

NCT03138798

Dental Support Device in the Second Stage of Labor at a Major Tertiary Care Center; A
Randomized Controlled Trial

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Icahn School of Medicine at Mount Sinai
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**Amendment
IRB-16-00761**

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1. Modification

Summary of the Modification Request

We determined prior to enrollment (but after initial approval) that our sample size needed to be extended to 348 total patients in order to be powered to detect a 20% difference in total pushing time.

Justification for the Modification

After initial study approval by the IRB, but prior to actually beginning enrollment, our team re-calculated our power analysis because we realized we did not account for the fact that the duration of the second stage of labor is not a normally distribute variable. For this reason, at the onset we recalculated the sample size. In order to be powered to detect a 20% reduction in pushing time, we need a total of 348 patients enrolled (174 patients per arm). We are requesting approval to enroll for a total of 348 patients.

This Modification Changes Yes
the Consent Document or
Information that May Affect
Subjects' Willingness to Continue
to Participate in the Research

Description of Changes in the Consent Document or Information that May Affect Subjects' Willingness to Continue to Participate in the Research

This only changes the wording of the section of the consent labelled "Length and Time and Number of People Expected to Participate". I have attached both the modified versions with/without tracked changes. Otherwise, these changes will not have any effect on patients' willingness to continue to participate.

Subjects Will Be Re-Consented or No
Provided with the New Information

Explanation Why Re-Consenting or Providing Subjects with the New Information is Not Necessary

The modification does not affect previously enrolled patients in our study.

2. Summary - Title

Protocol Title

Dental Support Device in the Second Stage of Labor at a Major Tertiary Care Center; A Randomized Controlled Trial

Principal Investigator Angela Bianco

When the application is complete, it will be sent to the PI for submission

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Primary Department Obstetrics/Gynecology

When the application is complete, it will be sent to the PI for submission

Application Initiated By Eric Bergh

Lay Summary

In an effort to reduce the rate of cesarean section, obstetric practices now allow for prolonged second stage of labor to accomplish vaginal delivery. However, this practice is not without risks and may lead to either operative delivery (vacuum or forceps assisted delivery) or cesarean section with significant maternal/neonatal morbidity. While the use of a dental support device in labor is not yet standard of care, limited evidence suggests that using such a device while pushing may improve maternal valsava and lead to a shortened second stage of labor by allowing them to push more effectively. Previous studies have been underpowered to find statistically significant results.

At our institution, we have a unique and heterogeneous inner-city population of laboring mothers with marked rates of maternal obesity. Our objective is to conduct a randomized controlled trial in which nulliparous patients are asked to use a dental support device throughout the entirety of the second stage of labor (while pushing with contractions). Our primary outcome is the duration of the second stage. Secondary outcomes will include cesarean section and operative delivery rates, as well as combined maternal and neonatal morbidity (Rates of post-partum hemorrhage, chorioamnionitis, perineal trauma, fetal weight, neonatal apgars etc...).

In this study we will use the dental support device, Laboraide, produced by Medivie. The device has Class 1 FDA approval, under the classification of non-fluid filled teething-ring device. Premarket review by the FDA was performed by the following FDA departments: Office of Device Evaluation (ODE), Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices (DAGRID) and Dental Devices Branch (DEDB). The device is marketed to laboring patients in the US and Europe to potentially help reduce pain and more efficiently produce a valsalva while pushing in labor. Finally, the device is not currently in use at MSSM. It will be purchased through OB/GYN departmental research funds and it is only being purchased for use in this study.

IF Number IF1937858

3. Summary - Setup

Funding Has Been Requested / Obtained	No
Application Type	Request to Rely on Mount Sinai IRB
Research Involves	Prospective Study ONLY
Consenting Participants	Yes
Requesting Waiver or Alteration of Informed Consent for Any Procedures	No
Humanitarian Use Device (HUD) Used Exclusively in the Course of Medical Practice	No
Use of an Investigational Device to Evaluate Its Safety or Effectiveness	No
Banking Specimens for Future Research	No
Cancer Related Research that Requires Approval from the Protocol Review and Monitoring Committee (PRMC).	No

Is this Cancer Related Research? Cancer Related Research is defined as research that has cancer endpoints or has a cancer population as part of or all of its targeted population. This includes protocols studying patients with cancer or those at risk for cancer.

