ENGAGEMENT IN RESEARCH ASSESSMENT

This form should be used to determine whether National Jewish Health is considered engaged in a specific **non-exempt** human subjects research protocol. Institutions that are engaged in non-exempt human subjects research are subject to the requirements of 45 CFR part 46. This form is derived from OHRP's Guidance on Engagement of Institutions in Human Subjects Research and FDA guidance including Frequently Asked Questions – Statement of Investigator (Form FDA 1572).

PI Name:	
Protocol Title:	
Sponsor:	
Reviewer: NJH HRPP Administrator	**Date:**

1. Do you have any interests, financial or otherwise, related to this submission that could present a conflict of interest?

☐ Yes
☐ No

2. **Circumstances Under Which National Jewish Health is Considered Engaged**

In general, organizations are considered engaged in human subjects research if their involvement in the research includes any of the following circumstances (except as noted).

Circumstance	Yes	No
a. National Jewish Health receives an award through a grant, contract, or cooperative agreement directly from HHS for the research (even if no study activities will be done at NJH)	☐	☐
b. National Jewish Health's employees or agents intervene for research purposes with any human subjects of the research by performing invasive or noninvasive procedures *Examples of invasive or noninvasive procedures include drawing blood; collecting buccal mucosa cells using a cotton swab; administering individual or group counseling or psychotherapy; administering drugs or other treatments; surgically implanting medical devices; utilizing physical sensors; and utilizing other measurement procedures* *(see 3 a, b, and c for exceptions)*	☐	☐
c. National Jewish Health's employees or agents intervene for research purposes with any human subjects of the research by manipulating the environment *Examples of manipulating the environment include controlling environmental light, sound, or temperature; presenting sensory stimuli; and orchestrating environmental events or social interactions*	☐	☐

(see 3 a and c for exceptions)		
d. National Jewish Health's employees or agents interact for research purposes with any human subject of the research *Examples of interacting include engaging in protocol dictated communication or interpersonal contact; asking someone to provide a specimen by voiding or spitting into a specimen container; and conducting research interviews or administering questionnaires* *(see 3 a, b, c, and d for exceptions)*	☐	☐
e. National Jewish Health's employees or agents obtain the informed consent of human subjects for the research	☐	☐
f. National Jewish Health's employees or agents **obtain** for research purposes identifiable private information or identifiable specimens from any source for the research. In general, **obtaining** identifiable private information or identifiable specimens includes, but is not limited to: i. Observing or recording private behavior; ii. Using, studying, or analyzing for research purposes identifiable private information or identifiable specimens provided by another organization; and iii. Using, studying, or analyzing for research purposes identifiable private information or identifiable specimens already in the possession of the investigators *In general, obtaining identifiable information/specimens engages an institution even if the institution's employees or agents do not directly interact or intervene with human subjects.* *OHRP considers private information or specimens to be individually identifiable when they can be linked to specific individuals by the investigators either directly or indirectly through coding systems* *(See 3 a, b, c, g, h, i, and j for exceptions)*	☐	☐
Additional Scenarios for FDA-regulated Clinical Investigations ☐ **NA**	**Yes**	**No**
a. National Jewish Health's employees or agents are listed as investigators on the study's Statement of Investigator (Form FDA 1572 for drugs or equivalent for devices) *Information regarding who should be listed as an investigator is available in FDA's 1572 guidance.*	☐	☐
b. National Jewish Health's facilities are listed as performance sites on the study's Statement of Investigator (Form FDA 1572 for drugs or equivalent for devices) *Information regarding when facilities are considered research facilities and should be listed is available in FDA's 1572 guidance.*	☐	☐
c. National Jewish Health's employees or agents are assigned study responsibilities on the study's delegation log	☐	☐

3. Circumstances Under Which National Jewish Health is Not Considered Engaged

In general, organizations are not considered engaged if their involvement in the research is limited to one or more of the following.

Circumstances	Yes	No
a. National Jewish Health's employees or agents perform commercial or other services for investigators provided that all of the following conditions also are met: i. The services performed do not merit professional recognition or publication privileges; ii. The services performed are typically performed by National Jewish Health for non-research purposes; and iii. National Jewish Health's employees or agents do not administer any study intervention being evaluated under the protocol *Examples include (assuming the conditions above are true): an appropriately qualified laboratory whose employees perform routine analyses of blood samples for investigators as a commercial service; a transcription company whose employees transcribe research interviews as a commercial service; a hospital whose employees obtain blood through a blood draw or collect urine or other specimens to provide to investigators as a service; a radiology clinic whose employees perform chest x-rays and send the results to investigators as a service*	☐	☐
b. National Jewish Health is **not** listed as a research site and NJH's employees or agents provide clinical trial-related medical services that are dictated by the protocol and would typically be performed as part of **routine** clinical monitoring and/or follow-up of subjects provided that all of the following conditions are also met: i. National Jewish Health's employees or agents do not administer the study interventions being evaluated under the protocol *(see 3 c below for an exception)*; ii. The clinical trial-related medical services are typically provided by National Jewish Health for clinical purposes; iii. National Jewish Health's employees or agents do not enroll subjects or obtain the informed consent of any subject for participation in the research; and iv. When appropriate, investigators from an institution engaged in the research retain responsibility for overseeing protocol-related activities and ensuring that appropriate arrangements are made for reporting protocol-related data to investigators at an engaged institution, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol	☐	☐
c. National Jewish Health is **not** listed as a research site and National Jewish Health's employees or agents administer the study interventions being tested or evaluated under the protocol limited to a one-time or short-term basis (e.g., study drug is administered by National Jewish Health to an out of town subject	☐	☐

