

## 10. SPONSORED PROJECTS: ADDITIONAL REQUIREMENTS

Most federal and private funding agencies will not award a grant for a research project involving human subjects until the Institutional Review Board has certified its approval. However, the University's system allows for concurrent processing of the human subjects review and the management review of a proposal.

### 10.1 The OCG Transmittal Form

The Proposal Transmittal Form is the form used by the Office of Contracts and Grants to obtain and document required management approvals when seeking external funding. This form contains a number of assurances, one of which pertains to involving human subjects. The proposal should be submitted to the CPHS in time for a decision before the proposal due date or at the time of award consideration.

Ideally, all research proposals would be reviewed and approved by the CPHS before the proposal is submitted for external funding. Investigators should affirm the approval on the Transmittal Form by specifying the date that the CPHS approval was given. (This is the date of the CPHS meeting – not the date of the letter.) Concurrent processing is more common however. The Transmittal Form, indicating that CPHS approval is pending and providing the date the project was submitted for review, may be processed.

### 10.2 Special Situations

Submission to the funding sponsor prior to CPHS approval:

Occasionally, CPHS approval may still be pending when OCG receives the proposal for submission. If the funding sponsor's policy allows submission before CPHS approval, then OCG will submit the proposal. The investigator is then responsible for notifying the sponsor when CPHS approval is received.

Funding awarded prior to CPHS approval:

Though unusual, a funding sponsor occasionally will make a conditional award before CPHS has approved the research project. When this occurs, the funding sponsor will specify a time limit (usually sixty days or less) for CPHS approval. Again, the investigator is responsible for notifying the sponsor of CPHS approval.

Developmental proposals:

Proposals in the development or concept stage pose a dilemma for investigators, funding sponsors, and the CPHS. Funding agencies may be unwilling to consider a proposal without CPHS approval, yet given the early stage of the project, the investigator may not be able to provide a complete protocol or consent document. In these situations, the CPHS may grant a "conditional approval" that will satisfy the sponsor, yet allow for additional review to protect the subjects. The investigator should include an explanation for the deficiencies in the application as well as a statement that research will not begin until the complete project has CPHS approval.

Program project grants and training grants:

Program projects are large, multiproject studies designed to produce a coherent body of research from many subprojects. Training grants also may include a variety of subprojects. The initial application to the CPHS should include the title of the overall program project, the principal investigator's name and contact information, and a list of the subprojects with the investigators' names and contact information for each. All subprojects in the program grant must be submitted to the CPHS separately. It is the responsibility of the principal investigator for the overall project to ensure that the subproject investigators submit their applications in time to allow for review and

approval. The CPHS will certify its approval of the overall project only after it approves all subprojects.

Additional endorsements:

Funding sponsors occasionally require additional documents of special assurances. If this situation arises, the investigator may contact the CPHS Coordinator for additional signatures or forms.

### 10.3 Changing the Title of a Research Project

Occasionally an investigator wants to change only the title of a research project to make it more competitive for a particular funding sponsor. Any change in the protocol of a research project must be approved by the CPHS.

Changes in the title can be handled in two ways:

1. If the original title will no longer be used, the principal investigator should explain the change in a letter to the CPHS that includes the original title and the latest CPHS approval date. A revised consent form must be enclosed (since the consent form gives the project's title). If the change is approved, the most recent approval date for the original study will apply to the new title.
2. If the original title is to remain active but funding is sought from another agency for a different title, the investigator should write to the CPHS office and request approval of an additional title. This request should certify that the study with the new title is identical to the study under the original title. The request should include a revised consent form as well as a copy of the grant application associated with the new title. This procedure may be used only when the research procedures are genuinely identical to those approved previously.

Several cautions apply to the second procedure:

- If the project does not receive funding and the investigator does not intend to use the title for another submission, the investigator should notify the CPHS that the title will be "retired."
- The CPHS does not want research titles to proliferate. Investigators who overuse the procedures may be prevented from employing them in the future.

Researchers must file for these changes **at least 30 days** before the grant submission date. In all cases investigators **must provide a copy of the grant proposal**.

### 10.4 Unfunded Proposals

If a proposal is not funded, the investigator should inform the CPHS whether or not the work will be conducted in the absence of external funding.