13 Sponsored Research: 13.2 Indefinite Plans for Human Subjects Research	Effective Date: 12/09/2011 Revised: 1/13/2023

When an award includes plans for the human subjects research that are indefinite, funding for such awards may be released, but is restricted until **Certification of IRB Approval** is complete. Refer to SOP 13.1 *Certification of IRB Approval* for more information.

1.0 Applicability.

This procedure applies to awards that have identified probable human subjects research activities that are not yet sufficiently developed to allow for **IRB Approval**. These include awards from federal or non-federal sponsors in which:

- specific projects and/or investigators have not yet been identified;
- human subject activities remain to be selected (research training grants);
- human subjects involvement depends upon initial research or development, such as development of survey instruments, literature review, pre-clinical work which may or may not include compound purification or animal studies), or other preliminary work;
- funds must be utilized to perform other portions of the project not involving human subjects research (e.g., hiring staff, software development, travel, or lab set up); or
- the **Principal Investigator (PI)** is authorized by Sponsored Programs Administration (SPA) for pre-award spending.

2.0 IRB pre-screening.

HRPP staff pre-screen applications where investigators require access to funding to develop definite plans for the involvement of human subjects prior to applying for IRB approval.

2.1 Pre-screening.

The PI creates an *IRB Protocol* in the IRB module of Novelution. In the Review Type Determination panel, the investigator indicates they are requesting a determination for a project lacking immediate plans for the involvement of human participants, their data, or their specimens. The investigator inputs the Purpose and Goals of the research, indicates the anticipated start date of activities involving human subjects and connects the IRB request for pre-screening to the applicable Sponsored Research record(s). Once the pre-screening is complete, HRPP staff issue a letter indicating that the project meets the requirements under 45 CFR 46.118. Investigators have one-year to 1) verify that the project continues to lack immediate plans for the involvement of human subject, their data, or specimens, or 2) obtain IRB approval for the proposed work.

2.2 IRB monitoring.

Novelution automatically contacts investigators (principal and co-principal investigators) designated on the pre-screening application 60-days prior the expiration. If the investigator has already obtained IRB approval for the work, they may:

- submit a *Closure Request* for the pre-screening application indicating the IRB approval # of the protocol(s),
- request continuation of the pre-screening,
- apply for IRB approval.

2.3 Multiple human research projects.
A single award may involve multiple human research projects, performed either by multiple investigators and/or in successive phases. When a single IRB Protocol does not cover all human research activities for the award, multiple protocols and/or amendments may be required. The PI is responsible for obtaining IRB approval prior to initiation of future human subjects research projects.

3.0 Extension of anticipated start date.
If IRB Approval is not obtained prior to the anticipated start date for the human research activities, SPA and GCA are notified. To continue uninterrupted use of award funds, the PI must promptly provide SPA with written justification for extension of the anticipated start date. SPA staff evaluate the request, and may take any of the following actions:

- approve continued access to funding until the revised start date
- recommend a no cost extension of the award
- discuss with the PI**,** requesting a change in scope of work from the sponsor
- suspend access to award funds until IRB Approval is attained

Human subjects research conducted prior to obtaining IRB Approval is subject to procedures for investigating allegations of noncompliance, as outlined in SOP *12.3 Complaints or Allegations of Noncompliance.*

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

Grant File: initiated with SPA upon receipt of a Proposal Transmittal Form (PTF); includes all versions of the funding proposal, relevant communications and signed award document; retained by GCA Office upon notice of funding

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 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:
45 CFR 46.118 Applications and proposals lacking definite plans for involvement of human subjects
FederalWide Assurance Terms

RELATED HRPP STANDARD OPERATING PROCEDURES:
2.2 NDSU Engagement in Human Subjects Research
2.3 Collaborative, Multi-site or Off-site Research
7.2 Criteria for IRB Approval
12.3 Complaints or Allegations of Noncompliance
13.1 Certification of IRB Approval