**HRP-503 PROTOCOL**

*Standard Protocol*

|  |
| --- |
| INSTRUCTIONS   * Use this HRP-503 Standard Protocol to prepare your study protocol for submission to the VU HRPP. This protocol will provide the VU HRPP with the main information about the research. * Attach all additional supplemental documents separate from this protocol (preferably in Word format) to the electronic IRB system submission (e.g., recruitment materials, consent/assent forms, data collection forms, required supplemental forms, pSite materials, site permissions, etc.). * **For EXEMPT RESEARCH, only complete the questions in GREEN FONT.** * Keep an electronic copy of this protocol. For modifications, the most recently approved version should be modified and submitted to the VU HRPP. * If a question or section is not applicable, state “NA”. |

**TITLE OF RESEARCH STUDY:** Click or tap here to enter text.

**PRINCIPAL INVESTIGATOR (PI)**

|  |  |
| --- | --- |
| ***PI Name*** | Click or tap here to enter text. |
| ***Department*** | Click or tap here to enter text. |
| ***Email Address*** | Click or tap here to enter text. |
| ***Telephone Number*** | Click or tap here to enter text. |

**VERSION NUMBER and/or DATE**: Click or tap here to enter text.

Table of Contents

[1.0 Study Summary 4](#_Toc186799186)

[2.0 Multi-Site Research 5](#_Toc186799187)

[3.0 Research Objectives 5](#_Toc186799188)

[4.0 Background 5](#_Toc186799189)

[5.0 Research Procedures 5](#_Toc186799190)

[6.0 Secondary Analysis of Pre-Existing Data or Biospecimens 6](#_Toc186799191)

[7.0 Audio Recordings / Video Recordings/ Photographs 7](#_Toc186799192)

[8.0 Use of Artificial Intelligence (AI) 8](#_Toc186799193)

[9.0 Devices 9](#_Toc186799194)

[10.0 Drugs 10](#_Toc186799195)

[11.0 Study Timeline 11](#_Toc186799196)

[12.0 Inclusion and Exclusion Criteria 12](#_Toc186799197)

[13.0 Protected Populations 12](#_Toc186799198)

[14.0 Vulnerable / Special Populations 13](#_Toc186799199)

[15.0 Total Number of Research Participants 14](#_Toc186799200)

[16.0 Location(s) of Research 15](#_Toc186799201)

[17.0 International Research 15](#_Toc186799202)

[18.0 Recruitment Methods 15](#_Toc186799203)

[19.0 Consent / Assent / Parental Permission 16](#_Toc186799204)

[20.0 Withdrawal of Research Participants 20](#_Toc186799205)

[21.0 Risks to Research Participants 20](#_Toc186799206)

[22.0 Potential Benefits of the Research 20](#_Toc186799207)

[23.0 Data Analysis, Management, Confidentiality, & Reporting 21](#_Toc186799208)

[24.0 Data and Specimen Banking 23](#_Toc186799209)

[25.0 Protocol Deviations / Unanticipated Problems / Adverse Events 24](#_Toc186799210)

[26.0 Compensation / Incentives for Research Participation 24](#_Toc186799211)

[27.0 Compensation for Research-Related Injury 25](#_Toc186799212)

[28.0 Economic Responsibility of Research Participants 25](#_Toc186799213)

[29.0 HIPAA: Accessing / Using Protected Health Information (PHI) from Covered Entity for Research Purposes 25](#_Toc186799214)

[30.0 Greater Than Minimal Risk: Provisions to Monitor the Data to Ensure Participant Safety 26](#_Toc186799215)

# **Study Summary**

|  |  |
| --- | --- |
| **Protocol Information** | **Description** |
| **Study Title** | Click or tap here to enter text. |
| **Research Objectives** | Click or tap here to enter text. |
| **Study Procedures** (e.g., survey, interview, focus groups, observations, behavioral intervention, etc.) | Click or tap here to enter text. |
| **Study Population(s)** | Click or tap here to enter text. |
| **Total Sample Size** | Click or tap here to enter text. |
| **Clinical Trial Registration Number** | NA  CTN: Click or tap here to enter text. |
| **Does anyone on the research team have a Conflict of Interest (COI) (individual and/or institutional)? (refer to** [**https://www.vanderbilt.edu/generalcounsel/compliance/coi/**](https://www.vanderbilt.edu/generalcounsel/compliance/coi/)**)** | No  Yes   * *If yes, explain the COI.*   Click or tap here to enter text.   * *If yes, confirm attachment of the COI management plan to the submission.*   Click or tap here to enter text. |

# **Multi-Site Research**

* 1. ***Select one.***

NA

VU IRB is the reviewing IRB for participating sites

List the sites: Click or tap here to enter text.

