Inc.
1905 E Mission Blvd, Ste 6
Fayetteville, AR 72703
479.334.2828
anna@namidalab.com

Shelby VanHoutan, MBA
Clinical Research Coordinator
Namida Lab, Inc.
1905 E Mission Blvd, Ste 6
Fayetteville, AR 72703
479.334.2828
shelby@namidalab.com

2. Introduction: Background Information and Scientific Rationale

2.1 Background Information

Determining the Sensitivity and Specificity of the Melody® assay



ROC curve for Breast Cancer vs. Healthy Controls.

Analysis of the development data set was outsourced to the statistical firm Elite Research, Irvine, TX, to develop an algorithm and scoring system by which samples could be classified. Stepwise linear regression analysis of the development data set (224 healthy controls and 45 confirmed breast cancer samples) was used to determine relevant covariates and produce a screening algorithm and scoring system. The coordinates of the ROC curve were used to select a diagnostic threshold of 0.1.

A smaller validation sample set (167 healthy controls and 15 breast cancer samples) was used to test the algorithm and diagnostic cutoff, followed by clinical validation of Melody® in the CLIA lab with 50 healthy control samples and 50 breast cancer samples.

False-positive and false-negative rates were determined strictly based on Melody® classification, not score. Tear samples were collected at the time of imaging procedures, tested at Namida Lab, Inc., and assigned a score and classification before confirming the final diagnosis from our clinical partner. Once received, the final diagnosis was then compared to the classification of High or Low determined through the Melody® algorithm.

Patients who were given a Low Melody® classification but tested positive for breast cancer were

considered false negatives. This occurred for 8% of samples. Patients were given a High Melody® classification, but no area of concern or suspicion was detected on their mammogram classified as false positive. This occurred in 46% of samples.

A standard screening population would typically be entering the continuum of care for a screening mammogram and would fall between the ages of 40-70. All healthy controls were collected at the time of the screening mammogram. Breast cancer samples were typically collected at the time of biopsy or diagnostic MRI. Previous imaging procedures were provided by clinical partners when providing diagnostic information.

Eighty-four percent of the breast cancer samples were collected from women entering the continuum of care at screening mammograms. Approximately five percent of breast cancer samples did not have any screening and were initially seen due to an area of concern. Sample collection for these individuals occurred at biopsy or diagnostic MRI. Screening procedures were not recorded for eight percent of breast cancer samples of the population.

Age distribution of the entire patient population was as expected, with 85% of our samples falling within the normal screening age range of 40-70. Specifically:

- 2% were < 39 years of age,
- 30% were 40-49 years of age,
- 25% were 50-59 years of age,
- 30% were 60-69 years of age,
- 13% were >70 years of age.

The VIOLA Study is a Clinical Utility Study to investigate the useability of Melody®, a tear-based screening assay for breast cancer. Melody® was developed and validated by Namida Lab, Inc., a high complexity Clinical Laboratory Improvement Amendments (CLIA) certified lab.

Key terms

- The Clinical Laboratory Improvement Amendment (CLIA) passed in 1988 was established to provide quality standards, strengthen federal oversight of clinical laboratories, and ensure the reliability and accuracy of patient test results. This program allows clinical labs to develop and validate their testing protocols which can only be run in the lab where the protocol was validated.
- Namida Lab, Inc. is a CLIA certified high complexity lab. (Appendix H)
- The FDA is responsible for developing and assigning CLIA test complexity categorization rules and guidance.
- Melody® is a high complexity lab-developed test that has been developed and validated by Namida Lab, Inc. and will be run only by Namida Lab, Inc.
- A clinical utility study evaluates the usefulness, benefits, and drawbacks of an intervention (1).

What is the Validation process for an LDT?

Requirements for validation of a lab-developed test are clearly outlined by CLIA (2).

- In short, each assay must meet guidelines for precision, accuracy, sensitivity, and specificity (both analytical and clinical), linearity, and assay range.
- Each laboratory drafts an umbrella Standard Operating Procedure (SOP) to conduct

validation of new assays.

- This SOP is then customized to each specific test the lab intends to offer. The medical director must approve all SOPs, and subsequent changes to SOPs, in the CLIA lab.
- After completing validation experimentation, all results are compiled in a validation report and then reviewed and approved by the medical director.

All CLIA labs are under the jurisdiction of their respective state, CLIA licensing boards, and undergo an inspection every two years. At the time of inspection, the lab must provide validation reports for all assays available on their testing menu for review.

What was the outcome for the validation of Melody®?

Designing the validation of Melody® was unique; because there are no lab-developed tests using protein biomarkers in tears, to our knowledge. The nature of the sample alone provided a new level of challenge that made the validation process more stringent. A summary of parameters analyzed and the results for the validation can be found in Table 1 and Table 2.

All performance criteria were successfully achieved. Clinical validation resulted in a sensitivity of 92% and a specificity of 54%. These values were in line with previously observed sensitivity and specificity values from development work (work unpublished).

Table 1: Summary of Analytical Validation

Study Parameter	Sample Description (Name, Number, Replicates)	Results	Comparison to Acceptance Criteria (Pass/Fail)
Accuracy	20 spiked LGF samples	Percent recovery between 80-120% for all samples	Pass
Intra-Assay Precision	24 replicates of 3 concentrations per analyte	All %CV less than or equal to 15%	Pass
Inter-Assay Precision	Duplicates of 3 concentrations 1xday for five days.	All %CV less than or equal to 15%	Pass
Sensitivity	20 replicates of blank per protein	S100A8 11% 21.10 pg/ml S100A9 14% CV 24.32 pg/ml	Pass
Linearity	7 unknown concentrations	Percent difference less than 15% for all samples	Pass

Table 2: Summary of Clinical Validation

Study Parameter	Sample Description (Name, Number, Replicates)	Results	Comparison to Acceptance Criteria (Pass/Fail)
Accuracy	26 samples 3 replicates each sample	92%	Pass
Sensitivity	52 LGF samples in duplicate	92%	Pass
Specificity	50 LGF samples in duplicate	54%	Pass
Stability of LGF samples	One pooled disease LGS One pooled non-disease LGS	N/A	Refer to Deviations and Section B, Number 4

What exactly is Melody®?

Part 1: Tear sample collection

Tear samples are collected using a small strip of filter paper, called a Schirmer strip, a Class I Medical Device typically used to test for dry eye. The strips have been repurposed for our need to collect tear (lacrimal) fluid and the subsequent proteins from the ocular cavity following protocols outlined in the literature (3, 4).

Tear collection is conducted through the following steps (Figure 1):

1. The strip is placed in the participants' lower eyelid, and having a foreign object in the eye will cause the eye to water.

(The tear (lacrimal) fluid released washes the inner surface of the eyelid and the ocular lens itself, allowing proteins to adhere to the strip.)

2. The strip is left until the liquid reaches the 25 mm mark or 5 minutes has passed.
3. The strip is then placed in a tube containing a buffered solution and is shipped overnight to Namida Lab, Inc.

Figure 1: Collection of tear sample.

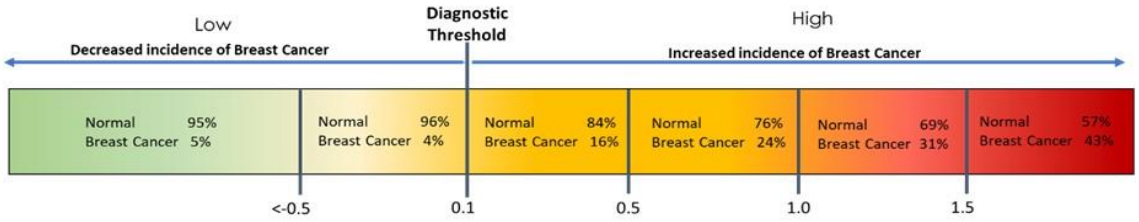
Part 2: Clinical Lab assay

During shipment, the proteins leave the strip and go into the buffered solution in the tube. It is

this solution that is evaluated using standard ELISA techniques in the high complexity CLIA lab. Namida Lab, Inc. is outfitted with a Hamilton Star Plus automated ELISA system. The data generated from the ELISA assay is used together with demographic information to generate a Melody® score. The score is then compared to the diagnostic threshold, and classification of High or Low is reported.

Site clinicians will receive a report containing both the score and the classification for the participant. In addition, the site clinicians will be given a Melody® scale (Figure 2) as a reference to use when discussing the results with the study participants. (Appendix I) It will be up to the individual site clinician's discretion to provide participants with a copy of their test results.

*Figure 2: Melody® Scale**



*The Melody® scale was generated using 705 samples evaluated during development and validation. Percentages in each range show the distribution of normal and breast cancer patients that fall within each range. The distribution of scores along the scale will continually be updated as new data is collected.

Melody® has been developed and validated as a breast cancer screening test. Melody® is not a replacement for screening mammography but is intended to be an adjunct testing option. The ideal patient population is women who are at a low-to-average risk for breast cancer (i.e., no family history, at or below 12% calculated lifetime risk, have not been labeled high risk by previous screening facility). These women may not be motivated to participate in yearly screening mammography or have easy access to a screening facility.

Research and development efforts are ongoing to optimize the diagnostic parameters, emphasizing methods to reduce the high false-positive rate. Future-focused studies will look at additional applications of Melody® for women with dense breasts, clarification of BiRADS category 3, and diagnostic applications to elucidate benign vs. breast cancer. These future-focused directions were developed in collaboration with key opinion leaders in breast cancer screening and breast cancer surgical oncology.

2.2 Rationale

About 1 in 8 US women, close to 13%, will develop invasive breast cancer throughout their lifetime. The most significant risk factors for breast cancer are sex, being a woman, and age, growing older. Evidence shows that national mammography screening programs have sufficiently reduced breast cancer-related mortality. Therefore, the utility of mammography used as a screening tool is not the subject in question.

However, both false-positive and false-negative breast cancer diagnosis, excessive biopsies, and irradiation linked to mammography application, as well as sub-optimal mammography-based screening, such as in the case of high-dense breast tissue in young females, altogether increase

awareness among the experts regarding the limitations of mammography-based screening (5).

Disparities in screening mammography are decreasing among medically underserved populations but persist among racial/ethnic minorities and low-income women. Additionally, uninsured women and those with no usual care have the lowest rates of reported mammogram use. Despite apparent increases in mammogram utilization, there is growing evidence that limitations in the national survey databases lead to overestimations of mammography-based screening, particularly among low-income racial and ethnic minorities (6).

A significant consideration of the Clinical Utility Study, VIOLA, is addressing the barriers such as cost, language and acculturation limitation, deficits in knowledge and cultural beliefs, literacy, and health system barriers such as insurance and having a source of regular medical care (7,8). Severe concerns regarding mammography as the "golden standard" approach, the demand for a complementary innovative strategy, and screening tool to cover the evident deficits are under review in the VIOLA Study.

2.3 Potential Risks and Benefits

2.3.1 Known Potential Risks

Possible risks from participation in study, questionnaires, and medical consultations might include minimal psychological discomfort.

- The survey questions will ask about personal experiences, family medical history, possible reproductive experiences such as pregnancy, menstrual cycles, and the body.
- The survey questions ask about personal breast health experiences, which may cause discomfort for some participants.

Possible risks from the collection of tears are rare but include conjunctivitis or scleral/corneal abrasion.

- Conjunctivitis is inflammation of the delicate membrane covering the internal part of the eyelid and is attached to the cornea.
- Scleral/corneal abrasion is irritation of the sclera, which is the white of the eye, or of the corneal, which is the membrane that covers the pupil and iris of the eye.

Possible risks from the test results include the potential for false-positive and false-negative results.

- False positives do occur. A false-positive result occurs when you receive a Melody® classification of High even though a screening mammogram finds no area of concern. The false-positive rate of Melody® is 46%.
- False negatives do occur. A false-negative result occurs when you receive a Melody® classification of Low even though a screening mammogram indicates an area of concern. The false-negative rate of Melody® is 8%.

2.3.2 Other Risks

There could be other unforeseeable risks.

2.3.3 Known Potential Benefits

The known potential benefits to participation in the VIOLA Study are indirect to the participant.

The benefit(s) may be incidental to participation:

- The study will likely yield generalizable knowledge about the participant's disorder or condition.
- The study will likely yield generalizable knowledge to understand the disorder or condition under study further.
- The study will likely yield participants contributing to knowledge, sharing experiences to benefit others, and potentially affecting a condition, culture, perspective, and feeling useful.

3. Objectives and Purpose

3.1 Primary Objective

Most women recognize screening mammography as the current gold standard in breast cancer screening. However, disparities are present, leaving groups of women without adequate access to screening. Gaps in access to screening exist due to geographic location, socio-economic status, race, and ethnicity (9).

3.2 Secondary Objective

Currently, Melody® is not intended to replace screening mammograms but an additional tool to facilitate more discussions between providers and patients. Tear sample collection can be done during any routine office visit and does not require specially trained personnel. The accessible collection allows patients to be tested in a clinic environment they are already familiar with by personnel they already know and trust. The goal for early iterations of Melody® is one more piece of clinical information gathered, leading to additional conversations about breast health, which may be the key to increased participation in annual or bi-annual screening mammograms.

3.3 Exploratory Objective

The clinical utility of a test is related to the value-added it has for patient management. A test has utility if its results (positive or negative) provide valuable information to the patient and the provider in making decisions about effective clinical care. It can take the form of improved efficiency in clinical decision making, streamlined clinical workflow, better patient outcomes, and/or cost offsets or avoidance.

The level of clinical utility evidence required will likely depend upon a variety of factors, including the current Standard of Care (SOC), the setting of care, and potential cost offsets to mitigate the added cost of care, as well as the magnitude of the cost of the test itself.

The VIOLA Study is primarily concerned with the use of Melody®, its impact on mammography screening rates, and the overall participation in the breast health continuum of care. Proving Melody's® clinical utility through effective clinical outcomes, economically efficient implementation, and adoptability in a workflow is crucial for incorporating the Standard of Care.

4. Study Design and Endpoints

4.1 Description of the Study Design

Analytical Observational Study

In analytical observational studies, researchers try to establish an association between

exposure(s) and outcome(s) (10). Depending on the direction of inquiry, these studies can be directed forward, known as cohort studies, or backward known as case-control studies.

The VIOLA Study is an analytical study designed to quantify a relationship or association between two variables – an exposure and an outcome. The exposure, Melody®, is pre-determined for all participants to receive as opposed to experimental studies where an investigator assigns each participant to receive or not receive a particular exposure.

The VIOLA Study was designed to be directed forward using a cohort population at multiple study sites. A cohort is defined as a "group of people with a shared characteristic." In cohort studies, different groups of people with varying levels of exposure are followed over time to evaluate the occurrence of an outcome. Melody® does not have varying levels of exposure but is an overall new exposure for the population.

This observational study will not dictate the cancer screening regimens that the site clinicians and participants utilize. Instead, this study collects data on individuals' cancer screening practices, cancer outcomes, and other factors if needed. Because no regimens are dictated, the VIOLA Study can capture information about and evaluate various cancer screening practices, including the use of different tests or cancer screening regimens.

The association of exposure to outcome this study is attempting to define: How does the use of Melody® before mammography affect participation rates in breast cancer screening?

4.2 Study Endpoints

4.2.1 Primary Endpoint

It is common knowledge that disparities exist in breast health, preventative care, and screening mammography. Namida Lab, Inc. knows the potential of Melody® to be a tool that bridges the gap between underserved populations and positive health outcomes. The administration of Melody® does not require additional appointments or trips and can be done by any member of a medical team.

As such, Namida Lab, Inc. is partnering with federally qualified health centers and large employers to evaluate the clinical utility of Melody®. Do women in populations with historically low compliance rates with screening mammography, who receive Melody® as the first step in the breast health continuum of care, participate in screening mammograms at higher rates than previous years?

4.2.2 Secondary Endpoint

Melody® will be offered by prescription only through a recognized medical study site. Results will be delivered to the site clinician and communicated to the participant through standard study site workflows. Namida Lab, Inc. is interested in evaluating if this additional clinician/participant consultation around Melody® test results will foster more participant confidence in the current continuum of care. Thus, increasing compliance with recommended breast cancer prevention and health screening guidelines.

4.2.3 Exploratory Endpoint

A widely accepted definition of clinical utility for an assay is that the assay results lead to a clinical decision with a high level of evidence to improve patient outcomes (11). Step one, Melody®, provides accurate diagnostic screening information. Step two, Melody's® results, when used in managing patients, given the benefits and harms, improves health outcomes in a clinically perceivable way compared with alternative management strategies. Melody® is proven useful if its results are actionable, driving a treatment decision that leads to a better outcome.

In a broad sense, the utility may be as simple as showing that Melody® provides equivalent or increased sensitivity and specificity, leading to equivalent or improved management decisions. Melody® is less invasive or incurs less patient harm. Melody® is less costly, providing, at minimum, the same benefit with fewer resources. Melody® is more widely or readily available than current screening options. Thus, more likely to be used to make patient management decisions across a more significant number of women. Does the clinical utility of Melody® increase participation in the breast health continuum of care?

5. Study Enrollment and Withdrawal

5.1 Participant Inclusion Criteria

To be eligible to participate in this study, an individual must meet all the following criteria:

- Female
- 40 to 74 years old
- Able to undergo the informed consent process
- Willingness to comply with all study procedures
- Available for the duration of the study
- In good general health and at average risk for developing breast cancer

5.2 Participant Exclusion Criteria

An individual who meets any of the following criteria will be excluded from participation in this study:

- Male*
- Currently diagnosed or are receiving treatment for breast cancer
- Have an uninvestigated area of suspicion or concern in their breast

*Note: While Namida Lab, Inc. understands that breast cancer also affects men, there are not enough samples in the repository from men with breast cancer to ensure the accuracy of the results of Melody® for men.

5.3 Strategies for Recruitment and Retention

Target sample size:

- An a priori power analysis was conducted using G*Power v3.1.9.2 to determine the minimum sample size required to find significance with a desired level of power set at 0.80 and alpha (a) level at 0.05. Based on this analysis, it was determined that a **minimum of 205 participants** were required to ensure adequate power for a Pearson's Chi-square Test of Independence. (12, 13, 14)

The anticipated site participants' accrual rate will vary; all sites and participants will be located within the United States. Participants will be recruited from outpatient clinics, larger employers, and/or the general public. Participant recruitment venues are site-specific, for example, outpatient clinic monthly clinical breast exam events. Potential participants will be identified and approached using inclusion/exclusion criteria and site-specific events and/or communication channels.

While exact recruitment methods will be specific to each site, the material will be made available in versions suitable for flyers, email, post through social media, or distributed by mail. Forward-facing participant recruitment materials have been submitted separately with indications on how it can be personalization to each site.

The VIOLA Study participants are all women due to the development and validation of Melody®. The objectives and endpoints encourage minorities, employee volunteers, economically disadvantaged, and/or a medically underserved population to participate in the VIOLA Study. The justification for involving vulnerable populations is because they are primarily affected by disparities in the healthcare system. Employee volunteers are included because study sites provide current medical care and have a trusted relationship with the employee volunteer as a current patient.

Careful considerations have been included in the study design and recruitment process to ensure minimal harm/risks and maximum participant protection. Participants will have access to translated study materials and access to additional healthcare navigation if needed. Employers will not be notified of study participation or Melody® results; participation or nonparticipation is confidential. Each participant will receive a $25 Walmart gift card when completing the VIOLA Study, and there is no cost to participate.

5.4 Participant Withdrawal or Termination

5.4.1 Reasons for Withdrawal or Termination

Participants are free to withdraw from the study at any time upon request. The sponsor-investigator or site-investigator may terminate a participant in the study if:

- Any clinical adverse event (AE), laboratory abnormality, or other medical condition or situation that occurs as continued participation in the study would not be in the participant's best interest.
- The participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation.
- The participant fails to follow directions for participating in the study.
- The study is canceled and/or for administrative reasons.

5.4.2 Handling of Participant Withdrawal or Termination

Participants may request to withdraw from the study at any time. Participants that choose to withdraw early from the study will be voluntarily surveyed for reasons for withdrawal. The site investigator should advise the participant if any safety procedures are recommended and determine if the participant is willing to complete those along with any other end of study activities.

Participants will be asked for permission to continue to utilize the data collected after the point of

withdrawal for study purposes. If they decline, all data past the note of withdrawal will be deleted from the record system. However, please note that the FDA requires that any information collected up to participant withdrawal cannot be removed from the study.

Participants that are employed by a study site are under no obligation to participate in the study. Employees may withdraw from the study at any time and for any reason. Neither the decision to participate in the study nor any decision to withdraw will affect performance appraisal or employment. Any employee may refuse to participate or may withdraw from the study at any time without penalty or anyone blaming the employee.

5.4.3 Withdrawal Process in Mobile App

Participants will have the option to withdraw from the study by tapping a "Withdraw from Study" button within the app. This action will disable notifications and will result in a cessation of data collection. If a participant calls the study site requesting withdrawal from the study, the study personnel will instruct the participant on initiating withdrawal on the app. It will not be possible for any party other than the participant to withdraw from the study within the app.

In the few cases where the participant has received a notification and has initiated contact with the study personnel and then selects "Withdraw from Study" on the app, they may still receive follow-up communication from the study personnel. In order to stop further communication, these participants would need to inform the site personnel that they wish to be withdrawn.

5.5 Premature Termination or Suspension of Study

This study may be suspended or prematurely terminated if there is sufficient reasonable cause. If the study is prematurely terminated or suspended, the sponsor-investigator will promptly inform the IRB and provide the reason(s) for the termination or suspension. Site investigators can request suspension of the Namida Lab, Inc. app to stop the research. The study may resume once concerns about safety, protocol compliance, data quality is addressed and satisfy the sponsor, IRB, and/or FDA.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Demonstration of efficacy that would warrant stopping
- Insufficient compliance to protocol requirements
- Data that are not sufficiently complete and/or evaluable
- Determination of futility

6. Study Agent

6.1 Study Agent Description

6.1.1 Acquisition

The complete Melody® assay collection kit consists of 25 single-use tear collection pouches and return shipping materials. The complete Melody® collection kit used at study sites will be obtained from Namida Lab, Inc. The collection kit components for tear sample collection and return shipping will be acquired directly from their production facilities by Namida Lab, Inc. According to participant enrollment rates, kits will be disbursed to the site investigator. Disbursement schedules will be arranged between Namida Lab, Inc. and study sites. (Appendix F)

6.1.2 Formulation, Appearance, Packaging, and Labeling

The component products included for single-use tear collection are Schirmer strips, collection tubes, and sterile 1x PBS solution. Components for tear sample collection will be in a sealed, tamper-proof pouch with only one set of single-use materials. The pouches will not use a commercial appearance. A label will be affixed to each complete Melody® collection kit box and single-use pouch with large text stating that the products are for the VIOLA Clinical Utility Study Only.

