**GUIDANCE: CPHS Communication**

**Policy:** It is the policy of UTHSC-H that all research involving human participants and deceased persons must be reviewed and approved by the Committee for Protection of Human Subjects if it falls in one of the following categories:

* + 1. Research conducted by any UTHSC-H employee (faculty, staff, administrative and professional), student, or resident in any facility/location (including Memorial Hermann Healthcare System, Harris County Psychiatric Hospital, Thomas Street Clinic, LBJ General Hospital).
    2. Research conducted by non-UTHSC-H investigators that involves subjects/patients from any UTHSC-facility (including Harris County Psychiatric Hospital). In such instances, a University faculty member must be identified who will agree to assume co-responsibility for the conduct of the research.

**New Applications –** Allactivities that meet the definition of human subjects research must be submitted to the CPHS for review and approval prior to initiation. The Principal Investigator may refer to the Investigator Handbook or contact the CPHS for assistance in making these determinations.

When a planned activity meets the definition of Human Subjects Research, the Principal Investigator should complete an application form via iRIS. The iRIS application form is a smart form and provides guidance for completion. The iRIS application form is automatically forwarded to Key Study Personnel and for departmental sign off before reaching the CPHS Office. The Principal Investigator will receive an acknowledgement when the form is received by the CPHS Office.

CPHS members rely on the documentation submitted by Investigators for initial review. Therefore, the material submitted must provide CPHS members with adequate information about a research proposal to assess if it meets the CPHS criteria for approval, or the ORSC Staff/CPHS Member will request the Principal Investigator for additional information.

Essential documents:

* + 1. Completed application form in iRIS
    2. Protocol
    3. Informed consent documents
    4. Investigator Brochure
    5. Recruitment materials
    6. Appropriate HIPAA documents
    7. Pediatric Risk Assessment form
    8. Grant Application
    9. Research Conflict of Interest Form
    10. Data collection forms
    11. CVs for the PI and Co-PIs
    12. Documentation of Human Subjects Education for the PI and all Key Study Personnel
    13. For Department of Health and Human Services (DHHS) – supported multicenter clinical trials:
        1. DHHS-approved sample ICF
        2. The complete DHHS-approved protocol

CPHS may also request the following additional documents:

1. Letters of Collaboration or Cooperation, including MOUs from other institutions and/or contact information
2. Letters of collaboration with departments
3. Letters of Support
4. IRB approval letters from other sites
5. Any other information necessary to conduct an adequate review of the proposed research.

**Change Requests and Protocol Amendments** – Changes in approved research, during the period for which CPHS approval has already been given, may not be initiated without CPHS review and approval except when necessary to eliminate apparent immediate hazards to the subject. The Principal Investigator must submit and receive approval from the CPHS before initiating any changes to a research study.

The Principal Investigator must submit the change request / protocol amendment via iRIS. The submission should include adequate information of the change / amendment including, but not limited to:

* 1. Description of Change/Amendment- A detailed explanation of changes proposed and rationale for the request,
  2. Amended documents e.g. informed consent document, protocol, questionnaire, survey form,
  3. Any other documentation that CPHS may specifically request
  4. Any other relevant documentation that is outlined in this policy and procedure to be given to subjects when, in the judgment of the CPHS, the additional information would add meaningfully to the protection of the rights, safety and/or well-being of the subjects.

**Continuing Review -** CPHS shall conduct continuing review of non exempt research at intervals appropriate to the degree of risk, but not less than once per year. The determination of the period of approval is made at the time of initial review or previous continuing review. Continuing Review is required as long as the research remains active including recruitment, enrollment, participant follow-up, and analysis of identifiable data. The ORSC Staff informs the Principal Investigator of the expiration date within the approval letter for initial review and subsequent continuing reviews. Automatic email reminders are sent by iRIS to the Principal Investigator 120, 90, 60 and 30 days prior to the expiration date. However, it is the Principal Investigator’s responsibility to ensure that approval is renewed before the expiration date.

The Principal Investigator must complete and submit a Continuing Review Form via iRIS. In addition, the Principal Investigator must also submit:

* + 1. **Revised copy of "Authorization for the Use of PHI" form in iRIS, if applicable, so that the Office of Research Support Committees can re-stamp the form with the new expiration date.**
    2. **Relevant study related documents, including but not limited to, multi-center trial reports, data safety monitoring board reports, NIH and/or other sponsored research reports, reprints of articles, adverse event logs, etc.**
    3. Any other documentation that CPHS may specifically request.

**Unanticipated problems involving risks to research subjects or others -** The Principal Investigator is responsible for the accurate documentation, investigation and follow‑up and timely reporting of the following problems:

1. Adverse event (any harm experienced by a participant regardless of whether the event was internal (on-site) or external (off-site) and regardless of whether the event meets the FDA definition of “serious adverse event”), which in the opinion of the principal investigator are both unexpected and related.
   1. An adverse event in which the nature and severity is not consistent with information in the relevant source documents is an unexpected adverse event.
   2. An adverse event is “related to the research procedures” when there are facts (evidence) or arguments to suggest a causal relationship.
2. Information that indicates a change to the risks or potential benefits of the research. For example:
   1. An interim analysis or safety monitoring report indicates that frequency or magnitude of harms or benefits may be different than initially presented to the IRB.
   2. A paper is published from another study that shows that the risks or potential benefits of the research may be different than initially presented to the IRB.
3. A breach of confidentiality.
4. Change in FDA labeling or withdrawal from marketing of a drug, device, or biologic used in a research protocol.
5. Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a research participant.
6. Incarceration of a participant in a protocol not approved to enroll prisoners.
7. Event that requires prompt reporting to the sponsor.
8. Sponsor imposed suspension for risk.
9. Complaint of a participant when the complaint indicates unexpected risks or cannot be resolved by the research team.
10. Protocol violation (meaning an accidental or unintentional change to the IRB approved protocol) that harmed participants or others or that indicates participants or others may be at increased risk of harm.
11. Sponsor imposed suspension for risk.
12. Unanticipated adverse device effect

**Study Completion:** When a study is completed, the PI should submit study completion reports within 30 days after completion of the study. Completion reports should be submitted using the Study Closure Report via iRIS.

**Applicable Regulations and Guidelines**

**Applicable Institutional Policies and Procedures**

**Attachments**

* Protocol Deviation Tracking Log
* Unanticipated Problems Tracking Log

**If you find errors in this document, please contact** [**clinicaltrials@uth.tmc.edu**](mailto:clinicaltrials@uth.tmc.edu)

|  |  |
| --- | --- |
| **Document Number:** | 402-007 |
| **Author:** | Clinical Trials Resource Center |
| **Effective:** | June 1, 2011 |
| **Revision History:** | None |
|  |  |
|  |  |