Each IRB is reviewing for their own site

VU will rely on another IRB for review

VU is solely a data coordinating site

# **Research Objectives**

* 1. ***Describe the purpose, specific aims, and primary and if applicable secondary objectives****.*

Click or tap here to enter text.

* 1. ***State the hypotheses to be tested. If not applicable, write NA.***

Click or tap here to enter text.

* 1. ***Briefly describe the data analysis plan for this research (e.g. types of statistical procedures, thematic analysis procedures, etc.).***

Click or tap here to enter text.

# **Background**

* 1. ***Describe the relevant prior experience and gaps in current knowledge.***

Click or tap here to enter text.

* 1. ***Briefly provide the scientific or scholarly background and rationale for the significance of the research based on the existing literature and/or preliminary data and how it will add to existing knowledge.***

Click or tap here to enter text.

# **Research Procedures**

***Please explain the research procedures in lay language. Be descriptive and concise. This section is meant to provide the VU HRPP/IRB a clear depiction of what the researcher and research participants will be doing during the entire lifecycle of the study (from recruitment to data analysis).***

* 1. ***Provide a description of the study design and all research procedures being performed, prospective and retrospective. Detail out each specific procedure, their duration, in what order, how they are being implemented, type of data collected, if other collaborators are involved (and how), etc. Be sure to also explain how research participants’ privacy and confidentiality will be maintained during study procedures.***

Click or tap here to enter text.

* 1. ***Does the research involve deception/incomplete disclosure?***

No (If no, skip Q5.2 (a), (b), (c))

Yes

1. ***State what the deception/incomplete disclosure is.***

Click or tap here to enter text.

1. ***Explain the justification for including deception/incomplete disclosure in the research (e.g., would affect the scientific validity of the research).***

Click or tap here to enter text.

1. ***Will participants be debriefed?***

No

* ***If no, why not?***

Click or tap here to enter text.

Yes.

* ***If yes, how and when? Be sure to attach the debriefing script/document separately in the electronic IRB system.***

Click or tap here to enter text.

* 1. ***State the alternative to participating in the research study (e.g., not to participate, standard of care, etc.).***

Click or tap here to enter text.

* 1. ***Does the research involve FERPA-regulated information (information from education records)?***

No

Yes. Please adhere to all [FERPA](https://studentprivacy.ed.gov/ferpa) regulatory requirements.

# **Secondary Analysis of Pre-Existing Data or Biospecimens**

***If the study requires a material transfer agreement (MTA) and/or a data use agreement (DUA), the research team must have a fully executed agreements.***

NA (skip section 6)

* 1. ***List the source(s) from which the research team will receive the data and/or biospecimens? If receiving from an online source, please provide the website link(s). If receiving from an international location, researchers must adhere to all relevant data/biospecimen privacy and sharing regulations/policies.***

Click or tap here to enter text.

* 1. ***Type of dataset (select all that apply)***

Limited dataset (may contain some identifying information)

Restricted access data

Publicly available data

Data from a different research study

Other: Click or tap here to enter text.

* 1. ***Identifiability of dataset and/or biospecimens***

Coded data and/or biospecimens (without access to code link)

Coded data and/or biospecimens (with access to code link)

Identifiable data and/or biospecimens

Genomic/genetic/DNA related data and/or biospecimens

* 1. ***Are you permitted to use the existing data and/or biospecimens for this proposed research?***

No

If no, please explain. Click or tap here to enter text.

Yes

# **Audio Recordings / Video Recordings/ Photographs**

*Please reference the* [*VU Office of Cybersecurity Video Recording Conference and Sharing Guidance*](https://chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://cdn.vanderbilt.edu/vu-URL/wp-content/uploads/sites/398/2024/03/27154222/Vanderbilt-Video-Conference-Recording-Sharing-Guidance_PDF_March2024.pdf)*.*

* 1. ***Select all that apply.***
     + NA (skip Q7.2 - Q7.7)
     + Audio Recordings
     + Video Recordings
     + Photographs

***Audio / Video Recordings***

* 1. ***How will audio and/or video recordings be obtained (e.g., video conference platform, digital recorder, cell phone, etc.)?***

Click or tap here to enter text.

* 1. ***Describe how and at what point audio and/or video recordings be transferred, if at all?***

Click or tap here to enter text.

* 1. ***How long and where will audio and/or video recordings be stored, and at what point will they be destroyed, if at all?***
  2. Click or tap here to enter text.

