

Institutional Review Board

MANUAL

Touro University Nevada



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Policies and Procedures for the Protection of Human Subjects

Role of the Institutional Review Board

The Institutional Review Board (IRB) exists primarily to provide protection for human subjects who participate in research. Thus, the main focus of the IRB is to review applications to identify the risks which may exist for potential research participants. However, one of the ethical justifications for research involving human participants is the social value of advancing scientific knowledge and promoting human welfare. If a research study is so methodologically flawed that little or no reliable information will result, it is unethical to put participants at risk or even to inconvenience them through participation in such a study. To this extent, the IRB must also consider the soundness of the methodology that is proposed for a research study, so that it can determine whether “risks to subjects are reasonable in relation to . . . the importance of the knowledge that may reasonably be expected to result” [Federal Policy §46.111(a) (2)].

Touro University Nevada (TUN) has obtained a Federal-wide Assurance for the Protection of Human Subjects from the U.S. Department of Health and Human Services, by agreeing to follow the Code of Federal Regulations [see <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>]. This designates that the IRB for TUN has the responsibility to review all research which involves the use of human subjects, regardless of the source of support for that research. The IRB is required to (1) identify the risks associated with participation in a research study, (2) determine that those risks will be minimized as much as possible, (3) identify the probable benefits of the research, (4) determine that any risks are reasonable in relation to the benefits for the participants and the importance of the knowledge to be gained, (5) insure that participants will be given an accurate and fair description of any risks or discomforts and any anticipated benefits, and (6) determine how long to approve the research and the need, if any, for periodic review while the study is being conducted. The IRB must also determine that there are adequate provisions to protect the privacy of the participants, to maintain the confidentiality of the research data, and to provide additional safeguards for any participants who are likely to be members of a vulnerable population.

The IRB usually approves research for a period of one year, which is the maximum allowed [Federal Policy §46.109(e)]. Investigators who need to continue their research beyond that time may request up to two one-year extensions. This request must be submitted to the Chair of the IRB using the ***Continuing Review Form***. The investigator needs to confirm that there have been no changes in the targeted participants, the materials, or the procedures for the research and those participants have not had any

adverse experiences thus far in the research. If there is a need to continue the research beyond a third year, a new protocol must be submitted and the IRB must do a full review of the protocol. In accordance with federal policy, some research projects may not be approved for a full year. This could occur, for example, because of the overall risk of the study or because some of the relevant information could not be provided at the time the protocol was first submitted (e.g., a fieldwork or ethnographic study in which the nature of the questions to be asked is not determined until the study is underway).

The investigator is obligated to promptly inform the IRB of any unexpected risks discovered while conducting the research and to promptly report any occurrence of serious harm to participants by completing the **Adverse Event Form** [Federal Policy §46.103(b) (5)]. Although the IRB does not anticipate situations calling for the following actions, it does have the authority to observe, or to require a third party to observe, the consent process and the research itself [Federal Policy §46.109(e)] or to suspend or terminate approval of research that is not being conducted in accordance with requirements it has established or that has been associated with unexpected serious harm to participants [Federal Policy §46.113].

Research Covered by TUN IRB Policies

Any human subject research that involves the use of TUN time, facilities, resources, and/or students is covered by these IRB policies. *Research* refers to a systematic investigation designed to develop or contribute to generalizable knowledge [Federal Policy §46.102(d)]. Activities sponsored by an outside agency that utilize TUN resources are considered to be under the auspices of both the TUN and the outside agency. In this case, approval must be obtained from IRBs for the protection of human subjects of both TUN and the outside agency. TUN IRB only reviews research proposals submitted by a principal investigator (PI) who is affiliated with TUN.

Research or related activities involving the use of human subjects that are conducted by TUN employees or students without the use of any University time, facilities, resources and/or students are not covered by these IRB policies. Individuals conducting such research outside the auspices of the TUN should inform themselves of their legal responsibilities. Research conducted by students within an established TUN course and in which the only participants are other students in the same course is not covered by these policies. Research in which the students in a course observe the public behavior of others but do not interact with them is also not covered by these policies. In both instances, the instructor of the course should be sure that appropriate research procedures are followed. Research in which the students in a course do interact with participants outside of the course (e.g., by conducting a survey) are covered by these IRB policies.

