INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS (IRB)

POLICIES AND PROCEDURES MANUAL

Touro University New York

JANUARY 2024

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INTRODUCTION

A Brief History of Human-Subjects Research[1]

The history of human-subjects research is replete with horrid examples of what happens when investigators fail to respect humans as they pursue research.

The Nuremberg trials exposed the Nazi war crimes related to human subjects research and subsequently the Nuremberg Code provided a clear statement of standards for research on human subjects. However, it is well documented that unethical research programs continued to be designed and conducted. For example, in the United States, the Willowbrook study of hepatitis transmission in a hospital for mentally impaired children and the Tuskegee Syphilis Study are horrific examples of egregiously unethical research designed and conducted long after the Nuremberg Code was in place. In each of these studies, investigators were confident that the research contributions justified the harm human subjects suffered. Ends of research justified the means.

The National Research Act of 1974 was passed in response to growing concern about the ethics violations in research. This act created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report of 1974 was the commission's summary of the ethical principles that form the basis of acceptable human-subjects research.

The three foundational Belmont principles are:

Respect for persons. This principle includes both respect for the autonomy of human subjects and the importance of protecting vulnerable individuals.

Beneficence. This principle requires that research maximize the benefit-to-harm ratio for individual subjects and for the research program as a whole.

Justice. The principle of justice in research focuses on the duty to assign the burden and benefits of research fairly.

The essential conflict in research is the duty to avoid a researcher pursuing research that allows "the ends to justify the means." Individual investigators, even those who are committed to ethical research, may not be sufficiently familiar to identify and avoid the influence of inherent conflicts of interest. IRBs must be independent from the investigator and provide oversight.

Research at Touro University involving humans as subjects is guided by the Belmont Report. We have chosen to apply those ethical principles whether or not the research is subject to federal regulation, and regardless of whether the research is funded or unfunded.

Federal Oversight (Office of Human Research Protection)[2]

The Office for Human Research Protections (OHRP) was created in June 2000 to lead the Department of Health and Human Services' (HHS) efforts to protect human subjects in

[1] AMA Journal of Ethics, The History and Role of Institutional Review Boards: A Useful Tension *Virtual Mentor.* 2009;11(4):311-316. doi: 10.1001/virtualmentor.2009.11.4.pfor1-0904.

[2] See https://www.hhs.gov/ohrp/

biomedical and behavioral research and to provide leadership for all federal agencies that conduct or support human subjects research under the Federal Policy for the Protection of Human Subjects, also known as the Common Rule. OHRP replaced the Office for Protection from Research Risks (OPRR), which was created in 1972 and was part of the National Institutes of Health (NIH). In June 2000, HHS established the National Human Research Protections Advisory Committee (NHRPAC) to provide HHS with expert advice and recommendations on human subject protections matters.

OHRP is part of the Office of the Assistant Secretary for Health in the Office of the Secretary of HHS. OHRP provides leadership in the protection of the rights, welfare, and wellbeing of human subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS).

OHRP provides clarification and guidance, develops educational programs and materials, maintains regulatory oversight, and provides advice on ethical and regulatory issues in biomedical and behavioral research. OHRP also supports the Secretary's Advisory Committee on Human Research Protections (SACHRP), which advises the HHS Secretary on issues related to protecting human subjects in research.

Significant changes to the Common Rule have been made in 2019 to the federal regulations governing research involving human subjects. These regulations are usually referred to as the **Common Rule** and are the regulations under which most human subjects research at the College falls. **The effective date of the Revised Common Rule was January 21, 2019.**

There are three key revisions in the Common Rule that impact human subjects research at Touro University:

1) Elimination of Continuing Review of Research Under Specific Conditions

The Revised Common Rule eliminates continuing review for many minimal risk studies. Unless an IRB determines otherwise, continuing review of research is not required if:

- The research is eligible for expedited review.
- The research has progressed to the point that it only involves data analysis.
- If an IRB chooses to conduct continuing review even when these conditions are met, the rationale for doing so must be documented.

2) Informed Consent Revisions

Under the Revised Common Rule, the requirements for informed consent have changed. Specifically, informed consent must begin with a concise and focused presentation of key information that will assist a prospective subject in understanding the reasons why one might or might not want to participate in the research. The consent form must also be organized and presented in a way that facilitates comprehension.

3) Exempt Research Revisions

The Revised Common Rule includes 8 categories for exceptions. These categories are described below in the section "Exemption Categories (pg. 15)."