***Photographs***

* 1. ***How will photographs be obtained?***

Click or tap here to enter text.

* 1. ***How long and where will photographs be stored, and when will photographs be destroyed?***

Click or tap here to enter text.

***Transcriptions***

* 1. ***Specify how the data will be transcribed (e.g., professional transcription service, AI transcription, research team, video conference transcription feature, etc.).***

Click or tap here to enter text.

* 1. ***Will there be third party access or ownership?***

Click or tap here to enter text.

* 1. ***Will the research team securely store transcripts in an identifiable, coded, or de-identified manner? It is recommended to securely store coded or de-identified transcripts to strengthen confidentiality protections of the data.***

Click or tap here to enter text.

* 1. ***How long and where will transcripts be stored, and at what point will they be destroyed, if at all?***

Click or tap here to enter text.

# **Use of Artificial Intelligence (AI)**

NA (skip section 8)

* 1. ***If the research will include the use of artificial intelligence (AI) to gather, store, and/or analyze research data, please list out the AI systems/tools used in this research (e.g., machine learning models, natural language processing tools, image recognition software, etc.)****.*
* Click or tap here to enter text.
* Click or tap here to enter text.
* Click or tap here to enter text.
  1. ***Describe any potential risks that are associated with the use of AI in the research (e.g., privacy, security of the data, bias, accuracy, etc.).***

Click or tap here to enter text.

* 1. ***How will potential risks be minimized from the use of AI in the research (e.g., confidentiality, etc.?***

Click or tap here to enter text.

# **Devices**

NA (skip section 9)

* 1. ***If the research involves the use of devices, select the regulatory approvals that apply, provide the name, purpose, and use of the device.***

***FDA-Approved Device***

|  |  |
| --- | --- |
| *FDA-Approved Device Name* | Click or tap here to enter text. |
| *Purpose of Device* | Click or tap here to enter text. |
| *Will the research team use the device per the approved labeling?* | Yes  No [If no, the study should be  submitted to the VUMC IRB.] |

|  |  |
| --- | --- |
| *FDA-Approved Device Name* | Click or tap here to enter text. |
| *Purpose of Device* | Click or tap here to enter text. |
| *Will the research team use the device per the approved labeling?* | Yes  No [If no, the study should be  submitted to the VUMC IRB.] |

***FDA-Cleared (510K) Device***

|  |  |
| --- | --- |
| *FDA-Cleared Device Name* | Click or tap here to enter text. |
| *Purpose of Device* | Click or tap here to enter text. |
| *Will the research team use the device per the approved labeling?* | Yes  No [If no, the study should be  submitted to the VUMC IRB.] |

|  |  |
| --- | --- |
| *FDA-Cleared Device Name* | Click or tap here to enter text. |
| *Purpose of Device* | Click or tap here to enter text. |
| *Will the research team use the device per the approved labeling?* | Yes  No [If no, the study should be  submitted to the VUMC IRB.] |

***IDE Exempt Device***

*Complete the IDE Exempt Device Form and attach it to your submission*

*(found on VU HRPP’s website).*

|  |  |
| --- | --- |
| *IDE Exempt Device Name* | Click or tap here to enter text. |
| *Purpose of Device* | Click or tap here to enter text. |
| *Will the research team use the device per the approved labeling?* | Yes  No [If no, the study should be  submitted to the VUMC IRB.] |

# **Drugs**

NA (skip section 10)

* 1. ***If the research involves the use of drugs, select the regulatory approvals that apply, provide the name, purpose, and use of the drug.***

***FDA-Approved Drug***

|  |  |
| --- | --- |
| *FDA-Approved Drug Name* | Click or tap here to enter text. |
| *How will the drug be used in the research (i.e., dosage and administration schedule)* | Click or tap here to enter text. |
| *Will the research team use the drug per the approved labeling?* | Yes  No [If no, the study should be  submitted to the VUMC IRB.] |

|  |  |
| --- | --- |
| *FDA-Approved Drug Name* | Click or tap here to enter text. |
| *How will the drug be used in the research (i.e., dosage and administration schedule)* | Click or tap here to enter text. |
| *Will the research team use the drug per the approved labeling?* | Yes  No [If no, the study should be  submitted to the VUMC IRB.] |

***IND Exempt Drug***

*Complete the IND Exempt Drug Form and attach it to your submission*

*(found on VU HRPP’s website).*

|  |  |
| --- | --- |
| *IND Exempt Drug Name* | Click or tap here to enter text. |
| *How will the drug be used in the research (i.e., dosage and administration schedule)* | Click or tap here to enter text. |
| *Will the research team use the drug per the approved labeling?* | Yes  No [If no, the study should be  submitted to the VUMC IRB.] |

