

## Determining Engagement

The purpose of this document is to provide guidance for making engagement determinations for proposed activities that are deemed **non-exempt human subjects research**. For information about determining whether a proposed activity is human subjects research, please see the Not Human Subjects Research Guidance Document. Please note, if a proposed activity is NHSR, there is no need to make an engagement determination.

### Introduction

Engagement is an important factor in determining if the proposed research activity requires IRB review per 45CFR46. Weill Cornell Medicine (WCM) IRB review is only required when WCM is engaged in non-exempt human subjects research activities.

WCM is considered engaged in a non-exempt human subjects research project when its *employees or agents*\* for the purposes of the research project obtain:

1. Data about the participants of the research through intervention or interaction with them;
2. Identifiable private information about the participants of the research; or
3. The informed consent of human participants for the research

*\*employees or agents are individuals acting on behalf of the institution, exercising institutional authority or responsibility, or performing institutionally designated activities*

Specifically, engagement means that WCM is responsible for the non-exempt human research and is required to:

1. Hold or obtain an applicable Office of Human Research Protections (OHRP)-approved Federalwide Assurance (FWA); and
2. Certify to the Health and Human Services (HHS) agency conducting or supporting the research that the research has been reviewed and approved by an IRB designated in the FWA, and will be subject to continuing review by an IRB

*Note, not all participating institutions and individuals need to be covered by an FWA or certify IRB review and approval of the research to the HHS agency conducting or supporting the research.*

### Institutions Engaged in Human Research

Examples where the institution is considered engaged in an HHS-conducted or -supported non-exempt human research project when the involvement of their employees or agents includes any of the following:

1. Institutions that receive an award through a grant, contract, or cooperative agreement directly from HHS for the non-exempt human research (i.e., awardee institutions), even where all activities involving human subjects are carried out by employees or agents of another institution.
2. Institutions whose employees or agents intervene for research purposes with any human subjects of the research by *performing invasive or noninvasive procedures*.
  - a. 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.

3. Institutions whose employees or agents intervene for research purposes with any human subject of the research by *manipulating the environment*.
  - a. Examples of *manipulating the environment* include controlling environmental light, sound, and temperature; presenting sensory stimuli; and orchestrating environmental events or social interactions.
4. Institutions whose employees or agents *interact* for research purposes with any human subject of the research.
  - a. 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.
5. Institutions whose employees or agents obtain the informed consent of human subjects for the research.
6. Institutions whose employees or agents obtain for research purposes identifiable private information or identifiable biological specimens from any source for the research. It is important to note that, in general, institutions whose employees or agents obtain identifiable private information or identifiable specimens for non-exempt human research are considered engaged in the research, even if the institution's employees or agents do not directly interact or intervene with human subjects. In general, obtaining identifiable private information or identifiable specimens includes, but is not limited to:
  - a. Observing or recording private behavior;
  - b. Using, studying, or analyzing for research purposes identifiable private information or identifiable specimens provided by another institution; and
  - c. Using, studying, or analyzing for research purposes identifiable private information or identifiable specimens already in the possession of the investigators.

In general, OHRP considers private information or specimens to be individually identifiable when they can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.

*Note: An institution relinquishing potential participants' PHI for screening or recruitment purposes does not satisfy the above criterion.*

### Institutions Not Engaged in Human Research

Institutions would be considered 'not engaged' in an HHS-conducted or -supported non-exempt human research project if the involvement of their employees or agents in that project is limited to one or more of the following:

1. Institutions whose employees or agents perform commercial or other services for investigators provided that all of the following conditions are also met:
  - a. The services performed do not merit professional recognition or publication privileges;
  - b. The services performed are typically performed by those institutions for non-research purposes; and
  - c. The institution's employees or agents do not administer any study intervention being tested or evaluated under the protocol.