The complete Melody® collection kit box will include, if applicable: the name of the product(s), a model number(s), a description of the product(s), safety, use, storage information, and manufacturer contact information. In addition, if applicable, any standard product manual package inserts will be included. The inserts detail safety information, a description of the product, directions for use, technical support, product specifications, regulatory statements, a component list, and packaging symbol and definition legends.

An affixed label will instruct users to consult an additional study-specific package insert that will also be included for use modifications on this insert. (Appendix F) This package insert will contain the name and description of this clinical study, new directions for use detailing the study indications and study procedure, and contact information for the sponsor-investigator and site investigators.

6.1.3 Product Storage and Stability

No seal will be broken until the site clinician is ready to collect the tear sample from the participant. Expiration dates will be verified before any seal is broken. According to the instruction manual specifications for temperature, humidity, and pressure, collection kits will be housed in a secure, designated location at the study sites. The collection kits will only be accessible to trained study personnel at the site until use.

6.1.4 Administration of Study Agent

All site investigators, clinicians, and personnel will receive hands-on training for the appropriate tear collection method and the proper time frame for the return shipment of tear samples. The Instructions for Use (IFU) will be available at all study sites and included in the collection kit box. (Appendix E)

6.1.5 Results of Study Agent Administration

In addition to the tear sample collection, sites will receive the participant Melody® result reports. The participant Melody® assay results will be returned digitally through a secure and encrypted messaging platform. Each site will have a designated inbox and will only have access to its site-specific participants. (Appendix I)

6.2 Study Agent Accountability Procedures

According to the disbursement schedule, collection kits and return shipping materials will be distributed to the study sites, which will specify ownership, storage, and use. The kit materials will be received by site personnel who have been trained in the safe handling and proper interim storage requirements. According to the study protocol and any site policies, the study site

personnel will maintain the proper receipt and transfer of all study products.

Should study products be unused and not defective or expired, they will be assigned to the next applicable study participant should the product not expire before the anticipated next enrollment. Defective, damaged, or expired products will be reported to Namida Lab, Inc. and disposed of or otherwise processed according to site-specific and manufacturer policies.

7. Study Procedures and Schedule

7.1 Study Procedures / Evaluations

7.1.1 Study Specific Procedures

All procedures listed are specific to the study and not considered part of standard clinical care. Specific questions and content are provided in the protocol appendix.

- Participant's informed consent will be obtained electronically through Namida Lab, Inc. mobile app if the participant has access to a device.*
- Study participant background questionnaire (Demographics, Medical History, Medication History, Family Medical History)
- Biological specimen collection and laboratory evaluation. (Melody® assay: tear sample collection)
- A discussion/medical consultation of the Melody® assay results will be provided to the participant.
- Administration of questionnaires regarding the assessment of study agent, Melody®, and patient-reported outcomes.

*The study sites will have devices on-site or permit paper submissions for participants who do not have their own devices.

7.1.2 Mobile App Eligibility and Enrollment Procedures

The potential participant will first download the Namida Lab, Inc. app. The app will automatically ensure compatibility with the iPhone iOS version and Android version. If compatible, the participant will continue forward in the app. (Appendix R). **See 7.1.6 for alternatives to digital.**

The participant will advance to a screen for new user enrollment to create a secure user account within the Namida Lab, Inc. mobile app. The participant will select the VIOLA Study from the list of available studies. The app will require a digital authentication token to determine eligibility for the study, which participants will receive from Namida Lab, Inc. during recruitment.

The study anticipates a substantial volume of participants screened and consented in the initial days following study opening. There is a potential risk of overwhelming the study infrastructure if all participants can instantly enter the study. To maintain operational efficiency, the study monitors will use an enrollment metering schema.

Participants eligible for inclusion may be delayed in consent and enrollment (participant recruitment and enrollment portion of the study). Enrollment metering will be adaptable based on study and clinical bandwidths, with metering instituted by invitation to consent.

7.1.3 Mobile App Consent, Baseline Demographics, and Medical History Collection

The Namida Lab, Inc. mobile application allows for secure and remote electronic consent and

participation in clinical research and utility studies. The Namida Lab, Inc. app utilizes the ResearchKit and ResearchStack open-source frameworks on the iOS and Android platforms.

As in other mobile-mediated research and studies, the informed consent process in the Namida Lab, Inc. app is conducted remotely in an entirely self-administered setting with no required contact with the study personnel before consent and enrollment. The approach to informed consent for the study has been adapted accordingly to ensure the ethical requirement of informedness, i.e., that participants are adequately informed about the study before participation, is met. **See 7.1.6 for alternatives to digital.**

Potential candidates and enrolled participants will be able to contact study site personnel and have the ability to ask questions and request clarifications at any time before or during the study. This site personnel will be available from the study start date until study closure. Participants who successfully pass the eligibility criteria will be directed to a page requesting their consent to participate. Participants will be asked to read and sign the informed consent and authorization document within the app if they agree to volunteer or participate. A copy of the signed informed consent and authorization document will be available for review and download to the participant via the app.

The participant will be considered 'enrolled' from this point. After consenting to participate, the participant will be directed to complete a brief questionnaire to collect self-reported baseline demographics and medical history. (Appendix D)

7.1.4 Overall Procedures for Enrolled Participants

After completing the baseline demographics and medical history questionnaires, the participant will schedule a sample collection appointment/walk-in at their study site. The study personnel will collect the tear sample and return it to Namida Lab, Inc. Namida Lab, Inc. will perform the Melody® assay lab-developed test and return the participant's results to their study site. The site clinician will review the Melody® results with the participant.

The participant will receive a notification informing them that the exit questionnaire has been published and is available to complete. Upon completing the exit survey, the participant will be notified that their participation in the study is complete. They will receive instructions to claim the $25 Walmart gift card.

7.1.5 Standard of Care Study Procedures

The Standard of Care is determined by the site investigator, clinicians, and personnel. It is not within the scope of our expertise or study endpoints to define the participant's path of care beyond the safe collection of the tear sample and medically supervised consultation of Melody® results.

7.1.6 Alternatives to Study Participation without Mobile Application

If the participant does not have access to a smartphone/tablet and/or affordable cellular data plans, they will not be excluded from the study. All sites will have a Namida Lab, Inc. provided tablet that participants may access to participate in the study.

If the participant chooses not to use the designed digital path, Namida Lab, Inc. will provide the

necessary physical copies of the study material. Each site will have physical copies of all study material, i.e., informed consent and questionnaires. The study personnel will engage with participants in the study using a traditional clinical trial model.

7.2 Laboratory Procedures / Evaluations

7.2.1 Clinical Laboratory Evaluations

Melody®, a tear-based screening assay for breast cancer developed and validated by Namida Lab, Inc., a high complexity CLIA certified lab.

7.2.2 Specimen Preparation, Handling, and Storage

The trained clinician and personnel will follow the step-by-step tear sample collection Instructions for Use (IFU) at the study site. (Appendix E)

At Namida Lab, Inc., the trained laboratory personnel will follow the step-by-step Standard Operating Procedure (SOP) for specimen preparation, handling, and storage. (Appendix G)

7.2.3 Specimen Shipment

After the tear sample has been collected from the participant, it should be placed in the pre-paid FedEx envelope for overnight shipment to Namida Lab, Inc. The sample must be mailed to Namida Lab, Inc. at 1905 Mission Blvd, Ste 6 Fayetteville AR 72703 (Attn: Kelsey Kirchner) on the same day it was collected.

Namida Lab, Inc. will accept samples Monday through Thursday, excluding holidays. There are no special shipping requirements such as cold storage or biospecimen labels. The postage is pre-paid, and Namida Lab, Inc. provides all shipping materials.

7.3 Study Schedule

7.3.1 Recruitment / Enrollment

Participant Recruitment / Enrollment (Study Intervention)

- Obtain informed consent of the potential participant.
- Obtain medical history to determine eligibility based on inclusion/exclusion criteria.
- Schedule visits for participants who are eligible and available for the duration of the study.
- Provide participants with site-specific instructions needed to prepare for the first study visit.

7.3.2 Baseline Assessments / Study Intervention

(Enrollment) / Baseline Visit / Study Intervention

- Obtain informed consent of potential participants verified by signature on study informed consent form.
- Verify inclusion/exclusion criteria.
- Obtain demographic information, medical history, and medication history.
- Collect tear (lacrimal) fluid sample for Melody® assay.
- Site-specific procedures, instructions provided to participants, observations after tear collection.

7.3.3 Follow-Up / Final Study Visit

Follow-up Visit (Assessment of Study Endpoints / Safety)

- Site-specific procedures and instructions provided to participants to review assay results: Melody® Scale, Score, and Classification.

Script-reporting results

*I received your test results back, and your Melody® classification is **** (High or Low), and your score is***.*

*According to the scale provided by Namida Lab, Inc., in the range, you fall into of *** to *** ***percent of women had breast cancer and ****were normal.*

(It is up to you and your practice's discretion to make recommendations for the next steps in screening)

*This practice follows the *** guidelines, and for a woman of your age and family history, we recommend a screening mammogram.*

(If your practice typically schedules screening mammograms on behalf of patients, you may offer to do that now.)

A member of the Namida Lab, Inc. clinical team will reach out to you with the next steps for the VIOLA Study.

Final Study Visit

- Site-specific procedures and instructions are provided to participants to complete the exit questionnaire(s).
- Site-specific final instructions to the participant if additional care is required.

7.3.4 Early Termination Visit

Site-specific determination to which of the procedures/evaluations required for the final study visit should be done at a termination visit if early termination occurs and if the participant is willing.

7.3.5 Unscheduled Visit

Site-specific as to how unscheduled visit(s) will be handled and documented.

7.3.6 Schedule of Events Table

Procedures	Study Design / Site Enrollment	Participant Enrollment / Screening / Study Intervention	Baseline assessment / Study Intervention	Follow-up Assessments of Study Endpoints / Safety	Follow-Up Assessment of Study Endpoints / Safety	End of Study Assessments

Recruit and consent study site	X					
Establish site PI and study agreement consent	X					
On-board and train study site personnel	X					
Define site opportunity/channel for participant recruitment	X					
Site-specific study materials from approved IRB submission	X					
Total participants (n=x is site-specific)		X				
Participant mobile app Terms of Use		X				
Obtain informed consent		X				
Screen potential participants by inclusion/exclusion criteria		X				
Obtain history/demographics through Questionnaire		X				
Sample Collection (Study Enrollment or Future Appointment – site-specific)		X	X			
Participant sample sent to Namida Lab, Inc.			X			
Namida Lab, Inc. runs Melody® Assay*			X			
Namida Lab, Inc. returns Melody® assay results to study site			X			
Site clinician/Namida Lab, Inc. review Melody® results (if requested)				X		
Site clinician and study participant review Melody® results				X		
Study participant completes exit Questionnaire					X	
Study personnel completes exit Questionnaire					X	
Namida Lab, Inc. distributes study participant incentive					X	
Ongoing study data analysis at Namida Lab, Inc.		X	X	X	X	
Namida Lab, Inc. completes all data of study endpoints from sites and participants						X
Namida Lab, Inc. closes site/study						X
Access to Future Studies** at Namida Lab, Inc.	X	X			X	
*Melody® Assay is a high complexity lab-developed test that has been developed and validated by Namida Lab, Inc. and will only be run by Namida Lab, Inc. **Future studies will be offered in a mobile app; participant will need to meet inclusion/exclusion, Re-Consent for a new study						

7.4 Concomitant Medications, Treatments, and Procedures

All concomitant prescription medications taken during study participation will be recorded as determined by the site investigator. Prescription medication is a medication prescribed only by a properly authorized/licensed clinician for this protocol. If required by site investigators, medications to be reported are concomitant prescription medications, over-the-counter medications, and non-prescription medications.

Per the exclusion criteria, any woman currently in treatment for breast cancer cannot participate in the VIOLA Study. This includes both local therapy and systemic/adjuvant therapy. Local therapy includes surgery, with or without radiation therapy to the breast and nearby lymph nodes. Systemic therapy uses drug therapies that travel throughout the body to get rid of cancer cells. It includes chemotherapy, hormone therapy, and HER2-targeted therapy.

8. Assessment of Safety

8.1 Specification of Safety Parameters

Safety is not an endpoint of this study but is a top concern of the sponsor and all site investigators, clinicians, and personnel. There can be a significant experience between participant and clinician when discussing breast cancer screening and screening results. Participant's overall and general well-being is the most significant safety concern; it is site-specific and primarily monitored by the site investigators and the clinical study personnel.

8.1.1 Definition of Adverse Events (AE.)

Adverse event means any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention-related.

8.1.2 Definition of Serious Adverse Events (SAE)

A serious adverse event or serious suspected adverse reaction: An AE or suspected adverse reaction is considered "serious" if, in the view of either the sponsor or principal investigator, it results in any of the following outcomes: death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions or a congenital anomaly/congenital disability.

Based upon appropriate medical judgment, important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when they may jeopardize the participant. This event may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

No examples of a serious adverse event are available for the administration and use of the study assay, Melody®.

8.1.3 Definition of Unanticipated Problems (UP)

Unanticipated problems involving risks to participants or others to include, in general, any incident, experience, or outcome that meets **all** the following criteria:

- Unexpected in terms of nature, severity, or frequency is given (a) the study procedures that are described in the protocol-related documents, such as the IRB-approved clinical utility study protocol and informed consent document; and (b) the characteristics of the participant population being studied; and
- Related or possibly related to participation in the clinical utility study ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the study); and
- Suggests that the study places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

8.2 Classification of an Adverse Event

8.2.1 Severity of Event

For AEs not included in the protocol-defined grading system, the following guidelines will be used

to describe severity.

- **Mild** – Events require minimal or no treatment and do not interfere with the participant's daily activities.
- **Moderate** – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
- **Severe** – Events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating.

8.2.2 Relationship to Study Agent

The site clinician's assessment of an AE's relationship to the study agent (Melody® assay) is part of the documentation process. However, it is not a factor in determining what is or is not reported in the study. If there is any doubt about whether a clinical observation is an AE, the event should be reported. All AEs must have their relationship to the study agent, Melody®, assessed. In a clinical trial, the study agent must always be suspect. To help assess, the following guidelines are used.

- **Related** – The AE is known to occur with the study agent. There is a reasonable possibility that the study agent caused the AE or a temporal relationship between the study agent and event. Reasonable possibility means there is evidence to suggest a causal relationship between the study agent and the AE.
- **Not Related** – There is no reasonable possibility that the administration of the study agent caused the event, there is no temporal relationship between the study agent and event onset, or an alternate etiology has been established.

8.2.3 Expectedness

The sponsor-investigator will be responsible for determining whether an AE is expected or unexpected. An AE will be considered unexpected if the event's nature, severity, or frequency is not consistent with the risk information previously described for the study agent, Melody®.

8.3 Time Period and Frequency for Event Assessment and Follow-Up

The occurrence of an AE or SAE may come to the attention of study personnel during study visits and interviews of a participant presenting for medical care or upon review by a study monitor.

All AEs, including local and systemic reactions not meeting SAEs' criteria, will be captured on the appropriate CRF. Information to be collected includes event description, time of onset, clinician's assessment of severity, relationship to study product/agent (assessed only by those with the training and authority to make a diagnosis), and time of resolution/stabilization of the event.

All AEs occurring while on study must be documented appropriately regardless of relationship. All AEs will be followed to an adequate resolution.

Any medical condition present at the time that the participant is screened will be considered baseline. Baselines are not reported as an AE. However, suppose the study participant's condition deteriorates at any time during the study. In that case, it will be recorded as an AE. UPs will be recorded in the data collection system throughout the study.

Changes in the severity of an AE will be documented to allow an assessment of the duration of

the event at each level of severity to be performed. AEs characterized as intermittently require documentation of onset and duration of each episode.

The site PI will record all reportable events with start dates occurring after informed consent is obtained until seven days (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation. At each study visit, the site investigator or clinician will inquire about AE/SAEs the occurrence of AE/SAEs since the last visit. Events will be followed for outcome information until resolution or stabilization.

8.4 Reporting Procedures

8.4.1 Adverse Event Reporting

All adverse events will be collected and reported to the IRB and Namida Lab, Inc. regularly and within 30 days.

8.4.2 Serious Adverse Event Reporting

The study site investigator will complete an SAE Form within the following timelines:

- All deaths and immediately life-threatening events, whether related or unrelated, will be recorded on the SAE Form and submitted to Namida Lab, Inc. within 24 hours of site awareness. See **Section 1, Key Roles** for contact information.
- Other SAEs, regardless of relationship, will be submitted to Namida Lab, Inc. within 72 hours of site awareness.
- All SAEs will be followed until satisfactory resolution or until the site investigator deems the event to be chronic or the adherence to be stable. Other supporting documentation of the event may be requested by Namida Lab, Inc. and should be provided as soon as possible.
- Namida Lab, Inc. will be responsible for notifying the IRB/FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than seven calendar days after Namida Lab, Inc.'s initial receipt of the information.

8.4.3 Unanticipated Problem Reporting

All possible unanticipated problems will be reported to the IRB within five (5) days of receiving notice of the event if the event requires immediate intervention to prevent serious harm to participants or others.

All other possible unanticipated problems will be reported to the IRB as soon as possible. Reported no later than ten (10) business days from the date of the event or from the date the sponsor-investigator is notified of the event.

Incidents or events that meet the OHRP criteria for unanticipated problems require creating and completing an unanticipated problem report form. The site investigator's responsibility is to report unanticipated problems to the study sponsor, Namida Lab, Inc., for further reporting to the IRB.

The unanticipated problem report will include the following information:

- Protocol identifying information: protocol title and number, PI's name, and the IRB project number.

- A detailed description of the event, incident, experience, or outcome.
- An explanation of the basis for determining that the event, incident, experience, or outcome represents an unanticipated problem.
- A description of any changes to the protocol or other corrective actions taken or proposed in response to the unanticipated problem.

Sponsor-investigator must promptly report (according to the above schedule) the following events to the IRB if the events occur within thirty (30) days of participants' active participation:

- Adverse events, which in the opinion of the sponsor-investigator, are both unexpected and related.
- An unanticipated event related to the utility study that exposes individuals other than the participants (e.g., investigators, research assistants, students, the public, etc.) to potential risk.
- Information that indicates a change to the risks or potential benefits of the utility study. For example:
    - An interim analysis or safety monitoring report indicates that the frequency or magnitude of harms or benefits may differ from initially presented to the IRB.
    - A paper is published from another study that shows that the study's risks or potential benefits may be different than initially presented to the IRB.
    - A breach of confidentiality.
    - Incarceration of a participant in a protocol not approved to enroll prisoners.
    - Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a participant.
    - Complaint of a participant when the compliant indicates unexpected risks or cannot be resolved by the study personnel.
    - Protocol violation (meaning an accidental or unintentional change to the IRB-approved protocol) that harmed participants or others or that indicates participants or others may be at increased risk of harm.
    - An event that requires prompt reporting to Namida Lab, Inc.
    - Namida Lab, Inc. imposed suspension for risk.
    - Any other event that indicates participants or others might be at risk of serious, unanticipated harms that are reasonably related to the study.

8.5 Study Halting Rules

Administration and result consultations of the Melody® assay will be halted when three grade 3 AEs are determined to be "probably related." The sponsor investigator will notify the IRB immediately when the third grade 3 event is reported, and enrollment screens will stop accepting new participants.

8.6 Safety Oversight

Safety oversight will be the responsibility of the sponsor principal investigator.

9. Clinical Monitoring

Clinical site monitoring is conducted to ensure that the rights and well-being of human subjects are protected. In addition, the reported study data are accurate, complete, and verifiable, and that the conduct of the study follows the currently approved protocol/amendment(s), with GCP,

and with applicable regulatory requirement(s). The study monitor will perform clinical site monitoring. The appointment and responsibilities of the study monitor are defined in section 13.5.

10. Statistical Considerations

10.1 Statistical and Analytical Plans

An a priori power analysis was conducted using G*Power v3.1.9.2 to determine the minimum sample size required to find significance with a desired level of power set at 0.80 and alpha (a) level at 0.05. Based on this analysis, it was determined that a minimum of 205 participants were required to ensure adequate power for a Pearson's Chi-square Test of Independence. (12, 13, 14) (Appendix L)

Each participant will be required to take an enrollment survey that collects information on race, ethnicity, and socio-economic status. Participant's addresses will be obtained as part of the requisition process for the CLIA lab, from which information on geographic location can be obtained. In addition to the factors listed above, the enrollment survey also collects information on status and type of health insurance, reproductive health, breast health knowledge, prior screening history, and family and personal history of cancer.

The exit survey has been designed to collect information on the participant experience with Melody® and comprehension of the information Melody® relayed through their site clinician. In addition, information is collected on participant's intention to schedule/participate in future screening mammograms and/or change in intention to participate in a previously scheduled screening mammogram.

Data will be analyzed using SPSS Statistics software. To determine the presence of significant changes, Unpaired T-tests or Mann-Whitney U-test will be used with a significance level set at $P < 0.05$.

Due to the effect of COVID-19 on screening rates, screening mammogram participation rates will be compared to rates reported for the state of Arkansas in 2019.

10.2 Statistical Hypothesis

Primary endpoint:

- H_o= Participation rates in yearly screening mammography with the incorporation of Melody® (examined by geographic location, socio-economic status, race, and ethnicity) will not be greater than participation rates recorded in 2019.
- H_1= Participation rates in yearly screening mammography with the incorporation of Melody® (examined by geographic location, socio-economic status, race, and ethnicity) will be greater than participation rates recorded in 2019.

Secondary endpoint:

- H_o= Participation rates in yearly screening mammography, with the incorporation of Melody® (examined by clinical sites), will not be greater than participation rates recorded

in 2019.

- H_o= Participation rates in yearly screening mammography, with the incorporation of Melody® (examined by clinical sites), will not greater than participation rates recorded in 2019.

10.3 Analysis Datasets

Primary endpoint datasets will be broken down by classifications outlined in the table below.

Primary Endpoint Characteristic

Ethnicity	
	Hispanic
	Non-Hispanic
Race	
	American Indian-Alaska Native
	Asian
	Black or African American
	Native Hawaiian or Other Pacific Islander
	White
Socio-economic status	
	$35,000 or less
	$35,000-$80,000
	$80,000-$130,000
	$130,000-$200,000
	$200,000 or higher
Geographic Location	
	Metropolitan
	Nonmetropolitan

Analysis of secondary endpoint datasets will be analyzed by comparing screening mammography participation rates reported by the clinical site from 2019 to screening mammography participation rates observed after the study.

10.4 Description of statistical methods

10.4.1 General Approach

For all variables of interest, percent change will be evaluated for statistical significance by Unpaired T-test or Mann-Whitney U-test as appropriate. Statistical significance will be set at $P < 0.05$.

10.4.2 Analysis of primary efficacy endpoints

Data for primary efficacy endpoints will be presented as follows:

Analysis of Primary Efficacy Endpoints

		VIOLA	2019	Total
Ethnicity	Hispanic	N (%of total for VIOLA)	N (% of total for 2019)	N (% of total)
	Non-Hispanic	N (%of total for VIOLA)	N (% of total for 2019)	N (% of total)

P value		***P* =?**		
Race	American Indian-Alaska Native	N (%of total for VIOLA)	N (% of total for 2019)	N (% of total)
	Asian	N (%of total for VIOLA)	N (% of total for 2019)	N (% of total)
	Black or African American	N (%of total for VIOLA)	N (% of total for 2019)	N (% of total)
	Native Hawaiian or other Pacific Islander	N (%of total for VIOLA)	N (% of total for 2019)	N (% of total)
	White	N (%of total for VIOLA)	N (% of total for 2019)	N (% of total)
P value		***P* =?**		
Socio-economic status	$35,000 or less	N (%of total for VIOLA)	N (% of total for 2019)	N (% of total)
	$35,000-$80,000	N (%of total for VIOLA)	N (% of total for 2019)	N (% of total)
	$80,000-$130,000	N (%of total for VIOLA)	N (% of total for 2019)	N (% of total)
	$130,000-$200,000	N (%of total for VIOLA)	N (% of total for 2019)	N (% of total)
	$200,000 or higher	N (%of total for VIOLA)	N (% of total for 2019)	N (% of total)
P value		***P* =?**		
Geographic Location	Metropolitan	N (%of total for VIOLA)	N (% of total for 2019)	N (% of total)
	Nonmetropolitan	N (%of total for VIOLA)	N (% of total for 2019)	N (% of total)
P value		***P* =?**		

10.4.3 Analysis of the Secondary Endpoints

Analysis of the secondary endpoints will be presented as follows:

Analysis of Secondary Endpoints

			VIOLA	**2019**	**Total**
Site 1		Followed through with screening mammogram	N (%of total for VIOLA)	N (% of total for 2019)	N (% of total)
		Did not follow through with screening mammogram	N (%of total for VIOLA)	N (% of total for 2019)	N (% of total)
	P value		***P* =?**		

The analysis will be conducted for each site enrolled in the VIOLA Study.

10.4.5 Adherence and retention analysis

During the participant's journey through the study, there are various points where adherence and retention can be assessed. A log will be generated for each site listing each participant who has enrolled, their contact information, and where they are in the study process.

1. Study enrollment - A list can be generated by the site of participants enrolled. In addition, participants can be tracked via Namida Lab, Inc.'s LIMS system, as an open order will be generated once the participant's enrollment is complete.
2. Sample collection - Once the participant has completed sample collection at their site, the order will be completed, and the sample received by the lab.
3. Exit survey - A notification method will be arranged by site, which will allow site personnel to alert Namida Lab, Inc. when the results have been reported to study participants. Once this has occurred, the participant will be sent an exit survey.
4. After completing the exit survey, the study participant will receive the $25.00 Walmart

gift card incentive. This will allow the study sponsor to track adherence and retention.

11. Source Documents and Access to Source Data/Documents

A Case Report Form will be completed for each participant enrolled in the clinical study. The investigator-sponsor will review, approve, and sign/date each completed CRF; the investigator-sponsor's signature serves as an attestation of the investigator-sponsor's responsibility for ensuring that all clinical and laboratory data are entered into the CRF are complete, accurate, and authentic. Any missing or spurious data will be accompanied by a note to file in the participant's record, which will clarify its reason and any action taken afterward.

Source Data are the clinical findings and observations, laboratory and test data, and other information in Source Documents. Source Documents are the original records (and certified copies of original records); including, but not limited to, all consent forms, app screens, app-based screening forms, regulatory documents, hospital medical records, physician or office charts, physician or nursing notes, participant diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, x-rays, etc. When applicable, information recorded on the CRF shall match the Source Data recorded on the Source Documents.

12. Quality Assurance and Quality Control

12.1 Training

The study site principal investigator, co-investigators, clinicians, and personnel involved in the study who have roles in sample collection and/or Melody® test result consultations have completed training to ensure safety and human ethics compliance. The study site investigator, designated for each site, must be available for participant-requested consultations.

The investigator-sponsor is responsible for site visits and training the appropriate personnel at each study site. This principal investigator will review the method of identifying and enrolling the appropriate participants in the study.

The sponsor principal investigator will provide the necessary documents and forms to assist each study site on participant recruitment, procedural follow-up, and the completion of forms for the study.

Each site shall ensure uniform data collection and protocol compliance as required by the study protocol and associated documents.

12.2 Quality Control Committee

The sponsor principal investigator will be responsible for quality control.

13. Ethics/Protection of Human Subjects *(Participants)*

13.1 Ethical Standard

The study will be conducted according to the current ICH GCP Guidelines and according to local applicable laws and regulations. The IRB will review all appropriate study documentation to safeguard the participants' rights, safety, and well-being. The study will only be conducted at sites

where IRB approval has been obtained. The protocol, sample ICF, advertisements (if applicable), written information is given to participants, safety updates, annual progress reports, and any revisions to these documents will be provided to the IRB by the sponsor-investigator as allowable by local applicable laws and regulations.

13.2 Institutional Review Board

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form must be obtained before any participant is enrolled. Any amendment to the protocol will require review, approval by the IRB before the changes are implemented in the study. All changes to the consent form will be IRB approved; a determination will be made regarding whether previously consented participants need to be re-consented.

13.3 Informed Consent Process

13.3.1 Consent and Other Informational Documents Provided to Participants

Consent forms describing the study agent, study procedures, and risks are given to the participant, and written documentation of informed consent is required before starting intervention/administering the study agent. The following consent materials are submitted with this protocol: Informed consent form, privacy policies, instructions for use, recruitment materials, participant surveys, a sample Melody® report, and Namida Lab, Inc. SOP and CLIA certificate. (Appendix)

The consent form will include the following:

- Purpose statement
- Participant commitment
- Costs
- Risks
- Benefits
- Disclosure of alternative
- Statement of confidentiality
- Study contact information

13.3.2 Consent Procedures and Documentation

Informed consent is a process that is initiated before the individual agrees to participate in the study and continues throughout the individual's study participation. Extensive discussion of risks and possible benefits of participation will be provided to the participant. Consent forms will be IRB-approved, and the participant will be asked to read, review, sign, and date the document.

The site investigator, clinician, and/or trained personnel will explain the utility study to the participant and answer any questions that may arise. All participants will receive a verbal explanation regarding their comprehension of the purposes, procedures, and potential risks of the study and their rights as study participants. Participants will have the opportunity to carefully review the written consent form and ask questions before signing.

The participant will have the opportunity to discuss the study or think about it before agreeing to

participate. The participant will sign the informed consent document before any procedures being done specifically for the study. The participant may withdraw consent at any time throughout the clinical utility study.

A copy of the informed consent document will be available to the participant for their records. The rights and welfare of the participant will be protected by emphasizing to them that the quality of their medical care will not be adversely affected if they decline to participate in this study.

13.3.3 Informed eConsent and HIPAA Authorization

The informed consent will be provided within the study app. It will employ ResearchKit and ResearchStack electronic consent framework for the signature view to obtaining signed and dated informed consent and HIPAA authorization before enrollment. *Traditional paper documents will be available for participants who chose not to use the mobile application.* Signed consent forms will be stored on an encrypted server that is 21 CFR Part 11 compliant. The reviewing IRB must approve the protocol and informed consent form before the commencement of the study. Any subsequent revisions to the informed consent form must also receive IRB approval before use. (Appendix O and Q)

13.4 Participant and Data Confidentiality

Participant confidentiality is strictly held in trust by the participating investigators, their personnel, Namida Lab, Inc., and their agents. This confidentiality is extended to cover the testing of biological samples and genetic tests in addition to the clinical information relating to participants. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence.

All records related to a participant's study data will be stored in locked filing cabinets or on computers protected with passwords. No information concerning the study of the data will be released to any unauthorized third party without the prior written approval of Namida Lab, Inc. The participant will not be identified by name in any publication of the VIOLA Study results.

The study monitor, other authorized representatives of Namida Lab, Inc., or representatives of the IRB may inspect all documents and records required to be maintained by the investigator, including but not limited to survey records, medical records (office, clinic, or hospital) and pharmacy records for the participants in this study. The clinical study site will permit access to such records.

The collection, transfer, and storage of data will be conducted in compliance with the HIPAA Security Rule and structured to minimize the risk of PHI disclosure. All recorded data will be entered into a password-protected database. All data entry forms will be accessed and completed electronically through a password-protected log-on.

All user interaction with the web/app-based system, from transmitting access passwords to entering sensitive participant data, is done via 128-bit encryption using the secure HTTPS protocol. Firewalls ensure that only the minimum traffic required for normal operations can traverse the network of web and database servers. The database production servers will be housed in secure institutional data center facilities and include failover protection designed to

minimize the potential for server downtime. Minimal required personnel are allowed direct access to production facilities. The study data will remain secure and be maximally protected using production-level data center servers. (Appendix M, N, O, P, Q)

13.4.1 Research Use of Stored Human Samples, Specimens, or Data

Intended Use: Samples and data collected under this protocol may be used to study biomarkers for cancer. No genetic testing will be performed.

Storage: Samples and data will be stored using codes assigned by the sponsor investigator. Data will be kept in password-protected computers. Only the sponsor investigator will have access to the samples and data.

Tracking: Data will be tracked using LIMS software at Namida Lab, Inc.

Disposition after the study: All stored samples will remain at Namida Lab, Inc. Study participants who request destruction of samples will be notified of compliance with such requests. All supporting details will be maintained for tracking.

13.5 Future Use of Stored Specimens

Data collected for this study will be analyzed and stored at Namida Lab, Inc. After the study is completed, archived data will remain at Namida Lab, Inc. under the supervision of Dr. Anna Daily. The study data may be available for use by other researchers, including those outsides of the study. Permission to retain data at Namida Lab, Inc. will be included in the informed consent.

These samples could be used for research into identifying different cancers, their complications, and other conditions for which individuals are at increased risk and improve screening and/or treatment.

During the conduct of the study, an individual participant can choose to withdraw consent to have biological specimens stored for future research. However, withdrawal of consent regarding bio-sample storage will not be possible after the study is completed.

13.6 Monitoring

The sponsor principal investigator shall select a Monitor(s) qualified by training and experience to monitor the study. A Monitor may be an employee of the principal investigator's organization or an organization contracted by the principal investigator. The Monitor shall assure that the investigators comply with the signed investigator agreement, the Clinical Investigation Plan/Protocol, IDE regulations, and any conditions of approval imposed by the Investigation Site IRB/EC or FDA.

Routine monitoring will occur to:

- Verify that participant enrollment is being achieved.
- Verify that the inclusion/exclusion criteria have been met at enrollment.
- Verify that the participant has signed the correct version of the informed consent.
- Review the medical records of all enrolled participants to ensure all adverse events have been captured and properly reported.

- Verify that the data and imaging are accurate, complete, and backed up by source documents.
- Verify that all contracts, certifications, and medical licenses for each site are valid through the duration of the study.

14. Data Handling and Record-Keeping

14.1 Data Collection and Management Responsibilities

Data collection is the responsibility of the clinical personnel at the site under the supervision of the site PI. The investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

All source documents should be completed in a neat, legible manner to ensure accurate interpretation of data. Black ink is required to ensure the clarity of reproduced copies. When making changes or corrections, cross out the original entry with a single line and initial and date the change. DO NOT ERASE, OVERWRITE, OR USE CORRECTION FLUID OR TAPE ON THE ORIGINAL.

Copies of the electronic CRF (eCRF) will be provided for use as source documents and maintained for recording data for each participant enrolled in the study. Data reported in the eCRF derived from source documents should be consistent with the source documents. The discrepancies should be explained and captured in a progress note and maintained in the participant's official electronic study record.

Clinical data (including AEs, concomitant medications, and expected adverse reactions data) and clinical laboratory data will be entered into a 21 CFR Part 11-compliant data capture system provided by Namida Lab, Inc. The data system includes password protection and internal quality checks, such as automatic range checks, to identify inconsistent, incomplete, or inaccurate data. Clinical data will be entered directly from the source documents.

14.2 Study Records Retention

The sponsor investigator will maintain records in accordance with Good Clinical Practice guidelines; to include, if applicable:

- FDA correspondence related to the IDE application and Investigational Plan; including copies of submittedform FDA 3500 A, supplemental IDE applications, current investigator lists, progress reports, a notice of device recall or disposition, and failure to obtain informed consent reports.
- IRB correspondence (including approval notifications) related to the clinical protocol, including copies of adverse event reports and annual or interim reports.
- Current and past versions of the IRB-approved clinical protocol and corresponding IRB-approved consent form(s) and, if applicable, participant recruitment advertisements.
- Signed Investigator's Agreements and Certifications of Financial Interests of Clinical Investigators.
- Curriculum vitae (sponsor investigator and clinical protocol site investigators).
- Certificates of required training (e.g., human subject protections, Good Clinical Practice, etc.) for the sponsor investigator and listed site investigators.

- Normal value(s)/range(s) for medical/laboratory/technical procedures or tests included in the clinical protocol.
- Laboratory certification information.
- Instructions for on-site preparation and handling of the tear sample collection kits and/or other study-related materials (i.e., if not addressed in the clinical protocol).
- Signed informed consent forms.
- Completed Case Report Forms; signed and dated by sponsor investigator.
- Source Documents or certified copies of Source Documents.
- Copies of sponsor investigator correspondence to site investigators, including notifications of adverse-effect information.
- Participant screening and enrollment logs.
- Retained biological specimen log.
- Interim data analysis report(s); and the
- Final clinical study report.

Study documents should be retained for a minimum of 2 years after the last approval of a marketing application in an ICH region, if applicable. These documents should be retained for a longer period, however, if required by local regulations. No records will be destroyed without the written consent of Namida Lab, Inc.

14.3 Protocol Deviations

A protocol deviation is any noncompliance with the clinical utility study protocol, GCP, or MOP requirements. The noncompliance may be either on the participant, the investigator, or the study site personnel. As a result of deviations, corrective actions are to be developed by the sponsor investigator and study site and implemented promptly.

These practices are consistent with ICH E6:

- 4.5 Compliance with Protocol, sections 4.5.1, 4.5.2, and 4.5.3
- 5.1 Quality Assurance and Quality Control, section 5.1.1
- 5.20 Noncompliance, sections 5.20.1 and 5.20.2.

Sponsor investigator or study site investigator must not make any changes to or deviate from the protocol, except to protect the life and physical well-being of a participant in an emergency. A site investigator shall notify the sponsor investigator and the reviewing IRB of any deviation from the protocol to protect the life or physical well-being of a participant in an emergency and those deviations that affect the clinical investigator's scientific integrity. Such notice shall be given as soon as possible, but no later than five working days after the emergency occurred, or per prevailing local requirements, if sooner than five working days.

All deviations from the protocol, with the reason for the deviation and the date of occurrence, must be documented and reported to the sponsor investigator using the appropriate case report form. Sites are also required to report deviations to the IRB per local requirements. Deviations will be reviewed and evaluated on an ongoing basis. As necessary, appropriate corrective and preventive actions (including notification, re-training, or discontinuation) will be put into place by the sponsor investigator.

14.3.1 Deviation Classifications

For consistency and reporting, deviations will be classified according to the scheme outlined below:

- Type A - Deviation to protect the life or physical well-being of a participant in an unforeseen emergency.
- Type B - Deviation based on medical judgment.
- Type C - Deviation due to misunderstanding of protocol requirements (training was an issue, and re-training may be required)
- Type D - Deviation due to a situation that is beyond control.
- Type E - Deviation due to an oversight, error, or protocol noncompliance.

If a trend or pattern is observed in a particular deviation type, the sponsor investigator will conduct a compliance visit. Documentation of such a visit and any subsequent training will be documented in the VIOLA Study regulatory binder.

14.4 Publication and Data Sharing Policy

De-identified data will be shared across multiple publication sites. Any publication is the responsibility of the sponsor principal investigator and is not contingent on any outside party. No commercial entity has any right to prevent or change the publication of the data.

15. Study Administration

15.1 Study Leadership

Namida Lab, Inc. will govern the conduct of the study. The Namida Lab, Inc. team will be composed of the Sponsor PI, study monitors, study site investigators, and collaborators.

16. Conflict of Interest Policy

The independence of this study from any actual or perceived influence is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this study will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the study. The study leadership has established policies and procedures for all study group members to disclose all conflicts of interest. It will establish a mechanism for the management of all reported dualities of interest.

17. Literature References

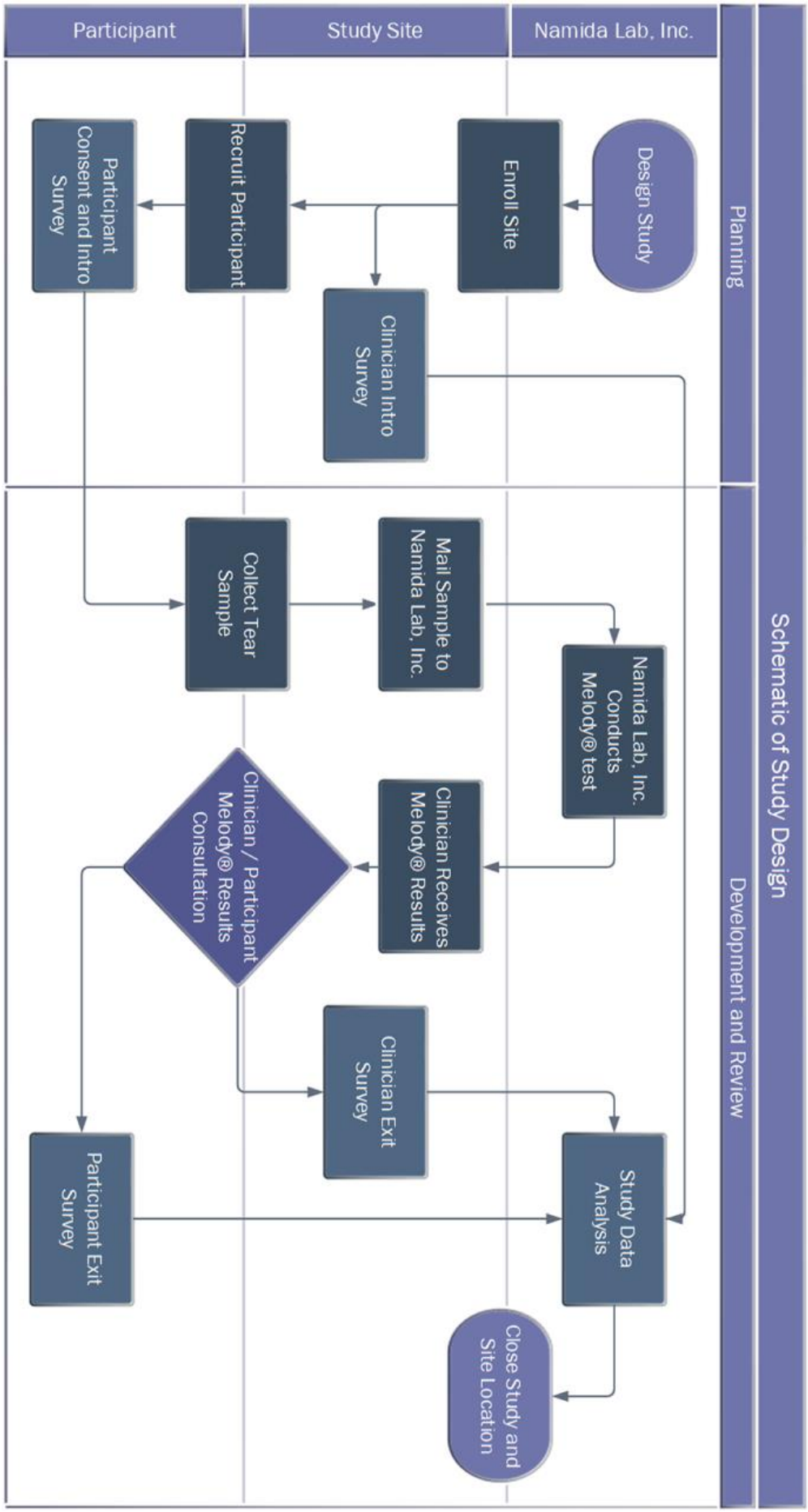
1. Smart A. A multi-dimensional model of clinical utility. Int J Qual Health Care. 2006 Oct;18(5):377-82. DOI: 10.1093/intqhc/mzl034. Epub 2006 Sep 2. PMID: 16951425.
2. Clinical Laboratory Improvement Amendments of 1988 (CLIA) 42 CFR section 493.1253 part (b)(1)(ii)(2003).
3. Grus FH, Joachim SC, Pfeiffer N. Proteomics in ocular fluids. Proteomics Clin Appl. 2007 Aug;1(8):876-88. DOI: 10.1002/prca.200700105. Epub 2007 Jul 18. PMID: 21136741.
4. Posa A, Bräuer L, Schicht M, Garreis F, Beileke S, Paulsen F. Schirmer strip vs. capillary tube method: non-invasive methods of obtaining proteins from tear fluid. Ann Anat. 2013 Mar;195(2):137-42. doi: 10.1016/j.aanat.2012.10.001. Epub 2012 Oct 23. PMID: 23357333.

5. Zubor, P.; Kubatka, P.; Kajo, K.; Dankova, Z.; Polacek, H.; Bielik, T.; Kudela, E.; Samec, M.; Liskova, A.; Vlcakova, D.; Kulkovska, T.; Stastny, I.; Holubekova, V.; Bujnak, J.; Laucekova, Z.; Büsselberg, D.; Adamek, M.; Kuhn, W.; Danko, J.; Golubnitschaja, O. Why the Gold Standard Approach by Mammography Demands Extension by Multiomics? Application of Liquid Biopsy miRNA Profiles to Breast Cancer Disease Management. Int. J. Mol. Sci. 2019, 20, 2878. https://doi.org/10.3390/ijms20122878
6. Peek ME, Han JH. Disparities in screening mammography. Current status, interventions, and implications. J Gen Intern Med. 2004 Feb;19(2):184-94. DOI: 10.1111/j.1525-1497.2004.30254.x. PMID: 15009798; PMCID: PMC1492136.
7. Bossuyt PM, Reitsma JB, Linnet K, Moons KG. Beyond diagnostic accuracy: the clinical utility of diagnostic tests. Clin Chem. 2012 Dec;58(12):1636-43. DOI: 10.1373/clinchem.2012.182576. PMID: 22730450.
8. Bossuyt PM, McCaffery K. Additional patient outcomes and pathways in evaluations of testing. Med Decis Making. 2009 Sep-Oct;29(5): E30-8. DOI: 10.1177/0272989X09347013. Epub 2009 Sep 2. PMID: 19726782.
9. McElfish PA, Su LJ, Lee JY, Runnells G, Henry-Tillman R, Kadlubar SA. Mobile Mammography Screening as an Opportunity to Increase Access of Rural Women to Breast Cancer Research Studies. Breast Cancer (Auckl). 2019 Sep 23;13:1178223419876296. DOI: 10.1177/1178223419876296. PMID: 31579384; PMCID: PMC6757489.
10. Ranganathan P, Aggarwal R. Study designs: Part 3 - Analytical observational studies. Perspect Clin Res. 2019;10(2):91-94. doi:10.4103/picr.PICR_35_19
11. Lesko LJ, Zineh I, Huang SM. What is clinical utility, and why should we care? Clin Pharmacol Ther. 2010 Dec;88(6):729-33. DOI: 10.1038/clpt.2010.229. PMID: 21081937.
12. Cohen, J. (1988). Statistical power analysis for the behavioral sciences (2nd ed.) Hillsdale, NJ: Lawrence Erlbaum Associates.
13. Erdfelder, E., Faul, F., & Buchner, A. (1996). G*Power: A general power analysis program. Behavior Research Methods, Instruments & Computers, 28, 1-11. Retrieved from http://link.springer.com/article/10.3758/BF03203630.
14. Faul, F., Erdfelder, E., Lang, A.G., & Buchner, A. (2007). G*Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. Behavior Research Methods, 39 (2), 175-191. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/17695343.
15. FDA. (2020, May 29). FDA's MyStudies Application (App) Technical Background. FDA.gov. https://www.fda.gov/drugs/science-and-research-drugs/fdas-mystudies-application-app-technical-background

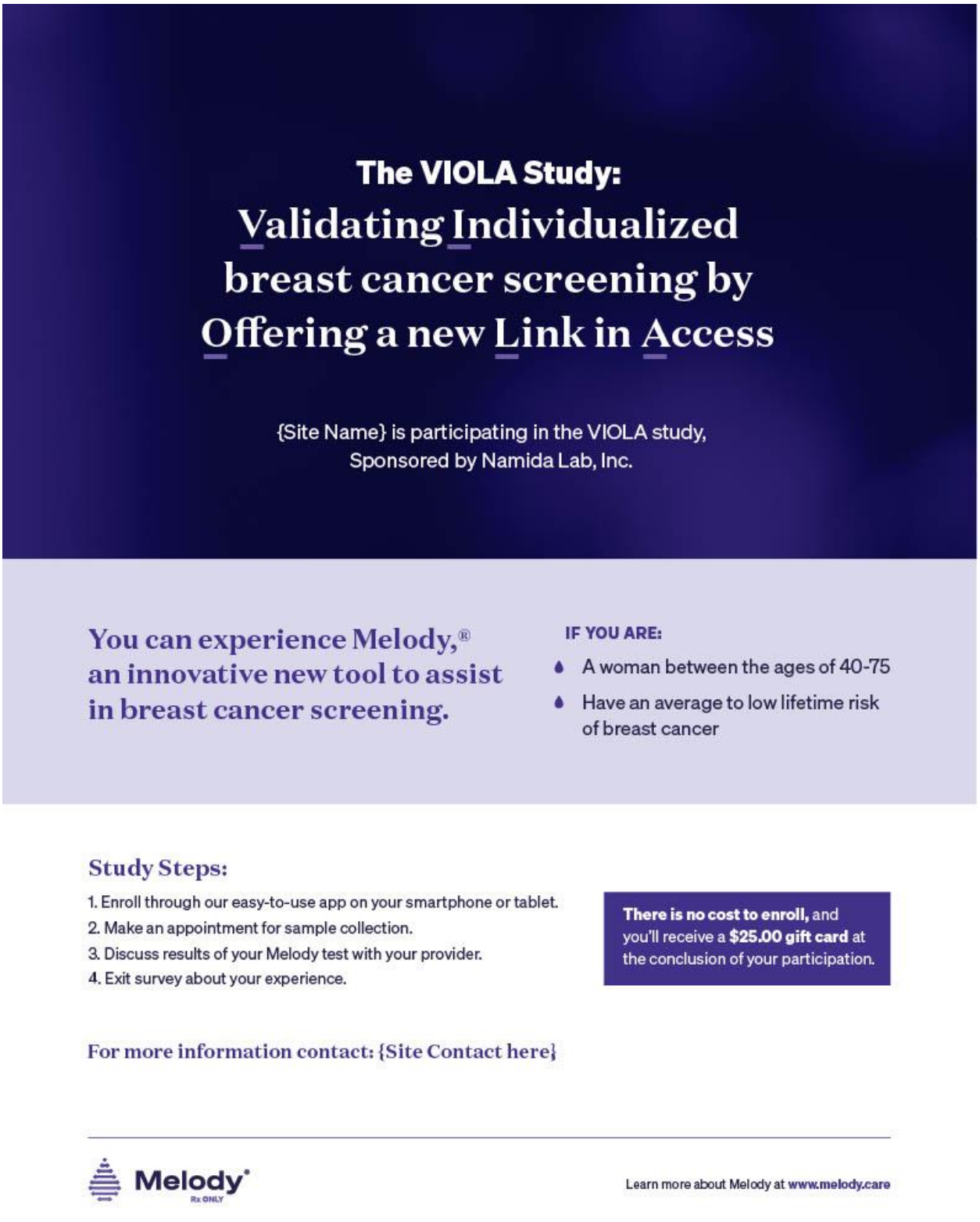
Appendix

A. Schematic of VIOLA Study Design

view the diagram on the next page in landscape


Schematic of Study Design
Planning
Development and Review
Participant
Study Site
Namida Lab, Inc.
Design Study
Enroll Site
Recruit Participant
Participant Consent and Intro Survey
Clinician Intro Survey
Collect Tear Sample
Mail Sample to Namida Lab, Inc.
Namida Lab, Inc. Conducts Melody® test
Clinician Receives Melody® Results
Clinician / Participant Melody® Results Consultation
Clinician Exit Survey
Participant Exit Survey
Study Data Analysis
Close Study and Site Location

B. Participant Recruitment Material



C. Informed Consent Form

INFORMED CONSENT FORM
AND
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**Namida Lab, Inc. / "The VIOLA Study Validating Individualized breast cancer screening by Offering a new Link in Access"**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

KEY INFORMATION
You are invited to take part in a research study. This research study is evaluating Melody®, a new tool to assist in breast cancer screening. Namida Lab, Inc. is sponsoring this research study.

The VIOLA Study is a Clinical Utility Study to explore and better understand the value, usage, and benefits of Melody®, a tear-based screening test for breast cancer. Melody® was designed and validated by Namida Lab, Inc., a high complexity Clinical Laboratory Improvement Amendments (CLIA) certified lab.

Melody® consists of two parts: tear sample collection and clinical lab test. Study participants will have a tear sample collected at a study site. The clinical lab test, Melody®, will be run at Namida Lab, Inc. The results of the Melody® test will be returned to the study doctor to be discussed with the participant.

Please read this form carefully. Take your time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether to take part or not. If you choose to take part in this study, you must sign your name at the end of this form and date it.

BACKGROUND AND PURPOSE
You are being asked to participate in this research study because you are a woman between the ages of 40 and 74, are at average risk for breast cancer, and are not being seen to evaluate an area of concern in your breast. Approximately 205 women will be enrolled in this study.

About 1 in 8 U.S. women (about 13%) will develop invasive breast cancer over the course of their lifetime. The most significant risk factors for breast cancer are sex (being a woman) and age (growing older).

Finding breast cancer early and getting state-of-the-art cancer treatment are the most important strategies to prevent deaths from breast cancer. Breast cancer that is found early, when it is small and has not spread, is easier to treat successfully. Getting regular screening tests is the most reliable way to find breast cancer early.

However, women face many challenges when it comes to regular breast cancer screening. Melody® was developed with those challenges in mind, providing better access and health outcomes. The purpose of the VIOLA Study is to better understand the gaps in access and participation in regular breast cancer screening.

Melody® is not a replacement for screening mammograms. Your Melody® score is an additional piece of information to discuss with your study doctor when making decisions about your breast health.

WHAT WILL HAPPEN DURING THE STUDY?

Your participation in this study will last approximately one month, will include around 1-2 study visits to the study center and the use of the Namida Lab, Inc. mobile application. A "mobile app" is defined as a software application that can be run on a mobile platform (for example, a handheld cell phone or tablet device, with or without wireless connectivity).

Study participants will be asked to download the Namida Lab app using their own device. The mobile app is free to download and requires no in-app purchases. The mobile app will be used, as a tool, in collecting data for the research, for example, your responses to surveys. The study site will have devices on-site or permit paper submissions for participants who do not have their own devices.

Participant confidentiality is strictly held in trust by the participating study doctor and their study staff, and the sponsor(s) and their agents. This confidentiality is extended to cover the testing of biological samples and genetic tests in addition to the clinical information relating to participants.

The collection, transfer, and storage of data will be conducted in compliance with the HIPAA Security Rule and structured to minimize the risk of Personal Health Information (PHI) disclosure. All recorded data will be entered into a password-protected database. All data entry forms will be accessed and completed electronically through a password-protected log-on.

Before any study-related tests and procedures are performed, you will be asked to read, sign, and date this consent document. To qualify to take part in this study, the following eligibility criteria must be determined:

- Female
- 40 to 74 years old
- Able to undergo the informed consent process
- Willingness to comply with all study procedures
- Available for the duration of the study
- In good general health and at average risk for developing breast cancer

If you qualify to take part in this study, then the following will happen:

- After completing the informed consent process, you will be asked to complete a survey through the Namida Lab, Inc. mobile app. This survey collects information to complete our study and generates your test results.
- You will need to make an appointment at your specified study center location with your study doctor to have a tear sample collected. Sample collection will be performed by your study doctor or study staff.
- Sample collection steps by your study doctor:
    - A small strip of filter paper, called a Schirmer strip, will be used to collect your tear fluid.
    - The strip will be placed just inside your lower eyelid.
    - You will be asked to keep your eyes closed for up to 5 minutes or less.
    - After a maximum of 5 minutes, the strip will be removed, placed in the collection tube, and sent to Namida Lab, Inc. for testing.
- When your study doctor receives your results, he/she will contact you to discuss your results over the phone or in person.
- After discussing your results with your study doctor, you will receive a study exit questionnaire through the Namida Lab, Inc. mobile app you used to register for the study.

EXPECTATIONS

If you participate in this study, you will be expected to:

- Download the Namida Lab, Inc. mobile app if you have access to a device
- Complete the informed consent form
- Complete all participant surveys/questionnaires
- Have your tear sample collected at your study center location
- Review your Melody® test results with your study doctor

RISKS, SIDE EFFECTS, AND/OR DISCOMFORTS

Possible risks from participation in study, questionnaires, and medical consultations might include minimal psychological discomfort.

- The survey questions will ask you about your personal experiences, family medical history, possible reproductive experiences such as pregnancy, and your body.

- This study asks questions about your personal breast health experiences, which may cause discomfort for some participants.

Possible risks from the collection of tears are rare but include conjunctivitis or scleral/corneal abrasion.

- Conjunctivitis is inflammation of the delicate membrane that covers the internal part of the eyelid and is attached to the cornea.
- Scleral/corneal abrasion is irritation of the sclera, which is the white of the eye, or of the corneal, which is the membrane that covers the pupil and iris of the eye.

Possible risks from the test results include the potential for false-positive and false-negative results.

- False positives do occur. A false-positive result occurs when you receive a Melody classification of High even though a screening mammogram finds no area of concern. The false-positive rate of Melody is 46%. This means that of 100 tests that appear positive, 46 will **not** be associated with an abnormal mammogram. False-positive tests may cause anxiety and cause you to undergo additional medical visits or procedures.
- False negatives do occur. A false negative result occurs when you receive a Melody classification of Low even though a screening mammogram indicates an area of concern. The false-negative rate of Melody is 8%. The means that of 100 tests that appear negative, only 8 will be associated with an abnormal mammogram. False-negative tests may cause you to feel wrongly assured. You might miss having additional medical visits or procedures that might be helpful.

The role of Melody® in helping you to decide whether to undergo further evaluations is not known. Currently, Melody has not been reviewed and approved by the seven recommending committees that determine breast cancer screening guidelines for the general public.

OTHER RISKS

There could be other risks that are unforeseeable.

As part of this research, you may be required to use one or more of the following: a phone or web app/site, an electronic study diary (eDiary), or a device that tracks information about you. While using these, information about you may be collected and shared with the researchers or people outside of the study. This data might include personal health information, location, call logs, text message history, web browsing history, or social media use.

A complete description of the data collection and sharing for an app, eDiary, or device can commonly be found in Terms of Use, End User License Agreement, or Privacy Policy associated with the device. If you would like to read these documents, request a copy or instructions about how to access this information from the study doctor.

participating in this study. If you tell the study staff that you think you have been injured, the staff will help you get the care you need.

If you are injured as a result of procedures done for the purpose of this study: the sponsor will pay for those medical expenses necessary to treat your injury that is not covered by your medical insurance or any other third-party coverage. By signing and dating this document, you will not lose any of your legal rights or release the sponsor, the study doctor, the study staff, or the study center location involved in the research from responsibility from mistakes.

The sponsor will need to know some information about you, like your name, date of birth, and Medicare Beneficiary Identifier (MBI) to pay medical expenses. This is because the sponsor has to check to see if you receive Medicare and, if you do, report the payment it makes to Medicare.

COSTS
There will be no charge to you for your participation in this study. The study-related procedures will be provided at no cost to you or your insurance company.

The study participant will be responsible for any costs associated with the use of the app, for example, increased cell phone costs for data use. There is no cost to download the app, and it requires no in-app purchases.

FUTURE RESEARCH STUDIES
Identifiers might be removed from your identifiable private information or identifiable biospecimens collected during this study and **could then be used for future research studies or distributed to another investigator for future research studies** without additional informed consent.

COMMERCIAL PROFIT
Your biospecimens collected during this study may be used for commercial profit (even if identifiers are removed), and **you will not share in this profit**.

CLINICALLY RELEVANT RESULTS
Research results that are clinically relevant, including individual research results, **will be disclosed to you** under these conditions: Results will only be provided to a licensed medical professional.

GENOME SEQUENCING

Researchers can look closely at large amounts of your genetic information by sequencing or "reading" every letter in your DNA (your genome). Reading a person's entire genetic code is called whole-genome sequencing. The research **will not include** whole genome sequencing (for example, sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns, or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject and/or concerns or complaints regarding this research study, contact:

- By mail:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00053749.

VOLUNTARY PARTICIPATION / WITHDRAWAL

Your decision to participate in this study is voluntary. You may choose not to participate or withdraw from the study for any reason, without penalty, loss of benefits to which you are otherwise entitled, and without any effect on your future medical care. However, please note the FDA requires any information collected up to the point of your withdrawal cannot be removed from the study. If you leave the study for any reason, the study doctor may ask you to have some end-of-study tests for your safety.

The study doctor or the sponsor can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you;
- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;

- If the study is canceled; or
- For administrative reasons.

If you are an employee of this research center, you are under no obligation to participate in this study. You may withdraw from the study at any time and for any reason. Neither your decision to participate in the study nor any decision on your part to withdraw will affect your performance appraisal or employment at this clinical research center. You may refuse to participate or you may withdraw from the study at any time without penalty or anyone blaming you.

CONSENT

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions, and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing and dating this consent document. I will receive a copy of this signed and dated consent document.

_____
Participant's Printed Name

_____ _____
Participant's Signature Date

_____
Printed Name of the Person Conducting the Consent Discussion

_____ _____
Signature of the Person Conducting the Consent Discussion Date

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the study doctor and study staff will use and share health data about you to conduct the study. Health data may come from your study records or existing records kept by your doctor or other health care workers. Health data may include:

- Your name
- Address
- Phone number
- Date of birth
- Medical history
- Information from your study visits, including all test results

For this study, the study staff may share health data about you with authorized users. Authorized users may include:

- Representatives of Namida Lab, Inc.
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study)
- The Food and Drug Administration (FDA) and other U.S. federal and state agencies
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported
- Governmental agencies of other countries
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study
- Other research doctors and medical centers participating in this study, if applicable
- A data safety monitoring board oversees this study, if applicable

Your health data will be used to conduct and oversee the research, including for instance:

- To see if the addition of Melody® in the breast health continuum of care works and is safe
- To compare the Melody® assay to other forms of breast cancer screening
- For other research activities related to the use of biomarker identification in tears

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law. It could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner. You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study.

No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign and date this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form, and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

D. Participant Study Enrollment Survey (Background, Demographic, Medical)

VIOLA Study:
Validating Individualized breast cancer screening
by Offering a new Link in Access

Study Participant Introduction Survey

Thank you for taking the time to participate in our study. Please answer the following questions to the best of your knowledge.

Section 1: Personal information and demographics:

Last Name: _____ First Name: _____ Middle Initial: _____

Date of Birth (mm/dd/yyyy) ____/____/_____

1. What type of health coverage or insurance do you have? (select one)
   - ☐ Employer-Sponsored or Spouse's Employer
   - ☐ Private insurance from the Health Care Marketplace (healthcare.gov)
   - ☐ Medicaid
   - ☐ Medicare
   - ☐ None of the above

2. What is your highest level of education? (select one)
   - ☐ High School Diploma / GED
   - ☐ Technical Degree / Associates Degree
   - ☐ Bachelors Degree
   - ☐ Graduate Degree or Higher
   - ☐ None of the above

3. What is your total annual household income? (select one)
   - ☐ $35,000 or less
   - ☐ $35,000 - $80,000
   - ☐ $80,000 - $130,000
   - ☐ $130,000 - $200,000
   - ☐ $200,000 or higher

4. What is your race? (select all that apply)
   - ☐ American Indian or Alaska Native
   - ☐ Asian
   - ☐ Black or African American
   - ☐ Native Hawaiian or Other Pacific Islander
   - ☐ White

5. What is your ethnicity? (select one)
   - ☐ Hispanic or Latino or Spanish Origin
   - ☐ Not Hispanic or Latino or Spanish Origin

Section 2: Reproductive health:

1. Are you currently using any of the following types of Contraception? (select one)
   - ☐ Pill Name if known: _____
   - ☐ Implant
   - ☐ Contraception Injection
   - ☐ Contraceptive Patch
   - ☐ Intrauterine device (IUD)
   - ☐ Vaginal Ring
   - ☐ None

2. Are you currently using any hormone replacement therapy? (select one)
   - ☐ Yes ☐ No

3. Please select what hormones you are currently taking: (select all that apply)
   - ☐ Testosterone
   - ☐ Estrogen
   - ☐ Progesterone
   - ☐ Other: _____

4. Hormone replacement medication name if known: _____

5. At what age did your periods begin? _____ (number)

6. Do you still have regular periods? (select one)
   - ☐ Yes ☐ No

7. If you Do Not have regular periods, please select one of the following reasons: (select one)
   - ☐ Menopause
   - ☐ Hysterectomy
   - ☐ Response to Birth Control
   - ☐ Uterine Ablation
   - ☐ Other (please describe): _____
   - ☐ Unknown

8. Do you still have ovaries? (select one)
   - ☐ Yes ☐ No

Section 3: Breast health:

1. Have you ever been told you have dense breast tissue? (select one)
   - ☐ Yes ☐ No

2. Are you currently on, or have you been told, you should be on a high-risk breast cancer screening protocol? (select one)
   - ☐ Yes ☐ No

3. Do you get an annual mammogram for breast cancer screening? (select one)
☐Yes ☐No

4. Do you get a bi-annual, every two years, mammogram for breast cancer screening? (select one)
☐Yes ☐No

5. When was your last screening mammogram? (enter date or select one)
(mm/dd/yyyy) ____/____/_____ ☐Unknown ☐N/A

6. Have you ever received an abnormal screening mammogram? (select one)
☐Yes ☐No

7. From your last mammogram, what BI-RADS assessment category was on your mammogram results report? (select one)
☐ 0 - Incomplete - Additional imaging evaluation and comparison to prior mammograms are needed.
☐ 1 - Negative
☐ 2 – Benign (non-cancerous findings)
☐ 3 – Probably benign finding (follow-up in a short time frame is suggested)
☐ 4 – Suspicious abnormality (biopsy should be considered)
    ☐ 4A – Finding with a low likelihood of being cancer (more than 2% but no more than 10%)
    ☐ 4B – Finding with a moderate likelihood of being cancer (more than 10% but no more than 50%)
    ☐ 4C – Finding with a high likelihood of being cancer (more than 50% but less than 95%), but not as high as Category 5
☐ 5 – Highly suggestive of malignancy (appropriate action should be taken)
☐ 6 – Known biopsy-proven malignancy (appropriate action should be taken)
☐ Unknown

Section 4: Personal history and family history of cancer:

1. Please list below any cancers you have or have had in your lifetime.

☐No personal history of cancer ☐Personal history unknown

Cancer Type	Year of diagnosis	Treatment	Treatment ongoing
		☐Chemo ☐Surgery ☐Radiation	☐Yes ☐No Further details:

2. Please list below any members of your family that have or have had: Breast, Ovarian, Prostate, Melanoma, Pancreatic, Stomach, Uterine, Thyroid, Colon, Sarcoma. **List the type of cancer from the choices above next to the name of the family member diagnosed.*

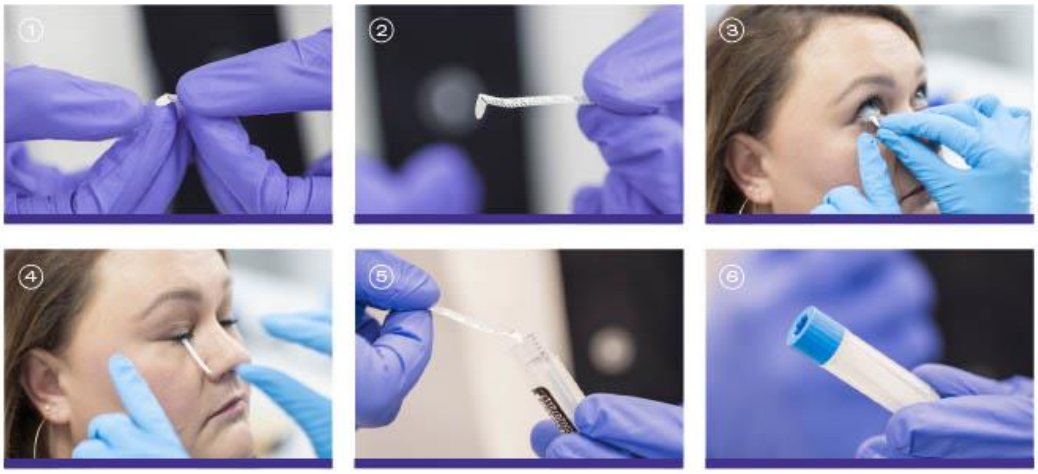
☐ No Family history of cancer ☐ Family history unknown

Immediate Family	
Mother	
Father	
Sibling	
Maternal Family	
Grandmother	
Grandfather	
Aunt	
Uncle	
Cousin	
Paternal Family	
Grandmother	
Grandfather	
Aunt	
Uncle	
Cousin	

E. Tear Sample Collection: Instructions for Use (IFU)

TEAR SAMPLE COLLECTION

Instructions for Use



01. Put on gloves.

02. Open the pouch and remove specimen tube. Firmly tap the bottom of the specimen tube on a flat solid surface to ensure all the buffer in the tube is in the bottom. Leave the tube in a vertical position. If the specimen tube falls over prior to adding the sample strip, simply repeat the tapping process prior to opening.

