NASA HRP-405 Appendix 1

Not Human Subjects Research (NHSR) Questionnaire

Date: Click or tap to enter a date.

General Information

Research Title:	Click or tap here to enter text.
PI:	Click or tap here to enter text.
NASA Center (if applicable):	Click or tap here to enter text.
Research location:	Click or tap here to enter text.
Funding source:	Click or tap here to enter text.

This form is for use when determining whether a project meets the regulatory definitions for Human Subject Research

Prospective review and approval by an IRB is required for all activiites that meet the regulatory definitions for *research* with *human subjects* (Common Rule) or a *clinical investigation* (FDA). Activities that do not meet the regulatory definitions are considered "Not Human Subjects Research" (NHSR) for which IRB oversight is not required.

Section I: Regulatory Definitions of *Research*

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Research is defined as "*a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge*" [*NASA 14CFR1230. 102(l); HHS 45CFR46.102(l)]*

Under FDA regulations, the terms "Research" and "Clinical Investigation" and "Clinical Study" are synonymous and are defined as:

"Any experiment that involves a test article and one or more human subjects that is either subject to requirements for prior submission to the Food and Drug Administration under section 505(i), or 520(g) of the act, or … results of which are intended to be submitted to, or held for inspection by the Food and Drug Administration as part of an application for a research or marketing permit." FDA 21CFR50.3(c)*

**A test article means any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the Federal Food, Drug and Cosmetic Act (21 CFR 50.3(j)).*

1.1 What are the aims of the proposed project or activities?

Click or tap here to enter text.

1.2 Systematic Investigation.

Does the project or activity involve a systematic investigation, including research development, testing, or evaluation?

A systematic investigation is an activity that involves a prospective plan to gather information (i.e., data collection (quantitative or qualitative)) and analysis to answer a question.

☐ **No.**

☐ **Yes.** The project/activity involves a ***systematic investigation***.

☐ **Unsure.**

1.3 Designed to contribute to Generalizable Knowledge.

Is the project/activity designed to develop or contribute to generalizable knowledge?

Activities designed to develop or contribute to generalizable knowledge are those designed to draw broadly applicable conclusions or generalize findings beyond a single individual or internal program, uncover underlying principles that have predictive value and can be applied to other circumstances, or develop or test scientific theories or hypotheses.

NOTE: Although publication is often viewed as evidence of research status, it is not the only criterion. In fact, "systematic investigations" often result in published information, yet they do not qualify as research because they were not designed to contribute to generalizable knowledge.

☐ **No.**

☐ **Yes.** The proposed project/activity is ***designed to contribute to generalizable knowledge***.

☐ **Unsure.**

1.4 FDA Clinical Investigation.

Does the project/activity involve a test article subject to FDA regulation (e.g., drug, biologic, medical device, food additive, etc.) **which requires prior submission to the FDA, or for which the results will be submitted to the FDA as part of a research or marketing permit?**

☐ **No.**
☐ **Yes.** The proposed activities are subject to FDA regulation.

☐ **Unsure.**

Checklist: Definition of Research Use responses to questions 1.1-1.4 to complete the checklist.	No	Yes	Not Sure
Is the project a ***systematic investigation*** (question 1.2) including research development, testing, and evaluation, designed to develop or contribute to ***generalizable knowledge***(question 1.3)?	☐	☐	☐
Does the project involve a research/clinical investigation regulated by the FDA(question 1.4)?	☐	☐	☐

If you answered "NO" to both, the project is NOT Human Subjects Research and IRB oversight is not necessary

- Please retain this worksheet as documentation with project files.
- If a formal determination from the NASA IRB is needed please submit this form to the NASA eIRB to receive formal documentation that the project is "Not Human Subjects Research"

If you answered "YES" or "NOT SURE" to either of the above in Section I: Definition of Research → proceed to Section II: Definition of Human Subject

Section II: Definition of Human Subject

Section II: Definition of Human Subject Research

Human Subject, defined as "*a living individual about whom an investigator (whether professional or student) conducting research:*

(1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; ***OR***

(2) Obtains, uses, studies, analyzes, or generates identifiable private information or biospecimens." [NASA 14CFR1230.102(e); HHS 45CFR46.102(e)]

FDA Human Subject defined as *"an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient."* [FDA 21CFR50.3(g), 21CFR56.103(e), 21CFR312.3(b), and 21CFR812.3(p)].

2.1 Describe the participants or population you intend to include the project.

Click or tap here to enter text.

2.1.a Does the population involve International Partners or astronaut crew?

☐ **No.** No astronaut or International Partner participants.
☐ **Yes.**

If yes, please describe:

Click or tap here to enter text.

2.2 Do the information or biospecimens collected or used for the project/activity involve living individual(s)?

☐ **No.** Individuals are NOT living – STOP. The project is NHSR.
☐ **Yes.** Individuals ARE living.

2.3 Does the project/activity:

(i) Obtain information or biospecimens through intervention or interaction with the individual(s), and use, study, or analyze the information or biospecimens; [HHS and NASA]

(ii) Obtain, use, study, analyze, or generate identifiable private information or identifiable biospecimens? [HHS and NASA]

or

(iii) Use the individual as a recipient of a test article or as a control? [FDA]

Intervention *– includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or subject's environment that are performed for research purposes.*

Interaction *– includes communication or interpersonal contact between investigator and subject.*

Private information *– includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and information that has been provided for specific purposes by an individual and that individual can reasonably expect will not be made public (e.g., medical record).*

Identifiable private information/biospecimen *– information/biospecimen for which the identify of the subject is or may readily be ascertained by someone on the research team or associated with the information/biospecimen.*

Test article *– means any drug, medical device, human food additive, color additive, electronic product or other article subject to regulation by the FDA.*

2.3.a Describe project procedures.

Click or tap here to enter text.

2.3.b If the project/activity *only* involves secondary use of data and/or biospecimens (i.e., no interaction or intervention with participations):

(1) **Describe the origin of the data/specimens** (i.e., purchased from a biobank, MedB data, existing data from another project):

Click or tap here to enter text.

(2) **Address whether the data/specimens will identifiable[1]**

Click or tap here to enter text.

[1] Identifiable: The identity of the subject is or may readily be ascertained by the investigator or associated with the information. This includes private information or specimens linked to specific individuals by the investigator(s) either directly or indirectly through coding systems. Includes when individuals can be indirectly identified through a combination of information included in the data.

Checklist: Definition of Human Subjects Use responses to questions 2.1-2.3 to complete the checklist.		No	Yes	Not Sure
	Are the information or biospecimens obtained or used for the research **about living individuals?**	☐	☐	☐
	If you answered "YES" or "NOT SURE" please continue with the questions. If you answered "NO", the activity is NOT Human Subject Research, no IRB review is needed			
Does the research involve Human Subjects?	Does the research involve **interaction** or **intervention** with humans?	☐	☐	☐
	Does the research obtain, use, study, analyze, or generate identifiable **private information** or **identifiable biospecimens**?	☐	☐	☐
	Does the research involve human subjects (healthy or patients) who will serve as the recipient of a **test article** or as a control?	☐	☐	☐
If you answered "YES" to any of the three questions above **the activity is Human Subject Research**, → **an eIRB submission is required.** If you answered "NO" to all three questions above, the activity is NOT Human Subject Research → **Submit this form through the eIRB for a Not Human Research Determination letter.** If you answered "NOT SURE" to any of the above, **please submit this form to the NASA eIRB and contact the NASA IRB Office.**				

3. Additional information, if any, that may be helpful to the NASA IRB in making this determination.

Click or tap here to enter text.