Examples include (assuming the services do not merit professional recognition or publication privileges):

- An appropriately qualified laboratory whose employees perform routine serum chemistry analyses of blood samples for investigators as a commercial service
  - A transcription company whose employees transcribe research study interviews as a commercial service
  - A hospital whose employees obtain blood through a blood draw or collect urine and provide such specimens to investigators as a service
  - A radiology clinic whose employees perform chest x-rays and send the results to investigators as a service
  - A survey firm if the above conditions are met, the firm typically performs surveys for non-research purposes, the firm is not administering any intervention, and the firm is not involved in obtaining the informed consent of human subjects for research
2. Institutions (including private practices) not selected as a research site whose 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 participants enrolled at a study site by clinical trial investigators (e.g., medical history, physical examination, assessment of adverse events, blood test, chest x-ray, or CT scan) provided that all of the following conditions are also met:
- a. The institution's employees or agents do not administer the study interventions being tested or evaluated under the protocol;
  - b. The clinical trial-related medical services are typically provided by the institution for clinical purposes;
  - c. The institution's employees or agents do not enroll participants or obtain the informed consent of any participant for participation in the research; and
  - d. When appropriate, investigators from an institution engaged in the research retain responsibility for:
    - Overseeing protocol-related activities; and
    - Ensuring 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
3. Institutions (including private practices) not initially selected as a research site whose 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., an oncologist at the institution administers chemotherapy to a participant as part of a clinical trial because the participant unexpectedly goes out of town, or is unexpectedly hospitalized), provided that all of the following conditions are also met:
- a. An investigator from an institution engaged in the research determines that it would be in the participant's best interest to receive the study interventions being tested or evaluated under the protocol;
  - b. The institution's employees or agents do not enroll participants or obtain the informed consent of any participant for participation in the research;

- c. Investigators from the institution engaged in the research retain responsibility for:
    - Overseeing protocol-related activities;
    - Ensuring the study interventions are administered in accordance with the IRB-approved protocol; and
    - 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
  - d. An IRB designated on the engaged institution's FWA is informed that the study interventions being tested or evaluated under the protocol have been administered at an institution not selected as a research site.
4. Institutions whose employees or agents:
- a. Inform prospective participants about the availability of research;
  - b. Provide prospective participants with information about the research (which may include a copy of the relevant informed consent document and other IRB approved materials) but do not obtain participants' consent for the research or act as representatives of the investigators;
  - c. Provide prospective participants with information about contacting investigators for information or enrollment; and/or
  - d. Seek or obtain the prospective participants' permission for investigators to contact them.

An example would be a clinician who provides patients with literature about a research study at another institution, including a copy of the informed consent document, and obtains permission from the patient to provide the patient's name and telephone number to investigators.

5. Institutions (e.g., schools, nursing homes, businesses) that permit use of their facilities for intervention or interaction with participants by investigators from another institution.

Examples would be a school that permits investigators from another institution to conduct or distribute a research survey in the classroom; or a business that permits investigators from another institution to recruit research participants or to draw a blood sample at the work site for research purposes.

6. Institutions whose employees or agents release to investigators at another institution identifiable private information or identifiable biological specimens pertaining to the participants of the research.

Note that where the institution is releasing identifiable private information or identifiable biological specimens, applicable regulations and laws still apply. Please direct these individuals to the Privacy Office for HIPAA-related concerns. If identifiable private information or identifiable biospecimens to be released were collected for another research study covered by the Common Rule, then:

- a. Ensure that the release would not violate the informed consent provided by the participants to whom the information or biological specimens pertain, or
- b. If the informed consent was waived by the IRB, ensure that the release would be consistent with the IRB's determinations that permitted a waiver of informed consent

Examples of institutions that might release identifiable private information or identifiable biological specimens to investigators at another institution include:

- Schools that release identifiable study test scores;
- An HHS agency that releases identifiable records about its beneficiaries; and
- Medical centers that release identifiable human biological specimens

Note that, in general, the institutions whose employees or agents obtain the identifiable private information or identifiable biospecimens from the releasing institution would be engaged in human research.

7. Institutions whose employees or agents:
  - a. Obtain coded private information or human biological specimens from another institution involved in the research that retains a link to individually identifying information such as name or social security number); and
  - b. Are unable to readily ascertain the identity of the participants to whom the *coded*\* information or specimens pertain because, for example:
    - The institution’s employees or agents and the holder of the key enter into an agreement prohibiting the release of the key to those employees or agents under any circumstances;
    - The releasing institution has IRB-approved written policies and operating procedures applicable to the research project that prohibit the release of the key to the institution’s employees or agents under any circumstances; or
    - There are other legal requirements prohibiting the release of the key to the institution’s employees or agents.