03. Remove the Schirmer strip package from the pouch. Open the Schirmer strip packaging following the peel here indication and remove the Schirmer strip.

04. Hold the Schirmer strip with the printed side facing up and the rounded end pointed away from you.

05. Fold the rounded end of the strip at the first black line until it reaches a 90-degree angle.

06. Instruct the patient to look up, and gently pull the patients lower eyelid, and place the folded portion of the strip inside the lower eye lid. Ask the patient close eyes.

07. Leave the strip in place for a total of **5 minutes** or until the tear fluid reaches the **25 mark** on the Schirmer strip.

08. After sample collection is complete, ask the patient to open their eyes and remove the strip.

09. Open the provided specimen tube and place the strip in the tube ensuring the folded end of the Schirmer strip enters the liquid first.

10. Replace the lid onto the specimen tube ensuring the lid is seated properly and securely.

11. Place printed label with barcode aligned vertically along the length of the tube.

12. Place the tube into the specimen tube transport container provided with the shipping supplies.

Melody®

1905 E Mission Blvd. Fayetteville, AR 72703 | www.melody.care

F. Melody® Sample Collection Kit Instructions for Use

TEAR SPECIMEN COLLECTION AND SHIPPING GUIDE

Use: to collect and ship tear samples for Melody®; a lab developed test for breast cancer screening.

Kit Contents:

Component	Manufacturer/Distributor
Schirmer Strip	Eye Care and Cure
Screw top sample tube	VWR
1XPBS	Namida Lab, Inc.

Tear sample collection kits provided by Namida Lab, Inc.

Single use tear sample collection kits are provided in boxes containing twenty-five kits.

Each collection kit comes pre-sealed in tamper evident packaging.

Each kit contains a Schirmer strip and specimen tube with buffer.

Tear sample collection kits may be stored at room temperature (20-22 °C) until use.

The specimen tube and Schirmer strip are provided pre-sealed in tamper evident packaging.
If kit appears to have been opened, do not use as kit components may have been affected.
If Schirmer strip appears to have been opened, do not use as it may no longer be sterile.

The tube contains a 1XPBS buffered solution.
Do not drink liquid in tube.
If liquid touches your skin or eyes, wash the area with water.

Collection Instructions:

**for visual representation of instructions also see Instructions For Use provided with clinic supplies.*

1. Put on gloves.
2. Open the pouch and remove specimen tube. Firmly tap the bottom of the specimen tube on a flat solid surface to ensure all the buffer in the tube is in the bottom. Leave the tube in a vertical position. If the specimen tube falls over prior to adding the sample strip, simply repeat the tapping process prior to opening.
3. Remove the Schirmer strip package from the pouch. Open the Schirmer strip packaging following the peel here indication and remove the Schirmer strip.
4. Hold the Schirmer strip with the printed side facing up and the rounded end pointed away from you.
5. Fold the rounded end of the strip at the first black line until it reaches a 90-degree angle.

6. Instruct the patient to look up, and gently pull the patients lower eyelid, and place the folded portion of the strip inside the lower eye lid. Ask the patient close eyes.
7. Leave the strip in place for a total of 5 minutes **or** until the tear fluid reaches the 25 mark on the Schirmer strip.
8. After sample collection is complete, ask the patient to open their eyes and remove the strip.
9. Open the provided specimen tube and place the strip in the tube ensuring the folded end of the Schirmer strip enters the liquid first.
10. Replace the lid onto the specimen tube ensuring the lid is seated properly and securely.
11. Place printed label with barcode aligned vertically along the length of the tube.
12. Place the tube into the specimen tube transport container provided with the shipping supplies (*see Packing for delivery to Namida Lab section for more details*).

Holding:
Tear samples may remain at room temperature (20-22 °C) until ready to ship to the laboratory. Specimens must be shipped to the lab the same day of collection.

Packaging for delivery to Namida Lab:

Shipping supplies provided by Namida Lab, Inc.

High-impact polystyrene sample tube holders with friction fit tops provided for both storing samples after collection and shipping samples.

Pre-labeled cushioned envelopes for mailing tear samples.

If shipping samples: Simply place the polystyrene sample tube holders, containing the collected samples, inside the pre-labeled mailer for shipment via FedEx.
Remove the adhesive strip cover and securely close the padded mailer with specimen tube transport container/s inside.
Record the tracking number and place the mailer in a designated FedEx drop box with express service.
When envelopes are picked up by FedEx and scanned, Namida Lab will receive an email alerting us to expect package arrival.
Samples must be placed in FedEx express service drop box prior to last pick-up time for the day of collection. Submitters are responsible for ensuring samples are shipped in a timely fashion.

If storing samples for pick-up: Place the polystyrene sample tube holders in the designated location in your clinic for pick up by courier.
Designated locations for pick-up will be assigned during clinic onboarding procedures.

For questions regarding specimen collection, packaging, and shipping:
Call Namida Lab, Inc. at (479) 334-2828 and ask to speak with Shelby VanHoutan.

G. Namida Lab, Inc. – SOP Specimen Preparation, Handling, and Storage

Namida Lab Inc.
1905 E. Mission Blvd. Ste. 6
Fayetteville AR, 72703

STANDARD OPERATING PROCEDURE

SOP Title:	**Specimen Preparation, Handling, and Storage Procedure**
SOP #:	**LAB-TP-023**
Version:	**1.0**
Replaces SOP #:	**N/A**
Approvals:	Refer to end of document for approval signatures.
Revision History:	Refer to end of document for revision history.
This Version's Put In Use Date:	_____
Previous Version/ Put In Use Date:	**N/A** / **N/A**
SOP Discontinued Date:	_____

I. PURPOSE

This document describes the procedure followed to prepare samples, handle samples, and store samples.

II. SCOPE

This procedure includes:

A. Preparation of samples
B. Handling of samples
C. Storage of samples

III. RESPONSIBILITY

A. Laboratory Personnel
1. are responsible for performing this procedure as described and completing all logsheets, logs, and documentation as described herein.

B. Technical/General Supervisor
1. ensures this procedure is performed as described by trained personnel and it is revised as needed.
2. is responsible for reviewing this procedure; at a minimum at the routine required review.

C. Laboratory Director
1. is responsible for reviewing this procedure; at a minimum, at the routine required review.

IV. MATERIALS *NOTE: ALL MATERIALS BELOW MAY BE EXCHANGED FOR AN EQUIVALENT UNLESS SPECIFIED OTHERWISE AS (CRITICAL).

A. Equipment
1. Ultra Low Freezer - Vendor: VWR

V. SPECIAL SAFETY PRECAUTIONS

A. Handling
1. Wear gloves, lab coat, and safety glasses while performing this assay
2. Avoid contact with eyes, skin, and clothing. Do not ingest or inhale. On contact, flush with copious amounts of water for at least 15 minutes.
3. When handling blood, plasma, or serum samples follow BSL level 2 protocols.

VI. PROCEDURE

A. Sample Preparation
1. None

B. Sample Handling
1. Samples will be tested immediately upon arrival and kept at room temperature until tested.

C. Sample Storage
1. Samples will have label created from order which includes first name, last name, date of birth, collection date, and unique patient ID.
2. Remaining samples will be stored in -80 degree freezer in Namida Clinical Laboratory.

VII. TROUBLESHOOTING

A. Equipment

1. Refer to EOPs or user manuals.

B. Any Issues or questions should be directed at the Supervisor on duty.

APPROVALS AND REVISION HISTORY

APPROVALS

Signatures required upon initial approval of version and at routine required review.

REVIEWER TITLE	APPROVAL SIGNATURE	DATE
Technical Supervisor		
Laboratory Director		

REVISION HISTORY

VERSION	REVISION DESCRIPTION
1.0	N/A; new document

H. Namida Lab, Inc. CLIA Certificate of Registration

CENTERS FOR MEDICARE & MEDICAID SERVICES

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF REGISTRATION

LABORATORY NAME AND ADDRESS

NAMIDA LAB, INC
1905 E MISSION BLVD, STE 6
FAYETTEVILLE, AR 72703

CLIA ID NUMBER
04D2182040

EFFECTIVE DATE
04/15/2020

LABORATORY DIRECTOR
LUCAS K CAMPBELL M.D.

EXPIRATION DATE
04/14/2022

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

Karen W. Dyer, Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

1743 certs1_080220

- If this is a Certificate of Registration, it represents only the enrollment of the laboratory in the CLIA program and does not indicate a Federal certification of compliance with other CLIA requirements. The laboratory is permitted to begin testing upon receipt of this certificate, but is not determined to be in compliance until a survey is successfully completed.
- If this is a Certificate for Provider-Performed Microscopy Procedures, it certifies the laboratory to perform only those laboratory procedures that have been specified as provider-performed microscopy procedures and, if applicable, examinations or procedures that have been approved as waived tests by the Department of Health and Human Services.
- If this is a Certificate of Waiver, it certifies the laboratory to perform only examinations or procedures that have been approved as waived tests by the Department of Health and Human Services.

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.GOV/CLIA
OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR
YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.

CLIA ID Number: 04D2182040
NAMIDA LAB, INC
1905 E MISSION BLVD, STE 6
FAYETTEVILLE, AR 72703

STATE AGENCY ADDRESS AND PHONE NUMBER:

HEALTH FACILITY SERVICES SLOT H9
ARKANSAS DEPARTMENT OF HEALTH & HUMAN SERVICES
5800 WEST 10TH STREET SUITE 400
LITTLE ROCK, AR 72204-9916
(501)661-2201

LABORATORY MAILING ADDRESS:

I. Melody® Sample Report

Namida Lab

Namida Lab Inc.
1905 E. Mission Blvd
FAYETTEVILLE, AR 72703

04D2182040
Lucas Campbell, M.D.

Name/DOB: **MelTest15, MelTest15 (12/12/1955)**
Patient ID: 21-095-012
Collected Date: 4/12/2021 1:10 PM
Approval date: 4/16/2021 10:50 AM

Sex: F
Age: 65

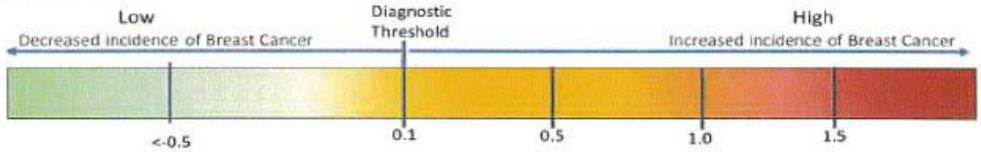
Provider: Campbell, Lucas, MD
Collecting Location: Namida Lab
Sample ID: MEL21000026
Entered by: Kirchner, Kelsey

Melody Test

Approved By: Kirchner, Kelsey

Melody Score **-0.509**

Reference Range:



Melody Score Interpretation **Low**

04/16/21 10:41 AM

Melody® is an adjunct clinical test that is intended to be based on the independent medical judgment of the ordering physician in conjunction with the patient's complete medical history and the result of standard care testing. It is recommended that a Melody score above 0.1 be clinically correlated with a structural examination of the breast tissue such as mammography.

Melody is not a replacement for a screening mammogram.

Melody Test type: Composite algorithmic analysis of tear protein biomarkers. Quantitative values of individual biomarkers are not reportable and are not associated with individual biomarker result reference ranges.

Precautions and Limitations:
Melody is intended for women ages 40-87 at average risk of developing breast cancer.

Melody may produce a false positive or false negative result. A Melody score below 0.1 does not guarantee the absence of breast cancer. Patients with a Melody score below 0.1 should be advised to continue participating in breast health standard care testing for their age group. A Melody score above 0.1 does not guarantee the presence of breast cancer. Patients with a Melody score above 0.1 should be referred for imaging.

Melody was developed and its performance characteristics determined by Namida Lab, Inc. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance is not necessary. This test is used for clinical purposes. Namida Lab, Inc. is regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high-complexity clinical testing.

Sample ID: MEL21000026/1
END OF REPORT (Final)

Page 1

J. Study Participant Exit Survey/Questionnaire

VIOLA Study:
Validating Individualized breast cancer screening
by Offering a new Link in Access

Study Participant Exit Survey

Thank you for taking the time to participate in our study. Please answer the following questions to the best of your knowledge.

Last Name: _____ First Name: _____ Middle Initial: _____

Date of Birth (mm/dd/yyyy) ____/____/_____

1. Before enrolling in the VIOLA Study, did you have an appointment for a screening mammogram?
   ☐Yes ☐No

2. How comfortable were you with the sample collection process? (circle one)

Very Uncomfortable	Uncomfortable	Comfortable	Very Comfortable
1	2	3	4

3. How would you rate the likelihood that you could do the sample collection process on your own? (circle one)

Very Unlikely	Unlikely	Likely	Very Likely
1	2	3	4

4. How would you rate your ability to understand your Melody® results? (circle one)

Very Difficult	Somewhat Difficult	Somewhat Easy	Very Easy
1	2	3	4

5. How would you rate the explanation of your Melody® results by your provider? (circle one)

Unacceptable	Poor	Fair	Excellent
1	2	3	4

6. How would you rate the ability of your provider to answer your questions about Melody®? (circle one)

Unacceptable	Poor	Fair	Excellent
1	2	3	4

7. How would you rate the length of time it took to get your results back from the Melody® test? (circle one)

Unacceptable	Poor	Fair	Excellent
1	2	3	4

8. How would you rate the reliability of the Melody® test? (circle one)

Unacceptable	Poor	Fair	Excellent
1	2	3	4

9. How would you rate your willingness to use Melody® to help you make decisions about your breast health in the future? (circle one)

Very Unlikely	Unlikely	Likely	Very Likely
1	2	3	4

10. After receiving your Melody® results, are you going to schedule/complete a screening mammogram and why?
☐Yes ☐No
Explanation:_____
_____
_____

11. May we contact you after you participate in the VIOLA Study if you are planning to have a screening mammogram?
☐Yes ☐No
If yes, please provide the best method of contact (mailing address/phone number /email):
_____

K. Study Site Provider Exit Survey/Questionnaire

VIOLA Study:
Validating Individualized breast cancer screening
by Offering a new Link in Access

Study Provider Exit Survey

Site Location ID: _____ Site Location PI: _____

1. How would you rate the process of the sample collection? (circle one)

Very Difficult	Somewhat Difficult	Somewhat Easy	Very Easy
1	2	3	4

2. How would you rate how the understandability of the Instructions for use for collecting tear samples? (circle one)

Very Difficult	Somewhat Difficult	Somewhat Easy	Very Easy
1	2	3	4

3. How would you rate the integration of sample collection in your clinic workflow? (circle one)

Very Difficult	Somewhat Difficult	Somewhat Easy	Very Easy
1	2	3	4

4. How likely do you think an individual could do this collection process at home? (circle one)

Very Unlikely	Unlikely	Likely	Very Likely
1	2	3	4

5. How would you rate the length of time to get results back on Melody®? (circle one)

Unacceptable	Poor	Fair	Excellent
1	2	3	4

6. How would you rate your understanding of the Melody® report? (circle one)

Very Difficult	Somewhat Difficult	Somewhat Easy	Very Easy
1	2	3	4

7. How comfortable were you communicating the Melody® lab results back to patients? (circle one)

Very Uncomfortable	Uncomfortable	Comfortable	Very Comfortable
1	2	3	4

8. How did you relay results to the participant? (chose one)
   - ☐ Over the phone
   - ☐ In-person consultation
   - ☐ Telemedicine visit
   - ☐ Other: _____

9. How would you rate your understanding of how to use the Melody® classification and score? (circle one)

Very Difficult	Somewhat Difficult	Somewhat Easy	Very Easy
1	2	3	4

10. How would you rate the usefulness of the information provided from Melody® in guiding your patients to make decisions about their breast health? (circle one)

Unacceptable	Poor	Fair	Excellent
1	2	3	4

11. How comfortable would you feel recommending this test to your patients in the future? (circle one)

Very Uncomfortable	Uncomfortable	Comfortable	Very Comfortable
1	2	3	4

12. As a provider, how many study participants did you ***strongly recommend*** they receive a screening mammogram after reviewing their Melody® results? _____ (number)

13. As a provider, how many study participants did you ***recommend*** they receive an annual screening mammogram after reviewing their Melody® results? _____ (number)

14. As a provider, how many study participants did you ***recommend*** they receive a bi-annual screening mammogram after reviewing their Melody® results? _____ (number)

15. How many study participants scheduled a screening mammogram after receiving a consultation about their Melody® result? _____ (number)

L. Namida Lab, Inc. Power Analysis (Sample Size)

Namida Lab (Anna Daily) - Power Analysis

This power analysis contains several pieces. First, we give you some technical information about understanding effect size and how it relates to your needed sample size. We also included information about how the effect size relates to your study. Then, the table shows you the sample size needed at various effect sizes. Remember, the greater the difference you expect to see between your groups or the stronger the correlation, the larger your effect is and thus, the smaller the sample size you need in order to detect it.

The first section of this report provides a basic conceptual understanding of power analyses and the elements in it that are used to calculate sample size. This will be followed with a discussion of the power analysis for your study. Table 1 presents a breakdown of the required minimum sample size at each power level for each effect size by hypothesis. The minimum sample needed at each power and effect level in the table is summarized at the bottom. The last section provides a breakdown of the screenshots of the power analyses at each power level at the moderate effect size so you can see how the sample size was calculated.

Understanding Effect and Sample Sizes

It is important to understand that the number attributed to a moderate effect size varies depending on the type of analysis used (e.g., correlation, regression, etc.). For example, when the research design calls for the use of an analysis of variance (ANOVA) model, a moderate effect size would be .25 measured as *f* (though partial eta-squared is another common measure, η^2_p). However, if the design requires the use of a multiple linear regression, a moderate effect size would be .15, measured as f^2. We provide low, moderate, and high effect sizes when calculating power analyses so that you can look at the minimum sample sizes needed and choose appropriately.

It is typically best for the researcher to attempt to achieve the sample size recommended by power analysis calculations using the low or moderate effect size because this will require a larger sample, which will give you a higher probability of detecting a true effect. As a practical matter, however, when the researcher does not have the resources to achieve a sample size this large, the moderate or upper-moderate effect size may still provide guidance on choosing a more modest sample size (or if previous research suggests that a larger effect is possible).

Your Power Analysis

The type of analysis best suited for your research is *Pearson's Chi-square Test of Independence* analysis. The associated percent change effect size was used for a low effect (Δ% = .10), moderate (Δ% = .20), and high (Δ% = .30) effect sizes to conduct the *a priori* power analysis. The alpha level was set at .05. The power levels were set at both .80, .85, and .90 for comparison. The power analysis was conducted using G*Power v3.1.9.2.

The results of the power analysis can be found in Table 1 below. Remember that power analysis calculations using lower effect sizes will tell you that you need larger samples, but these are the calculations easiest to justify. The calculations in the H1 hypothesis (percentage difference in compliance between treated and untreated groups) are the initial power calculation. The second calculation under accounting for 10% drop-out, increases the sample size to account for the drop-out rate you requested. Based on the moderate effect size of **Δ%** = 20% with a power level of .80, we recommend you recruit 205 participants for this study split evenly between treatment and non-treated groups (*N* = 103 each).

Table 1
Minimum Sample Size Needed for Range of Effect Sizes for Each Study Hypothesis

			Effect Size		
Hypothesis	Power level	Effect	Low	Moderate	High
H1: Compliance for Treatment vs Untreated groups		Δ%	10	20	30
Pearson's Chi-square test of Independence	.80		776	186	78
	.85		886	214	88
	.90		1038	248	104
Accounting for 10% drop-out rate		Δ%	10	20	30
	.80		854	205	86
	.85		975	235	97
	.90		1142	273	114
Minimum sample size		Δ%	10	20	30
	.80		854	205	86
	.85		975	235	97
	.90		1142	273	114

Note. Alpha level = .05. The numbers represented here are the total number of participants that would be needed for the sample.

Write-up to include in a methods section (if needed)

An *a priori* power analysis was conducted using G*Power v3.1.9.2 to determine the minimum sample size required to find significance with a desired level of power set at .80, an alpha (α) level at .05. Based on this analysis, it was determined that a minimum of 205 participants (two groups of 103) were required to ensure adequate power for a Pearson's Chi-square Test of Independence. (Cohen, 1988; Erdfelder, Faul, & Buchner, 1996; Faul, Erdfelder, Lang, & Buchner, 2007).

References

Cohen, J. (1988). Statistical power analysis for the behavioral sciences (2nd ed.). Hillsdale, NJ: Lawrence Erlbaum Associates.

