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**HRP-503H - Secondary Analysis of Data**

(v. 2017-1)

**Protocol Title:** Click or tap here to enter text.

**Principal Investigator:** Click or tap here to enter text.

**Protocol Version Number and/ or Date:** Click or tap here to enter text.

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| **INSTRUCTIONS****This template is intended to help investigators prepare a protocol that includes all of the necessary information needed by the IRB to determine whether a study meets approval criteria. Read the following instructions before proceeding:*** + 1. Use this protocol template for a research study that includes secondary analysis of previously collected data for which Determinations of Research Not Involving Human Subjects or Exemption are not allowed by the Data Holder/Sponsor. Additional templates for other types of research protocols are available in the system Library.
		2. Add this completed protocol template to the relevant application in IRES IRB in the “Basic Information” screen.
		3. There may be sections in this template that do not apply. If a section or question does not apply to the research study in question, provide the response “Not Applicable”.
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**General Information**

1. **What type of data will the study utilize?**

[ ]  Restricted access data set

[ ]  Limited data set (with certain HIPAA identifiers)

[ ]  Previously collected data for a different purpose/study

[ ]  Deidentified data that will be merged with other data sets so identification may be possible

[ ]  Other:

1. **The status of the data that this request applies to:**

[ ]  All data is currently in existence

[ ]  Data continues to be collected and will be sent to Yale PI in batches

1. **Additional Considerations:**
2. Will the information collected be used to create a data archive for future research?

[ ] No [ ] Yes

(If yes, stop completing this form and complete the *Repository Protocol template*).

1. Are there plans to contact subjects for follow-up or to collect any information using assessment

tools or other means to complete the information that is not currently available in the data set?

[ ] No [ ] Yes

(If yes, stop completing this form and use the Biomedical or Social, Behavioral or Educational (SBE) ResearchProtocol Template).

**Project Information**

1. Probable duration of study: (Please state the expected duration of the project, including all data analysis activities).
2. Purpose of the study: (describe briefly, including hypothesis).
3. Research plan:
4. Possible risks and benefits:
5. Where is the data currently residing?

URL if available:

1. Description of the data (must include discussion of original collection, consent from subjects, and data points available):
2. What permissions are needed to access the data (e.g. IRB approval, Data Use Agreement, etc.)?
3. Estimated number of records to be accessed:
4. Is a merger planned? [ ] No [ ] Yes

If yes, please provide information about the planned merger:

**Consent/HIPAA Considerations**

*Choose one answer as appropriate*

[ ]  Consent and/or HIPAA authorization are not necessary as subjects agreed to donation of their data for research via a consent process.

[ ]  Waiver of consent and/or HIPAA authorization for use of the data are requested.

**Data Security**

1. How is the data accessed by the PI?
2. Who will have access to the data, and how access to the data storage (whether paper-based or electronic) will be monitored.
3. What will happen with the data when use of the dataset is complete?
4. Describe the physical security of the data (location of the computers, etc.):
5. Which of the following security measures are required by the holder of the data/will be implemented by the PI?

[ ]  Data will be downloaded only to a secure computer or server

[ ]  Data will never be stored on personal computers/laptops

[ ]  Data points/lines that are not necessary for research will be deleted upon receipt of the dataset

[ ]  Systems housing the data will not be directly accessible from the internet

[ ]  When in use, the internet connectivity to the computer on which the data is used will be disabled

[ ]  The data will not be posted on any web or ftp server

[ ]  Password-enabled screen saver that activates after 15 minutes of inactivity

[ ]  Use of a strong password for file access (at least 8 characters long, will not contain real names, does not contain complete dictionary word, contains characters from each of the following four groups: lowercase letters, uppercase letters, numerals, and special characters)

[ ]  Data stored on laptops, mobile devices or removable media will be encrypted

[ ]  No copies or paper print outs of the data will be made

[ ]  Copies are allowed but they will be tracked by the PI and will not be available to anyone except an authorized staff member for the purpose of the research for which the subject data were made available

[ ]  Data Use Agreement will be in place

[ ]  The investigators will not attempt to identify the individuals

[ ]  No merger with other data set is allowed/will be performed

[ ]  Specific data security plan as required by the data holder will be followed (please attach)

[ ]  Other:

***Note****: Investigators are reminded that subject identifiers and the means to link subject names and codes with research data should not be stored on unencrypted moveable media.  Identifiers and code keys must be stored in a secure manner, e.g., Yale network servers.  All portable devices must contain encryption software, per University Policy 5100.  If there is a technical reason a device cannot be encrypted please submit an exception request to the Information Security, Policy and Compliance Office by clicking on url* [*http://its.yale.edu/egrc*](http://its.yale.edu/egrc) *or email* *it.compliance@yale.edu*

For help with Data Security, please see [*http://its.yale.edu/secure-computing/protecting-yales-data*](http://its.yale.edu/secure-computing/protecting-yales-data)

For information on Data Use Agreements, please see policies # 5039 on <http://hipaa.yale.edu/policies-procedures-forms>