Title: Health and Wellbeing of Pregnant and Post-Partum Women During the COVID-19 Pandemic

Document: Study Protocol

NCT number: 04385238

Date: 04 May 2020

Instructions: Complete this template to provide IRB members and designated reviewers with sufficient information to conduct a substantive review of human research. If applicable, submit a Sponsor's Protocol in addition to this document. Detailed instructions for preparing this template can be found in the Investigator's Manual. If the proposed human research is eligible for an Exemption Determination, see Appendix H of the Investigator Manual.

GENERAL INFORMATION	
Protocol/ESTR Record Number (if assigned): IRB20-0819	
Version Number: V11	**Version Date: 5/4/2020**
Principal Investigator (PI): Koenen, Karestan	
Principal Investigator's Harvard Affiliation: Faculty	
Protocol Title: Health and Wellbeing of Pregnant and Post-Partum Women During the COVID-19 Pandemic (WWCOVID)	

1. Specific Aims

To examine the experiences of pregnant and recently pregnant women to COVID-19.

2. Background and Significance

2.1 Provide the scientific background and rationale for the research.

Millions of women will give birth during the pandemic of Coronavirus Disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The consequences of COVID-19 for pregnant women and their offspring are unknown. This lack of information leads to anxiety among pregnant women, women who are considering getting pregnant, and their families. It is therefore important to assess the experiences of women during the COVID-19 pandemic.

2.2 Describe the significance of the research, and how it will contribute to generalizable knowledge.

The international nature of the proposed survey will gather information on the experiences of pregnant and recently pregnant women during the COVID pandemic, including evaluation of potential cultural and geographic differences. The knowledge will be of generalized interest during the pandemic.

3. Research Locations and Collaborating Sites

Research Locations refer to the geographic location that the research will take place, not to the institutions or researchers you may be collaborating with. All Research Locations should be listed in ESTR on the Research Locations page.

Collaborating Sites refer to institutions or researchers that are also taking part in the research study. All Collaborating Sites should be listed in ESTR on the Sites page.

There is no "research location". Participants from any country outside Europe (countries not included under GDPR) would complete a survey online voluntarily via website and app. Therefore, there is no specific location where data collection will take place. The data will then be stored (with

max security) in the Collaborating Site in California. The research will involve analysis of data from the investigators' computers, i.e., no lab will be necessary.

The Principal Investigators taking part in this research belong to the following institutions:

- Karestan Koenen, Harvard T.H. Chan School of Public Health, Boston, MA, USA
- Sonia Hernandez-Diaz, Harvard T.H. Chan School of Public Health, Boston, MA, USA
- Diego Wyszynski, Pregistry, Los Angeles, CA.

3.1. Where will the research activities take place? (check all that apply)

☒ **At Harvard; TH Chan School of Public Health** *list any non-Harvard LMA Schools here: A list of all Harvard Schools can be found here.*

☐ **At another location in Massachusetts;** *specify here:*

☒ **In another state in the U.S.;** *specify here:* Pregistry, Los Angeles, CA

☒ **Internationally;** *specify here:* Although it is a US based study, participants from other countries, excluding those covered by GDPR, can respond to the survey

3.2. Describe the sites or locations where the research will be conducted or overseen by the Harvard PI. (If conducting an online study, indicate the location of the researcher who is conducting the study.)

The Harvard Investigators will be located at the Harvard Chan School of Public Health in Boston. The Co-PI will be located in Pregistry, Los Angeles, CA. Since this is an online study there will be no research location, but the data for statistical analysis will be stored at a max security computer in California. The survey is anonymous and no identifying information will be collected. IP addresses will NOT be collected.

3.3. Describe plans for communication among sites regarding adverse events, interim results, protocol modifications, monitoring of data, etc. ☐ N/A.

The three Investigators are in regular contact via GoToMeeting, zoom and WhatsApp. They will continue to do so during the study. We anticipate face to face (online) meetings at least once a week initially, monthly later, and regular emails.

Describe any local (international or state) laws, regulations, and/or customs affecting the research (e.g., age of majority, mandatory reporting requirements, etc). ☒ N/A.