Clinical Trial	Yes
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*** A prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices).**
*** Used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective.**

Drugs / Biologics	No
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*** Drugs / Biologics That Are Not a Part of Standard Practice**
*** Controlled Substances**
*** Drugs / Biologics Supplied by the Research Sponsor or Purchased with Study Funds**

Ionizing Radiation for imaging or therapy, including X-Ray, Fluoroscopy, CT, Nuclear Medicine, PET andor Radiation Therapy:

* Purely for standard of care:	No
* In frequency or intensity that exceeds what is necessary for standard of care:	No

Hazardous Materials	No
---------------------	----

*** Recombinant DNA**

- * *Viral Vectors*
- * *Plasmids*
- * *Bacterial Artificial Chromosomes*
- * *Toxic Chemicals, Potentially Toxic Medications, Carcinogens*
- * *Autologous Cell Lines*

Request Use of Clinical Research No
Unit Resources

4. Summary - Background

Objectives

To determine if the use of a dental support device in the second stage of labor will decrease the time to vaginal delivery in an inner city population.

Background

Over the last several decades the rate of cesarean section has risen significantly in the United States to approximately 33% in 2013. This is particularly alarming given the increased risk for major maternal morbidity including abnormal placentation and hemorrhage associated with multiple repeat cesarean sections. In an effort to reduce the rate of cesarean section, obstetric practices now allow for prolonged second stage of labor to accomplish vaginal delivery. However, this practice is not without risks and may lead to either operative vaginal delivery (vacuum or forceps assisted delivery) or cesarean section. Maternal complications associated with these outcomes include higher rates of postpartum hemorrhage, febrile morbidity and perineal trauma. Furthermore, a prolonged second stage increases the risk for NICU admission, neonatal sepsis and asphyxia as well as lower Apgar scores.^[1] Techniques to increase the effectiveness of pushing may lead to a shortened second stage.

Dental support devices may improve maternal valsava through several mechanisms. These include increased muscle strength in different muscle groups^[2-5], increased isometric endurance during the pushing phase^[6], increased maintenance of physical activity^[7], and optimization of head and neck posture, causing increased cervical muscle strength and enhancing the valsalva maneuver, which increases the intrauterine pressure^[8, 9] Matsuo et al. ^[9] conducted a pilot study in which nulliparous women were randomized to a dental support device during the second stage and found a reduction in the duration of pushing. Because it was a pilot study, it was not powered to find statistically significant results. This was followed by a randomized controlled study by Aviram et al. ^[10] in which nulliparous Israeli women selected at random were asked to use the device while pushing in labor. They found a reduction in the rate of obstetric interventions (cesarean section and operative vaginal delivery) performed for prolonged second stage, however no difference was found in the overall duration of the second stage between groups. A major limitation was the requirement that experimental subjects only push with the device for a total of 10 minutes during the second stage. Furthermore, their population included women with an average pre-pregnancy BMI of 22 and they used a per-protocol analysis rather than intention-to-treat.

There have been no further studies to investigate the role of dental support devices in the second stage of labor. The existing evidence suggests that women who are actively pushing in labor may benefit from improvements in strength, endurance and posture which may be attained using a dental support device.^[9, 10] At our institution, we have a unique and heterogeneous inner-city population of laboring mothers with marked rates of maternal obesity. In line with national trends, our cesarean section rate has risen over the last several decades. We welcome any intervention which may reduce the duration of the second stage and thereby reduce maternal and neonatal morbidity and the need for obstetric interventions such as cesarean section or operative delivery.

Our objective is to conduct a randomized controlled trial in which nulliparous patients are asked to use a dental support device throughout the second stage of labor. Our primary outcome is the duration of the second stage. Secondary outcomes will include cesarean section and operative delivery rates, as well as combined maternal and neonatal morbidity (Rates of post-partum hemorrhage, chorioamnionitis, perineal trauma, fetal weight, apgars etc...)

