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 and monitoring.
HRPP staff pre-screen and track applicable awards to ensure timely IRB Approval prior to initiation of human subject activities, as described in SOP 13.1 Certification of IRB Approval.

2.1 Pre-screening.
HRPP staff forward the Request for IRB Pre-screening form to the PI for completion. The form captures basic information regarding preliminary human subjects activities and anticipated starting date(s). The PI completes the pre-screening form including signatures to verify accuracy and assure compliance with requirements for IRB review prior to initiation of human subjects research. HRPP staff review and sign the form, performing a preliminary review of the final approved Proposal, and highlighting the relevant sections for future reference. Copies of the signed form are provided to the PI, applicable department Head/Chair, SPA, and Grants and Contracts Accounting (GCA). HRPP staff may copy any other applicable section of the Grant File.

2.2 IRB monitoring.
HRPP staff track the anticipated start date of human subjects research and follow up with the PI to encourage timely submission of an IRB Protocol. The PI should indicate the pre-screening status on the protocol submission form. The Grant File may be requested from GCA, and proposal review is initiated as described in SOP 13.1 Certification of IRB Approval.

If an IRB Protocol has not been submitted several weeks prior to the anticipated start date for human subjects research, HRPP staff notify the PI with the Pending IRB for Funded
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 Certification of 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 Certification of 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
Federal Wide Assurance Terms
OHRP Guidance, IRB Review of Applications for HHS Support
Sponsored Programs Administration research proposal and award administration

RELATED FORMS AND LETTERS:
Request for IRB Pre-screening of Sponsored Project
Pending IRB for Funded Project letter
IRB Protocol Form
IRB Protocol Form: Exempt Categories

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