3.4. Identify any approvals or permissions required of collaborating institutions, community leaders, or government officials, including approval from another IRB or local research ethics committee. *Upload copies to the "Study-Related Documents" page in ESTR.* **☒ N/A because we are seeking an exempt designation since this is a fully anonymous survey..**

3.5. Will you collaborate with any researchers not affiliated with Harvard to carry out this study?

☐ **No** ☒ **Yes:** *If yes, list which institutions they are affiliated with. If they are not affiliated with an institution, indicate that here. If yes, also indicate their responsibilities and scope of work in conducting this research.*

Diego Wyszynski, MD, MHS, PhD, Pregistry, Los Angeles, CA .
Investigator. (Please see responsibilities below)

3.6. Will your collaborators interact with human subjects, have access to identifiable data/specimens, and/or be responsible for the design, conduct, oversight, or reporting of the research?
☐ **No** ☒ **Yes:** *If yes, indicate if the collaborators will obtain their own IRB review.*

Neither the collaborators nor the investigators at HSPH will have access to identifiable data. Participants will complete from their own computer, phones or tablets an online survey and will not provide any identifiers.

The collaborator participated in the idea and design and will participate in the conduct and reporting of research.

No, the collaborator was not planning to obtain his own IRB review for this project.

3.7. Will any institution conducting research activities as part of this study, including collaborators, rely on Harvard LMA for IRB review?
☐ **No** ☒ **Yes:** *If yes, list each relying institutions, their site responsible Investigator, and describe what research activities will be conducted there.*

Not the Institution, but our collaborator (the co-PI) would rely on Harvard LMA for IRB review. The research activities of the Harvard Investigators and our collaborator, Diego Wyszynski, (Pregistry, Los Angeles, CA) are described in 4.1.

4. Study Team

4.1. Describe the scope of work of the Harvard PI and research team. Indicate who is responsible for the design, conduct, implementation, and/or reporting of the research. Indicate who is responsible for the creation, design, and/or implementation of the study documents/tools.

The Harvard Investigators are responsible for the design, development of protocol, creation of questions for the interview, conduct, data analysis, and reporting of the research. As well as for ensuring the proper IRB permissions are obtained and indications from the IRB followed.

The co-PI outside Harvard is responsible for the design, development of protocol, creation of questionnaire, development of questionnaire online in apps and web, creation and maintenance of website, development of other tools if necessary, implementation of the study, creation and maintenance of research database with the necessary security protections, documents, funding, and reporting of the research. The co-PI is also the Director of the universal pregnancy registry (Pregistry), a more comprehensive enterprise with blogs and information for pregnant women. The WWCOVID survey is nested within this website and will benefit from the women who use it for enrollment and awareness about the existence of the Survey. The co-PI is responsible for maintaining the Pregistry infrastructure (but this is not part of the proposed research). The programmers/ web developers, marketing, etc staff from the Pregistry enterprise have helped with the development of the current project. They work for this co-PI at the Pregistry, but will not be involved in research activities.

4.2. Describe the Principal Investigator's experience conducting research at the study site(s) and familiarity with the local research context.

There will be no study sites or local research context since the study collects data online. The PIs have experience conducting surveys on mental health and wellbeing, as well as questionnaires for pregnant women specifically. Working in a small team allowed the rapid creation of the survey to implement quickly during the epidemic, i.e., data collection would need to start within days or weeks, before the end of the epidemic.

4.3. Describe how the Principal Investigator will ensure that sufficient time is devoted to conducting and completing the research.

Given the emergency to collect data now (when there are cases) we are launching the study without funding (which is of course unusual, but the circumstances are unusual). It should be noted that, once the online data collection and research database are ready (which they are), the Harvard Investigators will need relatively little effort until the time of reporting.
If funding is secured, the PI will submit funding information to the IRB via a modification.

4.4. Describe how all research staff members are trained to ensure that they are adequately informed about the protocol and study-related duties.

