13 Sponsored Research: 13.1 Certification of IRB Approval	Effective Date: **12/09/2011** Revised: 1/13/2023

The Institutional Review Board (IRB) reviews **Proposals** to external agencies that fund human subjects research. **Certification of IRB Approval** verifies that the involvement of human subjects described in the **Proposal** is consistent with that contained in any relevant **IRB Protocol(s).**

1.0 Applicability.

This procedure applies to all **Proposals** for external funding (grants, contracts, or cooperative agreements) that include any NDSU engagement in research involving human subjects**,** as outlined in Standard Operating Procedure (SOP) *2.2 NDSU Engagement in Human Subjects Research.* These **Proposals** are subject to **Certification of IRB Approval** to ensure consistency with any applicable **IRB Protocol(s**). This would include:

- proposals to federal or non-federal sponsors
- inter-disciplinary or multi-project proposals
- collaborative proposals involving multiple institutions

2.0 Proposal procedures.

NDSU policy requires a **Principal Investigator (PI)** to submit all **Proposals** for external funding through the Novelution Sponsored Research module.

3.0 Award procedures.

Upon notice of award or request for pre-award spending, IRB staff receive a Novelution task to initiate the **Certification of IRB Approval** process. Prior to award set up by Grants and Contract Accounting, IRB compliance issues require resolution as applicable below.

3.1 Eligible for certification.

When applicable **IRB Protocol(s)** have previously been reviewed and approved by the IRB, HRPP staff implement **Proposal** review as in section 4.0 below and document IRB approval and completion of the task requirement in Novelution.

When an applicable **IRB Protocol** has not been submitted, HRPP staff communicate with the **PI** to determine a timeline for submission. Unless an exception is identified as in 3.2 or 3.3 below, funds may not be released for use until IRB approval has been obtained.

3.2 Human subjects procedures under development.

A **Proposal** may lack definite plans for the involvement of human subjects. Such projects may require additional development, (e.g., hiring of staff, drafting of survey instruments) prior to submitting a protocol for IRB review. Awards for these projects are processed in accordance with SOP *13.2 Indefinite Plans for Human Subjects Research*.

3.3 Certification of IRB approval not required.

Certification of IRB Approval is not required when either the IRB of a collaborating institution (as **Prime Awardee**) will serve as **IRB of Record**, or the project does not

constitute NDSU engagement in human subjects research, as described in SOP 2.2). HRPP staff update the Novelution record as appropriate.

4.0 Proposal review.

The IRB reviews **Proposals** to certify that human subjects procedures described in the **Proposal** are consistent with any relevant pending or approved **IRB Protocol(s)**.

4.1 Review criteria.

The final version of the **Proposal** as awarded by the sponsor must be made available for review. The **Proposal** may be obtained from the PI, the Novelution record, or other sources (e.g., Grants.gov). Most **Proposals** will not include the same level of detail regarding human subjects procedures as required for **IRB Protocol** review. However, where such details exist in various sections of the **Proposal**, they must be consistent with those in the **IRB Protocol**, including information regarding:

- subject population and recruitment process
- any collaborating institutions and/or performance site(s)
- interventions and interactions with human subjects
- the number and qualifications of collaborating investigators and other members of the research team
- compensation strategies
- costs for subject protection measures, such as consent monitors or translators

4.2 Review process.

Review is conducted as applicable according to the following procedures:

4.2.1 Funded research.

Using the criteria listed above, a member of the IRB reviews **Proposals** to federal agencies involving non-exempt human subjects research. Access to the entire **Proposal** is recommended, as relevant information may appear in seemingly peripheral sections. The relevant Sponsored Research record(s) are linked to the **IRB Protocol** in Novelution and funding source(s) are listed on applicable approval letters.

4.2.2 Review by collaborator.

When NDSU issues a sub-award to a collaborating entity to perform a substantive portion of the research, including non-exempt human subjects procedures, the collaborator's IRB provides documentation of **Certification of IRB Approval**. The completed *Subrecipient Compliance Form* or other suitable documentation is retained with the Sponsored Research record and IRB records. Refer to SOP *2.3 Collaborative, Multi-site or Off-site* Research for more information.

5.0 Resolution of inconsistent human research procedures.

Substantive inconsistency between the award and applicable **IRB Protocol(s)** requires resolution prior to **Certification of IRB Approval.** Differences in research procedures (e.g., blood sampling, stress tests), participant groups (e.g., children, cognitively impaired), or research performance sites may be considered a substantive inconsistency. HRPP and SPA staff resolve the issue as applicable below.

5.1 Additional IRB approval(s).
Awards which include multiple human research activities require additional IRB Protocol(s), and/or protocol amendment(s), which may be submitted after completion of an initial study. The PI is responsible for obtaining IRB approval prior to initiation of future human subjects research projects.

5.2 Award revision.
A funding sponsor may require revision of the statement of work if significant changes are proposed by the PI. When the changes involve human subjects procedures, HRPP staff resolve the issue in conjunction with the investigator and SPA staff.

DEFINITIONS:

Certification of IRB Approval: verification that human subjects procedures described in a funding proposal are consistent with applicable IRB protocol(s)

Sponsored Research record: initiated by the PI prior to submitting a grant proposal; includes versions of the funding proposal, relevant communications, and signed award document

IRB Approval: granted when an IRB has reviewed an IRB protocol and determined that it meets all requirements for protecting the rights, safety and welfare of human subjects, as described in SOP 7.2 *Criteria for IRB Approval.*

IRB of Record: the institution whose IRB is responsible for review of a collaborative human research project involving multiple institutions.

IRB Protocol: an application submitted to the IRB for review, describing research procedures and protective measures involving human subjects

Principal investigator (PI): an NDSU faculty or staff member who has primary responsibility for the research.

Proposal: an application for funding that is submitted to an external agency to support NDSU research, instruction, or other activities. This also includes revisions, renewals and supplemental proposals.

REFERENCES:

FederalWideAssurance Terms
Submitting a Proposal
NDSU Policy # 801, Grant & Contract Administration – General Provisions

RELATED HRPP STANDARD OPERATING PROCEDURES:

2.2 NDSU Engagement in Human Subjects Research
2.3 Collaborative, Multi-site or Off-site Research
7.1 Exemption Determinations
7.2 Criteria for IRB Approval
13.2 Indefinite Plans for Human Subjects Research