|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study ID# |       | PI |       |  |

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| --- |
| **Non-Exempt Human Subject Research** |
| Engagement determination is only made after it is determined that the activity involves non-exempt human subject research.  |
| Yes | No |  |
| [ ]  | [ ]  | Does the activity involve research?  |
| [ ]  | [ ]  | Is the research human subjects? |
| [ ]  | [ ]  | Is the human subject research non-exempt? |
| * If yes, continue.
* If any of the answers is “No,” do not proceed, as an engagement determination is only made after it is determined that the activity involves non-exempt human subject research.
 |
| **MSU Employee or Agent** |
| To be considered engaged, the activity needs to involve an MSU employee or agent. |
| Yes | No |  |
| [ ]  | [ ]  | Does the non-exempt human subject research involve an MSU employee or agent?  |
| * If yes, continue.
* If no, please explain.
 |
| **Engagement Scenarios** |
| In general, MSU is considered engaged in non-exempt human subjects research project when the involvement of MSU employees or agents in that project includes any of the following: |
| Yes | No | Engagement Criteria |
| [ ]  | [ ]  | **MSU receives an award through a grant, contract, or cooperative agreement directly from a federal agency for the non-exempt human subjects research** (i.e. awardee institutions), even where all activities involving human subjects are carried out by employees or agents of another institution. (A1)* If yes, MSU is engaged in non-exempt human subject research.

Comments:       |
| [ ]  | [ ]  | **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. (A2)* If yes, see scenarios B.(1), B.(2), and B.(3) below for limited exceptions. If no exceptions apply, MSU is engaged in non-exempt human subject research.

[ ]  Exceptions ApplyComments:       |
| [ ]  | [ ]  | **Intervene for research purposes with any human subject 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. (A3)* If yes, see scenarios B.(1) and B.(3) below for limited exceptions. If no exceptions apply, MSU is engaged in non-exempt human subject research.

[ ]  Exceptions ApplyComments:       |
| [ ]  | [ ]  | **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. (A4)* If yes, see scenarios B.(1), B.(2), B.(3), and B.(4) below for limited exceptions. If no exceptions apply, MSU is engaged in non-exempt human subject research.

[ ]  Exceptions ApplyComments:       |
| [ ]  | [ ]  | **Obtain the informed consent of human subjects for the research.** (A5)* If yes, MSU is engaged in non-exempt human subject research.

Comments:       |
| [ ]  | [ ]  | **Obtain for research purposes identifiable private information or identifiable biological specimens from any source for the research.** In general, obtaining identifiable private information or identifiable specimens includes, but is not limited to: observing or recording private behavior; using, studying, or analyzing for research purposes identifiable private information or identifiable specimens provided by another institution; and using, studying, or analyzing for research purposes identifiable private information or identifiable specimens already in the possession of the investigators.* If yes, see scenarios B.(1), B.(2), B.(3), B.(7), B.(8), B.(9), and B.(10) below for limited exceptions. If no exceptions apply, MSU is engaged in non-exempt human subject research.

[ ]  Exceptions ApplyComments:       |
| Not Engaged |
| Institutions would be considered not engaged in non-exempt human subjects research project if the **involvement of their employees or agents in that project is limited to one or more of the following**. The following are scenarios describing the types of institutional involvement that would make an institution not engaged in human subjects research; there may be additional such scenarios: |
| Yes | No | Engagement Criteria |
| [ ]  | [ ]  | **Perform commercial or other services for investigators provided that all of the following conditions also are met:**[ ]  the services performed do not merit professional recognition or publication privileges;[ ]  the services performed are typically performed by those institutions for non-research purposes; and[ ]  MSU’s employees or agents do not administer any study intervention being tested or evaluated under the protocol.The following are some examples, assuming the services described would 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 transcribes 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. (B1)
* If yes and the involvement of MSU employees or agents is limited to one (or more) of the non-engaged scenarios, MSU would not be considered engaged in non-exempt human subject research

Comments:       |
| [ ]  | [ ]  | **MSU is not selected as a research site and 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 subjects 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 also are met:[ ]  the institution’s employees or agents do not administer the study interventions being tested or evaluated under the protocol;[ ]  the clinical trial-related medical services are typically provided by the institution for clinical purposes;[ ]  the institution’s employees or agents do not enroll subjects or obtain the informed consent of any subject for participation in the research; and[ ]  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.

Note that institutions (including private practices) not initially selected as research sites whose employees or agents administer the interventions being tested or evaluated in the study—such as administering either of two chemotherapy regimens as part of an oncology clinical trial evaluating the safety and effectiveness of the two regimens—generally would be engaged in human subjects research (see scenario B.(3) below for a limited exception (B2)* If yes and the involvement of MSU employees or agents is limited to one (or more) of the non-engaged scenarios, MSU would not be considered engaged in non-exempt human subject research.

