**HRP-503a PROTOCOL**

*Secondary Analysis of Existing Data or Biospecimens*

|  |
| --- |
| INSTRUCTIONS* Use this HRP-503a Protocol for research only involving secondary analysis of existing identifiable, private information or biospecimens. The data or biospecimens may be directly or indirectly identifiable (i.e., use of a code link). This protocol will provide the VU HRPP with the main information about the research.
* Data/biospecimens must be in existence by the time the research team submits to the VU HRPP (also known as retrospective data).
* *Secondary analysis* pertains to analysis of data and/or biospecimens that were originally collected via interaction or intervention with living individuals for another purpose (e.g., educational purposes, as part of a different research study, clinical purposes, etc.). If any data and/or biospecimens are prospectively collected, please do not complete this protocol and complete the HRP-503 Standard Protocol.
* If the research team accesses/obtains/uses/analyzes only *de-identified* data and/or biospecimens, the study does not need to be submitted to the VU IRB for review. De-identified data refers to all personally identifiable data that was originally linked to an individual, is destroyed, and one cannot link it back to that individual. If you are unsure if your research needs IRB review, please complete the VU Human Research Determination Tool or contact the VU HRPP at irb@vanderbilt.edu.
* Attach the completed HRP-503a Protocol, along with additional supplemental documents (preferably in Word format) in the electronic IRB system submission.
* 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.

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# STUDY SUMMARY

|  |  |
| --- | --- |
| **Protocol Information**  | **Description**  |
| **Study Title** | Click or tap here to enter text. |
| **Research Objectives** | 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

**2.1 *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 main hypothesis 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 relevant scholarly knowledge on this topic and gaps in it.***

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.

# TYPE OF DATA / BIOSPECIMENS

* 1. ***Select all that apply to this research.***

[ ] Existing Data Only

[ ] Existing Biospecimens Only

[ ] Existing Data and Biospecimens

* 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.
* Click or tap here to enter text.
* 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. ***Will the study require a data use agreement (DUA) and/or materials transfer agreement (MTA)? If the study requires a MTA and/or DUA, the research team must have a fully executed agreements.***

[ ]  NA

[ ]  DUA

[ ]  MTA

* 1. ***Does the research involve NIH Genomic Data? Researchers must follow the NIH Genomic Data Sharing (GDS) Policy***

[ ]  No

[ ]  Yes

* 1. ***Does the research involve HIPAA-regulated data?***

[ ]  No

[ ] [ ]  Yes

* 1. ***Will a data repository be created using the dataset(s)?***

[ ]  No

[ ]  Yes

* 1. ***Will a biorepository be created using these biospecimens?***

[ ]  No

[ ]  Yes

# STUDY POPULATION

* 1. ***Sample size =***Click or tap here to enter text.
	2. ***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.
	3. ***Children. Does the research intentionally include data or biospecimens from children?***

[ ]  No

[ ]  Yes

* 1. ***Prisoners. Does the research intentionally include data or biospecimens from prisoners? For research aimed at involving a broader subject population that only incidentally includes prisoners, select no.***

[ ]  No

[ ]  Yes

# CONSENT

* 1. ***Select all that apply to this research.***

[ ]  Consent was originally obtained for participants for the use of data for research purposes *(If the research team has a copy of the*

*original consent form, please attach it to the submission. Please*

*ensure it has no personally identifiable information on it.)*

[ ]

Signed Consent/Assent/Parental Permission Form (Re-Consent) from individuals whom the data or biospecimens are being obtained

[ ]

Waiver of HIPAA Authorization (attach the waiver to the

submission)

- Full Waiver of HIPAA Authorization

- Partial Waiver of HIPAA Authorization

[ ]

Waiver of Consent (WOC)

*If requesting a WOC for non-exempt research, researchers must provide a clear explanation regarding how the research meets all of the criteria for WOC below. WOC cannot be requested if original consent documents restricted use of the data or biospecimens as planned in this research protocol.*

|  |  |
| --- | --- |
| ***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. ***Re-Consent: Signed Consent/Assent/Parental Permission Form***

***Provide a description of the consent/assent/parental permission process. Be sure to depict when, where, and how re-consent will be obtained, by whom it will be obtained (e.g., research team member), and how privacy/confidentiality will be maintained during the consent process. (Refer to “HRP-090 – SOP – Informed Consent Process for Research” on VU HRPP’s website for more information.) If not applicable, write NA.***

Click or tap here to enter text.

# RISKS AND BENEFITS

*Risks*

* 1. ***Describe all foreseeable risks to research participants (e.g., loss of confidentiality, genetic risks or harm, legal, etc.)****.*

Click or tap here to enter text.

*Benefits*

* 1. ***Describe possible benefits of the research to participants. If there are no direct benefit to participants, state this****.*

Click or tap here to enter text.

# CONFIDENTIALITY PROTECTIONS

*It is best practice to store identifiers separately from the data/biospecimens that are received and use a code link to manage them on secure, encrypted networks/software/storage devices. When describing physical locations, ensure the data and/or biospecimens are restricted to the minimum amount of research personnel for enhanced confidentiality protections.*

* 1. ***How will the research team obtain the data and/or biospecimens (e.g., seeking access from an existing data/bio repository, PI was on a previous protocol from which the data/biospecimens were collected, requesting access from another research team, etc.?***

Click or tap here to enter text.

* 1. ***Where and how will data and/or biospecimens be securely stored?***

Click or tap here to enter text.

* 1. ***Who will have access to identifiable and/or coded data and/or biospecimens (e.g., research team members only, etc.)?***

Click or tap here to enter text.

* 1. ***How long will data and/or biospecimens be stored by the research team?***

Click or tap here to enter text.

* 1. ***How will the data and/or biospecimens will be destroyed? If retaining these indefinitely, please explain.***

Click or tap here to enter text.

* 1. ***Will the data or biospecimens be shared with others outside of the VU research team? If so, explain with whom and how.***

Click or tap here to enter text.

#  ANCILLARY REVIEWS

* 1. ***Does the research involve the use of recombinant DNA and synthetic nucleotide research involving humans and require institutional biosafety committee review and approval?***

[ ]  No

[ ]  Yes

 If yes, please address the following.

[ ]  The research is pending IBC review and approval.

[ ]  The research is approved by the IBC. (Attach the

approval letter to the submission.)

* 1. ***Does the research involve human stem cells?***

 [ ]  No

[ ]  Yes

If yes, please address the following.

[ ]  The research is pending a stem cell committee review and approval.

[ ] [ ]  The research is approved by a stem cell committee. (Attach the approval letter to the submission.)