TAYLOR UNIVERSITY INSTITUTIONAL REVIEW BOARD (IRB) POLICY

Approved by the Academic Policies Committee spring, 2001

1. STRUCTURE OF THE IRB

The IRB will include at least one member from each of the following: natural sciences, social sciences, education, business, student development and academic affairs. Student and non-academic representation can be considered as well at the discretion of the Academic Dean and if approved by the Faculty Personnel Committee. A chair and vice-chair are elected each year by the membership. The chair or vice-chair cannot be a student. IRB members will be from both campuses if it is feasible to select members from both campuses.

All future references to the chair implies both the chair and vice-chair. Having two individuals adept at interpreting the federal guidelines is intended to expedite research requests.

Chair responsibilities:

- Chairs will be provided with the materials required to perform their duties. They will be expected to understand and promote the ethical principles outlined in The Belmont Report, and to have a knowledge of the Federal regulations (45 CFR 46 and 21 CFR 50 and 56) and NIH/Clinical Center (CC) policies and procedures governing research involving human subjects. The chair is required to understand the Taylor University structure and the role of the IRB.

IRB Responsibilities:

- Review all university research projects sponsored by or done within the university structure that involves human subjects. These would include faculty, student and non-academic research. Non-academic research includes activities such as data analysis of alumni, graduation placement, or employee analysis by outside or institutional researchers. Review is based upon human subjects safety issues alone and not on the research or methodology.
- The IRB may approve, reject or require modification of any project based upon potential harm to subjects. Once approved, the project can come up for review at any time it deviates from the original proposal or a time to be determined in the approval. (generally 6 - 12 months with 12 months being the maximum)
- The chair can approve or request modifications in projects which represent only minor changes in previously approved proposals or new projects which involve only minimal risk of injury. The chair may disapprove such proposals and the researcher can then appeal to the entire IRB membership. Members of the IRB must be notified by the chair when an expedited approval or exemption has been made. Proposals may be circulated through campus or electronic mail except in cases where sensitive material is involved.
- The chair will maintain records of all proceedings and activities of the IRB. These will include copies of all proposals, minutes of meetings, and correspondence with the committee and researchers. Copies should be sent to the university archivist where they will be kept in a secure and access-controlled location due to possible privacy issues with certain research.
- Create the structure for future IRB functions. While we will look primarily at adult human subject research at this point, future adjustments of over-site may be needed for children or other categories listed in federal guidelines.
- Require and review informed consent documentation.
- Suspend and/or cancel research based upon need for further investigation

2. Appointment and term of IRB members

Federal guidelines encourage at least five members on the IRB including representatives of different research specialties, a member who is not a research trained practitioner, and a community representative. (Actual composition of the Taylor IRB is presented in section 1 Structure of the IRB.) Two other positions are discussed in relation to the IRB: a signatory official and a human protections administrator. The signatory official is the administrator with enough authority within the organization to enforce compliance with IRB expectations (he or she is called the signatory official based on the assumption that this person would sign the official assurance filed with the Department of Health and Human Services should the organization choose to file an assurance). The human protections administrator is the person in an organizational position that protects the rights of individuals in the organization (e.g. the ombudsman) and works with the IRB to keep it accountable in its efforts to protect subjects from harm. If Taylor University should decide to file an assurance, a signatory official and human protections administrator will need to be identified.

Since the IRB members' duties require specific kinds of expertise, they will be selected by the Vice President of Academic Affairs (VPAA) and approved by the Faculty Personnel Committee. When a position is scheduled to become vacant on the IRB the VPAA will select a person willing and able to fill that position and recommend him/her to the Faculty Personnel Committee (FPC). If the VPAA wishes to he/she may delegate the selection process to the FPC. The Faculty Personnel Committee will approve or reject the appointment with a simple majority vote and notify the VPAA of their action. If the committee rejects the appointment, they will explain to the VPAA their reasons for doing so.

IRB members will serve on a three year term with approximately one-third of them rotating off the committee each year. Each year, a Chair and Vice-Chair of the IRB will be selected by the members of the IRB. While it is expected that each member of the IRB will familiarize him or her self with the documents in section 7 of the IRB policy (the policy appendices), the Chair and Vice-Chair (or any other person who will determine the level of review needed for a project, who will deal with expedited reviews, or who will at any time head committee meetings) will need to be particularly familiar with them. In addition, it is recommended that the signatory official (if one is identified) human protections administrator (if one is identified), Chair, Vice-Chair, and any members who will determine the level of review needed for a project, who will deal with expedited reviews, or who will at any time head committee meetings be familiar with all of 45 CFR 46, 21 CFR 50 and 56, NIH/Clinical Center (CC) policies, and also read through the on-line tutorials provided at the DHHS Web site. If the university decides to file an assurance with the federal government to allow federal funding of research, familiarity with those tutorials is required.