1. Laughon, S.K., et al., Neonatal and maternal outcomes with prolonged second stage of labor. *Obstet Gynecol*, 2014. 124(1): p. 57-67.
2. Carr, A.B., et al., Postural contractile activities of human jaw muscles following use of an occlusal splint. *J Oral Rehabil*, 1991. 18(2): p. 185-91.
3. Forgione, A.G., et al., Strength and bite, Part 2: Testing isometric strength using a MORA set to a functional criterion. *Cranio*, 1992. 10(1): p. 13-20.
4. Forgione, A.G., N.R. Mehta, and W.L. Westcott, Strength and bite, Part 1: An analytical review. *Cranio*, 1991. 9(4): p. 305-15.
5. Parker, M.W., et al., Muscle strength related to use of interocclusal splints. *Gen Dent*, 1984. 32(2): p. 105-9.
6. Chakfa, A.M., et al., The effect of stepwise increases in vertical dimension of occlusion on isometric strength of cervical flexors and deltoid muscles in nonsymptomatic females. *Cranio*, 2002. 20(4): p. 264-73.
7. Ishijima, T., et al., The relationship between occlusal support and physical exercise ability. *J Oral Rehabil*, 1998. 25(6): p. 468-71.
8. Buhimschi, C.S., et al., Use of McRoberts' position during delivery and increase in pushing efficiency. *Lancet*, 2001. 358(9280): p. 470-1.
9. Matsuo, K., et al., Duration of the second stage of labor while wearing a dental support device: a pilot study. *J Obstet Gynaecol Res*, 2009. 35(4): p. 672-8.
10. Aviram, A., et al., The effect of intrapartum dental support use among nulliparous during the second stage of labor - a randomized controlled study. *J Matern Fetal Neonatal Med*, 2016. 29(6): p. 868-71.

11. Hansen, S.L., S.L. Clark, and J.C. Foster, Active pushing versus passive fetal descent in the second stage of labor: a randomized controlled trial. *Obstet Gynecol*, 2002. 99(1): p. 29-34.

Primary and Secondary Study Endpoints

The primary outcome will be duration of the second stage to vaginal delivery. Secondary outcomes include mode of delivery, estimated blood loss, uterine atony, chorioamnionitis as well as neonatal outcomes (i.e. birth weight, apgar scores, NICU admission).

Protocol Was Already Approved No
by the Icahn School of Medicine at
Mount Sinai (ISMMS) Institutional
Review Board (IRB) Under a
Different Principal Investigator

Protocol Was Previously Submitted No
to an External(non-ISMMS) IRB

5. Research Personnel

Name/Department	Role/Status	Contact	Access	Signature Authority	Phone	Email
Angela Bianco / Obstetrics/ Gynecology	Principal Investigator /		Signature Authority			
Eric Bergh /	CI /		Signature Authority			
Luciana Vieira /	CI /		Edit Access			
Katherine Connolly /	CI /		Edit Access			
Stephanie Factor /	CI /		Edit Access			
Joanne Stone /	CI /		Edit Access			
Brittany Noel Robles /	ARC /		Edit Access			
Catherine Bigelow /	CI /		Edit Access			
Patricia Rekawek /	CI /		Edit Access			
Amrin Khander /	CI /		Edit Access			
Jessica Spiegelman /	CI /		Edit Access			

6. Sites

Site Name Icahn School of Medicine at Mount Sinai

Other External Site Name

Contact Details

Approved

Approval Document

Funded By Mount Sinai

Other IRB

7. Subjects - Enrollment

Site Name Icahn School of Medicine at Mount Sinai
Subjects To Be Enrolled
348
Total Number of Subjects to be Enrolled Across All Listed Sites Above (Auto Populated) 348

8. Subjects - Populations

Inclusion Criteria

Inclusion criteria include nulliparous women (no prior deliveries) at > or equal to 37 weeks gestation, with a non-anomalous, singleton fetus in a vertex presentation.

Exclusion Criteria

Exclusion criteria include multiparity, history of prior uterine surgery such as cesarean section or myomectomy, multifetal gestation, unexplained vaginal bleeding, latex allergy, or contraindication to vaginal delivery (i.e. placenta previa, vasa previa, active vaginal bleeding, macrosomia etc).

Enrollment Restrictions Based Upon Gender, Pregnancy, Childbearing Potential, or Race

Yes

Upon Gender, Pregnancy, Childbearing Potential, or Race

Justify Restriction(s)

This is a study of laboring patients and therefore will be restricted only to pregnant patients.

Age Range(s) 18 to 64 Years

Targeted Population(s) Adults - Patients , Pregnant Women

Other Aspects that Could Increase Subjects Vulnerability

The risks to subjects are inherent to the labor process itself outside of the study. The only difference in care is the use of a dental support device during the second stage. This may potentially shorten the duration of active pushing and perhaps reduce the number of cesarean sections performed for arrest of descent. There is no inherent risk to using the device in labor as has been evidenced by previous studies ([1] Aviram et al., [2] Matsuo et al.)