Given the online data collection, only the three investigators have been working closely together to develop the protocol and the tools (brief survey). They are intimately familiar with the protocol and study-related duties (i.e., tabulate results and write reports and scientific publications after data collection).

4.5. Describe the minimum qualifications for each research role (e.g., RN, social worker, phlebotomist, statistician), their experience in conducting research, and their knowledge of the local research context.

NA. The PIs have played all the research roles for now (except for the programming and web development). The statistical analysis will not be very complicated, and the PIs will be able to do them.

5. Study Design

5.1. Describe the study design type.

Online survey to women who were pregnant during the COVID-19 epidemic

5.2. Does the study involve more than one participant group?

☒ **No** ☐ **Yes:** *If yes, identify each group here and throughout all applicable sections.*

Pregnant women will be the only participants enrolled. No question will be asked about babies.

5.3. Indicate the duration of a participant's involvement.

Participants will complete a single online survey (20 min approximately). There will be no follow up.

5.4. Indicate the total number of participants to be screened (if applicable) and/or enrolled (i.e., signed consent form). If the proposed research involves secondary data analyses only, indicate the number of data, documents, records, and/or specimens that will be obtained.

We expect to receive responses from around 5000 women. If we launch quickly.

5.5. List inclusion and exclusion criteria, including age ranges of all participants, and describe the screening process.

To be eligible for this study women must:
(1) be 18 years of age or older,
(2) self-identify as pregnant or recently pregnant (within the last 6 months),
(3) be fluent in the English language, and
(4) have access to a computer, tablet, or smartphone with an Internet connection.

The study population will consist of volunteers from any country in the world except European countries/those covered by GDPR.. It is expected that the Registry participants will represent a wide range of maternal age, race/ethnic background, and health status given the ubiquitous presence of smartphones and high-speed Internet connectivity among millennials (18 to 34 years of age) and Gen X (35 to 46 years of age).

Regarding the screening, when women click to participate in the Survey they will confirm the inclusion criteria above.

5.6. Describe study procedures.
The WWCOVID is designed as cross-sectional (no follow up) single online survey of adult pregnant women. Participation is voluntary. Women self-enroll online, consent to participate, and fill out one easy to read / easy to complete questionnaire. Responses will be entered by the participant directly into the Survey website or mobile app-based data capture system. No identifiers will be collected. The survey has been designed to not collect IP Address and location data based on that IP Address. We designed a custom-made survey using a Model View Controller (MVC) C# ASP.NET framework data-access technology known as the Entity Framework, which fetches the questions and options for answers from the Microsoft SQL database. The Entity Framework supports Code First technique, which allowed us to create model objects by writing simple classes and then the SQL database was created from those classes, enabling a clean and rapid development workflow much more flexible than the one used by companies such as Qualtrics and RedCap. A file containing the survey data will be stored in a US-based server only accessible to the Investigators.

5.7. Does the study involve the use of deception and/or incomplete disclosure?
☒ **No** ☐ **Yes:** *If yes, explain the use of deception/incomplete disclosure and describe why it is necessary to achieve the goals of the study.*

5.8. When all research-related study procedures are complete, are there plans for long-term follow up?

☒ **No** ☐ **Yes:** *If yes, indicate what data will be collected during this period.*

5.9. Does the study involve the collection of specimens (e.g. blood, cells, tissues, fluids, secretions, recombinant or synthetic nucleic acids, biological toxins, bacteria, virus, fungi, etc.)
☒ **No** ☐ **Yes:** *If yes, indicate the COMS Registration Number or plans to obtain COMS approval.*

5.10. Does the study involve the use of existing data, documents, records, and/or specimens for secondary analysis?
☒ **No** ☐ **Yes:** *If yes, indicate how, when, where, and from whom data, documents, records, and/or specimens will be obtained.*

5.11. Are there provisions for medical and/or psychological support resources available to participants (e.g., in the event of incidental findings, research-related stress)?
☒ **No** ☐ **Yes:** *If yes, describe the provisions and their availability.*

5.12. Describe the data and safety monitoring plan for the study. This plan should outline how study progress will be monitored throughout the lifecycle of the research to ensure the safety of subjects, as well as the integrity and confidentiality of data.