***Dietary Supplements***

*The dietary ingredients in these products can include vitamins, minerals,*

*herbs and other botanicals, amino acids, other dietary substances intended to supplement the diet, and concentrates, metabolites, constituents, extracts, or combinations of the preceding types of ingredients.*

|  |  |
| --- | --- |
| *Name of Dietary Supplement* | Click or tap here to enter text. |
| *How will the dietary supplement be used in the research (i.e., dosage and administration schedule)* | Click or tap here to enter text. |
| *Is the clinical investigation intended to evaluate the dietary supplement’s effect on the structure or function of the body* | Yes  No [If no, the study should be  submitted to the VUMC IRB.] |

# **Study Timeline**

* 1. ***Describe duration of an individual participant’s participation in the study.***

Click or tap here to enter text.

* 1. ***The anticipated timeframe to enroll all research participants****.*

Click or tap here to enter text.

* 1. ***The estimated timeframe (e.g., three years) for the investigators to complete this study (including analyses of identifiable and/or coded data).***

Click or tap here to enter text.

# **Inclusion and Exclusion Criteria**

* 1. ***Describe how individuals will be screened for eligibility.***

Click or tap here to enter text.

* 1. ***Inclusion Criteria*** 
     + Click or tap here to enter text.
     + Click or tap here to enter text.
     + Click or tap here to enter text.
     + Click or tap here to enter text.
     + Click or tap here to enter text.
  2. ***Exclusion Criteria. If excluding specific populations, please explain why.***
     + Click or tap here to enter text.
     + Click or tap here to enter text.
     + Click or tap here to enter text.

# **Protected Populations**

* 1. ***Select all the protected study population(s) that are intentionally being included in this research. For research aimed at involving a broader participant population that only incidentally includes any of these study populations, do not select any of the options below.***

Children

Pregnant women, Fetuses, or Neonates (uncertain viability or nonviable)

Prisoners

Wards of the state or any other agency, institution, or entity.

* 1. ***Children. If the research involves children, please answer the following.*** 
     + ***(a) Age range of children included in this research:***

Click or tap here to enter text.

* ***(b) Will the research involve implementation of a survey that has personal or sensitive questions and is being disseminated in an educational setting?***

No

Yes. *Note, the research may be subject to* [*PPRA*](https://studentprivacy.ed.gov/resources/protection-pupil-rights-amendment-ppra-general-guidance)

*regulations and may have specific requirements (i.e.,*

*parental permission). Please adhere to the relevant*

*regulatory requirements.*

* ***(c) Does the research involve collection of private, identifiable information from children from an online website?***

No

Yes. *Note, the research may be subject to* [*COPPA*](https://www.ftc.gov/legal-library/browse/rules/childrens-online-privacy-protection-rule-coppa)*, which*

*may have specific requirements (i.e., parental permission). Please adhere to the relevant regulatory requirements.*

* 1. ***Wards. If the research involves wards of the state or any other agency, institution, or entity, please answer the following, otherwise select NA****.*
     + ***(a) Is the research related to their status as wards?***

NA

No

Yes

* + - ***(b) Is the research conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as participants are not wards?***

NA

No

Yes

# **Vulnerable / Special Populations**

* 1. ***Select all vulnerable or special study population(s) that are intentionally being included in this research. For research aimed at involving a broader participant population that only incidentally includes any of these study populations, do not select any of the options below.***

*Adults with limited/diminished capacity to consent*

*Economically disadvantaged*

*Educationally disadvantaged*

*Students*

*Employees*

*Non-English speaking*

* 1. ***If the research involves non-English speaking study population(s), address the following.***
     + ***(a) List all language(s) other than English that apply in this research.***
       - Click or tap here to enter text.
       - Click or tap here to enter text.
       - Click or tap here to enter text.
     + ***(b) Will participant facing research study materials be translated to local language(s)? The translator must speak, read, and write the native language and English proficiently.***

No

Yes

* + - * ***(i) List the study materials that will be translated.***

Click or tap here to enter text.

* + - * ***(ii) Who translated the materials?***

Click or tap here to enter text.

* + - * ***(iii) Describe the qualifications of the translator (e.g., native speaker, individual with credentials in local language, professional translation service, etc.).***

Click or tap here to enter text.