The patients in our study are all laboring nulliparous women in the second stage of labor. All women in this study will have access to labor analgesia as requested by the patient. In addition, enrollment in this study will not alter the current strategies regarding labor analgesia or induction protocols.

1. Aviram, A., et al., The effect of intrapartum dental support use among nulliparous during the second stage of labor - a randomized controlled study. *J Matern Fetal Neonatal Med*, 2016. 29(6): p. 868-71.
2. Matsuo, K., et al., Duration of the second stage of labor while wearing a dental support device: a pilot study. *J Obstet Gynaecol Res*, 2009. 35(4): p. 672-8.

Safeguards to protect Subjects rights and welfare

There is always the risk of loss of confidentiality; however, there are procedures in place to minimize this risk. To ensure confidentiality, the following system will be adhered to: When subjects are enrolled in this study, they will be assigned a unique identification code. Corresponding medical record numbers for each code (keycode) will be stored in a password locked document on the MFM server that can be accessed only by members of the research team. At the conclusion of the data extraction, the outcome variable will be assessed and the key codes to the medical record numbers will no longer be necessary and that information will be permanently erased from the keycode file. Electronic data with identifiers will be encrypted according to Data Security Standards.

9. Subjects - Participation

Duration of an Individual Subjects Participation in the Study

Duration of participation begins at time of recruitment until time of delivery.

Duration Anticipated to Enroll All Study Subjects

We expect to recruit all patients within 6 months

Estimated Date for the Investigators Within one year
to Complete This Study

Procedures for Subjects to Request Withdrawal

A patient may request to withdraw from the study at any time by notifying their obstetric provider.

Procedures for Investigator to Withdraw Subjects

There are no anticipated circumstances under which subjects will be withdrawn from the research without their consent.

Participants Will Be Recruited Yes

Recruitment Method(s) Clinical Practice, Other

Specify Other Recruitment Method

Eligible participants will be asked by their provider if they are interested in learning about a study aimed at decreasing the duration of the second stage of labor. Subjects who are interested will meet with study personnel. All aspects of the study will be explained. Those subjects who are interested will undergo the informed consent process. After informed consent, patients will be randomly assigned to one of the 2 arms of the study; to use of a dental support device in the second stage (intervention arm) or labor without a dental support device (control group).

How Participants Will Be Identified

Participants will be identified after they are admitted to labor and delivery. If the patient is expected to delivery vaginally (i.e. the patient does not intend to delivery by cesarean section), the admitting provider will ask the patient if they are interested in learning more about our study. This conversation will occur immediately at the time of admission. The patient will then be approached by the consenting research team. Patients will be given a unique study ID for identification purposes.

Who Will Initially Approach Potential Participants Treating Physician

How Research Will Be Introduced to Participants

Eligible participants will be asked by their provider if they are interested in learning about a study aimed at decreasing the duration of the second stage of labor. Subjects who are interested will meet with study personnel. All aspects of the study will be explained. Those subjects who are interested will undergo the informed consent process. After informed consent, patients will be randomly assigned to one of the 2 arms of the study; to use of a dental support device in the second stage (intervention arm) or labor without a dental support device (control group).

How Participants Will Be Screened

All research-related discussions will be held in the patient's private room. Any questions will be answered and fully discussed to maximize patient comfort. If they meet eligibility criteria and chose to participate they will be randomized and receive care within the accepted standards.

10. Subjects - Pregnant Women

Preclinical Studies Including Those on Pregnant Animals and Clinical Studies Including Those on Non-Pregnant Women Have Been Conducted

Data for Assessing Potential Risks to Pregnant Women and Fetuses

Previous studies have identified no inherent risk in using a dental support device in labor. ([1] Aviram et al., [2] Matsuo et al.)

1. Aviram, A., et al., The effect of intrapartum dental support use among nulliparous during the second stage of labor - a randomized controlled study. *J Matern Fetal Neonatal Med*, 2016. 29(6): p. 868-71.
2. Matsuo, K., et al., Duration of the second stage of labor while wearing a dental support device: a pilot study. *J Obstet Gynaecol Res*, 2009. 35(4): p. 672-8.

PI must attest that all of the following are true.