3. The IRB review process

All research projects gathering data on humans must be submitted to the Chair or Vice-Chair of the IRB. The Chair or Vice-Chair will determine if the project is exempt from oversight, can receive an expedited review, or will need a normal review. Based on the classification of the project the following will happen:

Exempt

Projects will be ruled exempt if they meet the guidelines set forth in 45 CFR 46 101(b).

Should a project be determined to be exempt from IRB evaluation:

1. The researcher who submitted the project will receive notification of the project's exempt status.
2. The other members of the IRB will receive copies of the submitted materials (or the materials will be filed where members can access them if they wish) and the notification of exempt status.
3. A copy of the submitted materials and notification will be filed (see section 5 maintaining documentation).

The chair and vice-chair can establish a mechanism for the approval of exempt studies that are being implemented by students. This alternative approval process would allow university faculty not on the IRB to approve student research that meets the criterion for exempt research. If the Chair and Vice-Chair elect to set up such a process they must inform the VPAA of the process that has been established. Such a process must provide reasonable assurance that only exempt studies will be approved in such a way.

Expedited

Projects will receive an expedited review if they meet the guidelines set forth in 45 CFR 46 110 and the list of categories of research appropriate for expedited review as provided by the Department of Health and Human Services.

Should a project be determined to be appropriate for an expedited review:

1. The Chair or Vice-Chair who identified the project's appropriateness for expedited review will evaluate the project and approve it, send it back for further work, or reject it (within one week if possible).
2. If the project is sent back for revisions or rejected, the researcher can appeal to the full IRB for a normal review.
3. If the project is approved, the other members of the IRB will receive copies of the submitted materials (or the materials will be filed where members can access them if they wish) and the notification of expedited approval.
4. A copy of the submitted materials and notification will be filed (see section 5 maintaining documentation).

Normal

Should a project be determined to be appropriate for a normal review (i.e. not appropriate for exempt or expedited status):

1. The materials for the project will be sent to all members of the IRB and a meeting date will be set. For a quorum, the meeting must have over fifty percent of the committee members present including the Chair or Vice-Chair of the IRB. If someone other than the Chair or Vice-Chair heads the meeting, that person will need to have the familiarity with appropriate federal code and guidelines expected of the chair and be a member of the committee. If there is any reasonable reason to believe that a member of the IRB has a conflict of interest regarding a particular project, she or he may participate in discussion of that project but can not make any motion or second regarding it and cannot vote on any motion or second made regarding it. In this circumstance that person cannot be counted toward the quorum needed for business to be conducted.
2. The committee will approve, send back for revision, or reject the project and notify the researcher of its decision. If the project is rejected, the researcher can revise and

resubmit the project but there is no organizational appeal for a project rejected due to inappropriate or unacceptable harm.
3. A copy of the submitted materials and notification will be filed (see section 5 maintaining documentation).

4. Conducting meetings

A "meeting" for the IRB can be conducted in person in a synchronous manner or electronically in a synchronous or asynchronous manner as long as all materials related to the research being considered are only available to people on the IRB and or who are approved for access and understand that all such information is absolutely confidential (this qualification allows for supervisors of the campus network -- who have access to all materials on it -- to be approved).

For a quorum, the meeting must have over fifty percent of the committee members present including the Chair or Vice-Chair of the IRB. Someone other than the Chair or Vice-Chair may head a meeting if that person has the same familiarity with appropriate federal code and guidelines expected of the Chair and is a member of the committee.

Any person may keep the minutes of a meeting as long as the secretary's identity is identified in the minutes.

Minutes of each meeting will be kept and will include:

1. who attended,
2. what was discussed,
3. motions made and specific counts of votes for, against, and abstaining, and,
4. a basic explanation for the decisions made.

5. Maintaining documentation

As indicated under section 3 (the IRB review process), a copy of all submitted materials and decisions by members of the IRB will be kept in secure storage (inaccessible to unauthorized persons). Also filed will be minutes of all meetings as indicated in section 4 (conducting meetings).

All filed documentation must be secure and only be available to the archivist, the project's original researchers, current members of the IRB, any administrator at the associate vice president level or higher, or any person given permission to review specific materials through a vote of the current IRB.

6. Notifying campus members of the IRB

The Chair and Vice-Chair will make efforts each year to make the campus population aware of its responsibilities to submit any and all proposals for human subject research to the IRB and receive approval before any data collection is begun. Documentation of these efforts will be filed each year in the central location where all proposals and notifications are filed.