who is unexpectedly hospitalized), provided that <u>all</u> of the following conditions also are met: i. An investigator from an institution engaged in the research determines that it would be in the subject's best interest to receive the study interventions ii. National Jewish Health's employees or agents do not enroll subjects or obtain the informed consent of any subject for participation in the research; iii. Investigators from the institution engaged in the research retain responsibility for: a. Overseeing protocol-related activities; b. Ensuring the study interventions are administered in accordance with the IRB-approved protocol; and c. Ensuring appropriate arrangements are made for reporting protocol-related data to investigators at the engaged institution, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol; and iv. The IRB of the engaged institution is informed that study interventions being tested or evaluated under the protocol have been administered at an institution not listed as research site		
d. National Jewish Health's employees or agents: i. Inform prospective subjects about the availability of the research ii. Provide prospective subjects with information about the research (which may include the consent form and other IRB approved materials) but do not obtain any subject's consent for the research or act as representatives of the investigators; iii. Provide prospective subjects with information about contacting investigators for information about enrollment; and/or iv. Seek or obtain the prospective subjects' permission for investigators to contact them *An example of this would be a clinician who provides patients with literature about a research study at another institution, including a copy of the consent form, and obtains permission from the patient to provide the patient's name and telephone number to the investigators*	☐	☐
e. Use of National Jewish Health facilities for intervention or interaction with subjects by investigators from another institution *Examples of this would be a school that permits investigators from another institution to conduct or distribute a research survey; or a business that permits investigators from another institution to recruit research subjects or to draw a blood sample at the work site for research purposes*	☐	☐
f. National Jewish Health's employees or agents **release** identifiable private information or identifiable biological specimens to investigators at another institution pertaining to the subjects of the research.	☐	☐

• National Jewish Health will validate that the release of information or specimens is consistent with the informed consent (and HIPAA authorization when applicable) provided by the subject or the waiver of consent (and waiver of HIPAA authorization when applicable) approved by the IRB.		
g. National Jewish Health's employees or agents: i. Obtain coded private information or specimens from another institution involved in the research that retains a link to individually identifying information; and ii. Are unable to readily ascertain the identity of the subjects to whom the coded information or specimens pertain because, for example: a. National Jewish Health's employees or agents and the holder of the key enter into an agreement prohibiting the release of the key to National Jewish Health's employees or agents under any circumstances; b. The releasing institution has IRB-approved written policies and procedures applicable to the research that prohibit the release of the key to National Jewish Health's employees or agents under any circumstances; or c. There are other legal requirements prohibiting the release of the key to National Jewish Health's employees or agents	☐	☐
h. National Jewish Health's employees or agents access or utilize individually identifiable private information **only** while visiting an institution that is engaged in the research, provided their research activities are overseen by the IRB of the institution that is engaged in the research	☐	☐
i. National Jewish Health's employees or agents access or review identifiable private information for purposes of study auditing	☐	☐
j. National Jewish Health's employees or agents receive identifiable private information for purposes of satisfying FDA reporting requirements	☐	☐
k. National Jewish Health's employees or agents author a paper, journal article, or presentation describing a human subjects research study	☐	☐

Additional Comments:

Definitions:

For the purposes of this document:

Coded means that:

a. identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, and/or combination thereof (i.e., the code); and

b. a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

Employees or agents refers to individuals who: (1) act on behalf of the institution; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities. "Employees and agents" can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation.

Individually identifiable means that the identify of the subject is or may readily be ascertained by the investigator or associated with the information. In general, OHRP considers information or specimens to be individually identifiable when they can be linked to specific individuals by the investigator either directly or indirectly through coding systems. FDA regulations do not restrict applicability of their regulations to when information or specimens are individually identifiable (i.e., use of de-identified human specimens in a clinical investigation evaluating the safety or effectiveness of a diagnostic device would be subject to FDA regulations).

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

Interaction means communication or interpersonal contact between investigators and a subject. Interaction may be in person or remote and includes activities such as surveys and questionnaires (as methods of communication).

Private information means 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 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).

For NJH HRPP Use Only

Reviewer Notes:

Determination:

- ☐ National Jewish Health would be considered engaged in the proposed research study
- ☐ National Jewish Health would not be considered engaged in the proposed research study
- ☐ Additional information is needed, describe: