The University of Toledo
Department for Human Research Protections
Institutional Review Boards
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The University of Toledo - Central IRB Submission Requirements

The University of Toledo has negotiated an agreement with two external IRB for the review of biomedical research; Western Institutional Review Board (WIRB) and Schulman Institutional Review Board (SAIRB). Research studies may be sent to a Central IRB **upon approval by the IRB Chair or Designee**. UT research which cannot be sent to Central IRBs for review, regardless of sponsorship or phase, includes all gene transfer therapy protocols and protocols that UT or the investigator determine should be reviewed on site due to a local concern within the institution or community.

The University of Toledo investigator must prepare all required materials for the initial review and submit the packet to the UT DHRP/IRB office. The packet should include the following:

1. A signed Documentation for Central IRB Submission Checklist
2. All associated study documents including but not limited to; the CIRB Application, study protocol and informed consent forms on the respective UT-WIRB or UT-SAIRB approved templates.

Submission to the Central IRB cannot proceed until the packet is verified by the UT DHRP Administration. The investigator will be contacted if additional information is needed or when the packet is approved. Turnaround time for a **complete** packet is typically within two (2) working days of receipt. The principal investigator is then responsible for forwarding the UT approved documentation packet to the Central IRB.

All subsequent communication (unless they involve major changes) will be between the investigator and the Central IRB until the final IRB approval documents are emailed to the UT IRB office.

Upon reconciliation of the Contract and Informed Consent Form(s), the DHRP office will notify the Central IRB to release the approved documents to the investigator.

As with all human subject research, the Principal Investigator is responsible for insuring that all federal, state, local, institutional and sponsor required approvals are in place before becoming engaged in human subject research, for having prior IRB approval for all changes to this research, for providing all required continuing review/status reports to the IRB and for submitting a Final Report to the IRB when this research is terminated.

Submissions after Initial Approval

After the initial UT authorization process had been accomplished, the investigator should submit all subsequent study documents directly to the Central IRB following the guidelines provided by the Central IRB. These may include the following:

- Amendments to protocol documents or personnel *(see NOTE below)*
- Adverse event reports, protocol violations and/or unanticipated problems which occur at The University of Toledo *(The UT IRB should also be notified of internal AEs /UPs per DHRP policy.)*
- IND safety reports or other event reports from sponsors which are not submitted to the Central IRB on the investigator's behalf
- Continuing review reports
- Closure notification

NOTE: If a modification to the research includes changes in PI, co-investigator or key personnel, the investigator must notify the DHRP/IRB office ***at the same time*** they submit the change to the Central IRB.

If a modification occurs to the UT required consent template language (e.g., compensation for injury, HIPAA Authorization, costs), the submission must be sent to the DHRP/IRB office ***prior*** *to* submission to the Central IRB to ensure the institution is in agreement with proposed language.

The UT DHRP administrative processing fee for all Initial Central IRB submissions is $500.00. Fees are subject to periodic increases per industry standards.

The Chair or Chair Designee of the Biomedical IRB will make the determination to approve a Central IRB submission or require study oversight by the University of Toledo IRB.

Current CIRB Submission Criteria:

Western IRB (WIRB)

Research protocols eligible for Western IRB review must meet the following criteria:

1. Phase III and Phase IV industry sponsored pharmaceutical studies not involving gene transfer therapy and not involving a specific local concern that increases the risk to benefit ratio to the participant will be reviewed by WIRB.
2. Industry sponsored device studies may be reviewed by WIRB if it is determined by the Institution's IRB Chair or his/her designee that it is appropriate for WIRB review. *(Agreement Amended 01/26/2015)*
3. Some Phase II human subject research may be reviewed by WIRB although the Institution's IRB Chair or his/her Designee or the IRB Committee must evaluate Phase II industry sponsored research and make a determination on a study by study basis as the appropriateness of allowing review of these studies by WIRB.
4. The Institution's IRB Chair or his/her Designee reserves the right to require Institution's review for any human subject research conducted by faculty, staff, students, or volunteers of the Institution.
5. All research to be reviewed by WIRB must he presented to the Institutional Contact for determination of appropriate review prior to being submitted to WIRB. All submissions to WIRB will be accompanied by a sign-off sheet and/or cover letter signed by the Institution Contact or his or designee.
6. Select Phase I pediatric studies, wherein the agents used are not for first use in humans, but first in children use, may be reviewed by WIRB if it is determined by the Institution's IRB Chair or his/her designee that it is appropriate for WIRB review.

Schulman Associates IRB (SAIRB)

Research protocols eligible for Schulman Associates IRB review must meet the following criteria:

1. The National Institutes of Health (NIH) definition of a clinical trial [*A prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices)]*;
2. The protocol must be written and designed by the sponsor;
3. The sponsor must be a for-profit entity/company;
4. The research must not involve planned emergency research, xenotransplantation, gene transfer, or embryonic stem cells;
5. The research must not federally funded or funded from another not-for-profit agency; and
6. The Principal Investigator (PI) must meet The University of Toledo requirements to serve as PI on a research project. *(A University faculty member or employee with the requisite expertise and training to conduct, supervise and oversee the safe, ethical and regulatory compliant conduct of the research.)*