- * No inducements, monetary or otherwise, will be offered to terminate a pregnancy.***
- * Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.***
- * Individuals engaged in the research will have no part in determining the viability of a neonate.***

11. Procedures - Narrative

Description of the Study Design

This study is considering how the use of a dental support device may reduce the overall time to vaginal delivery in the second stage of labor. We will also assess other maternal and neonatal outcomes including rate of cesarean section, risk of infection (i.e. chorioamnionitis), bleeding, uterine atony, cesarean delivery and use of regional analgesia.

Description of Procedures Being Performed

At the time of randomization, patients in the intervention group will receive a new dental support device. The device is similar in appearance to a traditional athletic mouth guard but is designed to be comfortable and much less bulky. It is made of durable BPA free cushioned material which is easily placed in the mouth and fits between the patient's molars with a connecting bridge that fits in front of the patient's incisors. Patients will be asked to wear the device while pushing in the second stage and will be directly observed during the second stage by either the labor nurse or physician who is in the room. In between pushes the patient may either remove the device or leave it in place. We believe there is minimal risk associated with the use of a dental support device in the second stage of labor. Use of such a device has been well described in the Obstetric literature as safe with minimal risks. ([1] Aviram et al., [2] Matsuo et al.) Patients randomized to the control group will not receive a Laboraide device and will push in the second stage of labor without the use of a dental support device.

1. Aviram, A., et al., The effect of intrapartum dental support use among nulliparous during the second stage of labor - a randomized controlled study. *J Matern Fetal Neonatal Med*, 2016. 29(6): p. 868-71.
2. Matsuo, K., et al., Duration of the second stage of labor while wearing a dental support device: a pilot study. *J Obstet Gynaecol Res*, 2009. 35(4): p. 672-8.

Description of the Source Records that Will Be Used to Collect Data About Subjects

Data will be collected from documentation in the electronic medical record (EPIC).

Providers (either nurse or physician) caring for the patient in the second stage of labor will also be given a Second Stage Data Collection Sheet to be completed immediately after delivery in order to ensure accurate documentation of full dilation and time spent pushing in labor.

Finally, data will be collected from surveys that are completed after delivery by patients who are randomized to use a device.

Description of Data that Will Be Collected Including Long-Term Follow-Up

Data collected will include demographic variables such as age, parity, BMI, , as well as gestational age, bishop score, indication for induction, mode of delivery, time to full dilation, time to delivery, epidural use, and length of ruptured membranes. Neonatal outcomes including birthweight, apgars, NICU admissions will be assessed, as well as maternal outcomes including EBL, chorioamnionitis, and tachysystole.

Data will be analyzed on an intention to treat basis. Statistical analysis will be performed by SAS using X 2 test or Fisher exact test (categorical variables) and student t-test or Mann-Whitney U test (continuous variables). Statistical significance will be set at $p < 0.05$.

Research Requires HIV Testing No

12. Procedures - Genetic Testing

Genetic Testing Will Be Performed No

Guidance and Policies > Future Use Data Sharing and Genetic Research

13. Procedures - Details

Surveys or Interviews	No
Audio / Photo / Video Recording	No
Deception	No

Results of the Study Will Be Shared No
with Subjects or Others

14. Procedures - Compensation

Compensation for Participation No

15. Consent - Obtaining Consent

Consent Process

Adult Consent

Where and When Consent Will Be Obtained

All research-related discussions will be held in the patient's private room. Any questions will be answered and fully discussed to maximize patient comfort. If they chose to participate they will be randomized and receive care within the accepted standards.

Waiting Period for Obtaining Consent

The consent process will take place after admission to the labor floor and before the onset of the second stage of labor. It is not feasible to consent patients prior to the onset of labor as the majority of patients who deliver at Mount Sinai receive their prenatal care in locations a various private offices in New York City. Their first presentation to the Mount Sinai labor floor is generally either for a planned induction of labor or because they are already experiencing contractions in the early/first stage of labor.

SOP HRP-090 Informed Consent Yes
Process for Research Is Being
Used

PPHS Worksheets, Checklists and SOPs

Process to Document Consent in Will Use Standard Template
Writing

Non-English Speaking Participants No
Will Be Enrolled

Justification for Not Enrolling Non-English Speaking Participants

The patient will be consented after admission to the labor floor and informed consent will be obtained in the patient's private room. All study participants must be English speaking. Due to limited funding for individual fellow projects, the majority of available resources will be directed to acquiring devices for our study and we will not have the resources to translate the consent into other languages. Furthermore, the Laboraide device only supplies product documentation in English and Hebrew. We will be following SOP HRP-090 Informed Consent Process for Research.

