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Institutional Review Board

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**NDSU Collaborative, Multi-site or Off-site Research Worksheet**

*Use this form to determine requirements for training, FWA and IRB review of research conducted at non-NDSU sites or in cooperation with non-NDSU entities. (Ref:* [*SOP 2.3*](http://www.ndsu.nodak.edu/research/irb/documents/2.3CollaborativeMultisiteoffsiteResearchSept2010.pdf)*)*

Title of Project:

Project directed or supervised by:

NDSU Name: Dept.:

Non- NDSU entity Name:

External funding:

N/A

Federal funds  Non-federal funds

Agency: Primary awardee:

Subcontractor:

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| **I. Other institutions and research sites**  *List all non-NDSU institutions who will collaborate or assist with research, and/or serve as a research site.* |

Name of entity:  Contact person(s):

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| **II. Engagement in research**  Determine whether the non-NDSU entity is ‘engaged in human subjects research’. |

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| **A. ‘Engaged in Research’**: An institution is considered to be engaged in human subjects research when their employees or agents will perform any one or more of the following activities:  1. Receive a direct award, grant or contract to perform human subjects research.  2. Direct or supervise a human subjects research project.  3. Intervene with participants for research purposes by performing invasive or noninvasive procedures *(exceptions: when an institution’s activities are limited to those described in B1 – B4 below, the institution is not engaged).* Examples may include, but are not limited to:   * administering counseling or psychotherapy * drawing blood * obtaining buccal mucosa cells using a cotton swab * administering drugs or other treatment * utilizing physical sensors, or other measurement procedures     4. Intervene with participants for research purposes by manipulating the environment *(exceptions: when an institution’s activities are limited to those described in B1 – B4 below, the institution is not engaged).* Examples may include:   * controlling environmental light, sound, or temperature * presenting sensory stimuli * orchestrating environmental events or social interactions   5. Interact with participants for research purposes *(exceptions: when an institution’s activities are limited to those described in B1 – B4 below, the institution is not engaged).* Examples may include, but are not limited to:   * engage in protocol dictated communication or interpersonal contact * ask someone to provide a specimen by voiding or spitting into a container * conduct research interviews * administer questionnaires   6. Obtain informed consent of human subjects for non-exempt research *(exceptions: when an institution’s activities are limited to those described in B3 – B4 below, the institution is not engaged).*  7. Obtain private identifiable information or specimens from any source for research purposes *(exceptions: when an institution’s activities are limited to those described in B1, B5, or B7 below, the institution is not engaged).* Examples may include, but are not limited to:   * observing or recording private behavior * using, studying or analyzing private identifiable information or specimens provided by another institution * using, studying or analyzing private identifiable information or specimens already in the possession of the investigator(s).   8. Utilize private information or human specimens (including de-identified materials) from any source for research subject to FDA regulations. |
| **B.**  **Not ‘Engaged in Research’**:  \* When the involvement of an institution’s employees or agents is *limited* to one or more of the following activities, the institution is considered NOT engaged in human subjects research:  1. Perform commercial or other services for investigators, provided that:   * services do not merit professional recognition or publication privileges, * services are typically performed for non-research purposes, ***and*** * employees or agents do not administer any research intervention being evaluated under the protocol.   *\*\*Some examples of services may include: interview transcription performed by a transcription company, blood draw or analysis performed by a hospital lab, data collection or analysis performed by a survey firm.*  2. Permit use of facilities to allow another institution’s investigators to intervene or interact with subjects.  3. Assist with recruitment by informing or providing prospective subjects with information about research (may include a consent document or other IRB-approved materials) or contact information for investigators; provided they do not obtain consent or act as a representative for the research.  4. Seek or obtain prospective subjects permission for investigators to contact them directly; or release lists of names/contact information, private information or biological specimens to another institution *(IRB approval is required when releasing data or specimens originating from a research project.)*  5. Access or utilize identifiable private information only while visiting an institution engaged in the research, provided that their IRB has approved the study  6. Author a paper, journal article, or presentation describing a human subjects research study  7. Obtain de-identified or coded private information or human biological specimens from another institution involved in the research that retains a link to individually identifying information, and the NDSU investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:   * the NDSU investigator(s) and the holder of the key enter into an agreement prohibiting the release of the key to the investigators 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 NDSU investigator(s) under any circumstances, or * there are other legal requirements prohibiting the release of the key to the NDSU investigators.   **NOTE:** The IRB has final authority to determine whether the use of private information or human biological specimens from living individuals constitutes NDSU engagement in human subjects research. ***Consult the IRB office for more information.*** |

**Role of non-NDSU collaborator or entity:** *(describe role in research for each entity)*

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Based on the definitions above, the non-NDSU entity is:

Not engaged in research >>> When submitting a protocol for NDSU IRB review:

* Describe the role of the non-NDSU entity where applicable on the protocol.
* **Do Not** list non-NDSU entity’s employees or agents as co-investigators or research team members. Human subjects training is not required for those individuals.
* Provide documentation of permission or IRB approval from the non-NDSU entity. The NDSU PI remains responsible for complying with any additional requirements of the outside entity prior to initiating research at/with that entity, which may include review by their IRB.
* The remaining sections of this form are not applicable.

Engaged in research:

* Completed form may be attached to protocol or documents submitted to the IRB
* Continue to next section to determine requirements for FederalWide Assurance (FWA) and IRB review.
* For purposes of this document, the non-NDSU entity or institution will be referred to as the ‘collaborator’ or ‘collaborating institution’.