Erdfelder, E., Faul, F., & Buchner, A. (1996). G*Power: A general power analysis program. Behavior Research Methods, Instruments, & Computers, 28, 1–11. Retrieved from http://link.springer.com/article/10.3758/BF03203630

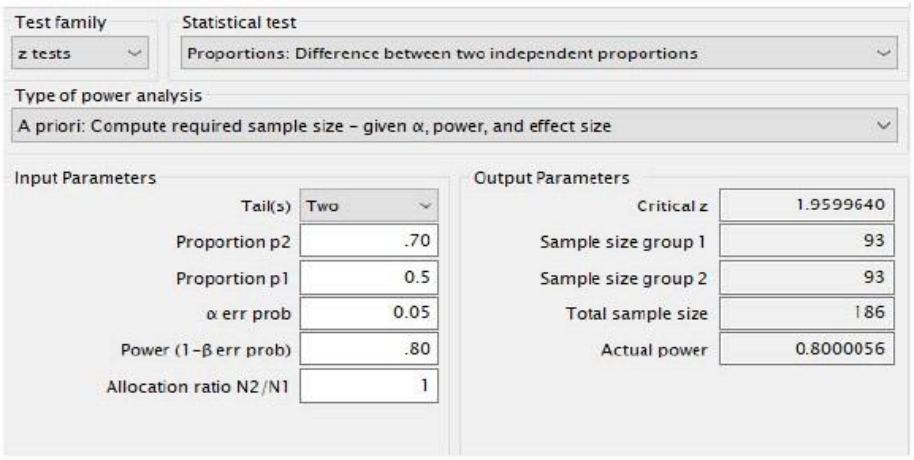
Faul, F., Erdfelder, E., Lang, A. G., & Buchner, A. (2007). G*Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. Behavior Research Methods, 39(2), 175–191. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/17695343

G*Power Screen-shots

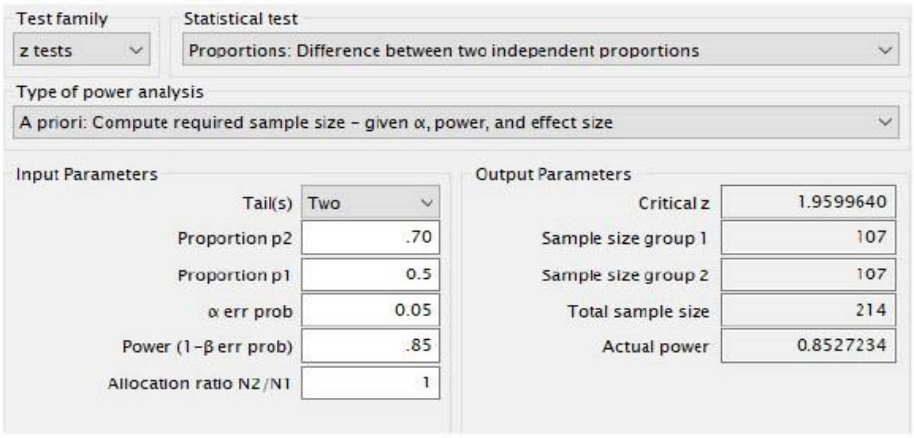
Screenshots

Moderate Effect Size (Δ% = 20)

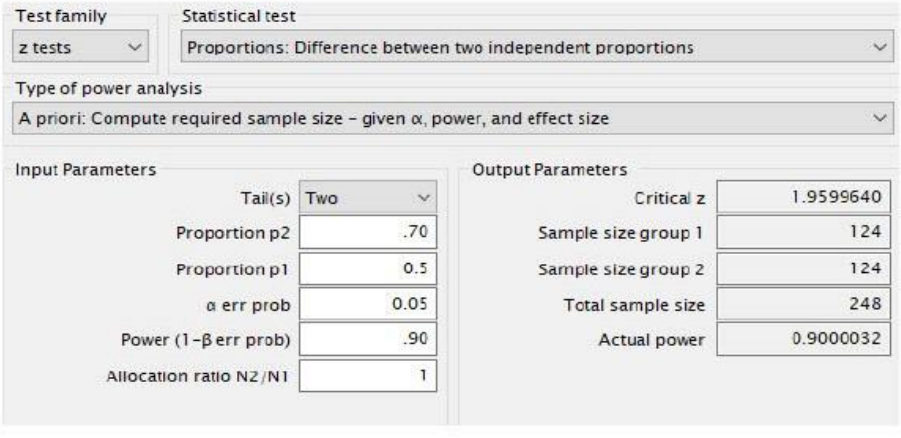
Power = .80



Power = .85



Power = .90



M. Namida Lab, Inc. Privacy Policy

Namida Lab

NOTICE OF PRIVACY PRACTICES

EFFECTIVE DATE: _____

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

UNDERSTANDING YOUR HEALTH RECORD/INFORMATION

Each time you visit a hospital, physician, dentist, or other healthcare provider, a record of your visit is made. Typically, this record contains your symptoms, examination and test results, diagnoses, treatment, and a plan for future care or treatment. This information often referred to as your health or medical record, serves as a basis for planning your care and treatment and serves as a means of communication among the many health professionals who contribute to your care. Understanding what is in your record and how your health information is used helps you to ensure its accuracy, better understand who, what, when, where, and why others may access your health information, and helps you make more informed decisions when authorizing disclosure to others.

YOUR HEALTH INFORMATION RIGHTS

Unless otherwise required by law, your health record is the physical property of the healthcare practitioner or facility that compiled it. However, you have certain rights with respect to the information. You have the right to:

1. **Receive a copy of this Notice of Privacy Practices** from us upon enrollment or upon request.
2. **Request restrictions on our uses and disclosures of your protected health information** for treatment, payment, and health care operations. This includes your right to request that we not disclose your health information to a health plan for payment or health care operations if you have paid in full and out of pocket for the services provided. We reserve the right not to agree to a given requested restriction.
3. **Request to receive communications of protected health information in confidence.**
4. **Inspect and obtain a copy of the protected health information** contained in your medical and billing records and in any other Practice records used by us to make decisions about you. If we maintain or use electronic health records, you will also have the right to obtain a copy or forward a copy of your electronic health record to a third party. A reasonable copying/labor charge may apply.
5. **Request an amendment to your protected health information**. However, we may deny your request for an amendment, if we determine that the protected health information or record that is the subject of the request:
   - was not created by us, unless you provide a reasonable basis to believe that the originator of the protected health information is no longer available to act on the requested amendment;
   - is not part of your medical or billing records;
   - is not available for inspection as set forth above; or
   - is accurate and complete.

   In any event, any agreed upon amendment will be included as an addition to, and not a replacement of, already existing records.
6. **Receive an accounting of disclosures of protected health information** made by us to individuals or entities other than to you, except for disclosures:
   - to carry out treatment, payment and health care operations as provided above;
   - to persons involved in your care or for other notification purposes as provided by law;
   - to correctional institutions or law enforcement officials as provided by law;
   - for national security or intelligence purposes;
   - that occurred prior to the date of compliance with privacy standards (April 14, 2003);
   - incidental to other permissible uses or disclosures;
   - that are part of a limited data set (does not contain protected health information that directly identifies individuals);
   - made to patient or their personal representatives;
   - for which a written authorization form from the patient has been received
7. **Revoke your authorization to use or disclose health information** except to the extent that we have already been taken action in reliance on your authorization, or if the authorization was obtained as a condition of obtaining insurance coverage and other applicable law provides the insurer that obtained the authorization with the right to contest a claim under the policy.
8. **Receive notification if affected by a breach of unsecured PHI**

HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED

This organization may use and/or disclose your medical information for the following purposes:

Treatment: We may use and disclose protected health information in the provision, coordination, or management of your health care, including consultations between health care providers regarding your care and referrals for health care from one health care provider to another.

Payment: We may use and disclose protected health information to obtain reimbursement for the health care provided to you, including determinations of eligibility and coverage and other utilization review activities.

Regular Healthcare Operations: We may use and disclose protected health information to support functions of our practice related to treatment and payment, such as quality assurance activities, case management, receiving and responding to patient complaints, physician reviews, compliance programs, audits, business planning, development, management, and administrative activities.

Appointment Reminders: We may use and disclose protected health information to contact you to provide appointment reminders.

Treatment Alternatives: We may use and disclose protected health information to tell you about or recommend possible treatment alternatives or other health related benefits and services that may be of interest to you.

Health-Related Benefits and Services: We may use and disclose protected health information to tell you about health-related benefits, services, or medical education classes that may be of interest to you.

Individuals Involved in Your Care or Payment for Your Care: Unless you object, we may disclose your protected health information to your family or friends, or any other individual identified by you when they are involved in your care or the payment for your care. We will only disclose the protected health information directly relevant to their involvement in your care or payment. We may also disclose your protected health information to notify a person responsible for your care (or to identify such person) of your location, general condition, or death.

Business Associates: There may be some services provided in our organization through contracts with Business Associates. Examples include physician services in the emergency department and radiology, certain laboratory tests, and a copy service we use when making copies of your health record. When these services are contracted, we may disclose some or all of your health information to our Business Associate so that they can perform the job we have asked them to do. To protect your health information, however, we require the Business Associate to appropriately safeguard your information.

Organ and Tissue Donation: If you are an organ donor, we may release medical information to organizations that handle organ procurement or organ, eye, or tissue transplantation or to an organ donation bank, as necessary to facilitate organ or tissue donation and transplantation.

Worker's Compensation: We may release protected health information about you for programs that provide benefits for work related injuries or illness.

Communicable Diseases: We may disclose protected health information to notify a person who may have been exposed to a disease or may be at risk for contracting or spreading a disease or condition.

Health Oversight Activities: We may disclose protected health information to federal or state agencies that oversee our activities.

Law Enforcement: We may disclose protected health information as required by law or in response to a valid judge ordered subpoena. For example, in cases of victims of abuse or domestic violence; to identify or locate a suspect, fugitive, material witness, or missing person; related to judicial or administrative proceedings; or related to other law enforcement purposes.

Military and Veterans: If you are a member of the armed forces, we may release protected health information about you as required by military command authorities.

Lawsuits and Disputes: We may disclose protected health information about you in response to a court or administrative order. We may also disclose medical information about you in response to a subpoena, discovery request, or other lawful process.

Inmates: If you are an inmate of a correctional institution or under the custody of a law enforcement official, we may release protected health information about you to the correctional institution or law enforcement official. An inmate does not have the right to the Notice of Privacy Practices.

Abuse or Neglect: We may disclose protected health information to notify the appropriate government authority if we believe a patient has been the victim of abuse, neglect, or domestic violence. We will only make this disclosure if you agree or when required or authorized by law.

Fund raising: Unless you notify us you object, we may contact you as part of a fund-raising effort for our practice. You may opt out of receiving fund raising materials by notifying the practice's privacy officer at any time at the telephone number or the address at the end of this document. This will also be documented and described in any fund-raising material you receive.

Coroners, Medical Examiners, and Funeral Directors: We may release protected health information to a coroner or medical examiner. This may be necessary to identify a deceased person or determine the cause of death. We may also release protected health information about patients to funeral directors as necessary to carry out their duties.

Public Health Risks: We may disclose your protected health information for public health activities and purposes to a public health authority that is permitted by law to collect or receive the information. The disclosure will be made for the purpose such as controlling disease, injury, or disability.

Serious Threats: As permitted by applicable law and standards of ethical conduct, we may use and disclose protected health information if we, in good faith, believe that the use or disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public.

Food and Drug Administration (FDA): As required by law, we may disclose to the FDA health information relative to adverse events with respect to food, supplements, product and product defects, or post marketing surveillance information to enable product recalls, repairs, or replacement.

Research (inpatient): We may disclose information to researchers when an institutional review board that has reviewed the research proposal and established protocols to ensure the privacy of your health information has approved their research.

OUR RESPONSIBILITIES

We are required to maintain the privacy of your health information. In addition, we are required to provide you with a notice of our legal duties and privacy practices with respect to information we collect and maintain about you. We must abide by the terms of this notice. We reserve the right to change our practices and to make the new provisions effective for all the protected health information we maintain. If our information practices change, a revised notice will be mailed to the address you have supplied upon request. If we maintain a Web site that provides information about our patient/customer services or benefits, the new notice will be posted on that Web site.

Your health information will not be used or disclosed without your written authorization, except as described in this notice. The following uses and disclosures will be made only with explicit authorization from you: (i) uses and disclosures of your health information for marketing purposes, including subsidized treatment communications; (ii) disclosures that constitute a sale of your health information; and (iii) other uses and disclosures not described in the notice. Except as noted above, you may revoke your authorization in writing at any time.

FOR MORE INFORMATION OR TO REPORT A PROBLEM

If you have questions about this notice or would like additional information, you may contact our Privacy Officer, Anna Daily, PhD, at the telephone or address below. If you believe that your privacy rights have been violated, you have the right to file a complaint with the Privacy Officer at Namida Lab or with the Secretary of the Department of Health and Human Services. The complaint must be in writing, describe the acts or omissions that you believe violate your privacy rights, and be filed within 180 days of when you knew or should have known that the act or omission occurred. We will take no retaliatory action against you if you make such complaints.

The contact information for both is included below.

U.S. Department of Health and Human Services
Office of the Secretary
200 Independence Avenue, S.W.
Washington, D.C. 20201
Tel: (202) 619-0257
Toll Free: 1-877-696-6775
http://www.hhs.gov/contacts

Namida Lab
Anna Daily
Privacy Officer
1905 E Mission Blvd. Suite 6
Fayetteville, AR 72703
479-334-2828

NOTICE OF PRIVACY PRACTICES AVAILABILITY

This notice will be prominently posted in the office where registration occurs. You will be provided a hard copy; at the time we first deliver services to you. Thereafter, you may obtain a copy upon request, and the notice will be maintained on the organization's Web site (if applicable Web site exists) for downloading.

N. Namida Lab, Inc. Policies for PHI Use and Disclosures (HIPAA)

Namida Lab

POLICIES AND PROCEDURES FOR PHI USE AND DISCLOSURES

INTRODUCTION

These policies and procedures address handling, safeguarding, using, and disclosing protected health information (PHI). Under HIPAA, covered entities must ensure the privacy of a patients' protected health information.

PHI refers to all information (oral, paper-based documents, and electronic documents) that relates to an individual including but not limited to:

- Medical information
- Billing information
- Financial information
- Names and other identifying information such as:
  - Telephone numbers
  - Fax numbers
  - Electronic Mail addresses
  - Social security numbers
  - Medical record numbers
  - Birth date
  - Date of death
  - Health plan beneficiary numbers
  - Account numbers
  - Certificate/license numbers
  - Vehicle identifiers and serial number, including license plate numbers
  - Device identifiers and serial numbers
  - Full face photographic images and any comparable images
  - Any other unique identifying number characteristic, or code

POLICIES AND PROCEDURES

MINIMUM NECESSARY

1. When using or disclosing protected health information, we will take reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.

2. The following are situations in which the Minimum Necessary provisions would **not** apply:

   - Uses or Disclosures that are required by law
   - Uses or Disclosures made to the individual
   - Uses or Disclosures made pursuant to an authorization
   - Disclosures to a health care provider for treatment purposes
   - Disclosures to the Secretary of Health and Human Services for enforcement purposes
   - Uses or Disclosures that are required for compliance with HIPAA requirements

3. Before using or disclosing information consider two basic questions:

   a. How much information is needed to fulfill the purpose of this request?
   b. Are we about to provide information that is not necessary to fulfill the purpose of this request?

   For example: When an insurance company requests documentation that the patient was treated for a broken arm, it is not necessary to provide information about the patient's treatment for high blood pressure.

TREATMENT

1. PHI may be used by or disclosed to the appropriate health care providers to provide patients with medical treatment or services.

2. The identity of any person contacting this practice requesting protected health information (PHI) must be verified before any disclosure may take place.

3. Staff members must also verify the requesting person's authority to have access to the PHI.

4. In cases where a public official is requesting PHI, you must verify the identity of the requester by examining reasonable evidence, such as a written statement of identity on agency letterhead, an identification badge or similar proof of status. In addition, the legal authority must be determined and verified by examining the reasonable evidence, i.e., a written request provided on agency letterhead that describes the legal authority for requesting the release.

PAYMENT

1. PHI may be used or disclosed so that the treatment and services patients receive may be billed and payment may be collected from the patient, an insurance company or a third party.

2. PHI may be used or disclosed to obtain prior approval or to determine whether a patient's insurance will cover the treatment.

HEALTHCARE PURPOSES

1. PHI may be used or disclosed to appropriate personnel in reviewing treatment and services and in evaluating the performance of staff in caring for patients.

APPOINTMENT REMINDERS

1. The minimum necessary medical information may be used to contact patients as a reminder that they have an appointment for treatment or medical care.

2. If a patient makes a reasonable request for an appointment reminder via an alternative method of notification (such as e-mail), the medical staff will honor such a request.

IMMUNIZATION DISCLOSURES

1. We may provide proof of immunization to a school where State or other law requires the school to have such information prior to admitting the student, without written authorization.

2. Before providing immunization information to a school we will attempt to obtain authorization to release the immunization information. The authorization may be oral, from a parent , guardian or other person in loco parentis for the individual or from the individual themselves if the individual is an adult or an emancipated minor.

3. We should document the agreement obtained.

4. The agreement if obtained will remain in effect until revoked.

MARKETING COMMUNICATIONS

1. Communications for marketing purposes can only be made with a patient's prior written authorization. The three exceptions to this are:

    a. communications we make about our own health care products or services;
    b. communications for treatment purposes;
    c. communications for purposes of case management or care coordination or to recommend alternative treatments, therapies, health care providers, or settings of care AND it does not involve direct or indirect payment for making such communication.

2. The minimum necessary PHI should be used/disclosed in those marketing communications.

3. Communication about a product or service that encourages recipients of the communication to purchase or use that product or service must NOT involve direct or indirect payment for making such communication and must be among one of following groups of communications below:

    a. The communication only describes a drug or biologic that has been previously prescribed or administered, provided the amount of the payment is reasonable
    b. Our organization makes the communication pursuant to an authorization from the recipient of the communication
    c. A business associate makes the communication pursuant to its business associate agreement

FUND RAISING

1. Any fund raising communications to patients should include "clear and conspicuous" opt-out language. We will take "reasonable efforts" to not send further fundraising communications to those who opt-out.

2. We will treat any opt-out as a revocation of authorization.

3. The use of demographic information, date of birth, department of service (e.g., pediatrics, oncology, etc), treating physician, and outcome information (e.g., optimal, sub-optimal, death, etc) in making fund raising communications is allowed. However, the minimum necessary standard still applies and only the minimum amount of PHI should be used or disclosed to accomplish the intended purpose.

DISCLOSURE FOR DECEASED INDIVIDUAL

1. We may use and disclose a deceased individual's PHI to family members and others who were involved in an individual's care, unless doing so is inconsistent with any prior expressed wishes or preferences of the deceased individual.

TO AVERT A SERIOUS THREAT TO HEALTH OR SAFETY

2. We may use and disclose PHI about patients when necessary to prevent a serious threat to the patient's health and safety or the health and safety of the public or another person. Any disclosure, however, would only be to someone able to help prevent the threat.

LAWSUITS AND DISPUTES

1. PHI may be disclosed in response to a subpoena, discovery request, or other lawful order from a court.

AS REQUIRED BY LAW

1. We will disclose PHI about patients when required to do so by federal, state or local law.

AS PERMITTED BY LAW

1. To the extent that the law permits us to release information, we may disclose PHI if asked to do so by a law enforcement official as part of law enforcement activities; in investigations of criminal conduct or of victims of crime; in response to court orders; in emergency circumstances.

O. Namida Lab, Inc. Mobile App Privacy Policy

Namida Lab Mobile App PRIVACY POLICY

Last updated on May 4, 2021.

OVERVIEW

Welcome to Namida Lab! Namida Lab is a mobile application that has been designed to provide a digital option for clinical research. This application allows for secure and remote electronic consent, collection of research data, and important updates for study participants. Please review our Privacy Policy carefully. If viewing in our mobile application, tap "Accept" to acknowledge that you understand the ways in which Namida Lab may process your personal information. You may be asked additional questions as you use the app to ensure we have your consent to collect and use your personal information for specific purposes. For your convenience, we summarized some highlights below, but you should still review the entire Privacy Policy in detail.

Namida Lab may process your personal information for the following purposes:

- Providing you with the service accessed through this mobile application including through service providers, such as our cloud hosting provider, that are contractually bound to protect your personal information.
- As directed by your sponsor (ex: your health insurer or healthcare provider) per our business associate agreement governed by HIPAA.
- Hosting your personal information in data centers within the United States of America.
- De-identifying your personal information (so it no longer identifies you) and using the resulting information in aggregated or non-aggregated form for product improvement, marketing, research, and to provide services to our customers; and
- Meeting our legal obligations.

If you do not agree to your personal information being processed for these purposes, or with any other terms of our Privacy Policy below please do not use our mobile application.

INFORMATION COLLECTION AND USE

This Privacy Policy is designed to inform users how Namida Lab, Inc. ("Namida Lab," "we," "our," or "us") collects and uses your information through our applications and related services (collectively, the "Service"). "Personal Information" is information that identifies you, including health information, as categorized below. Some information may fall under multiple categories. By tapping "Accept" at the end of this Privacy Policy, you consent to Namida Lab collecting and using your information as described below. You may have been invited to use the Service from a sponsoring third party such as your healthcare provider, health insurance provider, employer, care manager, or as part of a clinical study (your "Sponsor"). It is your choice whether or not to provide us with such information but if you decline, you may not be able to use part or all of our Service as some information is necessary. You can change some privacy settings at any time by going into the mobile application settings.

What information Namida Lab collects

1. Information you provide: We may ask and collect information such as your name, email address, phone number, address, birthdate, and gender to register your account as well as other information in the below categories. We use this information to manage your account, verify your identity, and deliver the Service to you.

2. Information we receive from third parties: We may receive information about you, including what is listed in other categories, from your Sponsor or other third parties as directed by your Sponsor. This information may include demographic information, medical history, health insurance information, or other information that your Sponsor has directed us to process. We use this information to fulfill contractual obligations to your Sponsor, as directed by your Sponsor, and to deliver the Service to you. The collection, processing, and sharing of this information is controlled by your Sponsor.

3. Health Information: Since we are a health-related application, we collect information about your health. This category can include diagnoses, symptoms, medical procedures, medications, discharge dates, clinical notes, physical characteristics, provider information, and other biometric information. We use this information to provide the Service to you such as using your medication information to provide medication notifications.

4. Communications: We collect the content of communications made through our Service between your Sponsor and you. This content can include information under other categories as well as any other information you decide to communicate. We use this content to provide you a record of your communications as well as use it in de-identified form as discussed below.

5. Integration data: We may use automated methods to track data from your other apps, fitness wearables, biometric monitoring devices, and other integrations that you have allowed to communicate with our Service. This integration data is then contained in our application for both you and your Sponsor to see and use. You may be prompted to provide access to the camera functionality of your device, we use this access to scan for optical character recognition (OCR) features, and to allow you to include attachments in communications. We do not otherwise collect images or recordings you have on your device. If using the Android version of our app, you may be prompted to allow access to location data for the purposes of the Bluetooth connection, however, we do not collect your location data.

6. Information unrelated to the application: Namida Lab may also collect personal information outside of the Service such as through our websites. This information can include your browsing activities on our site, your IP address, cookie information, and the pages you request. We use this information for such uses including security, content improvements, sales, and marketing.

7. Analytics information: We may collect usage data about how you use our Service such as how you use the application, what content you read and favorite, content of messages within our Service, integration data, and device information. We use this analytics information to improve the Service for you, your Sponsor, and other users.

8. Log files: To maintain security, fulfill compliance requirements, and generally make sure the Service is operating correctly, we collect information such as IP addresses, server requests, login events, device information, crash reports, usage activity, or other information to discover and

respond to events indicating possible service interruptions, security threats, fraud, or other illegal activity. We may also use this information to enforce our EULA, for compliance, and other legal obligations. Where feasible we limit the identifiable and sensitive information contained in these log files.

9. Support information: If you contact us regarding questions, issues, or requests regarding the use of our Service, our support team may view your Personal Information, as well as any additional information you provide, in order to assist. We may also ask follow-up questions to gather more information as necessary to address your issue. This information is stored as a record of your support request.

10. Optional information: We may also collect additional information, with your consent, that is not necessary for use of our Services such as product feedback, surveys, usage analytics, and testimonials. We use this information to improve and market our Service. Your Sponsor may request this information as well to improve their products and services. You have the right to object to processing of your personal data for direct marketing purposes by contacting help@namidalab.com or by using the "unsubscribe" link in an email you receive.

Sharing

Namida Lab does not rent, lease, or sell your Personal Information. We share your Personal Information with your Sponsor as per our agreement with your Sponsor that allows you to use the Service. Your Sponsor may share your Personal Information or direct us to share your Personal Information to third parties such as your Sponsor's affiliates or service providers. Your Sponsor may also provide us Personal Information or direct us to use your Personal Information in ways not specifically mentioned above. Contact your Sponsor to learn more about how they use your Personal Information.