There will be no intervention or modification of any clinical practice or behavior. This is an observational survey with no direct contact and no follow up of participants. Therefore, there will be no data safety and monitory board.

Since it is a one-time survey, there will not be follow up of surveys during the research.
Since respondents answer anonymously and we do not collect any identifiers, there is no concern about data confidentiality.
Regarding security and data privacy protection, please see sections below.
If there is any breach into the database we would notify the IRB. We will not be able to notify the subjects since we are not collecting identifying information or contact information.

5.13. Are there any anticipated circumstances under which participants will be withdrawn from the research without their consent?
☒ **No** ☐ **Yes:** *If yes, describe the circumstances for withdrawal as well any associated procedures to ensure orderly termination, appropriate referrals, and/or follow-up care.*

6. Recruitment Methods ☐ **N/A.** *Skip to next section.*
Upload recruitment materials to the "Local-Site Documents" page in ESTR.

6.1. Indicate how, when, where, and by whom participants will be recruited. Provide a list of materials used to recruit participants, e.g., emails, posters, and/or scripts here.

Information about the Survey will be made available on the Pregistry website (https://corona.pregistry.com/). The Survey page on the website will include general information about the objectives of the Survey, inclusion criteria, contact information, and instructions to enroll. Women would voluntarily click on the website to enroll at any time they wish.

If any other recruitments materials were to be implemented, the specific potential notes or scripts will be submitted to the IRB for approval prior to implementation.

7. Consent Process

Upload consent form(s) and debriefing materials, if applicable, to the "Local-Site Documents" page in ESTR.

7.1. Describe how the research team will invite participants to take part in the research and obtain consent to participate. If the research team will not obtain informed consent, provide justification for requesting a waiver or alteration of consent (and/or parental permission).

There will not be written informed consent for this Survey. Eligible women will give consent by clicking "next" and completing the survey on website or mobile app.

7.2. Describe how the research team will document the consent process (e.g., participant/researcher will both sign and date the consent document; participants will thumbprint the consent document; electronic consent will be obtained and associated with the participant's research record). If the research team will not obtain signature and date, provide justification for requesting a waiver or alteration of documentation of consent (and/or parental permission).

We request a waiver of consent since this is a brief online survey with no follow up and no identifiers will be collected.

7.3. Will participants be offered a copy of the consent information?

☐ **Yes** ☒ **No:** *If no, explain why not.*

7.4. If consent will be obtained in a language other than English, identify the language(s) that consent information will be provided, who will be responsible for translation, and the provisions for communicating this information to participants. ☒ **N/A**

7.5. If the research involves deception and/or incomplete disclosure, describe the debriefing process. Explain when participants will be debriefed, who will debrief them, and how they will be debriefed. ☒ **N/A**

7.6. If the research involves secondary use of existing data, documents, records, and/or specimens, and the research team will not obtain consent, describe how consent was originally obtained. Additionally, either upload the original consent form to the ESTR record or confirm that the original consent process obtained participants' permission to share or use their data/specimens for future research projects. ☒ **N/A**

8. HIPAA Privacy Protections ☒ **N/A.** *Skip to next section.*

HIPAA applies to US-based research involving the collection of use of protected health information (PHI) from a hospital, health center (including the Harvard Dental Center), health plan, or health insurance plan.

8.1. Describe plans for obtaining authorization to access protected health information or provide the rationale for a waiver of authorization.

9. Research Subject to the European Union (EU) General Data Protection Regulation (GDPR) ☒ **N/A.** *Skip to next section.*

GDPR applies to research involving the collection of "personal data" from research subjects who are located in the EEA. The EU/EEA includes the 28 states of the European Union (Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, & United Kingdom) and four additional countries: Iceland, Liechtenstein, Norway and Switzerland.

9.1. Describe plans to collect and/or obtain "pseudonymized data" (e.g., coded data) and/or identifiable data and/or biospecimens from participants in the EEA.

