



## Coordination of Certification of Committee on Clinical Investigation Review, and Acceptance of Grants and Contracts for Sponsored Research

### Policy

It is the policy of the Office of Sponsored Programs (OSP) and the Office of Clinical Investigation (or CCI) to ensure that all sponsored research that involves human subjects, biological specimens/materials, or medical records/databases is certified by the Clinical Investigation Office as being reviewed and approved by the Committee on Clinical Investigation (Children's Hospital's IRB), or as being exempt from review. Many sponsor organizations require the Hospital to provide certifications of approval either before or during the grant application or clinical trial agreement review process. Whether or not a sponsor requests such documentation, OSP will ensure that all projects receive CCI certification as a condition of funding acceptance.

### Procedures

#### Office of Sponsored Programs

The Office of Sponsored Programs is responsible for all grants and contracts awarded to Children's Hospital for research purposes by federal and state agencies, and nonprofit organizations. Funds for research sponsored by the federal and state government, and nonprofit organizations, are accepted only if there are provisions for the appropriate dissemination of data and for publication freedom; only if all human subject protection measures are followed; and, only if the terms are consistent with applicable laws and regulations, and the policies of Children's Hospital. A copy of the grant application and other documents should be routed at the just-in-time phase or at the time of grant award acceptance in accordance with the chart below, whether or not the sponsor requests certification. Since the definition of "human subjects research" may not be obvious, (e.g., the research may include commercially available specimens and cell lines), any question regarding the applicability of the Hospital's human subjects research review policies should be directed to the Office of Clinical Investigation at ext 5-7052.

When a grant involves human subjects research at one or more collaborating institutions, the principal investigator (PI) will be responsible for collecting certifications (approval notices) for all participating sites for inclusion with the materials.

The human subjects research education certification required by NIH will be prepared at the same time the application is reviewed to certify IRB approval. The Office of

Sponsored programs accesses the information required to provide this certification through the database maintained by the CCI.

## **Procedure for Clinical Investigation Office**

A copy of the grant application is available to the CCI administrative staff, who will verify approval status and provide the certification required. If human studies take place at collaborating institutions, documentation of those institutions IRB approval and assurance status is required. A valid approval date is one that is no earlier than one year before the expected award date. When studies are "pending" review, it is the investigator's responsibility to follow-up and ensure that IRB approval is available in time for funding agency review. If review and IRB approval is not complete, a "pending" certification will be submitted. In this situation, either a new protocol or an amendment must be submitted to cover all of the human subject work in the grant. If more than one protocol covers the work, all protocols must be approved and currently active. This institutional policy is effective even in the absence of a sponsor certification requirement.

Non-competing continuing applications and progress reports will not require a review by the CCI staff unless there is a change or modification to the human subject activities. The OSP staff has access to the CCI database and can access the latest approval status. If there are any questions, the continuing application will be referred to the CCI staff. CCI approval must be obtained throughout the award period during which the activities are conducted.

## **Clinical Investigation Review of Grant Applications**

Department of Health and Human Services (HHS) regulations require that each application or proposal for HHS-supported human subject research be reviewed and approved by the Clinical Investigation Office. The Clinical Investigation staff must review the actual grant application in addition to any other protocol materials. The review will ensure that all activities referenced in the grant application have been reviewed and approved by the CCI. A copy of the grant application is provided to the primary and secondary reviewers and any reviewer who wishes to see it. A copy of the grant application is retained in the protocol files. CCI staff are advised that information related to human subject protections sometimes appears in peripheral sections. Such information may include:

- The number and qualifications of collaborating investigators and other members of the research team;
- Cooperating institutions or performance sites that may require separate or additional IRB review or a federal-wide assurance;
- Characteristics of the proposed research facility that may affect subject safety or confidentiality of data;
- The feasibility of financial commitments made to the subjects; and
- The cost of proposed subject protection measures, such as consent monitors or translators.

## **Grants with Indefinite Plans for Human Subject Involvement or Projects that do not Involve Human Subjects at the Onset**

Certain types of applications and proposals lack definite plans for the involvement of human subjects either because the specific human subject activities have not yet been fully developed, or, as is the case in some training or career development grants, no specific plan for research with human subjects has been indicated. In such instances, the application or proposal need not be reviewed by the Clinical Investigation staff prior to an award; the investigator can receive approval in principle for the project by filling out an appropriate form. However, studies on humans may begin only after an individual protocol receives CCI approval. This form certifies that the investigator will not begin any human subject activities until a protocol is submitted and approved by the CCI.

### **Award Processing**

A certification of approval must be provided to OSP prior to acceptance of an award or prior to PI access to funds, whether or not such approval is required by the sponsor organization. In the absence of CCI approval, funds may be accepted by exception only on a case-by-case basis after evaluation by OSP. Exceptions may be granted for reasons related to the sponsor-approved project work schedule, i.e., no human research related activities will take place in the initial grant period, and use of funds is otherwise not prohibited by sponsor.

