1. POLICY

In addition to reviewing the application for human subjects research, the IRB is required by the Department of Health and Human Services (DHHS), pursuant to 45 CFR 46.103(f), to review the grant application or proposal for DHHS-supported or other federally funded human subjects research. The purpose of this review is to ensure that the protocol covers the human subjects research activities described in the grant proposal(s) supporting the research and that any such activities that are not covered have been/will be covered by an IRB approved protocol. Discrepancies between IRB protocols and grant proposals must be resolved before any funds are released to the investigator in support of human subjects research. Consistent with agency policies, this review may be part of the "just-in-time" (JIT) process used in making awards.

Specific Policies

1.1 Timeline of Grant - Protocol Review

New Funding – New Protocol

New proposals submitted through the Sponsored Projects Office (SPO) to agencies for consideration of support must identify if human subjects research will occur. It is the responsibility of the investigator to obtain IRB approval before initiating the human subjects research. Ideally, the IRB reviews the new grant proposal only when the grant has been funded, or funding is imminent, and the review should take place as part of the initial review of the human subjects research application. The Sponsored Projects Office will not release funds for human subjects research until IRB approval is confirmed by OPHS.

New Funding – Existing Protocol

There will be instances when new funding is obtained and an approved protocol already exists, such that the grant cannot be reviewed at the time of that the initial application is reviewed by the IRB. In this situation, investigators are required to submit an Amendment application to the IRB to add the new funding source to the existing protocol. SPO will release funding for human subject research only after OPHS has confirmed that all human subjects research issues are resolved and the amendment has been approved by the IRB.

Existing Funding – New or Existing Protocol

In addition, there will be instances when there is an existing award for which the investigator will need to amend an existing protocol or submit a new protocol (e.g. for a new phase or direction that is different enough to warrant a new protocol) and the IRB will need to review the existing grant proposal/award for comparison with the new or amended protocol. In this situation, OPHS will obtain the necessary grant proposal/award information for the IRB to review and confirm that the proposed activities are within the scope of the award supporting the research.

Just-In-Time (JIT) Funding – New or Existing Protocol

An agency's procedures may require that the IRB review the grant proposal prior to the award being made to the institution or when the proposal is under consideration. This is the only time that the IRB will review a grant proposal that has not yet been funded. If the proposal is not funded, OPHS staff will ask for it to be removed from the protocol at the time of the next Continuing Review.

1.2 Multi-Project Awards

Certain types of awards (e.g., training grants and center grants) are designed to support multiple projects involving numerous investigators. When definite human subjects research plans are lacking under an active award, investigators cannot conduct any human subjects research supported by the award until the proposed activities under the award receive IRB review and approval or a determination of exemption. Each individual investigator is responsible for ensuring that, if supported by a multi-project award, his or her own human subjects protocol receives and maintains appropriate compliance approvals.

1.3 Multi-Site Research

The requirement for IRB review of each new grant application or proposal for DHHS-support applies only to the primary grantee institution. The IRBs at other participating institutions need not review the grant application. However, documentation of IRB approval of any human subjects research conducted by collaborators and/or sub-contractors must be provided to the IRB of the primary institution.

2. SCOPE

These policies and procedures apply to all Investigators, IRB staff and members and to research submitted to the IRB.

3. RESPONSIBILITY

The Director serves as the consultant to SPO and/or OPHS staff if there is a question as to whether a grant proposal involves human subjects research. The Director (or his or her designee) pre-reviews the grant proposal and protocol.

The Director (or designee) is responsible for assigning IRB members to a grant-protocol review.

An IRB member is responsible for conducting a thorough review of the pertinent sections of the grant application or proposal and making all appropriate assessments for the IRB.

4. PROCESS OVERVIEW

All federal agency proposals and awards are reviewed by SPO staff to ensure that all awards to support human subjects research have appropriate current compliance approvals and that they are reviewed by the IRB. This review will be done before an award is released to support human subjects research.

OPHS Analyst staff will complete a preliminary comparison of the new grant proposal against the protocol and note any comments in an email to the IRB Chair (or designated IRB reviewer). The grant proposal is generally sent to the IRB Chair (or designated reviewer) for review by email; however, there may be circumstances when it may have to be faxed or provided to the IRB member in hardcopy. If the grant proposal describes a protocol that has been determined to be exempt, then the IRB Analyst staff member will route the grant proposal to the OPHS Director (or his/her designee) for final review to ensure no additional activities are described in the grant proposal that are not covered by the exempt protocol. For non-exempt protocols and grant proposals, a designated IRB member will review the grant proposal to determine whether the proposed research is consistent with the relevant protocol(s) submitted to, or previously approved by, the IRB.

An electronic as well as hardcopy version of the grant proposal is accessible to OPHS and will be made available to any IRB member who wishes to review it. Salary information on budget pages may be redacted by OPHS staff before the proposal is distributed, or the PI can do this before submitting a copy with his or her protocol application.

If there are discrepancies between the proposed grant activities and the protocol(s) already reviewed and approved by the IRB then verification of IRB approval will be delayed until the Investigator submits appropriate documentation per RR 404 – Amendment Review – and the IRB reviews and approves all activities as described in the grant proposal. If, as a result of changes imposed by the funding agency, the investigator will be doing less than what was proposed in the original grant proposal, documentation confirming the deletion of said activities must be obtained from the funding agency and provided to the IRB as part of the grant-protocol review process.

If the grant-protocol comparison does not yield any concerns, the funding will be approved as part of the protocol and information about the approval will be made available to SPO.

For New Applications to conduct Human Subjects Research the Principal Investigator may be asked to correlate the proposed procedures/methodology in the protocol to specific aims as proposed in the research proposal to facilitate IRB review.

As part of the continuing review of IRB approved protocols, the PI is asked to report any funding source that is supporting any part or all of the protocol. If there is such a funding source, the investigator will be asked at a minimum to provide the title of the grant, the name of the sponsoring agency and the SPO proposal number.

OPHS will provide copies of IRB approvals to agency officials upon direct request however it is preferred to coordinate this information request through the research administrators in SPO. If certification documentation is required by a funding agency (e.g. Form 310) such documentation will be signed by an individual with an authorized institutional signature authority.

5. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.111, 45 CFR 46.115, 45 CFR 46.118, 45 CFR 46.122

21 CFR 56.108, 56.111