* + - * ***Minimal Risk Research: A translation attestation statement from the translator is required (e.g., “I attest the research study materials translated from \_\_\_\_\_\_to \_\_\_\_\_\_ are accurate and complete to the best of my knowledge.”). Please separately attach to the submission.***
      * ***Greater than Minimal Risk Research: Certified back translations are required. Please attach to the submission.***
  1. ***If the research involves individuals who may be vulnerable to coercion or undue influence or who may need additional safeguards given the context of the research, please list them here and explain the safeguards that will protect their rights and welfare.***

Click or tap here to enter text.

# **Total Number of Research Participants**

|  |  |
| --- | --- |
| **Total Number of Research Participants to be Enrolled Under the Purview of VU** | Click or tap here to enter text. |
| **Multi-Site Research: Total Number of Research Participants to be Enrolled Study-Wide Across All Participating Sites** | Click or tap here to enter text. |

# **Location(s) of Research**

* 1. ***List all of the location(s) where the research will occur and the study procedures that will take place there.***

|  |  |
| --- | --- |
| ***Research Location/Sites***  *City, State (if applicable), Country* | ***Study Procedures Taking Place at this Location*** *(i.e., recruitment, consent, data collection/receipt, etc.)* |
| Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. |

# **International Research**

NA

* 1. ***Is a local ethics committee (LEC) review and approval required for this research?***

*No*

*Yes*

* + - * ***If yes, please explain which country(ies) the LEC is required for and confirm here that the researcher will obtain LEC review and approval prior to beginning human research at this location(s).***

*[Note: For international locations where no LEC review and approval is required, an “International Research Consultant Form” (found on VU HRPP’s website) may be needed. This is required for Expedited and Greater than Minimal Risk. This is not required for Exempt, but it may be requested by the VU HRPP to be completed.*

# **Recruitment Methods**

* 1. ***Describe who, when, where, and how potential participants will be identified and recruited for this research study. If there are multiple study populations, please explain the recruitment methods for each study population (e.g., recruitment for teacher interviews will include XYZ methods and recruitment for the community member online survey will include XYZ methods). Be sure to also explain how research participants’ privacy and confidentiality will be maintained during recruitment.***

Click or tap here to enter text.

* 1. ***Describe the recruitment materials that will be used to recruit research participants.***

Click or tap here to enter text.

* + - *Attach copies of all recruitment materials (preferably in Word format) in the electronic IRB system.*
    - *Note, for recruitment occurring on social media for research involving sensitive information, consider whether it’s important for participants to be aware that social media sites may have access to their likes, responses, shares, and comments on the recruitment posting.*

# **Consent / Assent / Parental Permission**

* 1. ***Select all consent/assent/parental permission methods that apply to the research.***

***ADULTS***

*Signed Consent Form ((signed by the participant or legally authorized representative (LAR; when applicable))*

*Waiver of Documentation of Consent (no signature; information sheet/consent script provided to participants)*

*Waiver of Consent (no consent obtained from participants)*

*Waiver or Alteration of Some Required Elements of Consent*

***CHILDREN***

*For international research, please consider the legal age for consent under the applicable law of the jurisdiction in which the research will be conducted.*

*Signed Assent Form*

*Age range*: Click or tap here to enter text.

*Waiving Documentation of Assent (providing study information, obtaining*

*assent, no signature obtained)*

*Age range:* Click or tap here to enter text.

*Waiver of Assent*

*Age range:* Click or tap here to enter text.

*Signed Parental Permission from One Parent/Legal Guardian*

*Signed Parental Permission from Both Parents/Legal Guardians*

*Waiver of Parental Permission (from one or both parents/legal guardians)*

* 1. ***Provide a detailed description of the consent/assent/parental permission process by study population. Be sure to depict when, where, and how it will be obtained, by whom it will be obtained (e.g., research team member), and how privacy/confidentiality will be maintained during the consent/assent/parental permission process. (Refer to “HRP-090 – SOP – Informed Consent Process for Research” on VU HRPP’s website for more information.)***

Click or tap here to enter text.

* + - ***Adults with Limited/Diminished Capacity to Consent: Provide an explanation of the process to determine whether an individual is capable of consent and who will provide permission (e.g., Legally Authorized Representative (LAR) (e.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child)). Refer to HRP-013 - SOP - LARs, Children, and Guardians on VU HRPP’s website***

Click or tap here to enter text.

* + - ***Children***
      * ***If children turn the legal age to consent as an adult during the study, explain the consent process for their continued participation in the research as adults.***

Click or tap here to enter text.

* + - * ***Waiver of Assent: Please provide a justification for requesting a waiver of assent.***

Click or tap here to enter text.

