



Wellstar Research Institute

Request for Non-Human Subjects Research Determination

Instructions: To request a written determination that an activity is non-human subjects research, please submit this form to the Wellstar Research Institute (WRI) via the WRI Inbox (research@wellstar.org). If you have any questions about whether an activity is non-human subjects, please contact the WRI for guidance. All exempt and non-human subjects research may proceed pending any other relevant institutional approvals without IRB review once the WRI makes the determination. However, if the activity is not exempt and deemed to be human subjects research, it must be reviewed by the IRB before initiation.

Principal Investigator _____ Department _____
 E-mail _____ Phone _____
 Co-PI(s) _____ E-mail _____
 Sub-Investigator _____ E-mail _____

1. Protocol/Project Information

Note – if you request a non-human subject determination and the research meets the definition of human subjects research, this may delay the review of your project.	
Sponsor (if applicable)	
Protocol Title	
Anticipated Start Date	
Anticipated End Date	
Student Project (Yes/No)	
If Yes, Type of Project (Thesis, Dissertation, Capstone, other)	

The IRB uses “WORKSHEET: Human Research Determination (Job Aid)” to determine whether an activity is research. This worksheet can be found on the Wellstar Research Institute web site and may be used to guide the information you provide in your description below.

A. RESEARCH

As defined by the Department of Health and Human Services’ (DHHS) regulations: “*a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.*”

1. Yes No Is the activity an investigation? (*Investigation*: e.g., a searching inquiry for ascertaining facts; detailed or careful examination; experiment that involves an FDA-regulated test article)
2. Yes No Is the investigation systematic? (*Systematic*: having or involving a system, method, or plan)?
3. Yes No Is the systematic investigation designed to develop or contribute to knowledge? (*Designed*: done with purpose/intent. *Develop*: to elaborate or expand in detail. *Contribute*: to be an important factor in; help to cause. *Knowledge*: facts, information.)
4. Yes No Is the knowledge generalizable? (*Generalizable*: universally applicable)

B. HUMAN SUBJECT

As defined by DHHS regulations: “*a living individual, about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.”*

Check all that apply:

1. Yes No The investigator will gather data about living individuals through intervention OR interaction. For example, physical procedures or manipulations of those individuals or their environment. (*Intervention*); Communication or interpersonal contact with the individuals. (*Interaction*)

2. Yes No The investigator will gather data about living individuals that is private. For example, the data includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place. The information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). (*Private*)

3. Yes No The investigator will gather data about living individuals that is identifiable. For example, the participant's identity is or may be readily ascertained by the investigator, or will be associated with the information; the research involves the use of coded* data/specimens (*Identifiable*)

C. CODED DATA

Coded* means a living individual's identifiable information such as name or social security number has been replaced by a code, such as a number, letter, or combination thereof, **and there is a key to link the code to the identifiable information of that individual in existence. Coded data are considered identifiable under the Common Rule.

If research involves the use of coded data/specimens, that were NOT explicitly collected for the proposed research activity through an interaction or intervention with living individuals, then one of the following must be true:

1. Yes No The provider of the data/specimens will remove the code before sending the data/specimens to the researcher.
OR
2. Yes No The holder of the key and investigator enter into an agreement prohibiting the release of the key to the investigator under any circumstances until the individuals are deceased. Provide a copy of this agreement (informal email exchange is sufficient);
OR
3. Yes No The investigator has documentation of written policies and operating procedures from a repository or data management center that prohibits the release of the key to the investigators under any circumstances until the individuals are deceased (provide this documentation);
OR
4. Yes No There are other legal requirements prohibiting the release of the key to the investigator until the individuals are deceased

D. HUMAN SUBJECT

As defined by FDA regulations: "an individual who is or becomes a participant in research, either as a recipient of the test article or as a control."

Does the activity involve human subjects as defined by FDA regulations? The activity involves human subjects if EITHER of the following checked YES:

- Yes No An individual will be a recipient of any test article (i.e., drug, medical device) or as a control.
- Yes No An individual on whose specimen a medical device will be used.

E. STUDY ACTIVITIES

Provide a response to each of the following questions. Indicate N/A where item is not applicable.

1. Purpose, specific aims, and/or objectives:

2. Target population:

3. Procedures used to gather information (e.g., communication or interpersonal contact with individuals, manipulation of individuals, manipulation of an individual's environment, or physical procedures). Indicate if these procedures would be conducted as part of the standard of care, regardless of the research.

4. Description of data/samples gathered about individuals without using interaction or intervention, including names of datasets, URLs, etc.

a) **What data will be collected, how and by whom the data will be analyzed?**

b) **How were the data/samples originally gathered from individuals (e.g., obtained as part of another IRB approved protocol at this institution/another institution or as a part of routine clinical practice)?**

c) **Can the collected information be directly or indirectly associated/linked with individual identities?**

d) **Can others directly or indirectly associate/link the collected information with individual identities?**

e) **List and attach with submission a copy of any applicable agreements (e.g., Data Use Agreement – DUA, an attestation from the data provider) that indicate that under no circumstances will you have access to the identities (or links to identities) of individuals from whom the data was collected.**

Principal Investigator Assurance and Acknowledgement

I certify that the information provided in this application and supporting documentation is complete and accurate. As the principal investigator, I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protections of the rights and welfare of human subjects, and strict adherence to any situations designated by the Wellstar Research Institute (WRI). I accept and will conform to all federal, state, institutional, and WRI provisions concerning the protection of human subjects in research. I will ensure all personnel involved in the research will be