For any activities related to human subjects to be covered under the IRB policies, a research component must be present. In general, if one of the goals of the investigation is an expansion of scientific knowledge, a research component is inherent in the activity, and the project should be reviewed by the IRB.

Investigators affiliated with TUN have the normal legal protections provided by the TUN, if their activities have IRB approval and if they are working within the scope of their employment or TUN affiliation. If these conditions have not been met, TUN will not be in a position to protect TUN investigators performing research with human subjects.

IRB Forms

All forms mentioned in the manual can be found under documents on TUN Blackboard, the TUN website under the Research Department, or by contacting the Department of Research.

Application Procedures

Investigators must electronically submit all appropriate completed forms to the Chair of the IRB and to the Department of Research using the **TUN IRB Application Form**. The application must include specific references to any attachments (e.g., consent forms, tests, interview questions) that are needed, and must be included with the electronic application. Do not submit any other documents as the IRB is unable to review them.

When submitting an application to the IRB, investigators need to take into consideration the IRB's deadlines for its regularly scheduled meetings and the possibility that the IRB might request additional information and/or changes in the protocol and thus need to review the protocol again at a subsequent meeting. Applications should be submitted at least two weeks before the regularly scheduled IRB meeting for them to be reviewed before the desired starting date for the research and before any deadlines of funding agencies.

Questions about Research Procedures and Application Procedures

Questions about the application procedures for human subject's approval may be directed to the Chair of the IRB, or the Department of Research. Any exceptions to the policies outlined in this manual must be approved by the IRB.

Structure of the IRB

The IRB shall consist of at least five members with varying backgrounds. Members are expected to have appropriate professional expertise, maturity, and experience to thoroughly review a variety of research activities conducted at TUN. Members should also be sensitive to relevant professional standards, community attitudes and diversity, applicable laws, and institutional requirements. At least one member of the IRB must have no affiliation with TUN other than serving on the IRB. The IRB shall not consist entirely of members of the same sex or members of one profession. The IRB shall include at least one member whose primary concerns are in a nonscientific area. No member of the IRB shall be involved in the initial review or any continuing review of an activity in which the member is an investigator or a sponsor, except to provide information requested by the IRB. The IRB may invite individuals with competence in special areas to serve as non-voting reviewers when dealing with complex issues. A quorum shall consist of a majority of the IRB's membership. Members of the IRB are appointed by the TUN Faculty Senate in consultation with the Director of the Department of Research. The Chair of the IRB is appointed by the CEO/Senior Provost of Touro Western Division. Appropriate administrative assistance and support for IRB functions are to be provided by TUN through the Department of Research.

Review Process for Applications

IRB applications are forwarded to members of the IRB in advance of the scheduled meeting dates to allow time for each member to individually review each application. The applications are then discussed at the scheduled meeting by the full IRB. A quorum, defined as a majority of the IRB's membership, must be present for the meeting for any vote to occur.

IRB members consist of faculty, administrators, employees, and community members who have volunteered to serve in this capacity in addition to their other obligations to TUN or the community. While the IRB attempts to be as responsive as possible to investigators, it may not be able to respond as quickly as investigators sometimes request.

For example, an "expedited review" has a particular meaning under federal regulations, and that this type of review (described in the next paragraph) may actually require a longer amount of time than the usual process, contrary to expectations about the word "expedited." For this reason, when an expedited review is requested, the IRB will usually consider that request only for an application that has a clearly stated explanation for urgency, is submitted at a time when there is more than one month between regularly scheduled meetings of the IRB, could not reasonably have been submitted in a more timely fashion, and can possibly be reviewed using the "expedited" process more quickly than if it were reviewed at the next scheduled meeting.

When an expedited review is appropriate, the Chair of the IRB will forward the application to at least two IRB members for their independent review. If those IRB members and the Chair agree that an expedited review is permitted the Chair will so inform the investigator and notify the IRB at its next meeting. If the reviewers do not agree on an action, or if any of them so request, the protocol will be considered ineligible for expedited review and will be placed on the agenda for the next meeting.