To provide the Service, we may also share your Personal Information with our service providers and subcontractors for functionality, to communicate with you, measure performance, or improve our product. We may also disclose your Personal Information in response to a legal process, such as a law enforcement action, a subpoena, or to demonstrate compliance. Finally, we may transfer your Personal Information to an entity or individual that attempts or does acquire, buy, or merge with all or part of Namida Lab, or through some other business reorganization.

Machine Learning

Parts of the Service may involve the use and development of machine learning. Machine learning includes the use of computer algorithms to automatically detect patterns in data. To develop, support, and use these algorithms we may use the information categorized above and De-identified Information as defined below. We use machine learning to provide functionality, improve your experience, provide services to your Sponsor, optimize our operations, and other related business purposes.

De-identified Information

In addition to the categories and uses above, we may remove the identifiable parts of your Personal Information to create de-identified information ("De-identified Information"). De-identified Information may be combined with other information into aggregated datasets. We use De-identified Information in the following ways:

1. Disclosure for Business Purposes: We may license, use, disclose, or otherwise share De-identified Information with institutional clients, partners, investors, and contractors for any purposes related to our business practices.
2. Product Improvement: We may use De-identified Information for product improvement including the Service including the development of machine learning algorithms.
3. Research: We may use De-identified Information for research whether scientific, marketing, or business in nature. This research may be made public through publications such as within a scientific journal.

STORAGE AND RETENTION

Your Personal Information will be stored in our cloud hosting provider's data centers within the United States. We retain your Personal Information for as long as reasonably necessary to provide you the Service, as per your Sponsor's instructions, or to comply with legal obligations. For details about where and how long your Sponsor stores your Personal Information, please contact your Sponsor. We may retain De-identified Information indefinitely.

CONFIDENTIALITY AND SECURITY

Namida Lab has a legal duty under HIPAA to protect your Personal Information as a Business Associate of your Sponsor. We have put in place reasonable physical, technical, and administrative controls designed to safeguard against the unauthorized access, maintain data security, and correctly use your Personal Information. Any third-party service providers we use must undergo a vetting process and sign confidentiality agreements before we utilize them to provide the Service. Some of these security measures rely upon you. Please keep your login credentials secret, avoid public Wi-Fi networks, and log out of any shared devices. If you ever suspect a security issue with your account, contact help@namidalab.com immediately.

CHILDREN

Our Service is not directed to children. Namida Lab does not knowingly collect Personal Information from children under the age of 13 except with permission of a child's parent or legal guardian through our caregiver account feature. If we find that we collected Personal Information from a child under the age of 13 without proper consent, we will immediately delete that Personal Information.

RIGHTS TO PERSONAL INFORMATION

You or an authorized agent, such as a parent or authorized caretaker, may request access, changes, or deletions to your Personal Information and request information about our collection, use and disclosure of such information by contacting us at help@namidalab.com. We use best efforts to keep our records as accurate and complete as possible. You can help us maintain the accuracy of your information by notifying us or your Sponsor of any changes to your Personal Information as soon as possible. Since we are a HIPAA Business Associate of your Sponsor, we may need to forward your request to your Sponsor who will ultimately decide on how to accommodate your request. Your Sponsor may fulfill your request directly or instruct us to assist in some way, and in the latter case we will coordinate with them to promptly fulfill your request. We, or your Sponsor, may require you to verify your identity before fulfilling the request such as through asking you to log into the app, providing a verification code,

answering security questions, or some other means. We may also deny your request when required by law or if the request would likely reveal Personal Information about another individual.

GENERAL

The Service may contain links or deep links to other websites, open search results, public feeds, or curated channels all of which are independent from Namida Lab. Namida Lab has no control and is not responsible for the content, privacy practices, or advertisements on third party websites or for any loss or damage incurred in connection with your use of such links or dealings with the operators of these non-Namida Lab websites. We encourage you to review the privacy statements of each third-party website. Namida Lab is not responsible for any disclosures you make to third parties regarding your Personal Information, including family members or friends.

CHANGES TO THIS PRIVACY POLICY

We may update this Privacy Policy from time to time by posting a new version online and within our application. You should check this page occasionally to review any changes as well as within the settings section of our app. If we make any material changes, we will notify current users by providing notice through the Namida Lab app or via email. We may request your consent to the new terms; otherwise, your continued use of the Service, or continued provision of Personal Information to us, will be subject to the terms of the then-current Privacy Policy.

YOUR CALIFORNIA PRIVACY RIGHTS

Certain California privacy laws, including the California Consumer Privacy Act ("CCPA") require that we provide California residents specific information about how we use their personal information.

Categories of Personal Information that We Collect, Disclose, and Sell

Below please find the categories of personal information about California residents that we collect, sell, and/or disclose to third parties or service providers for a business purpose.

Categories of personal information	Do we collect?	Do we disclose for business purposes?	Do we sell?
NAME, CONTACT INFORMATION AND IDENTIFIERS: Identifiers such as a real name, alias, postal address, unique personal identifier, online identifier, Internet Protocol (IP) address, email address, account name, social security number, driver's license number, passport number, or other similar identifiers.	*YES*	*YES*	*YES*
CUSTOMER RECORDS: Paper and electronic customer records containing personal information, such as name, signature, social security number, physical characteristics or description, address, telephone number, passport number, driver's license or state identification card number, insurance policy number, education, employment, employment history, bank account number, credit	*YES*	*YES*	*YES*

card number, debit card number, or any other financial information, medical information, or health insurance information.			
PROTECTED CLASSIFICATIONS: Characteristics of protected classifications under California or federal law such as race, color, sex, age, religion, national origin, disability, citizenship status, and genetic information.	*YES*	*YES*	*YES*
PURCHASE HISTORY AND TENDENCIES: Commercial information, including records of personal property, products or services purchased, obtained, or considered, or other purchasing or consuming histories or tendencies.	*YES*	*YES*	*YES*
BIOMETRIC INFORMATION: Physiological, biological or behavioral characteristics that can be used alone or in combination with each other to establish individual identity, including DNA, imagery of the iris, retina, fingerprint, face, hand, palm, vein patterns, and voice recordings, keystroke patterns or rhythms, gait patterns or rhythms, and sleep, health, or exercise data that contain identifying information.	*YES*	*YES*	*YES*
USAGE DATA: Internet or other electronic network activity information, including, but not limited to, browsing history, search history, and information regarding a resident's interaction with an internet website, application, or advertisement.	*YES*	*YES*	*YES*
GEOLOCATION DATA: Geographic location information about a particular individual or device	*YES*	*YES*	*YES*
AUDIO/VISUAL: Audio, electronic, visual, thermal, olfactory, or similar information.	*YES*	*YES*	*YES*
EMPLOYMENT HISTORY: Professional or employment-related information.	*YES*	*YES*	*YES*
EDUCATION INFORMATION: Information that is not publicly available personally identifiable information as defined in the federal Family Educational Rights and Privacy Act (20 U.S.C. section 1232g, 34 C.F.R. Part 99).	*YES*	*YES*	*YES*
PROFILES AND INFERENCES: Inferences drawn from any of the information identified above to create a profile about a resident reflecting the resident's preferences, characteristics, psychological trends, predispositions, behavior, attitudes, intelligence, abilities, and aptitudes.	*YES*	*YES*	*YES*

California Consumer Rights
California law gives consumers the right to make the following requests, up to twice every 12 months:

- The right to request a copy of the personal information that we have collected about you in the prior 12 months.

- The right to request details about the categories of personal information we collect, the categories of sources, the business or commercial purposes for collecting information, and the categories of third parties with which we share information.
- The right to request deletion of the personal information that we have collected about you, subject to certain exemptions.
- The right to opt-out of sale of your personal information. To exercise your opt-out rights, please contact us at the contact information below.

The CCPA prohibits discrimination against California consumers for exercising their rights under the CCPA and imposes requirements on any financial incentives offered to California consumers related to their personal information, unless the different prices, rates, or quality of goods or services are reasonably related to the value of the consumer's data. We do not discriminate against consumers when they exercise their CCPA rights.

CONTACT

If you have questions or suggestions about this Privacy Policy, please email Namida Lab at help@namidalab.com, call 479-334-2834, or write to us at:

Namida Lab, Inc.
ATTN: Privacy Officer
1905 E Mission Blvd. Suite 6
Fayetteville, AR 72703, USA

P. Namida Lab, Inc. Mobile App Cookie Policy

Namida Lab Mobile App Cookie Policy

NAMIDA LAB INC.
COOKIE POLICY

This Cookie Policy was last updated on April 27, 2021.

At Namida Lab ("we," "us," "our") we want to make sure that you are aware of the technologies being used by our company and certain other third parties when visiting our websites. We use these technologies to improve performance of our websites and web pages (collectively "Sites") and their features as well as to create a better experience for you. These technologies may include cookies and web beacons. These technologies (collectively "Tracking Technologies") may be stored and accessed from your device when you visit our Sites. This policy pertains to all Namida Lab Sites that link to this policy, our use of Tracking Technologies, and your right to control your personal information. For information about the use of personal information by our applications, please refer to our Privacy Policy and EULA. BY CONTINUING TO USE OUR SITES YOU AGREE TO THE TERMS SET OUT WITHIN THIS POLICY.

What are Tracking Technologies?

"Cookies" are small text files that we place in visitors' computer browsers to store their preferences. The web server for the site you are visiting may later retrieve this file to monitor the browser activities and connect the web server requests to sessions. Cookies are also useful for authentication such as selecting options like "remember me" on login screens, where available. Cookies may be temporary and limited to the session or they may be persistent and exist after the session ends.

"Web beacons" are small clear graphic images used to track visits to websites or viewing of emails. For example, web beacons can be used to count the users who visit a web page or to deliver a cookie to the browser of a visitor viewing that page. Other terms for web beacons are clear gifs and pixel tags.

Which Tracking Technologies do we use?

We use both cookies and web beacons ("Tracking Technologies"). Web beacons may be used to deliver a cookie to your device when you visit our Sites.

How do we use Tracking Technologies?

Strictly Necessary - We use first- and third-party Tracking Technologies to manage cookie consent and compliance, optimize page load times, deliver Site operability, script functionality, and Site security. These Tracking Technologies are essential for our Site to function and cannot be turned off. If you choose to disable these technologies, some, or all of the functionalities of the Site will not work. These Tracking Technologies do not store any personally identifiable information. Some of these technologies are persistent and some are session based.

Functionality - We use first- and third-party Tracking Technologies to deliver video content, language preferences across pages, customer support tools, authentication, to identify session information, as well as to help measure and improve the usability of our Site. These Tracking Technologies enhance the functionality and personalization of our Site and store information like browser type, device type, and

operating system. If you choose to disable these technologies, some, or all of the functionalities of the Site will not work. Some of these technologies are persistent and some are session based.

Performance - We use first- and third-party Tracking Technologies to optimally deliver services and content, to limit data collection, and to identify campaign effectiveness. If you disable these technologies, we will not be able to see how our Site is performing for you. We also will not be able to see when you have visited our Site. These Tracking Technologies collect aggregated information such as whether visitors are first-time or returning users, the time spent on our Site, and the pages and content visited. Some of these technologies are persistent and some are session based.

Targeting - We use first- and third-party Tracking Technologies to help us understand what content is most relevant to you. We use Google Analytics, Google AdWords Conversion tracker, other Google services, and Mouseflow. These Tracking Technologies may be used by us and our advertising partners to deliver relevant content to you. These technologies may be used to store personally identifiable information about you such as location, mouse activity, and heatmapping. If you choose to disable these Tracking Technologies, you will experience less relevant marketing. Some of these technologies are persistent and some are session based. We abide by Google's remarketing principles and prohibitions for personalized advertising.

How to manage and remove Tracking Technologies?

When you first visit our Site, you will be presented with a cookie banner. You can select your cookie preferences by clicking the "manage my cookie settings" button on the banner. Within the Functional, Performance, and Targeting categories, you may select your preferences. Press the "Confirm My Choices" button to save those preferences. You may opt out of ad serving on Google's opt out page. If you are concerned about third party cookies served by other networks, you can visit the Network Advertising Initiative opt-out page for more information. If you wish to opt out of Mouseflow's analytics tool you can do so here. Other Tracking Technologies like those for security and functionality, are necessary for the use of our Sites and you must cease use of the Sites if you do not want those Tracking Technologies set on your device.

To remove cookies that have already been stored, you can use your browser settings to clear the cookies from your browser. See the resources listed below for helpful links.

Cross-site Tracking and Do-Not-Track

Namida Lab does not track users across other websites so our practices will not change if you have set a "do not track" signal on your browser. We encourage you to make sure you set your browser settings to match your preferences. For more information on Do Not Track signals, see all about do not track.

Updates to this policy

Namida Lab may update this policy from time to time by posting a new version on its Sites. We encourage you to check this page regularly for the latest information on our Tracking Technology practices.

Resources

Below are some links to external resources you may find helpful regarding how different browsers handle Tracking Technologies. These resources are completely external to Namida Lab and Namida Lab makes no guarantees or warranties as to their content. If your browser is not listed below, you should consult the documentation that your browser's provider makes available.

Google Chrome

Mozilla Firefox

Microsoft Edge

Apple Safari

Questions and Suggestions

If you have questions, concerns, or suggestions, please email Namida Lab at help@namidalab.com or write to us at:

ATTN: Privacy Officer
Namida Lab Inc.
1905 E Mission Blvd. Suite 6
Fayetteville, AR 72703, USA

Q. Namida Lab, Inc. Mobile App End-User License Agreement (Terms of Use)

Namida Lab Inc. Mobile App End-User License Agreement (Terms of Use)

NAMIDA LAB INC.
END-USER LICENSE AGREEMENT

Last update: April 27, 2021

ENTERING THE AGREEMENT

BY CLICKING THE 'I AGREE' BUTTON, OR BY INSTALLING, OR USING NAMIDA LAB'S SOFTWARE ("SOFTWARE"), MOBILE APPLICATION ("MOBILE APPLICATION"), WEBSITE ("WEBSITE"), PLATFORM, ANY INCLUDED DOCUMENTATION, ANY OF NAMIDA LAB'S SERVICES RELATED TO OR ENABLED BY SUCH SOFTWARE, MOBILE APPLICATION, OR WEBSITE (COLLECTIVELY, SUCH SOFTWARE, WEBSITE, MOBILE APPLICATION, AND RELATED SERVICES, "SERVICES") YOU (OR YOUR CAREGIVER IF YOU ELECT HIM OR HER INTO RECEIVING THE SERVICES) ("YOU" OR "USER") ACKNOWLEDGE THAT YOU HAVE READ THIS AGREEMENT, UNDERSTAND IT, AND AGREE TO BE BOUND BY THE TERMS AND CONDITIONS OF THIS AGREEMENT (THE "AGREEMENT"). THIS WILL BE A LEGALLY BINDING AGREEMENT BETWEEN YOU AND NAMIDA LAB INC. ("NAMIDA LAB", "WE", "US" OR "OUR") AND YOUR USE OF THE SERVICES IS ENTIRELY VOLUNTARY.

YOU MAY HAVE BEEN INVITED TO USE THE SERVICES FROM A SPONSORING THIRD PARTY SUCH AS YOUR HEALTHCARE PROVIDER, HEALTH INSURANCE PROVIDER, EMPLOYER, CARE MANAGER, OR AS PART OF A CLINICAL STUDY (YOUR "SPONSOR").

IF YOU DO NOT AGREE WITH THE TERMS AND CONDITIONS OF THIS AGREEMENT, YOU SHOULD REJECT THEM BY NOT CLICKING ON 'I AGREE' AND BY NOT INSTALLING OR USING THE SOFTWARE.

YOUR ACCESS TO AND USE OF OUR SOFTWARE AND SERVICES IS SUBJECT IN ALL RESPECTS TO THE TERMS OF OUR PRIVACY POLICY AVAILABLE AT WWW.NAMIDALAB.COM/PRIVACYPOLICY, AS WE MAY UPDATE THAT PRIVACY POLICY FROM TIME TO TIME ON REASONABLE NOTICE TO YOU AS DESCRIBED UNDER OUR PRIVACY POLICY ("PRIVACY POLICY").

YOU FURTHER ACKNOWLEDGE AND UNDERSTAND THAT THIS AUTHORIZATION IS NOT A CONDITION FOR RECEIVING ANY TREATMENT, PAYMENT, OR BENEFIT AND YOU UNDERSTAND THAT YOU'RE REFUSING TO AGREE TO THE TERMS OF THIS AGREEMENT, INCLUDING THIS AUTHORIZATION, WILL NOT AFFECT ANY TREATMENT, PAYMENT, OR BENEFIT FOR WHICH YOU MAY BE ELIGIBLE. HOWEVER, YOU ACKNOWLEDGE AND UNDERSTAND THAT IF YOU DO NOT AGREE TO THE TERMS AND CONDITIONS OF THIS AGREEMENT, YOU WILL NOT BE PROVIDED WITH ACCESS TO THE SERVICES AS DESCRIBED HEREIN.

USE OF MOST FEATURES OF THE SERVICES REQUIRES AN ONLINE CONNECTION (WI-FI, CELLULAR DATA) BETWEEN YOUR MOBILE DEVICE AND THE INTERNET. YOU ARE SOLELY RESPONSIBLE FOR ALL COSTS AND EXPENSES OF SUCH CONNECTION, AS SPECIFIED IN YOUR SUBSCRIBER PLAN OR CONTRACT WITH YOUR COMMUNICATION SERVICE PROVIDER. SOME OF THE FEATURES WITHIN THE SERVICES MAY BE DEPENDENT ON YOUR WIRELESS SERVICE AND THE WIRELESS COVERAGE WITHIN THE AREA IN WHICH YOU ARE LOCATED AT THAT TIME.

THESE TERMS AND CONDITIONS INCLUDE A CLASS ACTION WAIVER. THIS AGREEMENT LIMITS THE REMEDIES THAT MAY OTHERWISE BE AVAILABLE TO YOU IN THE EVENT OF A DISPUTE.

THE SERVICES ARE NOT A SUBSTITUTE FOR AND IS NOT INTENDED TO PROVIDE PROFESSIONAL MEDICAL ADVICE, DIAGNOSIS, OR TREATMENT. THE SERVICES ARE NOT INTENDED TO REPLACE YOUR RELATIONSHIP WITH YOUR CARE MANAGER, ADVOCATE, DOCTOR, OR ANY OTHER QUALIFIED HEALTHCARE PROVIDER. IF YOU THINK YOU MAY BE HAVING A MEDICAL EMERGENCY, CALL YOUR PROVIDER OR 911 IMMEDIATELY. ALL SERVICES ARE PROVIDED 'AS IS' AND WITHOUT WARRANTY OR REPRESENTATION.

1. SUSPENSION OF SERVICES; TERMINATION

a. We have the right to cancel the Services at any time at our discretion for any reason or for no reason. Without limiting the generality of the foregoing, you specifically acknowledge that Namida Lab has the right to terminate or suspend your account in the event that we determine, at our sole discretion, that you have violated this Agreement, including participating in any activities that adversely affect other users' experiences. Unless we have expressly agreed to otherwise, we are not obligated to provide you with the reason for suspending or terminating your access to our Services. You agree not to use the Services if you have been previously removed or banned by us.
b. If you violate this Agreement, your permission to use the Software and Content automatically terminates and you must immediately destroy any copies you have made of any portion of the Software or Content. Your records containing your Personal Data are available in accordance with our Privacy Policy. Termination will not limit any of Namida Lab's rights or remedies at law or in equity.
c. Namida Lab may also suspend or terminate your access if we have reason to believe that you have violated or may have violated another's intellectual property rights.
d. You acknowledge and agree that the Software is under development and will continually change as Namida Lab may determine from time to time. Namida Lab reserves the right to terminate any portion of the Software, or any Services related to the Software at any time.

2. MODIFICATION OF TERMS

a. Namida Lab reserves the right to modify this Agreement at any time and for any reason. Namida Lab will post the most current version of this Agreement at https://www.namidalab.com/eula. If Namida Lab makes material changes to this Agreement, you will receive notification via the Mobile App.
b. Notwithstanding the foregoing, you are responsible for complying with the updated terms posted online at Namida Lab's website even if these updated terms appear online at Namida Lab's website before being posted on the Mobile App. Your continued use of the Mobile App after Namida Lab publishes notice of changes to this Agreement indicates your consent to the updated terms.

3. DESCRIPTION OF SERVICES

a. Namida Lab provides a digital clinical study management platform. Our platform connects people with health and health-related resources provided by their Sponsor to help them feel

confident, cared for, and supported by the healthcare they have, every day. Resources may include, among other things, educational articles, assessments and screeners, links to third party sites, reminders and alerts, recommendations and tasks, biometric/medication/symptom trackers, health plan benefits and administration information, and access to health plan staff.

b. Namida Lab strives to be a worthy steward of the data with which we are entrusted. In accordance with our Privacy Policy, we collect data about our members as they interact with the Software and use it to personalize the individual experience as well as continually improve the platform overall, among other things. We may share data with your Sponsor and other partners who have undergone a strict approval process. We do not share data with advertisers.

4. LICENSE GRANT

a. Subject to the terms and conditions of this Agreement, Namida Lab hereby grants you a personal, non-transferable, non-exclusive, non-sublicensable, revocable, royalty free, limited license to:
   i. Download, install and use the Software for your own internal, non-commercial purposes on a mobile device owned or otherwise controlled by you ("Mobile Device"); and
   ii. Access and use on such Mobile Device the Services and the Content (as defined below) made available in or otherwise accessible through the Software.

b. You also acknowledge that portions of the Software, including substantial portions of the Services accessible as part of the Software, will be provided via remote access from your Mobile Device to Namida Lab's platform.

c. You may copy the Software onto your Mobile Device, and you may make one (1) copy of the Software for backup or archival purposes. You agree that (i) your use and possession of such copies shall be solely under the terms and conditions of this Agreement, and (ii) you shall place the same proprietary and copyright notices and legends on all such copies as included by Namida Lab on any media embodying an authorized copy of the Software originally provided by Namida Lab. Except as described in this section you are not permitted to copy the Software or Content.

5. LICENSE RESTRICTIONS

a. To the extent permitted by applicable law, you shall not:
   i. sublicense, sell, distribute, rent, lease, transfer, loan or otherwise convey or commercially exploit the Software or the content made available through the Software ("Content") or any portion thereof to anyone, and under no circumstance may you use or allow the use of the Software in any manner other than as expressly set forth above.
   ii. modify the Software, incorporate the Software in whole or in part in any other product or create derivative works based on all or part of the Software.
   iii. use the Software in connection with a service bureau, time sharing or fee-for- service arrangement with third parties.
   iv. Remove or obscure any copyright notice, trademark notice, or other proprietary rights notice displayed on or in conjunction with the Services.
   v. Modify, translate, adapt, merge, make derivative works of, disassemble, decompile, reverse compile, or reverse engineer any part of our Services.
   vi. Access, view any source code or object code of Namida Lab or our licensors; or

vii. Remove, disable, circumvent, or otherwise create or implement any workaround to any copy protection, rights management, or security features in or protecting the Software. If you dispose of any media embodying Software or Content, you will ensure that you have completely erased or otherwise destroyed any Software and Content stored on such media.,

viii. At Namida Lab we are strong supporters of Open Standards and Open-Source Software as foundations of innovation for our own technology development. An important aspect of that support is proper adherence to licensing and attribution policies for components embedded in our products.

b. THE SOFTWARE IS NOT INTENDED FOR USE IN ANY SITUATION IN WHICH THE FAILURE OF THE SOFTWARE COULD LEAD TO DEATH OR BODILY INJURY OF ANY TYPE. YOU ARE SOLELY RESPONSIBLE FOR USING THE SOFTWARE IN A MANNER CONSISTENT WITH ALL APPLICABLE INTERNATIONAL, REGIONAL, FEDERAL, NATIONAL, STATE, AND LOCAL LAWS.