\**Coded means:*

- 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*

8. Institutions whose 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.
9. Institutions whose employees or agents access or review identifiable private information for the purposes of study auditing (e.g., a government agency or private company will have access to individually identifiable study data for auditing purposes).
10. Institutions whose employees or agents receive identifiable private information for purposes of satisfying U.S. Food and Drug Administration reporting requirements.
11. Institutions whose employees or agents author a paper, journal article, or presentation describing a human subjects research study.

## Cooperative Research

When multiple institutions are engaged in the same non-exempt human research project, institutions may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements to avoid duplication of effort, in accordance with the Common Rule.

When WCM is engaged in only part of a cooperative research project, the WCM IRB must review and approve the part(s) of the research in which WCM is engaged. Note, the reviewing IRB may decide to review the entire research study, even if information about the entire study is not necessary to approve the institution's part of the research under the Common Rule. An exception to this scenario is when WCM is the primary awardee for an international research project.

## Food and Drug Administration

The Food and Drug Administration (FDA) does not have a comparable process that aligns with OHRP's engagement guidance. If you have an application in which only FDA regulations would apply, please contact the HRPO Team for assistance.

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### Sources:

1. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html>
2. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/determining-when-institutions-are-engaged-in-research/index.html>
3. <https://www.youtube.com/watch?v=7gmRz0dNUmI>

## Engagement Checklist

If you have already determined the proposed activity is Not Human Subjects Research (NHSR), you do not need to continue with this checklist to determine if WCM is engaged in the activity. If you have not yet made an HSR determination, you may proceed with this checklist. If the result of this checklist determines that WCM is not engaged in the proposed activity, you do not need to make an HSR determination. Please see the NHSR Guidance document for assistance if needed.

If using this checklist, please complete prior to determining whether the proposed activity is exempt or non-exempt HSR.

Engagement	
The WCM employee(s) or agent(s) will (select all that apply):	
	Receive a grant, contract, or cooperative agreement directly from HHS for non-exempt human research (even if no human research activities are conducted by WCM employees or agents)
	Intervene for research purposes with any human subjects of the research by performing invasive or non-invasive procedures
<i>Invasive or non-invasive procedures includes drawing blood, buccal swabs, administering individual or group therapy, administration of drugs or other treatments, surgically implanting devices, use of physical sensors, etc.)</i>	
	Intervene for research purposes with any human subject of the research by manipulating the environment
<i>Examples of manipulating the environment include controlling environmental light, sound, or temperature, presenting sensory stimuli, and orchestrating environmental events or social interactions.</i>	
<input type="checkbox"/>	Interact for research purposes with any human subject of the research
<i>Examples of interacting include engaging in protocol dictated communication or interpersonal contact, asking someone to provide a specimen, and conducting research interviews/questionnaires, etc.)</i>	
<input type="checkbox"/>	Obtain the informed consent of the human subjects for the research
	Obtain for research purposes identifiable private information or identifiable biospecimens from any source for the research. This includes: <ul style="list-style-type: none"> <li>(a) Observing or recording private behavior</li> <li>(b) Using, studying, or analyzing for research purposes identifiable private information or identifiable biospecimens provided by another institution; and</li> <li>(c) Using, studying or analyzing for research purposes identifiable private information or identifiable biospecimens already in the possession of the investigators.</li> </ul>
<i>Note, obtain does not include the simple possession of PHI in the medical record. Private information or specimens are individually identifiable when they can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.</i>	
<p style="color: red;">If you selected any of the above, WCM is engaged in the research and IRB review is required.</p> <p style="color: red;">If you did not select any of the above, WCM is likely not engaged. You may see below to confirm IRB review is not required.</p>	

Not Engaged
Select all scenarios that apply to the proposed activity:

	<p>WCM employees or agents perform commercial or other services for investigators where:</p> <ul style="list-style-type: none"> <li>(a) The services performed do not merit professional recognition or publication privileges;</li> <li>(b) The services performed are typically performed by those institutions for non-research purposes; and</li> <li>(c) The employees or agents do not administer any study intervention being tested or evaluated under the protocol</li> </ul>
	<p>WCM is not selected as a research site and WCM employees and 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 participants enrolled at a study site by clinical trial investigators provided that:</p> <ul style="list-style-type: none"> <li>(a) WCM's employees or agents do not administer the study interventions being tested or evaluated under the protocol;</li> <li>(b) The clinical trial-related medical services are typically provided by the institution for clinical purposes;</li> <li>(c) WCM employees or agents do not enroll participants or obtain the informed consent of any participant for participation in the research; and</li> <li>(d) When appropriate, investigators from another institution engaged in the research retain responsibility for: <ul style="list-style-type: none"> <li>(i) Overseeing protocol-related activities; and</li> <li>(ii) Ensuring 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</li> </ul> </li> </ul>
<p><i>Examples include medical history, physical examination, assessment of adverse events, blood test, chest x-ray, or CT scan.</i></p>	
	<p>WCM is not initially selected as a research site and WCM employees or agents administer the study interventions being tested or evaluated under the protocol limited to a one-time or short-term basis provided that:</p> <ul style="list-style-type: none"> <li>(a) An investigator from an institution engaged in the research determines that it would be in the participant's best interest to receive the study interventions being tested or evaluated under the protocol;</li> <li>(b) WCM's employees or agents do not enroll participants or obtain the informed consent of any participant for participation in the research;</li> <li>(c) Investigators from the institution engaged in the research retain responsibility for: <ul style="list-style-type: none"> <li>(i) Overseeing protocol-related activities;</li> <li>(ii) Ensuring the study interventions are administered in accordance with the IRB-approved protocol; and</li> <li>(iii) Ensuring appropriate arrangement 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</li> </ul> </li> <li>(d) An IRB designated on the engaged institution's FWA is informed that study interventions being tested or evaluated under the protocol have been administered at an institution not selected as a research site.</li> </ul>
<p><i>Examples include an oncologist at the institution administers chemotherapy to a research participant as part of a clinical trial because the participant unexpectedly goes out of town, or is unexpectedly hospitalized)</i></p>	
	<p>WCM employees or agents:</p> <ul style="list-style-type: none"> <li>(a) Inform prospective participants about the availability of research;</li> <li>(b) Provide prospective participants with information about the research (which may include a copy of the relevant informed consent document and other IRB approved materials) but do not obtain participants with information about contacting investigators for information or enrollment; and/or</li> <li>(c) Seek or obtain the prospective participants' permission for investigators to contact them</li> </ul>

*An example would be a clinician who provides patients with literature about a study at another institution, including a copy of the informed consent document, and obtains permission from the patient to provide the patient's name and telephone number to investigators.*

WCM allows use of their facilities for intervention or interaction with participants by investigators from another institution.

WCM employees or agents release to investigators at another institution identifiable private information or identifiable biological specimens pertaining to the participants of research.

*Where the institution is releasing identifiable private information or identifiable biological specimens, applicable regulations and laws still apply. Please direct these individuals to the Privacy Office for HIPAA-related concerns. Note, if identifiable private information or identifiable biospecimens to be released were collected for another research study covered by the Common Rule, ensure that the release would not violated the informed consent provided by the participants to whom the information or biological specimens pertain, or if the informed consent was waived by the IRB, ensure that the release would be consistent with the IRB's determinations that permitted a waiver of informed consent under the Common Rule.*

WCM employees or agents obtain coded private information or human biological specimens from another institution involved in the research that retains a link to individually identifiable information and are unable to readily ascertain the identity of the participants to whom the coded information or specimens pertain because:

- The institution's employees or agents and the holder of the key enter into an agreement prohibiting the release of the key to those employees or agents under any circumstances;
- The releasing institution has IRB-approved written policies and procedures applicable to the research project that prohibit the release of the key to the institution's employees or agents under any circumstances; or
- There are other legal requirements prohibiting the release of the key to the institution's employees or agents

*Coded means:*

(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*

WCM 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.

Institutions whose employees access or review identifiable private information for purposes of study auditing (e.g., a government agency or private company).

Institutions whose employees or agents received identifiable private information for purposes of satisfying U.S. FDA reporting requirements.

WCM employees or agents author a paper, journal article, or presentation describing a human subject research study.

**If you selected any of the above, WCM is not engaged in the research and IRB review is not required.**

**If you did not select any of the above, return to the above sections of this form to determine if WCM is engaged in the research and IRB review is required.**