Level of Risk

The IRB uses the following definitions when reviewing protocols to determine their level of risk to participants:

1. *Exempt*: Some categories of research are considered “exempt” under federal regulations. Examples include observational research on adults (but not children or minors) when the observations are recorded in a way that does not allow individual participants to be identified, reviews of pre-existing records or surveys that are completely anonymous, and studies which evaluate public service or benefit programs. Investigators of potential exempt research must complete and submit the ***Exempt Determination Form*** to IRB for review. For more specific information, see Federal Policy §46.101(b).
2. *No Risk*: Research is approved as “no risk” when no harm or discomfort is anticipated for participants.
3. *Minimal Risk*: Research is approved at “minimal risk” when the probability and magnitude of harm or discomfort anticipated for participants are no greater than what might be encountered in daily life or during the performance of routine physical or psychological examinations or tests [Federal Policy §46.102(i)]. (Note that only “minimal risk” is defined in the federal regulations.)
4. *At Risk*: Research is approved as “at risk” when the probability and/or the magnitude of possible harm (physical, psychological, social, or economic) from participation in a research study are more than minimal.

The following descriptions provide additional information about some possible kinds of risks that may occur in research studies:

1. *Physical Harm*: An example of minor physical harm would be the pain associated with taking a blood sample from a vein. Note, however, that taking a blood sample could be a significant risk to a hemophiliac; participants should be screened for this condition if the research is to be considered minimal risk. Similarly, outdoor exercises that might be considered relatively safe for healthy adults could be dangerous for persons with asthma.

2. *Psychological Harm*: An example of psychological harm would be stress or feelings of guilt or embarrassment from thinking or talking about one's own behavior or attitudes on sensitive topics such as drug use, sexual orientation, selfishness, or violence. These feelings may be aroused from being interviewed or from filling out a questionnaire. Another kind of risk would be an invasion of privacy, for example, from covert observation (even in a public place) of behavior that participants would likely consider private. Still another risk of psychological harm occurs when there is inadequate protection for the confidentiality of data that has been given voluntarily (e.g., by retaining audiotapes or videotapes longer than is necessary to analyze the relevant information).
3. *Social and Economic Harm*: Some invasions of privacy or breaches of confidentiality could result in embarrassment or harm to a participant's reputation within his or her business or social group, a loss of employment, or criminal prosecution. Areas of particular sensitivity include such topics as alcohol or drug abuse, child or partner abuse, and sexual behavior.
4. *Inadequate Protection for the Confidentiality of Research Data*: Where identifiers of individual participants are not required by the design of the research study, none should be recorded. If identifiers are recorded, they should be separated, if possible, from the data; stored securely, with linkage restored only when necessary to conduct the research; and destroyed when they are no longer needed. More elaborate procedures may be needed in some studies, either to give participants the confidence they need to answer questions truthfully (e.g., promising to submit course grades before analyzing data from one's own students) or to enable the investigator to offer honest assurances of confidentiality. Even when participants are otherwise anonymous, there may be a danger of deducing the identity of individual participants by combining specific pieces of information collected during the research about the participants. Additional precautions may be needed to deal with these circumstances.

In some studies, keeping the identity of participants confidential may be as important as or more important than keeping the research data confidential. In those instances, any written record linking participants to the study may be a threat to confidentiality. Even in studies where confidentiality is not a concern, no lists should be retained identifying those who elected not to participate.

Where data are being collected about sensitive issues (such as illegal behavior, alcohol or drug use, or sexual practices or orientation), protection of confidentiality consists of more than just preventing accidental disclosure of the data. There have been instances where the identities of participants, or research data about particular participants, have been sought by law enforcement agencies, sometimes by subpoena and with the threat of incarcerating an uncooperative researcher. Some investigators may need to obtain a federal certificate of confidentiality [Public Health Service Act §301(d)]

to protect the privacy of their participants. The certificate protects the investigator from being compelled to provide the names or other identifying characteristics of research participants in any federal, state, or local civil, criminal, administrative, legislative, or other proceeding. (Its precedence over state law has been upheld in the New York Court of Appeals.) The certificate does not protect identifiable data that the participant may disclose about other people.