6. RESERVATION OF RIGHTS

a. You agree and acknowledge that:

i. the Software is licensed to you, not sold, and Namida Lab transfers no ownership interest in the Software, in the intellectual property in any Software or in any Software copy, to you under this Agreement or otherwise.

ii. Namida Lab and its licensors reserve all rights not expressly granted to you hereunder.

iii. Namida Lab or its licensors reserve and shall retain all right, title and interest in and to the Software (including, but not by way of limitation, any images, algorithms, photographs, animations, video, audio, music, and text incorporated in the Software)

iv. The Software is protected by United States Copyright Law and international treaties relating to protection of copyright; and

v. The Software includes, and this Agreement will cover, any updates, upgrades or bug fixes for the Software provided to you.

7. USE OF CONTENT

a. The Software and Content may contain typographical errors, other inadvertent errors, or inaccuracies. We reserve the right to make changes to the Software, document names, Content, descriptions or specifications of products or Services, or other information without obligation to issue any notice of such changes.

b. You may view, copy, download, and print Content and Attachments (defined below) that are available through the Software, subject to the following conditions:

i. The Content and Attachments may be used solely for your personal informational purposes. No part of this Software or its Content may be reproduced or transmitted in any form, by any means, electronic or mechanical, including photocopying and recording for any other purpose.

ii. The Content may not be modified.

iii. Copyright, trademark, and other proprietary notices may not be removed.

c. Nothing contained on the Website or in the Software or Services should be construed as granting, by implication, estoppel, or otherwise, any license or right to use this Software or any Content displayed on our Website, through the use of framing or otherwise, except: (a) as

expressly permitted by these terms of use; or (b) with our prior written permission or the permission of such third party that may own the trademark or copyright of material displayed on our Website.

8. USER SUBMITTED CONTENT

a. You are responsible for all Content and personal data (including photos) that you submit, post, or otherwise make available to or through the Services ("Attachments"). By doing so, you represent and warrant to Namida Lab that such Content and Attachments is not the confidential information of another person or entity and that you have all necessary permission to submit, post, and otherwise make available such Content and Attachments. Namida Lab makes no claims to ownership of Content and Attachments you submit, post, or otherwise make available to or through the Services and you continue to retain all ownership rights in such Content and Attachments and the right to use your Content and Attachments as you determine.
b. However, you do grant to Namida Lab, our affiliates, contractors, service providers and agents a worldwide, nonexclusive, perpetual, irrevocable, global, royalty-free right and license (subject in all cases to the Privacy Policy) (a) to use, reproduce, modify, adapt, publish, translate, create derivative works from, distribute, publicly perform, and publicly display Content for the purpose of delivering, developing, improving, and marketing the Services; (b) to develop, support and use Content to develop algorithms to detect patterns in data; and (c) to use, reproduce, analyze, aggregate and otherwise process personal data in accordance with the Privacy Policy.
c. When you upload or share a child's name, photo or a photo related to your child into the Software, you acknowledge that such image or name is not confidential and that you have all necessary permission to submit, post, and otherwise make the photo and name available and consent to Namida Lab using that photo within the Software but solely as needed to provide the Services.

9. ACCEPTABLE USE POLICY

a. You agree that the following actions shall constitute a material breach of these Terms, and that you will not upload or transmit any communications or content of any type that:
    i. constitutes unsolicited offers, advertisements, proposals, junk mail, or spam that other users of the Services will see or receive. This includes, but is not limited to, unsolicited advertising, promotional materials or other solicitation materials, bulk mailing of commercial advertising, chain mail, pyramid schemes, informational announcements, charity requests, and petitions for signatures.
    ii. infringes upon or violates any rights of any party.
    iii. impersonates another person or entity or creates a false impression or misleads others as to the origins of your communications.
    iv. infringes on the intellectual property, copyright, trade secret, privacy, or publicity rights of others.
    v. is unlawful, obscene, derogatory, defamatory, threatening, harassing, abusive, slanderous, hateful, offensive, or embarrassing to any other person or entity as reasonably determined by Namida Lab.
    vi. promotes violence, illegal drug use, or substance abuse or describes how to perform a violent act, use illegal drugs, or abuse other substances.

vii. harvests or otherwise collects information about others, including email addresses, without their consent.
viii. discloses the personal data of others, including names, email addresses, telephone numbers, or any other confidential or personally identifiable information (other than in a caregiver capacity, as applicable)
ix. distributes viruses or another harmful computer code.
x. restricts or inhibits any other person from using or enjoying the Services, or which, in the reasonable judgment of Namida Lab, exposes us or any of our customers, partners, affiliates, or suppliers to any liability or detriment of any type; or
xi. deals with minors under 13 years of age without the consent of their parents.

10. PERSONAL DATA

a. By using the Services, you authorize Namida Lab to collect, receive, use, and disclose your personal information as defined and described in our Privacy Policy: https://www.namidalab.com/privacypolicy. Namida Lab agrees to use and protect your personal information in accordance with the Privacy Policy and applicable laws.
b. You agree that Namida Lab may collect and use Personal Data and technical data and related information, including, but not limited to, unique device identifiers and other technical information ("Aggregate Data") about your device, system and application software, and peripherals that is gathered periodically to facilitate the provision of software updates, product support, and other services to you (if any) related to the Software, and to track and report your activity inside of the Software, including for analytics purposes.
c. Namida Lab's use and disclosure of any Personal Data and Aggregate Data will be conducted in compliance with all applicable laws and regulations. You agree that:
    i. you consent to such disclosures and uses of Aggregate Data.
    ii. Namida Lab is not obligated to pay any amount to you or otherwise compensate you or any other person in any way for such disclosures and uses.
    iii. Namida Lab is not required to furnish you with any other information of any kind regarding such disclosures and uses; and
    iv. to the extent that you have proprietary interest in any such Aggregate Data, you waive any right to such interest, and you waive any right to seek compensation for such disclosures or uses.

11. ASSUMPTION OF RISK

a. Namida Lab does not nor does it intend to provide clinical or diagnostic advice.
b. Please do not ask Namida Lab for--or rely on--anything that we communicate as medical advice. Although the Services may contain articles on medical topics, we make no warranty whatsoever that any of the articles are accurate. Even if a statement we make about a health or medical issue is accurate, it may not apply to you or somebody in your care's symptoms.
c. The health or medical information we write about is general and cannot substitute for the advice of a licensed medical professional. Namida Lab takes no responsibility for the results or consequences of any attempt to use or adopt any of the information presented in our materials. You should not interpret anything in our Services as an attempt to offer or render a medical opinion or otherwise engage in the practice of medicine.

d. Always seek the advice of your physician or other qualified health provider with any questions you may have regarding a medical condition. If you think you, or somebody in your care, may have a medical emergency, call your doctor or 911 immediately.

12. PASSWORD PROTECTION

a. You are responsible for taking all reasonable steps to ensure that no unauthorized person accesses your account.
b. It is your responsibility to:
    i. select a strong password.
    ii. control the distribution of your password or account information.
    iii. authorize, monitor, and control access to and use of your account and password; and
    iv. inform us of any need to deactivate your password or change your registration as soon as possible.
    v. Namida Lab is not responsible or liable to you in any way if information is intercepted by an unauthorized person, either in transit or at your home, business, or other place of access.

13. Login Credentials and Access

a. Your access to the Software must be via login credentials ("Login Credentials"). You agree that you are responsible for protecting your Login Credentials from unauthorized use, and you are responsible for all activity that occurs under those Login Credentials. You agree to notify us immediately if you believe that any of Your Login Credentials have been or may be used without your permission so that appropriate action can be taken.
b. You may not (i) create more than one account to access the Software, (ii) share your Login Credentials with any third party or (iii) transfer your account to any third party.
c. Namida Lab is not responsible for any loss or damage caused by, or expense incurred by you as a result of, your failure to safeguard your Login Credentials.
d. Namida Lab will protect as confidential any Personal Data that you may provide to complete the applicable online forms to establish your Login Credentials with Namida Lab.
e. You agree to provide, maintain, and update true, accurate, current, and complete Personal Data on the screens that collect information from you in connection with the Software, and represent that you will not misrepresent your identity or your affiliation with any person or entity.

14. Export Restrictions

a. The Software may be subject to US export control laws, including the Export Control Reform Act and its associated regulations.
b. You shall not, directly, or indirectly, export, re-export, or release the Software to, or make the Software accessible from, any jurisdiction or country to which export, re-export, or release is prohibited by law, rule, or regulation.
c. You shall comply with all applicable federal laws, regulations, and rules, and complete all required undertakings (including obtaining any necessary export license or other governmental approval), prior to exporting, re-exporting, releasing, or otherwise making the Software available outside the US.

15. ENFORCEMENT OF TERMS

You agree that Namida Lab's licensors referenced in the Software are third-party beneficiaries of this Agreement and may enforce this Agreement as it relates to their intellectual property. Sections of this Agreement which by their nature survive expiration or termination of this Agreement shall survive according to their terms.

16. US GOVERNMENT RIGHTS

The Software is commercial computer software, as such term is defined in 48 C.F.R. § 2.101. Accordingly, if you are an agency of the US Government or any contractor therefore, you receive only those rights with respect to the Software as are granted to all other end users under license, in accordance with (a) 48 C.F.R. § 227.7201 through 48 C.F.R. § 227.7204, with respect to the Department of Defense and their contractors, or (b) 48 C.F.R. § 12.212, with respect to all other US Government licensees and their contractors.

17. Access to our Software by Minors

The Children's Online Privacy and Protection Act requires that online service providers, which are directed to children under the age of 13 years old, obtain parental consent before they collect personally identifiable information online from these children. Namida Lab does not knowingly collect Personal Data from children under the age of 13, and our Software is not directed at users under the age of 13. **You hereby acknowledge and agree that children under the age of 13 are prohibited from using our Software.** A parent, guardian, or personal representative may use the Software on behalf of a child under the age of 13. Furthermore, you acknowledge and agree that minors between the ages of 13 and 17 may use our Software, but that a parent, guardian, or personal representative must consent to this Agreement and our Privacy Policy on their behalf.

18. THIRD PARTY SERVICES

a. In some instances, you may be able to access, schedule, or otherwise use services or view content provided by a third party, such as telehealth services, testing services, or other services related to your health or health benefits, via the Software (the "Additional Services").
b. These Additional Services are not provided by Namida Lab. These Additional Services are provided by third parties and may be subject to additional terms and conditions. Namida Lab may ask you to provide information in association with your use of these Additional Services, subject to our Privacy Policy.
c. Namida Lab may agree to allow advertisers to respond to certain search terms with advertisements or sponsored material. You acknowledge and agree that Namida Lab is not responsible for these Additional Services, including their accuracy, completeness, timeliness, validity, copyright, compliance, legality, decency, quality, or any aspect thereof.
d. Some of these Additional Services may use Content under license from Namida Lab. Namida Lab is not responsible for and we do not endorse any features, content, advertising, products, or other materials on other websites or applications, whether or not Namida Lab is affiliated with those Additional Services. You assume all risk and we disclaim all liability arising from your use of the Additional Services.

e. You acknowledge and understand that should you choose to provide any Personal Data as a part of the Additional Services the recipients of such Personal Data, after it is disclosed, may not be subject to the same obligations under federal privacy laws or other Applicable Laws and Regulations, and such third-party sites may use or re-disclose the information in accordance with applicable laws and regulations and their respective privacy policies.

19. DEVICE INTEGRATIONS

a. The Software may also act as a notification system with respect to specific events that may be detected by a biometric device you own or control that is connected to the Software. Do not use the Software as a substitute for the direct monitoring and verification of specific events. Namida Lab is not responsible for your biometric device, including its accuracy, security, completeness, timeliness, validity, copyright, compliance, legality, decency, quality, or any aspect thereof. Information that we and/or your Sponsor receives from your device will be considered Content.
b. The third-party device manufacturers of your biometric device may require you to read or consent to the device manufacturer's terms of service, privacy policy, or other user agreements (the "Manufacturer User Agreements"), and they may prevent you from connecting your device to the Software without first consenting to those agreements. By using the Services, you agree to comply with the terms of the Manufacturer User Agreements.

20. UPDATES

a. Namida Lab may from time to time in its sole discretion develop and provide Software updates, which may include upgrades, bug fixes, patches, other error corrections, and/or new features (collectively, including related documentation, "Updates"). Updates may also modify or delete in their entirety certain features and functionality.
b. You agree that Namida Lab has no obligation to provide any Updates or to continue to provide or enable any particular features or functionality. Based on your Mobile Device settings, when your Mobile Device is connected to the internet either: (a) the Software will automatically download and install all available Updates; or (b)you may receive notice of or be prompted to download and install available Updates.
c. You shall promptly download and install all Updates and acknowledge and agree that the Software or portions thereof may not properly operate should you fail to do so. You further agree that all Updates will be deemed part of the Application and be subject to all terms and conditions of this Agreement.

21. CONSENT TO ELECTRONIC COMMUNICATIONS AND SOLICITATION.

a. By downloading the Mobile App, you authorize Namida Lab to send you (including via email and push notifications) information regarding the Services and the Mobile App, such as: (a) notices about your use of the Services, including notices of violations of use; (b) updates to the Services and new features or products; and (c) promotional information and materials regarding our products and services.
b. You can review your account notification settings and adjust your messaging preferences, including opting-in to additional messages or unsubscribing to certain messaging through the Mobile App settings.

22. DISCLAIMER OF WARRANTY

a. NAMIDA LAB PROVIDES THE SOFTWARE TO YOU "AS IS", WITH ALL FAULTS, AND WITHOUT WARRANTY OF ANY KIND, EXPRESS, STATUTORY, IMPLIED OR OTHERWISE, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NON-INFRINGEMENT. NAMIDA LAB MAKES NO REPRESENTATION OR WARRANTY THAT THE SOFTWARE IS ACCURATE, COMPLETE OR UP TO DATE.
b. NAMIDA LAB MAKES NO REPRESENTATION OR WARRANTY OF ANY KIND WITH RESPECT TO THE USE OR THE RESULTS OF THE USE OF ANY DATA OR INTERACTIONS OF ANY USER. NO ORAL OR WRITTEN INFORMATION OR ADVICE GIVEN BY ANY NAMIDA LAB EMPLOYEE, REPRESENTATIVE OR DISTRIBUTOR SHALL CREATE A WARRANTY FOR THE SOFTWARE, AND YOU MAY NOT RELY ON ANY SUCH INFORMATION OR ADVICE. NAMIDA LAB'S LICENSORS EXPLICITLY DISCLAIM ANY AND ALL WARRANTIES WITH RESPECT TO THE SOFTWARE.

23. LIMITATIONS OF LIABILITY AND RELEASES

a. IN NO EVENT SHALL NAMIDA LAB OR ITS LICENSORS BE LIABLE TO YOU FOR ANY SPECIAL, CONSEQUENTIAL, PUNITIVE, EXEMPLARY, INCIDENTAL, OR INDIRECT DAMAGES OF ANY KIND (INCLUDING WITHOUT LIMITATION THE COST OF COVER, DAMAGES ARISING FROM LOSS OF DATA, USE, PROFITS OR GOODWILL), WHETHER OR NOT NAMIDA LAB HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY ARISING OUT OF THIS AGREEMENT. THESE LIMITATIONS SHALL APPLY NOTWITHSTANDING THE FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY.
b. NAMIDA LAB'S MAXIMUM AGGREGATE LIABILITY ARISING OUT OF THIS AGREEMENT AND/OR YOUR USE OR POSSESSION OF THE SOFTWARE, INCLUDING WITHOUT LIMITATION ANY CLAIMS IN TORT (INCLUDING NEGLIGENCE), CONTRACT, BREACH OF WARRANTY, STRICT LIABILITY OR OTHERWISE, AND FOR ANY AND ALL CLAIMS COMBINED, WILL NOT EXCEED U.S. $1.

24. EXCLUSIONS

SOME JURISDICTIONS DO NOT ALLOW THE EXCLUSION OF IMPLIED WARRANTIES OR LIMITATIONS ON CERTAIN TYPES OF DAMAGES, SO THE ABOVE DISCLAIMERS AND LIMITATIONS MAY NOT APPLY TO YOU WITH RESPECT TO CERTAIN TYPES OF DAMAGES OR CLAIMS.

25. NOTICES

Notices to you hereunder shall be sent to the email address provided by you when you registered to download and install the Software. Notices to Namida Lab shall be sent to the attention of the Legal Department at Namida Lab, Inc. 1905 E Mission Blvd. Suite 6, Fayetteville, AR 72703. Each party may change such address upon written notice to the other party.

26. GOVERNING LAW

a. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Arkansas, USA without regard to its conflicts of laws provision. The United Nations Convention on Contracts for the International Sale of Goods shall not apply.
b. The parties hereby consent to the exclusive jurisdiction and venue in the state courts in Washington County, Arkansas or any federal court located therein. In any action or proceeding

to enforce or interpret this Agreement, the prevailing party will be entitled to recover the costs and expenses (including reasonable attorneys' fees) that it incurred in connection with such action or proceeding and enforcing any judgment or order obtained.

27. CLASS ACTION WAIVER

WHERE PERMITTED BY APPLICABLE LAW YOU AND NAMIDA LAB AGREE THAT EACH MAY BRING CLAIMS AGAINST THE OTHER ONLY IN YOUR OR NAMIDA LAB'S INDIVIDUAL CAPACITY AND NOT AS A PLAINTIFF OR CLASS MEMBER IN ANY PURPORTED CLASS OR REPRESENTATIVE ACTION. You further acknowledge and agree that no arbitrator or judge may consolidate more than one person's claims or otherwise preside over any form of a representative or class proceeding. This Class Action Waiver section will survive any termination of this Agreement.

28. GEOGRAPHIC RESTRICTIONS

The Content and Services are based in the United States and provided for access and use only by persons located in the United States. You acknowledge that you may not be able to access all or some of the Content and Services outside of the United States and that access thereto may not be legal by certain persons or in certain countries. If you access the Content and Services from outside the United States, you are responsible for compliance with local laws.

29. ASSIGNMENT

This Agreement and any rights and licenses granted hereunder may not be transferred or assigned by you without Namida Lab's prior written consent but may be assigned by Namida Lab without restriction. Any assignment attempted to be made in violation of this Agreement shall be void. This Agreement shall be binding upon and inure to the benefit of the parties hereto, and their permitted successors, heirs, and assigns. You may not sublicense, delegate, assign or otherwise transfer this Agreement, the license granted herein, or any other of your rights or obligations under this Agreement, in whole or in part.

30. COMPLETE AGREEMENT; SEVERABILITY

This Agreement supersedes all proposals, oral or written, all negotiations, conversations, discussions, agreements, and all past course of dealing between you and Namida Lab relating to the Software or the terms of its license to you, and may only be modified in writing signed by you and Namida Lab. In the event any term of this Agreement is held by a court of competent jurisdiction not to be enforceable, such unenforceability shall not affect the remaining terms of this Agreement in such jurisdiction or render unenforceable or invalidate such terms and provisions of this Agreement in other jurisdictions. Upon such determination that any of the terms or provisions of this Agreement are held to be invalid under any applicable statute or rule of law, they shall be severed from this Agreement and the remaining provisions of this Agreement shall be interpreted so as best to reasonably effect the intent of the parties and the parties agree to replace any invalid or unenforceable provisions in a mutually acceptable manner in order that the transactions contemplated hereby be consummated as originally contemplated to the greatest extent possible. No waiver of any right or obligation contained herein shall be given except in writing signed by the party against whom the waiver is sought to be enforced.

If you have any questions about this license agreement, please contact help@namidalab.com.

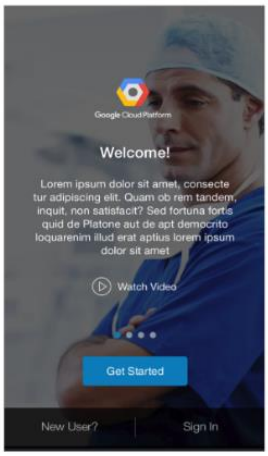
You can also reach us by mail:

Namida Lab, Inc.
ATTN: Legal
1905 E Mission Blvd. Suite 6
Fayetteville, AR 72703, USA

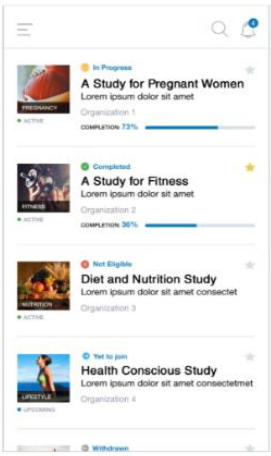
*** YOU ACKNOWLEDGE THAT YOU HAVE READ THIS AGREEMENT, UNDERSTAND IT, AND AGREE TO BE BOUND BY ITS TERMS AND CONDITIONS. ***

R. Namida Lab, Inc. Mobile App Participant Facing Screenshot(s)

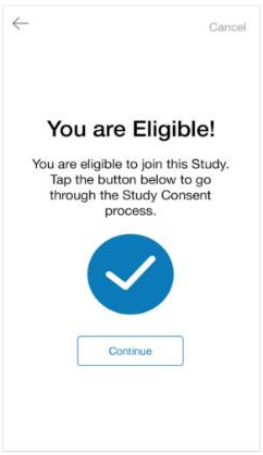
Sign-up



Discovery

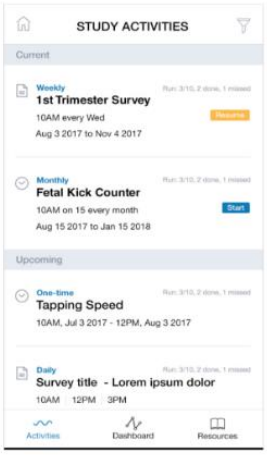


Eligibility

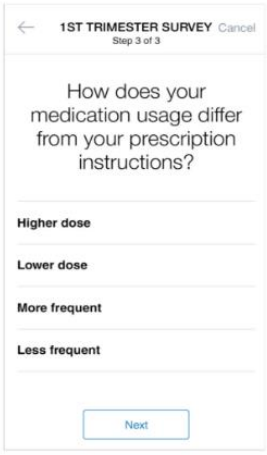


eConsent

Task list



Activities



Reminders

Feedback