10. Research Subject to the Family Educational Rights and Privacy Act (FERPA)

☒ **N/A.** *Skip to next section.*

FERPA applies to research involving the collection of individually identifiable information from student records or personal education information from an education program (defined as: any program principally engaged in the provision of education, including, but not limited to, early childhood education, elementary and secondary education, postsecondary education, special education, job training, career and technical education, and adult education).

10.1. Describe plans to collect and/or obtain individually identifiable information from student records or personal education information from an education program.

11. Vulnerable Populations ☒ **N/A.** *Skip to next section.*

11.1. Identify all vulnerable populations (e.g., children; pregnant women, human fetuses, neonates; prisoners; elderly; economically disadvantaged; employees or students of the investigator or sponsor; undocumented individuals; refugees; racial and/or ethnic minorities; illiterate or low-literacy; military personnel; terminally ill; cognitively impaired or mentally ill; persons with a stigmatizing disease or condition, e.g. AIDS/HIV, etc.) and describe safeguards to protect their rights and welfare.

The population will include information from the pregnant women. However, since this is only a survey, non-interventional study, there is no risk associated with participation. Since no personal data will be collected, loss of confidentiality is not a risk either.

12. Risks

Risks may be physical, psychological, social, legal, reputational, and/or financial.

12.1. Describe the reasonably foreseeable risks, discomforts, and/or inconveniences to participants and/or the group/community to which they may belong. Indicate the probability, magnitude, and duration of each risk.

No risk is foreseeable. Women will be filling out the questionnaire privately on her phone or computer, if any question were uncomfortable, she can always skip, or withdrawn form participation. We minimized the inconvenience by creating a pleasant, easy to complete and not too long set of questions.

No identifiers will be collected including the responders IP address. We will include resources at the end of the survey and refer them to Preregistry. We do not query drug or alcohol use.

12.2. Identify whether any of the information collected, if disclosed outside of the research, could reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, insurability, or reputation.

No, we do not think it is reasonable to think that in the unlikely event of breach of confidentiality, knowledge of the responses would place women at risk. We ask about mental health, but we do not collect any information that could identify the participant.

12.3. Outline provisions in place to minimize each risk identified above.

Even though identifiers will not be collected, information from the survey will be maintained securely and will not be shared with any external parties.

We use a US-based dedicated Windows hosting server running on an Amazon EC2 instance in alignment with HIPAA and HITECH compliance requirements. Amazon EC2 is a scalable, user-configurable compute service that supports multiple methods for encrypting data at rest. We perform application-level encryption of PHI as it is processed within a Microsoft SQL database platform hosted in an Amazon EC2 instance. The data are encrypted using standard libraries in Amazon Web Services using its HIPAA Security and Compliance application framework and leveraging the Transparent Data Encryption features in Microsoft SQL. We integrate our website and mobile apps running in Amazon EC2 with AWS KMS SDKs, simplifying the process of key management and storage. We also implement encryption of data at rest using full disk encryption (FDE). Network traffic containing PHI encrypts data in transit. For traffic between external sources (such as the internet or a traditional IT environment) and Amazon EC2, we use the open standard transport encryption mechanism Transport Layer Security (TLS). Additionally, internal to the Amazon Virtual Private Cloud (VPC) for data traveling between Amazon EC2 instances, our network traffic containing PHI is encrypted.

13. Benefits

13.1. Describe the potential benefits to individual participants, if any, and/or society. If there are no direct benefits, state that here. Note: payment/compensation is not a benefit.

There may not be a direct benefit to the participant, other than feeling part of a community and feeling that they are helping other mothers like them in the future.

14. Participant Privacy

14.1. Describe provisions to protect participants' privacy (their ability to control and limit the extent, timing, and circumstances of sharing information about themselves with others, e.g., the use of a private interview room) and to minimize any sense of intrusiveness that may be caused by study questions or procedures.

Participants will complete the questions privately, from their devices, at any time they want. They can skip questions, and they can stop responding if they decide to do so.