Informed Consent

Informed consent assures that prospective participants understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate. It is a continuing process, not just a piece of paper; especially in a lengthy study, it may be necessary to obtain consent on more than one occasion. It protects both the participant and the investigator, who otherwise faces legal hazards. Investigators may seek consent only under circumstances that provide prospective participants or their representative's sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. Furthermore, the information must be written in language that is understandable to the participants. If the prospective participants include persons who are unlikely to be familiar with specific technical terms, persons with limited verbal or cognitive skills, or persons whose primary language is not English, special care must be taken to ensure that both oral presentations and written consent forms are comprehensible to all participants. When participants may include members of a vulnerable population (such as children, elderly persons, prisoners, or economically or educationally disadvantaged persons), additional safeguards are needed to protect the rights and welfare of those subjects.

When children and/or adolescents are participants in a research study, the investigator must solicit both the assent of the children and the permission of their parents or guardians. There are limited exceptions for situations in which the parents' interests may not adequately reflect the child's interests. In certain circumstances, older adolescents may have the legal authority to give their consent even though they are not yet legally considered adults (i.e., are under the age of 18). Also, the Buckley Amendment requires parental consent for release of records or identifiable information about children in public schools, and instructional materials to be used in connection with research must be available for inspection by parents or guardians.

To minimize the possibility of coercion or undue influence, it is generally preferred that participants be recruited by open, written invitation rather than by personal solicitation. For similar reasons, it is also preferred that professors not solicit their own students as participants and that supervisors not include their own employees in research. If advertising will be used to recruit participants, the IRB needs to review that advertising to be sure that the information will not be misleading to potential participants. Similarly, if participants are to be paid for their time, either monetarily or through a gift, the IRB

needs to review the amount of the payment and provisions for full, partial, or no payment (for example, if a participant withdraws part way through the research) to assure that participants will not be unduly influenced by the payment.

In most cases, federal regulations require that participants sign a written consent form [Federal Policy §46.117], although the consent document is not a substitute for discussion of the relevant information with prospective participants. Participants must be given a clear and fair explanation of the research procedures, their risks and benefits, and provisions for confidentiality in the research. Each participant must provide informed consent prior to participation. The person who signed the consent form must be given a copy as a reference and reminder of the information conveyed.

A “short form” may sometimes be approved for the consent [Federal Policy §46.117(b)(2)]. This means that the information is presented orally to prospective participants without a written version of it in the consent document. The IRB must review and approve a written summary of what will be presented orally. The participant must sign the short consent form (stating that the information has been provided orally), and a third person must witness the oral presentation and must sign both the short consent form and a copy of the written summary of the oral presentation. The investigator obtaining the consent must also sign the written summary. A copy of the written summary must be provided to the participants even though they are not asked to sign the written summary.

A waiver of written consent or using an alternate method to document consent may only be considered if (1) the research involves no more than minimal risk, (2) the waiver or alteration will not adversely affect the rights and welfare of the participants, (3) the research could not reasonably be carried out without the waiver or alteration, and (4) whenever appropriate, participants are provided with additional pertinent information in a debriefing after their participation [Federal Policy §46.116(d)]. Furthermore, especially in studies which involve the collection of sensitive information (e.g., sexual or criminal activity), a request to waive written consent may be considered only if (1) the only record linking the participant to the research would be the consent document and the main risk in the research would be the potential harm from a breach of confidentiality (in this case, participants must be asked whether they want documentation of their consent, and they may elect to sign a consent form or not), or (2) the research is no more than minimal risk and involves no procedures for which written consent would normally be required outside of the research context [Federal Policy §46.117(c)]. The IRB may still require that a written statement of pertinent information be provided to participants who do not sign a consent form.

It may be appropriate to waive written consent (but not informed consent) for fieldwork studies where the nature of the continuing interactions with the investigator is not easily reduced to a consent form. For some observational studies of people who are not aware that they are being observed or who are unaware that their behavior is being recorded

for research purposes, it may be appropriate to completely waive the consent requirement if the knowledge to be gained is important, but such research can also raise serious ethical concerns about protecting the privacy of the unwitting participants. Similarly, it may be appropriate to waive the consent requirement for studies of pre-existing records if the information contained in the files is not particularly sensitive, the investigator has devised procedures to protect the confidentiality of the information to be collected, and the study could not practicably be carried out if consent were required.

