

**HRP-503G – PROTOCOL FOR REASEARCH NOT INVOLVING HUMAN SUBJECTS**

**(2018-1)**

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

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

**Version 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 research project involves human subjects. Continuing IRB oversight is not required for studies that are considered Not Human Subjects Research.    **Read the following instructions before proceeding:**   1. Use this protocol template to request a determination that research does not involve human subjects. Templates for human subject research protocols are available in the system Library. 2. If a section or question does not apply to your research study, type “Not Applicable” underneath. 3. Once completed, upload your protocol in the “Basic Information” screen in IRES IRB system. |

1. Is an investigational device or drug being used to test the specimens in this research?

**Yes  No**

***If you answered yes to this, under FDA regulations the Not Human Subjects determination does not apply. You must complete a protocol for full IRB review.***

1. **State the study hypothesis and give a brief description of methodology**: *Write here*
2. **Describe the type of data or specimens to be studied**: *Write here*
3. **Give estimated numbers of data or specimens:** *Write here*
4. **Describe the source of data or specimens:** *Write here*
   1. Does this study include data from an international location?

**Yes  No**  If yes, specify location: *Write here*

1. **Describe any coding of data or specimens, including information on who holds the key to the code:** *Write here*
2. **Choose one of the following categories for consideration.**

Project requires the collection/analysis of data regarding health facilities, businesses or other organizations or units which are not individual persons.

Project requires data or specimens from deceased persons and no data about or specimens from living individuals will be collected.

Project requires using only anonymous human data or specimens that is not readily ascertainable to investigators. *Specimens/data may not be coded*.

***Please note: all of the following requirements need to be met in order for this category to apply:***

* No contact with human subjects by the PI or any research team member for this study is involved for the proposed activity.
* Identifying information either was not obtained or has been destroyed prior to receipt by the study team so that data cannot be linked or re-linked to identifiable human subjects.

Project requires using only coded data which cannot be linked either directly or indirectly to coding systems by the investigators because of one or more of the following (check all that apply):

The investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased.

There are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased (attach applicable materials or reference the applicable protocol here).

There are other legal requirements prohibiting the release of the key to investigators, until the individuals are deceased (Provide explanation).

***Please note: all of the following requirements need to be met in order for this category to apply:***

* No contact with human subjects by the PI or any research team member for this study is involved for the proposed activity.
* Data or specimens are/were collected for another purpose and no extra data/specimens are/were collected for this purpose.
* Identifying information has been removed so that data cannot be linked or re-linked to identifiable human subjects by the PI or any member of the research team for this study.
* *Note: A code kept by the original researcher is allowed, but the PI for this study can have no means to identify individual human subjects.*

Project requires using human data or specimens with limited direct HIPAA identifiers (e.g., use of a limited data set), such as dates and zip code: *Specimens may or may not be coded.*

***Please note: all of the following requirements need to be met in order for this category to apply:***

* ⁮No contact with human subjects by the PI or any research team member is involved for the proposed activity.
* Data or specimens are/were collected for another purpose.
* There is a data use agreement in place for a limited data set.