* + - * ***Waiver of Parental Permission: Please provide a justification for requesting a waiver of parental permission (research protocol is designed for conditions or for participants for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, children who are neglected or abused).***

Click or tap here to enter text.

* 1. ***Specify how long and where signed consent forms will be securely stored.***
* *Research subject to the DHHS 45 CFR 46 (Common Rule): Research records must be retained for at least 3 years after completion of the research.*
* *HIPAA-regulated research: Research records must be retained for at least 6 years after completion of the research.*

Click or tap here to enter text.

* 1. ***Waiver of Documentation of Consent (WOD):***

NA

*If requesting a WOD, one of the criteria must be met. Researchers must provide a clear explanation regarding how the research meets the selected criteria for WOD.*

|  |  |
| --- | --- |
| ***WOD Criteria*** | ***Explanation*** |
| *The only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern.* | Click or tap here to enter text. |
| *The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.* | Click or tap here to enter text. |
| *If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.* | Click or tap here to enter text. |

* 1. ***Waiver of Consent(WOC)***

NA

*If requesting a WOC, researchers must provide a clear explanation regarding how the research meets all of the criteria for WOC.*

|  |  |
| --- | --- |
| ***WOC Criteria*** | ***Explanation*** |
| *The research involves no more than minimal risk to the subjects.* | Click or tap here to enter text. |
| *The research could not practicably be carried out without the requested waiver or alteration.* | Click or tap here to enter text. |
| *If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.* | Click or tap here to enter text. |
| *The waiver or alteration will not adversely affect the rights and welfare of the subjects.* | Click or tap here to enter text. |
| *Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.* | Click or tap here to enter text. |

* 1. ***Waiver or Alteration of Some Basic and/or Additional Elements of Consent. Select all consent elements requesting to be omitted or altered and provide a clear justification why the consent element(s) is being omitted or altered. For instance, some studies that involve deception/incomplete disclosure will omit or alter an element of consent for the purposes of the scientific validity of the research.***

|  |  |
| --- | --- |
| ***Elements of Consent being Omitted or Altered*** | ***Justification why the Consent Element(s) is being Omitted or Altered*** |
| *A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures that are experimental.* | Click or tap here to enter text. |
| *Risks* | Click or tap here to enter text. |
| *Benefits* | Click or tap here to enter text. |
| *Alternative procedures* | Click or tap here to enter text. |
| *Confidentiality* | Click or tap here to enter text. |
| *Whom to Contact* | Click or tap here to enter text. |
| *If Additional Elements Apply to the Research and You Plan to Exclude Them (additional cost to participants, participant withdrawal consequences or investigator-initiated termination from the research, new findings affecting willingness to participate, approximate number of participants to be enrolled, use of participants’ biospecimens for commercial profit, disclosure of clinically relevant research results, whole genomic sequencing of participants’ biospecimens)* | Click or tap here to enter text. |

# **Withdrawal of Research Participants**

* 1. ***Describe procedures that will be followed when participants withdraw from the research, including partial withdrawal from procedures, with continued data collection. What will the research team do with a participant’s data/samples? Will participants be notified of this; if so, how? Will any data/samples be destroyed; if so, at what point and how?***

Click or tap here to enter text.

* 1. ***Describe anticipated circumstances under which participants can be withdrawn from the research without their consent and any procedures for orderly termination (e.g., steps taken to remove a participant from a behavioral intervention)****.*

Click or tap here to enter text.

# **Risks to Research Participants**

* 1. ***Risks: Describe all potential foreseeable risks to research participants as they relate to their involvement in the research. Consider risks such as physical, psychological/emotional, privacy, confidentiality, legal, social, economic, reputational, etc.***
     + *If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.*
     + *If applicable, indicate which procedures may have risks to an embryo or fetus should the participant be or become pregnant.*
     + *If applicable, describe risks to others who are not research participants (e.g., group harm to a particular community, etc.)*

Click or tap here to enter text.

* 1. ***Minimizing Risks: Provide a clear explanation of how the research team plans to minimize each of the research-related risks.***

Click or tap here to enter text.

# **Potential Benefits of the Research**

* 1. ***Describe the potential benefits that individual research participants may experience from taking part in the research. If there is no direct benefit to participants, clearly state that****.*

Click or tap here to enter text.

* 1. ***Describe the broader potential benefits of this research to science, society, or others.***

Click or tap here to enter text.