Comments:       |
| [ ]  | [ ]  | **MSU not initially selected as a research site and 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 research subject as part of a clinical trial because the subject unexpectedly goes out of town, or is unexpectedly hospitalized), provided that all of the following conditions also are met:[ ]  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 being tested or evaluated under the protocol;[ ]  MSU’s employees or agents do not enroll subjects or obtain the informed consent of any subject for participation in the research;[ ]  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

[ ]  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. (B3)* If yes and the involvement of MSU employees or agents is limited to one (or more) of the non-engaged scenarios, MSU would not be considered engaged in non-exempt human subject research.

Comments:       |
| [ ]  | [ ]  | Perform one or more of the following:[ ]  Inform prospective subjects about the availability of the research;[ ]  provide prospective subjects 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 subjects’ consent for the research or act as representatives of the investigators;[ ]  provide prospective subjects with information about contacting investigators for information or enrollment; and/or[ ]  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 informed consent document, and obtains permission from the patient to provide the patient’s name and telephone number to investigators. (B4)* If yes and the involvement of MSU employees or agents is limited to one (or more) of the non-engaged scenarios, MSU would not be considered engaged in non-exempt human subject research.

Comments:       |
| [ ]  | [ ]  | **Permit use of their facilities for intervention or interaction with subjects 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 subjects or to draw a blood sample at the work site for research purposes. (B5)* If yes and the involvement of MSU employees or agents is limited to one (or more) of the non-engaged scenarios, MSU would not be considered engaged in non-exempt human subject research.

Comments:       |
| [ ]  | [ ]  | **Release to investigators at another institution identifiable private information or identifiable biological specimens pertaining to the subjects of the research.**Note that in some cases the institution releasing identifiable private information or identifiable biological specimens may have institutional requirements that would need to be satisfied before the information or specimens may be released, and/or may need to comply with other applicable regulations or laws. In addition, if the identifiable private information or identifiable biological specimens to be released were collected for another research study covered by 45 CFR part 46, then the institution releasing such information or specimens should:* ensure that the release would not violate the informed consent provided by the subjects to whom the information or biological specimens pertain (under 45 CFR 46.116), or
* if 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 45 CFR 46.116 (c) or (d).

Examples of institutions that might release identifiable private information or identifiable biological specimens to investigators at another institution include: schools that release identifiable student 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 biological specimens from the releasing institution would be engaged in human subjects research. (B6)* If yes and the involvement of MSU employees or agents is limited to one (or more) of the non-engaged scenarios, MSU would not be considered engaged in non-exempt human subject research.

Comments:       |
| [ ]  | [ ]  | **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 are unable to readily ascertain the identity of the subjects 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 the 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.

 For purposes of this document, coded means that:* 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
* a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

 Although this scenario resembles some of the language in OHRP’s Guidance on Research Involving Coded Private Information or Biological Specimens, it is important to note that OHRP’s Guidance on Research Involving Coded Private Information or Biological Specimens addresses when research involving coded private information or specimens is or is not research involving human subjects, as defined in 45 CFR 46.102(f). As stated above in Section II., this Guidance on Engagement of Institutions in Human Subjects Research should only be applied to research projects that have been determined to involve human subjects and that are not exempt under HHS regulations at 45 CFR 46.101(b). (B7)* If yes and the involvement of MSU employees or agents is limited to one (or more) of the non-engaged scenarios, MSU would not be considered engaged in non-exempt human subject research.

Comments:       |
| [ ]  | [ ]  | **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**. (B8)* If yes and the involvement of MSU employees or agents is limited to one (or more) of the non-engaged scenarios, MSU would not be considered engaged in non-exempt human subject research.

Comments:       |
| [ ]  | [ ]  | **Access or review identifiable private information for purposes of study auditing** (e.g. a government agency or private company will have access to individually identifiable study data for auditing purposes). (B9)* If yes and the involvement of MSU employees or agents is limited to one (or more) of the non-engaged scenarios, MSU would not be considered engaged in non-exempt human subject research.

Comments:       |
| [ ]  | [ ]  | **Receive identifiable private information for purposes of satisfying U.S. Food and Drug Administration reporting requirements**. (B10)* If yes and the involvement of MSU employees or agents is limited to one (or more) of the non-engaged scenarios, MSU would not be considered engaged in non-exempt human subject research.

Comments:       |
| [ ]  | [ ]  | **Author a paper, journal article, or presentation describing a human subjects research study**. (B11)* If yes and the involvement of MSU employees or agents is limited to one (or more) of the non-engaged scenarios, MSU would not be considered engaged in non-exempt human subject research.

Comments:       |

**[ ]  MSU is engaged in non-exempt human subjects research**

**[ ]  MSU is NOT engaged in non-exempt human subjects research**

Comments:

|  |
| --- |
| Determination made by: |
| Name: |       | Date: |       |  |
|  |
|  |