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| 1. **FederalWide Assurance (FWA)**   Determine if a collaborating institution or research site will require an FWA. |

**NDSU:** NDSU holds an approved FWA from OHRP: # FWA00002439. For current expiration date, visit: <https://www.ndsu.edu/research/for_researchers/research_integrity_and_compliance/institutional_review_board_irb/>.

**Collaborating institution(s) or research site(s)** is ‘engaged’ in research, and:

Holds an approved FWA from OHRP>>> Skip to Section IV.

Project is NOT supported by federal funds (either directly, or through sub-contracts) >>> no FWA required; skip to Section IV.

Project is exempt human research >>> no FWA required; skip to Section IV.

Project is non-exempt human research funded by HHS or another Common Rule agency >>> FWA required. Mark as applicable:

NDSU is primary awardee >>> FWA requirement may be met by either:

1. Collaborating institution may apply to OHRP for their own FWA; or
2. NDSU may agree to extend its FWA to cover the collaborating institution. This option is subject to approval of the Institutional Official (IO), and may be utilized only under limited circumstances when:
   * collaborating institution does not routinely conduct human subjects research
   * research is directed or supervised by an NDSU PI (faculty or staff)
   * collaborator agrees in writing to permit the research to be conducted at their institution (if applicable), and
   * each employee/agent of the collaborating institution signs an Individual Investigator Agreement (IIA), accepting responsibility to comply with NDSU policy and procedures for subject protections.

Collaborating institution is primary awardee >>> The institution must apply to OHRP for their own FWA. NDSU cannot extend applicability of its FWA in this instance.

**Continue to Section IV to determine appropriate IRB review arrangement.**

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| **IV. IRB Review**  *When multiple institutions are engaged in the same research project, cooperative IRB review arrangements may be used to avoid duplication of effort.* |

**NDSU IRB as IRB of record:**

The NDSU IRB may agree to serve as the IRB of record (primary IRB) when an NDSU faculty or staff will direct or supervise the research. This determination is made on a case-by-case basis, subject to approval by the IRB and IO. Additional criteria may include any of the following:

* NDSU is primary awardee, if funded
* collaborating entity does not have an IRB
* collaborating entity has agreed to rely on NDSU IRB for review and oversight of the research,
* NDSU IRB has, or is able to obtain sufficient knowledge of the local research context (if non-exempt research)

**NOTE:**  When submitting the protocol to NDSU IRB:

* Exempt research:
  + List collaborator’s employees or agents on the protocol.
  + **Upload** training documentation for collaborator’s employees or agents into Novelution.
  + If the collaborator’s institution has an IRB, they MUST contact their IRB to determine if they are willing to rely on NDSU’s review, or if joint review (both IRB’s review) will be required. Provide documentation to the NDSU IRB with your submission.
  + If the collaborating institution does not have an IRB, submit a letter of permission/cooperation or other documentation from each collaborating entity engaged in research stating:
    - a brief description of the entity’s role in the research
    - a statement that appropriate training will be completed prior to involvement of human subjects
    - a statement that the project will be conducted according to the approved protocol and NDSU policy for protecting research subjects.

*(A protocol may be approved prior to receipt of the letter, providing all other requirements have been met.)*

* Non-exempt research:
  + If collaborating entity has an FWA, the following is required:
    - IRB Authorization Agreement (IAA) also known as a Reliance agreement - prepared by IRB staff
  + If collaborating entity does **not** have an FWA, the following is required:
    - List collaborator’s employees on the IRB protocol and submit training documentation
    - Letter of permission from collaborating entity
    - Independent Investigator Agreement (IIA) signed by each collaborator’s employee or agent engaged in the research

**Collaborator IRB as IRB of record:**

The NDSU IRB may rely on a collaborating institution’s IRB for review and oversight of the research when NDSU’s role in the research is limited. This determination is made on a case-by-case basis, subject to approval by the IRB and IO. The collaborating institution must hold an approved FWA, and agree to provide review and oversight for the research. Additional criteria may include, but are not limited to:

* collaborating IRB policies and procedures are at least equivalent to NDSU IRB
* collaborating IRB’s review would provide more appropriate expertise, oversight and knowledge of local research context

**NOTE:** When NDSU relies on review of a collaborator’s IRB:

* Upload a copy of collaborating IRB’s complete protocol, supplemental materials (e.g. consent forms, questionnaires, etc.), and approval documentation into Novelution.
* Current CITI training is required for NDSU employees or agents.
* **Upload** training documentation for collaborator’s employees or agents listed in Novelution.
* Exempt research:
  + Document acceptance with a letter signed by IRB Administrator or IRB Chair
* Non-exempt research:
  + Document agreement with IRB Authorization Agreement (IAA).

**Joint Review:**

Each IRB may elect to review all, or *only that portion* of the research in which their institution is engaged. This arrangement, subject to approval by the IRB and/or IO/designee, may be made under any of the following circumstances:

* + - the IRBs involved are unable to agree on a primary IRB designation
    - collaborating institution does not have an approved FWA
    - collaborator’s IRB policies and procedures are not equivalent to those of NDSU IRB

**NOTE:** When the NDSU IRB reviews only the NDSU portion of the research:

* **do not** list collaborator’s employees or agents on the protocol
* training requirements of NDSU IRB apply only to NDSU employees