Sometimes investigators plan to withhold information about the real purpose of the research, or even to give participants false information about some aspect of the research. This means that the participant's consent may not be fully informed. The degree to which this is acceptable depends on whether the information to be withheld would influence the decision of prospective subjects about participating in the research. When subjects have unwittingly participated in research or have knowingly participated in research that involved some form of deception, they should be debriefed afterward with pertinent information about the study whenever this can be done in a way that reduces rather than produces pain, stress, or anxiety.

Although institutions are not required to provide care or payment for research injuries, the IRB generally expects investigators to provide a way for participants to obtain at no cost any services necessitated by research injuries. This information needs to be provided in the consent form. In any case, the consent process must not involve the use of any exculpatory language through which the participant is made to waive or to appear to waive any of his or her legal rights, or releases or appears to release the investigator, sponsor, institution, or their agents from liability for negligence [Federal Policy §46.116].

Actions of the IRB

When reviewing an application, the IRB may decide to approve the research, to conditionally approve the research with a request for minor modifications, to request that the protocol be resubmitted with additional information and/or more substantive modifications, or to disapprove the research (in general, disapproval would only occur if the IRB finds significant risks in the research that cannot be minimized, or when recommendations from the IRB for minimizing such risks have been declined by the investigator). The Chair of the IRB may communicate these initial decisions by e-mail to the investigator, particularly when the IRB has requested modifications to the research. A letter indicating approval of the research will be sent when the protocol is fully approved. The Chair is authorized to act on behalf of the IRB to either approve the minor modifications submitted in response to a conditional approval or refer the revised protocol to the IRB for its review.

When making these decisions, the IRB also makes its judgment of the level of risk in the proposed research. Applications may be classified as exempt or approved as

involving no risk, minimal risk, or more than minimal risk. Risks must be considered reasonable for the research, appropriate procedures must be used to minimize any risks, and the potential benefits of the research must outweigh the potential risks.

Requests for Reconsideration

If an applicant believes that decisions of the IRB or changes requested by the IRB are incorrect, unfair, or improper, the applicant may submit a request for reconsideration to the IRB. The request should be made in writing to the Chair of the IRB and should include the reasons for disagreement with the IRB's action. The request for reconsideration will be considered by the full IRB, and the applicant will be invited to attend the meeting of the IRB when the request for reconsideration is discussed.

Unanticipated Risks

Any unanticipated problems involving risk to participants or others must be immediately reported to the IRB in writing by completing the **Adverse Event Form**.

Reporting Changes to an Approved Protocol.

Any significant changes to a previously approved protocol must be submitted to the IRB by completing the **Amendment Request Form** or the **Reporting Deviations Form**. Examples of significant changes include a different or additional principal investigator, an intention to recruit participants from a different source or via a different advertising method, changes in the consent form, and changes in any materials or equipment used in the project, changes in the research procedures, or the discovery of previously unidentified risks in the research. The IRB will respond with a letter indicating its approval of the proposed changes or, if it is unable to approve the changes, its request for additional information or for alternative changes. Investigators should not change their protocol until approved by IRB.

Requests for Extension

If the research will extend past the expiration date of IRB approval for the study, the investigator will need to ask for a renewal by completing the **Continuing Review Form**. When the IRB has approved an extension for the research, a letter will be sent confirming that approval.

When requesting such an extension, the investigator should be aware of the IRB's deadlines for its regularly scheduled meetings. Requests for extension must be submitted at least two weeks before the regularly scheduled meeting for them to be considered for approval before the expiration date of the prior approval and

before any deadlines of funding agencies. The IRB is not obligated to send a reminder notice to the investigator about this requirement.

Records and Reporting Requirements

Investigators are required to obtain and keep, for a period of three years after the conclusion of the research, documentary evidence of informed consent from the participants.

The IRB is required to maintain documents related to each of its activities, including applications (and attachments) received, requests for modification or extension of approval, reports of adverse reactions, correspondence with investigators, minutes of meetings (with details of IRB deliberations), and a list of IRB members. These records must be maintained for at least three years after the conclusion of the research. Records related to specific research activities are not open to persons who are not members of the IRB, other than for auditing functions by federal agencies engaged in the protection of human subjects.