

APPENDIX I SUMMARY OF STANDARD OPERATING PROCEDURES FOR HUMAN PARTICIPANT RESEARCH

1. ALL activities, which include the collection of information or data on human participants, must be reviewed by the Office of Research. If you have questions about what information you need to submit and the extent of the review process required, consult the OSU CHS Institutional Review Board (IRB) application packets or call the Office of Research at (918) 561-1400. Typically, the determination made will call for an Expedited Review or Full Review by the IRB.
2. Support provided by the Office of Research includes:
 - i. Aid/consultation in preparing documents for review contained within the IRB application packet.
 - ii. Initial review of Informed Consent documents for compliance to institutional, state and federal regulations. **Note:** Not all states require the same components to an informed consent, so if you are working on a multi-site (international or national trial) the informed consent provided by the funding agency may not meet Oklahoma state law requirements and will require changes that must be approved by the funding agency. Submit this form as early as possible.
 - iii. Data Collection Support for a limited number of projects is available. If you want or need support, be sure to include the Office of Research in the budget preparation to assure recovery of cost from the funding agency.
 - iv. Notification of Continuing Review. All approved projects must submit to the IRB a report for review of progress through the Office of Research, annually, unless required more frequently by the IRB. While it is the PI's responsibility to ensure the Continuing Review is submitted the appropriate time for review, the Office of Research will try and provide PIs with reminder notices.
 - v. Training. Staff in the Office of Research can offer assistance in organization and training of departmental staff in program operations, consenting of patients, data collection, etc.
 - vi. Internal Audits. In addition to the above support, the Office of Research will perform internal audits of all ongoing projects as needed to assure compliance by the principal investigators (PI) and their support staff. Issues typically looked for include, but are not limited to:
 - a. prior consent of participants
 - b. adverse event documentation/reporting and adherence to procedures
 - c. confidentiality
 - vii. External Audit Support. When or if external agencies come on site to audit protocols such as FEDERAL, FDA, Contracted Site Management Organization, etc., the Office of Research will work with you to provide support for a successful audit.
3. IRB Function and Process: Completed applications for IRB review are submitted to the Office of Research for transmittal to the IRB. The IRB meets monthly and PI's are required to submit complete applications at least 10 working days before the regularly scheduled meeting to be included on the agenda. In addition, the PI or a knowledgeable representative should plan to attend the meeting to respond to questions from board members.
 - i. Initial IRB Review includes, but is not necessarily restricted to the following:
 - a. Basic scientific review
 - b. Risk: benefit analysis
 - c. Special/Vulnerable Participant Inclusion
 - d. Informed Consent Review
 - e. Participant Compensation
 - f. Project advertisements when applicable
 - g. Ongoing IRB Review Includes:

- 1)Change in Protocol Notification: Any change in the protocol made by a PI or outside agency must be submitted to the IRB for review before implementation.
- 2)Adverse Event Review: Adverse event (AE) reports and in particular serious adverse events (SAE) will be submitted to the appropriate outside organizations and copied to the IRB via the ORSP.
- 3)Annual Progress Report Review: Reports are submitted for on-going review as required by the responsible outside agency or IRB. These reports will occur annually unless required more often by the IRB. This IRB Policy and Procedure Manual includes forms for this purpose, Appendix C. Typical information included in this progress report are:
 - Number of patients enrolled
 - Review of AE/SAE's
 - Review of changes to protocol
 - Current Informed Consent Form
- 4)Notification of Termination: If a PI terminates a protocol for cause prematurely or receives notice from an outside agency of "intent to" or "notice of immediate termination" he/she will transmit that information to the Office of Research and IRB immediately.

Note: The IRB and the Office of Research have the authority to halt enrollment of participants in any protocol if conditions warrant. Typical situations which could result in this action are: continued failure of PI to act responsibly in the management of the study after initial warning by the Office of Research/IRB or a judgment that multiple AE's or a SAE warrants such action.