16. Consent - Documents**Consent Documents**

Type 502a Consent
Name 502_a Consent
Upload CONSENT_502a_10_24_17.doc

Consent Templates

17. Data - Collection

Health Related Information Will Be Yes
Viewed, Recorded, or Generated

Description of Health Information That Will Be Viewed, Recorded, or Generated

Data collected from the electronic medical record will include demographic variables such as age, parity, BMI, as well as gestational age, bishop score, indication for induction, mode of delivery, time to full dilation, time to delivery, epidural use, and length of ruptured membranes. Neonatal outcomes including birthweight, apgar scores, NICU admissions will be assessed, as well as maternal outcomes including estimated blood loss, chorioamnionitis, and tachysystole.

Non-Health Related Information Will No
Be Viewed or Recorded

HIV / AIDS Related Information Will No
Be Viewed or Recorded

Data That Will Be Viewed, Recorded, or Generated Contains No
ANY of the Following Directly Identifiable Information

- * **Name**
- * **Social Security Number**
- * **Medical Record Number**
- * **Address by Street Location**
- * **Telephone Number**
- * **Fax Number**
- * **Web Uniform Resource Locators (URLs)**
- * **Internet Protocol (IP) Address**
- * **Health Plan Beneficiary Number**
- * **Account Number**
- * **Certificate**
- * **License Number**
- * **Vehicle Identification Number (Including License Plate Numbers)**
- * **Full-Face Photographic Images**
- * **Biometric Identifiers (Finger and Voice Prints)**
- * **Geographical Subdivisions Smaller Than a State**
- * **All Elements of Dates for Dates Directly Related to an Individual (i.e., Birth Date, Admission Date, Discharge Date)**
- * **Email Address**

Data Collection Sheet

Data Collection Sheet.docx

A Data Collection Sheet is required if you are either performing a retrospective review, or your study meets the category of exempt 4 research, or your study meets the category of expedited 5 research. Please upload it here.

Data Collection Source(s)

Participant, Medical Chart (Paper or Electronic)

18. Data - Storage

Location Where Data Will Be Stored

Each patient will be assigned a unique identification code. The code will be linked to the name and date of birth in an encrypted password-protected linking key code file which will be stored on the PI's personal network folder in the Hospital IT server, accessible by the PI only. The data will be stored in a separate password-protected database by the unique identification code. The database will be stored on a secure desktop at Mount Sinai hospital (5 E 98th St, Second Floor, Room 249, Department of OB/GYN, New York, NY 10029) and accessible only to members of the research team.

Identifiable patient information (consent forms & consent documentation) are kept separately from any data collected. All physical data is stored in a locked cabinet in our department (5 E 98th St, Second Floor, Room 249, Department of OB/GYN, New York, NY 10029).

How will the data be stored? With a Code That Can Be Linked to the Identity of the Participant

Research Personnel Responsible for: Angela Bianco

Accessing Data Yes

Receipt or Transmission of Data Yes

Holding Code That Can Be Linked to Identity of Participants Yes

Research Personnel Responsible for: Eric Bergh

Accessing Data Yes

Receipt or Transmission of Data Yes

Holding Code That Can Be Linked to Identity of Participants No

Research Personnel Responsible for: Luciana Vieira

Accessing Data Yes

Receipt or Transmission of Data Yes

Holding Code That Can Be Linked to Identity of Participants No

Research Personnel Responsible for: Katherine Connolly

Accessing Data Yes

Receipt or Transmission of Data Yes

Holding Code That Can Be Linked to Identity of Participants No

Research Personnel Responsible for: Stephanie Factor

Accessing Data Yes

Receipt or Transmission of Data Yes

Holding Code That Can Be Linked to Identity of Participants No

Research Personnel Responsible for: Joanne Stone

Accessing Data Yes

Receipt or Transmission of Data Yes

Holding Code That Can Be Linked to Identity of Participants No

Research Personnel Responsible for: Brittany Noel Robles

Accessing Data No

Receipt or Transmission of Data No

Holding Code That Can Be Linked to Identity of Participants No

Research Personnel Responsible for: Catherine Bigelow

Accessing Data No

Receipt or Transmission of Data No

Holding Code That Can Be Linked to Identity of Participants No

Research Personnel Responsible for: Patricia Rekawek

Accessing Data No

Receipt or Transmission of Data No

Holding Code That Can Be Linked to Identity of Participants No

Research Personnel Responsible for: Amrin Khander

Accessing Data No

Receipt or Transmission of Data No

Holding Code That Can Be Linked to Identity of Participants No

Research Personnel Responsible for: Jessica Spiegelman

Accessing Data No

Receipt or Transmission of Data No

Holding Code That Can Be Linked to Identity of Participants No

Duration Data Will Be Stored

Final data analysis and publication is anticipated in the fall of 2017. Data will be destroyed following publication.