15. Data Confidentiality

15.1. Indicate the identifiability of the data/specimens:

☒ Data/specimens will not contain any direct or indirect identifiers (anonymous data).
☐ Data/specimens will contain direct or indirect identifiers, but the research team will remove them upon receipt (de-identified data).
☐ Data/specimens will contain indirect identifiers (i.e., number, letter, symbol, or combination thereof) and the research team will maintain a key that links identifiers to individual participants (coded data).
☐ Data/specimens will contain direct identifiers (identifiable data).
☐ None of the above; describe:

15.2. Have any identifiable data/specimens been de-identified for use in this research study?
☒ No ☐ Yes: *If yes, describe how you will prevent any re-identification.*

15.3. Identify where data/specimens will be stored (e.g., on campus at Harvard or remotely, in a specimen laboratory) and describe the provisions to maintain confidentiality (e.g., password protection, encryption, locked filing cabinets, etc.). Refer to the Investigator Manual and the Harvard Research Data Security Policy for additional information.

Data from the Survey will be stored in real time in the Survey's secure database. We use a US-based dedicated Windows hosting server running on an AWS EC2 Instance. The Root storage and File are handled by a Windows Server 2019 through IIS service. We also use an SQL Server 2017 for database. Finally, unique 2048-bit SSH-2 RSA key pairs are utilized to access the server and database

15.4. Indicate whether any data/specimens will be transferred/transmitted and describe the plan to share the data/specimens (e.g., outside of Harvard, to other researchers, to collaborators). Indicate who may request access and how. If data/specimens will be transferred/transmitted/shared, describe how, when, and to whom.

The Survey data will be maintained securely and will not be shared with any external parties. Data summaries will be generated for reports and publications.

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15.5. Indicate whether participants' permission will be obtained to share their data/specimens and/or use their data/specimens in other future research projects.

No, there is no plan to share their data.

15.6. Indicate who is responsible for data/specimen management and how the research team and/or other collaborators are permitted access to information.

The Investigators are responsible for the conduct of the Survey and data management. Any potential collaborator or students/fellows working with the investigators would have access only to de-identified analytic files for specific analysis. At this point, there are no students working on this but if they join this project they would be supervised by the investigators and we will notify the IRB as needed.

15.7. Indicate how long data/specimens will be stored and describe the plans at the end of the storage period (e.g., are data/specimens destroyed, returned to data/specimen provider, etc.).

Data will be most relevant during the COVID pandemic, but maybe useful for many years (depending on COVID-19 development), the de-identified data will be most likely stored for many years.

16. Data/Statistical Analyses Plan

16.1. Describe plans for analysis (including the statistical method, if applicable).

The analysis will describe the wellness and mental health status of pregnant women during the COVID-19 pandemic. The distributions of mental health scales will be stratified by socio-demographic, healthcare access and COVID-19 characteristics. Descriptive tables will display, as appropriate, medians, ranges, means, standard deviations, and percentages.

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16.2. Is there a sample size/power calculation?

☒ **No** ☐ **Yes:** *If yes, describe the calculation and the scientific rationale, and, if applicable, by site and key characteristics such as participant demographics.*

Not applicable, we will recruit all eligible participants that fill out the online questionnaire.

17. Costs and Compensation ☒ N/A. *Skip to next section.*

17.1. Identify any costs that participants may incur during the study, including transportation costs, childcare, or other out-of-pocket expenses.

17.2. Identify remuneration that participants may receive during the study. Specify the amount, timing of disbursement, and method (e.g. money, gift cards, in-kind, incentives, raffles, and transportation). Describe how compensation will be calculated and paid if a participant withdraws. If any participant will receive a single payment more than $100, or $600 or more in one calendar year, refer to Harvard University Financial Policy on Human Subject Payments.

18. Sharing Study Results ☒ **N/A.** *Skip to next section.*

18.1. Describe the plan to share study results with individual participants, the participant group/community, and/or others.

Results from the Survey will be reported at the aggregate level and presented at scientific meetings. Publications and presentations will be prepared by the Investigators.