# **Data Analysis, Management, Confidentiality, & Reporting**

* 1. ***Please select all data points from below that will be collected as part of this research at any point during the research lifecycle.***

Name

Email Address

Phone Number

Mailing Address (or the equivalent)

Zip Code

Social Security Number (SSN)

Medical Record Number (MRN)

Date of Birth (full date: MM/DD/YYYY)

Full Date(s) (MM/DD/YYYY) (e.g., admission date, discharge date, etc.)

Age

Gender

Race / Ethnicity

Internet Protocol (IP) Address Numbers

Biometric Identifier (e.g., fingerprint, face ID, etc.)

Identifiable Social Media User Information (e.g., username)

None of the Above

* 1. ***Confidentiality Protections. Provide a clear explanation of the confidentiality protections the research team will implement.***

Click or tap here to enter text.

Coded Data = Identifiers are retained but separated from the research data and linked with a code (code link). If anyone on the study team has access to the code link, then the data is still considered identifiable. Using a code link is a best practice to strengthen confidentiality protections when storing personally identifiable information.

De-identified = All personally identifiable information that was originally linked to the data is destroyed and one cannot trace the data back to an individual.

Anonymous = No personally identifiable information is ever linked to the data and one cannot trace the data back to an individual.

*Deductive Disclosure = The ability to triangulate certain variables collected and identify an individual.*

* 1. ***Data Storage/Use/Transmission. Please explain the following****.*
     + ***(a) How* *will the data be securely stored, physically and electronically? Will a code link be used and how will it be securely protected (e.g., who has access, how long will it be used, etc.?***

Click or tap here to enter text.

* + - ***(b) Where will the data be stored?***

Click or tap here to enter text.

* + - ***(c) How long will data be stored?***

Click or tap here to enter text.

* + - ***(d) Who will have access to the securely stored data?***

Click or tap here to enter text.

* + - ***(e) Who is responsible for receipt or transmission of the data?***

Click or tap here to enter text.

* + - ***(f) Will the data be transferred or shared with anyone outside of the research team? If so, please explain how, to whom, and for what purpose? If a data use agreement (DUA) is needed, please state that a DUA will be executed.***

Click or tap here to enter text.

* 1. ***Biospecimen Storage/Use/Transmission. Please explain the following****.*

NA (skip Q23.4(a) - (g))

* + - ***(a) What data will be linked with the specimens?***

Click or tap here to enter text.

* + - ***(b) How will the specimens be securely stored? Will a code link be used and how will it be securely protected (e.g., who has access, how long will it be used, etc.?***

Click or tap here to enter text.

* + - ***(c) Where will the specimens be stored?***

Click or tap here to enter text.

* + - ***(d) How long will the specimens be stored? Specify the methods of storage and destruction of specimens.***

Click or tap here to enter text.

* + - ***(e) Who will have access to the securely stored specimens?***

Click or tap here to enter text.

* + - ***(f) Who is responsible for receipt or transmission of the specimens?***

Click or tap here to enter text.

* + - ***(g) Will the specimens be securely transferred or shared with anyone outside of the research team? If so, please explain how, to whom, and for what purpose.***

Click or tap here to enter text.

* 1. ***Sharing of Results with Participants. Describe whether results will be shared with research participants or others and if so, describe how the results will be shared.***

Click or tap here to enter text.

* 1. ***Reporting Data. Describe how results will be reported (e.g., aggregated data, individual de-identified quotes, identifiable quotes with participant permission, etc.)****.*

Click or tap here to enter text.

* 1. ***Certificate of Confidentiality. Will the research team obtain a Certificate of Confidentiality for this research? Note, effective October 1, 2017 (CoCs) are automatically deemed to be issued for any NIH-funded research that collects or uses identifiable, sensitive information that was on-going on or after December 13, 2016. If your research falls within this timeframe or is currently sponsored by the NIH, select yes.***

NA

No

Yes *(If yes, please ensure the CoC clause is included in the consent form*  *(found in the consent template on the VU HRPP website).)*

# **Data and Specimen Banking**

NA

* 1. ***If data or specimens will be banked for future use, describe where the specimens will be stored, how long they will be stored, how the specimens will be accessed, how permission will be obtained and who will have access to the specimens.***

Click or tap here to enter text.

* 1. ***List the data to be stored or associated with each specimen. Specify if there will be any personally identifiable information (PII) associated with the specimens, either directly or via the use of a code link (where PII is stored separately from the coded specimens.***

Click or tap here to enter text.

# **Protocol Deviations / Unanticipated Problems / Adverse Events**

* 1. ***List the process for the reporting of protocol deviations, unanticipated problems, or adverse events involving risk to participants or others. Indicate where and how to submit adverse events/unanticipated problems and the time frame in which to submit. List the regulatory authorities and their contact information for reporting, if needed.***

Click or tap here to enter text.