Please see the following Routing Chart and Requirements in Detail by type of grant submission.

## When to Obtain Certification of Clinical Investigation Review

At the time of submission, most applicants state that IRB approval is pending with the understanding that the approval will be requested at the just-in-time phase for federal grants and award acceptance for other types of sponsors.

Type Application	PI submits to CIC first, then to OSP	PI submits to OSP directly
<u>Competing to NIH</u>		X
<u>Competing to All Other Sponsors</u>		X
<u>Noncompeting Progress Report to NIH</u> w/Human subject Changes = NO		X
w/Human subject Changes = YES		X
New key personnel for educ cert = YES		
<u>Noncompeting Progress</u> Report to Other Sponsors w/Human subject Changes = NO w/Human subject Changes = YES		X
<u>Follow-up Certifications</u> , i.e., after initial "pending" certification	X	

What to Submit to Clinical Investigation,

- Copy of grant application
- Copy of completed CHERP online coversheet (competing) or the Noncompeting Continuation Progress Report Proposal Summary Form (noncompeting) with human subjects protocol(s) or exemption information inserted
- Copy of sponsor's application instructions or guidelines, including any human subject research certification forms provided by the sponsor. If application is to a federal agency, the CIC Office will prepare the certification using the optional "Form 310" unless a different form is provided. If application is to a private organization, the CIC Office will provide a signed certification on its letterhead.
- Copies of certifications obtained from any collaborating institutions that have human subjects research

## Requirements in Detail

### Competing NIH

NIH provides no option for submitting IRB approval or education certification at the time of application submission. OSP staff will verify whether or not human subjects are involved during application review, and will provide the PI with contact information for the Clinical Investigation staff as needed. After the application is reviewed by the initial review group (study section) and is determined to be

"fundable," NIH will request certifications "Just in Time" (JIT). PIs are advised to prepare and submit a human subject protocol application to the Clinical Investigation Office at that time without delay, and to ensure the provision of training for all key personnel named in the grant and involved in human subject research.

To obtain human subject /IRB certification for NIH, OSP grant officers work directly with CCI administrators in securing the appropriate protocol approval letters/forms. OSP also retrieves human subjects training certificates directly from the CCI database. OSP grant officers submit Just-in-time directly to the NIH.

### **Competing All Other Sponsors**

All competing applications to federal or private, nonprofit sponsors, excluding applications to NIH, are submitted to OSP. If JIT is requested or if the application is approved for funding, OSP obtains protocol number from the PI and completes the CCI Request for Human Subjects Approval Certification of Sponsored Projects form. OSP and CIC work together in securing the appropriate IRB protocol approval documents. This includes proposals submitted via the Development Office or Children's Hospital Trust. If there is no sponsor requirement for certification, and a protocol has not yet been submitted to the Clinical Investigation Office for review, certification review may be delayed until notification of the award. However, investigators should note that the Hospital will generally not accept an award, or will restrict access to funds, until the PI ensures that the human studies have CCI approval. OSP will not set-up the CHB project ID until all appropriate protocols are approved.

### **No Competing Continuation Progress Reports to NIH (type 5s)**

- **If there are NO changes in the involvement of human subjects since the last submission:** The PI does not submit materials to the CCI. The application is submitted directly to OSP where staff will compare protocol information from previous reviews and access protocol records for the current, valid date. If there is any change regarding the involvement of human subjects in the protocol information or any discussion of changes in the research in the progress report, the application must be submitted first to the Clinical Investigation Office.
- **If there ARE changes in the involvement of human subjects since the last submission:** The PI submits the application with the completed OSP Noncompeting Continuation Progress Report Proposal Summary Form for continuation applications directly to OSP and OSP works with CCI to ensure that the appropriate IRB protocol approvals are in place.
- After certification, the PI submits the application to OSP for application review and endorsement.
- **If there are NEW KEY PERSONNEL involved in human studies since the last submission,** a Key Personnel Training/Education Certification Form must be submitted with the application for the new personnel. This is required for the new personnel only, and is not repeated for individuals previously certified under the grant. The PI completes a Children's Hospital Human Subjects Research Education Certification Form with grant, identifying information and names of new key personnel. OSP typically retrieves these forms. If training form can not be located, OSP would contact the CCI directly for more information, etc.

## No Competing Continuation Progress Reports to Other Sponsors

- If there are **NO** changes: same as 3
- If there **ARE** changes: same as 3

## Follow-up Certifications-(i.e., after initial "pending" certification) -- All Sponsors

In the event an initial certification needs updating (i.e. initial certification is "pending" or date is over one year old), the PI must submit materials to the Clinical Investigation Office for review and certification.

## Related Content

None Identified

## Document Attributes

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