19. Research Related Injuries ☒ **N/A.** *Skip to next section.*

19.1. Describe plans for medical care and compensation for research-related injuries.

20. Reportable Events

20.1. Outline plans for communicating reportable events to the IRB, Sponsor, or others as applicable (e.g., adverse events, unanticipated problems involving risks to participants or others, breach of confidentiality).

NA, de-identified data.
Any data breaches or participant complaints will be reported to the IRB within 5 business days.

21. Regulatory Compliance

21.1. Describe plans for monitoring regulatory compliance. The monitoring plan should include how you will ensure proper record keeping, retention of required regulatory documents and participant files, and adherence to the IRB-approved protocol and/or IRB policies and procedures. Monitoring plans should describe 1) who is responsible for file maintenance, 2) what will be maintained, 3) how often files will be reviewed and using what method, and 4) where documentation will be retained (for both Regulatory Documents and Participant files).

The Investigators are responsible for file maintenance (e.g., IRB documentation). Regarding records with patient information: The online survey will not collect identifiers. Data will be reviewed regularly to produce monthly reports using aggregate measures.
Please see data security procedures above.

22. Data or Biospecimen Sharing ☒ **N/A.** *Skip to next section.*
If you plan to establish a repository, please submit a separate application using the HLC Repository Protocol Template.

22.1. Describe the plan to send data/specimens to research collaborators outside of Harvard.
☐ **N/A**

22.2. Describe the plan to receive data/specimens from collaborators outside of Harvard.
☐ **N/A**

23. Clinical Trials ☒ **N/A.** *Skip to next section.*

Complete this section for clinical trials, including NIH funded clinical trials or applicable clinical trials (ACT) under the FDA Amendments Act. To determine if a study meets the definition of a clinical trial, follow the guidance in the "Preparing the Research Protocol" section of the Investigator Manual.

23.1. Describe plans for registering this project in a clinical trials registry, e.g., clinicaltrials.gov. If available, provide the registry record number.

23.2. Describe plans for posting the clinical trial consent form on a publicly available federal website per federal requirements in the Common Rule (45§46.116(h)).

24. Device *This section should be completed if the study involves the use of any device on/in/with human subjects.* ☒ **N/A.** *Skip to next section.*

24.1. Describe the device, including the generic or common name, brand name (if applicable), purpose, function/operation, and whether it is an implant. Indicate who is providing this device for research use.

24.2. Indicate the FDA status of the device as it is being used for the proposed research:
☐ FDA-approved device being used "on-label" (i.e., FDA-approved purpose, population, manner).
☐ FDA-approved device that is being used "off-label" (i.e., for a different purpose, population, or in a different manner than approved).
☐ Not approved by the FDA.

24.3. Indicate the IDE Status of this device:
☐ The use of this device has an IDE.
☐ The use of the device qualifies for an Abbreviated IDE.
☐ The use of the device is exempt from the IDE requirements.

24.4. Has the FDA made a determination as to whether the device is Significant Risk or Non-Significant Risk? ☐ No ☐ Yes: *If yes, indicate the FDA's determination.*

24.5. Describe plans for storage control, and dispending of the product so that (1) only authorized investigators will use the product; (2) the product will only be used in participants who have provided consent, and (3) there will be documented tracking of each product, including unique identifiers and any return/disposal.

25. Drug/Biologic *This section should be completed if the study involves the use of any drug/biologic on/in/with human subjects.* ☒ **N/A.** *Skip this section.*

25.1. Describe the drug or biologic, including the generic or common name, brand name (if applicable), dosing, route of administration, number of doses, timing of administration. Indicate who is providing the drug, biologic, supplement for research use.

25.2. Indicate the IND Status of this drug or biologic and who holds the IND:

☐ There is an IND approval from the FDA for the use of this item.
The IND is held by:

☐ An IND application has been, or will be, submitted to the FDA.
The IND will be held by:

☐ An IND approval is not required.

25.3. Describe how dispensing, delivery and administration will be performed, and by whom. Include information about control (e.g., locked storage), tracking (e.g., lot number, returned pills), documentation, storage, and return/disposal.