# **Compensation / Incentives for Research Participation**

*Please see VU’s Participant Payment Policy:* [*https://finance.vanderbilt.edu/policies/Human\_Subject\_Participation\_Payment\_Policy.pdf*](https://finance.vanderbilt.edu/policies/Human_Subject_Participation_Payment_Policy.pdf)

* 1. ***Describe the type of compensation/incentive provided to participants.***

*NA (skip section 26)*

*Monetary (e.g., cash, physical/electronic gift card, electronic cash transfer)*

*Non-monetary (e.g., choice of specific item, lottery/raffle for an item, course credit)*

*Third party compensation (e.g., survey firm providing compensation/incentive)*

*Other:* Click or tap here to enter text.

* 1. ***Describe the amount and timing of the compensation/incentive provided to participants as a part of this research.***
     + *If the incentive is non-monetary, explain what amount the incentive is worth monetarily.*
     + *If compensation is pro-rated by procedure involvement, please state that here. If using a lottery/raffle as an incentive, describe the total number of payments/items and the odds of receiving the payment/item.*

Click or tap here to enter text.

* 1. ***State how the compensation/incentive will be offered to participants*** *(e.g., emailed a $25 electronic gift card, in-person $10 cash compensation, etc.).*

Click or tap here to enter text.

* 1. ***If providing compensation that may appear coercive or unduly influential, explain how this potential risk is minimized.***

Click or tap here to enter text.

# **Compensation for Research-Related Injury**

NA (skip Q27.1)

* 1. ***Greater Than Minimal Risk Research Only: Describe the available compensation in the event of research related injury. Otherwise write “NA”.***

Click or tap here to enter text.

# **Economic Responsibility of Research Participants**

* 1. ***Clearly describe any costs that research participants may be responsible for because of participation in the research. If none, write "no costs”.***

Click or tap here to enter text.

# **HIPAA: Accessing / Using Protected Health Information (PHI) from Covered Entity for Research Purposes**

* 1. ***Will the study use or access protected health information (PHI) (HIPAA regulated information) from a covered entity for research purposes?***

NA (skip Q29.1(a) - (b))

Synthetic derivative dataset

Yes

1. ***If yes, select all that apply.***

HIPAA authorization in the consent form (content found in

the informed consent template on VU HRPP’s website)

HIPAA partial waiver of authorization (using/accessing PHI

only for determining eligibility for inclusion in the research)

HIPAA full waiver of authorization (using/accessing PHI as

research data)

1. ***If yes, select the PHI that will be used or accessed in this research.***

Name

All geographic subdivisions smaller than a State (including

street address, city, county, zip code)

All elements (except years) of dates related to an

individual

(date of birth, admission date, discharge date, date of death, exact age if over 89)

Telephone numbers

Fax numbers

Email address

Medical record numbers (MRN)

Social security numbers (SSN)

Health plan beneficiary numbers

Account numbers

Certificate/license numbers

Vehicle identifiers and serial numbers, including license

plate numbers

Device identifiers and serial numbers

Web universal resource locators (URLs)

Internet protocol (IP) address numbers

Biometric identifiers, including fingerprints and voiceprints

Full-face photographic images and any comparable images

# **Greater Than Minimal Risk: Provisions to Monitor the Data to Ensure Participant Safety**

NA

***Describe the Data Safety Monitoring Plan (DSMP) / Data Safety Monitoring Board (DSMB).***

* 1. ***Describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether research participants remain safe. The plan might include establishing a data safety monitoring board (DSMB) and a plan for reporting DSMB findings to the IRB and the sponsor.***

Click or tap here to enter text.

* 1. ***What data are reviewed, including safety data, untoward events, and efficacy data.***

Click or tap here to enter text.

* 1. ***How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).***

Click or tap here to enter text.

* 1. ***The frequency of data collection, including when safety data collection starts.***

Click or tap here to enter text.

* 1. ***Who will review the data.***

Click or tap here to enter text.

* 1. ***The frequency or periodicity of review of cumulative data.***

Click or tap here to enter text.

* 1. ***The statistical tests for analyzing the safety data to determine whether harm is occurring.***

Click or tap here to enter text.

* 1. ***Any conditions that trigger an immediate suspension of the research.***

Click or tap here to enter text.

This template satisfies AAHRPP elements 1.7.B, I.8.B, I-9, II.2. A, II.2.I, II.3.A, II.3.B, II.3.C-II.3.C.1, II.3.D-F, II.4.A, III.1.C-F, II.2.D