Steps That Will Be Taken to Secure the Data During Storage, Use, and Transmission

Each patient will be assigned a unique identification code. The code will be linked to the name and date of birth in an encrypted password-protected linking key code file which will be stored on the PI's personal network folder in the Hospital IT server, accessible by the PI only. The data will be encrypted and will be stored in a separate password-protected database by the unique identification code. The encrypted database will be stored on a secure desktop at Mount Sinai hospital and accessible only to members of the research team.

Identifiable patient information (consent forms & consent documentation) are kept separately from any data collected. All physical data is stored in a locked cabinet in our department.

Data Analysis Plan Including Any Statistical Procedures

Data will be analyzed on an intention to treat basis. Statistical analysis will be performed by SAS using chi-square test or Fisher exact test (categorical variables) and student t test or Mann-Whitney U test (continuous variables). Statistical significance will be set at $p<0.05$.

19. Data - Safety Monitoring

More Than the Minimum Data Safety Monitoring Will Be Done No

The following minimum requirements apply to all projects, including retrospective reviews of medical records, use of tissue samples, and many minimal risk studies, such as observational and survey research. Because these minimum requirements apply to all studies, a specific written DSMP will not usually be required for projects that do not pose greater than minimal risk to subjects. The MSSM PPHS may alter the required level of monitoring if appropriate.

For all projects, the principal investigator must have a plan to assure that data integrity will be maintained during its collection, storage and analysis. All research projects must adhere to MSSM recommendations on the storage of research data. Loss of data containing identifiable information is reportable to the IRB within 5 business days.

Any problems concerning the consent process and any subject complaints should be monitored by the investigator. Reports of such problems must be made at least annually. The discretion of the protocol director will guide the need to report these problems immediately or more frequently.

The principal investigator is, typically, the monitoring entity for the minimum DSMP. When a principal investigator is not a faculty member, the supervising faculty member must be responsible for the data and safety monitoring aspect of the protocol.

Will the Research Include Data Coordinating Center Activities? No

20. Financial Administration

This information will help the Financial Administration of Clinical Trials Services (FACTS) office determine whether a Medicare Coverage Analysis (MCA) is needed for the research study. If you have any questions while completing this form, please contact the FACTS office at (212) 731-7067 or FACTS@mssm.edu.

Clinical Research Study Category Investigator Initiated

Payment Options:

*** Option 1: No protocol-required services will be billed to patients or third-party payers.**

Does Not Need MCA

*** Option 2: Protocol-required services (i.e., routine care services) will be billed to patients or third-party payers. Must Have MCA**

** Option 3: Study is initiated and federally funded by a Government Sponsored Cooperative Group who will only pay for services that are solely conducted for research purposes and other protocol-required services (i.e., routine care services) will be billed to patients or third-party payers. Billing Grid Only Required, NO MCA*

*** Option 4: Study involves only data collection and has no protocol-required clinical services. Does Not Need MCA**

*** Option 5: Study is not described in any of the above options. Please describe the study and specify whether External Sponsor (i.e., industry, government, or philanthropic source) and/or patient/third party payer will pay for protocol required services. MCA MAY Be Required**

Payment Option

Option 1

No MCA is needed per option selected above.

Payment Option 1:

** Option 1A: Department/collaborating departments will act as internal sponsor paying for all protocol-required services and no protocol-required services will be billed to patients or third party payers.*

*** Option 1B: Study involves protocol-required clinical services and an External Sponsor (i.e., industry, government, or philanthropic source) will pay for all protocol-required services.**

Payment Option 1

Option 1A

21. Attachments

Type	Name	Version	Status	Filename	Uploaded Date
Consent Documents	CONSENT_502a_10_24_17.doc	New		CONSENT_502a_10_20/25/2007	