Touro University: Role of the Institutional Review Board

Touro University has established the Institutional Review Board (TouroNY-IRB) to protect the rights and welfare of human research subjects who are recruited to participate in research activities conducted under the auspices of the University. The academic programs primarily served by the TouroNY-IRB include: the College of Osteopathic Medicine (COM; Harlem, Middletown, and Montana campuses); the College of Pharmacy (COP); the School of Health Sciences (SHS), Touro's Graduate Schools of Business (GSB), Education (GSE), Psychology, Information Technology (IT), Jewish Studies, and Social Work (GSSW); the schools that constitute Touro's Undergraduate Division; and the Jacob D. Fuchsberg Law Center.

The IRB operates under an approved Federal Wide Assurance (FWA00015486 and is registered with the U.S. Department of Health and Human Services (DHHS) Office of Human Research Protections(OHRP). The IRB reports to the Senior Vice President for Research Affairs. Administrative support is provided to the IRB by the IRB Administrator.

The IRB is only concerned about projects that involve human subject participants and meet the federal definition of research. Here are the definitions of *research* and *human subjects* as provided in the federal regulations 45 CFR 46:

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains 1) Data through intervention or interaction with the individual, or 2) Identifiable private information.

Studies that fit any of the categories below typically do not need IRB review.

1. Data collection for internal departmental, school, or other University administrative purposes. Examples: teaching evaluations.

2. Service surveys issued or completed by University personnel for the intent and purposes of improving services and programs of the University or for developing new services or programs for students, employees, or alumni, as long as the privacy of the subjects is protected, the confidentiality of individual responses is maintained, and survey participation is voluntary.
3. Information-gathering interviews where questions focus on things, products, or policies rather than people or their thoughts regarding themselves. Examples: canvassing librarians about their libraries' inter-library loan policies or periodical purchases.
4. Course related activities designed specifically for educational or teaching purposes, where data are collected as part of a class exercise or course requirement **but are not intended for use outside of the classroom.** (See below)
5. Biography research involving a living individual that is not generalizable beyond that individual.
6. Quality improvement projects may or may not need IRB review. Projects where this is a clear intent to contribute to generalizable knowledge and use the data derived from the project will need to be reviewed.
7. Case history or Case Study which are published and/or presented at national or regional meetings are not considered research if the case is limited to a description of the clinical features and/or outcome of a three or fewer participants and do not contribute to generalizable knowledge.
8. Publicly available data do not require IRB review. Examples: census data, labor statistics.
9. Coded private information or biological specimens that were not collected for the currently proposed projects do not need IRB review as long as the investigator cannot link the coded data/specimens back to individual subjects. If the data/specimen provider has access to the identity of the subjects (e.g. subjects' names, addresses, etc.), the investigator must enter into an agreement with the data/specimen provider that states under no circumstances will the identity of the subjects be released to the investigator. Note: Investigators cannot independently make this determination. These projects require verification from the IRB Chair or their designee.)

Research involving human subjects that needs approval from the IRB generally falls into one of the following categories:

- Basic and applied research that is conducted by faculty and other staff members eligible to serve as Principal Investigators under University policy.
- Doctoral dissertation or master's and undergraduate senior honor thesis research that is conducted by students. These projects require a faculty advisor designated as responsible for oversight or as a co-Principal Investigator. See Table 1: Faculty Responsibilities in Student Research.

- Professional curriculum students such as medical students and pharmacy students These projects require a faculty advisor designated as responsible for oversight or as a co-Principal Investigator. See Table 1: Faculty Responsibilities in Student Research.

Other student projects, such as research assignments in research methods classes, may require IRB review and approval. Specific criteria are outlined in Table 1, Faculty Responsibilities in Student Research. Faculty advisor or class instructor should consult with the IRB for guidance.

Table 1:
Faculty Responsibilities in Student Research

Guidelines For A Classroom-Based Research Project:

A main characteristic of research is generalizability. Projects that inherently are not generalizable do not require IRB review. Research assignments in research methods classes are often specifically designed to satisfy a course requirement or to teach a particular skill such as interview, observation or survey techniques, data analysis, or research design. Oftentimes they are not intended to continue beyond the classroom in a way that would suggest generalizable research. These studies do not require IRB review if they meet the following criteria:

- Project is limited in scope.
- Subjects are recruited in a voluntary manner.
- Project present no more than minimal risk to participants.
- Data collected do not lead to generalizable results.
- No identifiers are collected.
- Surveys/questionnaires/interviews, if used, should be completely anonymous.
- No monetary compensation or any type of other support from an external company/organization/agency for collecting, analyzing, or reporting the results of this project is involved.
- Data collected are not archived or saved in any way to be used in the future.

Faculty and students working on such projects should ensure full disclosure about the purpose of their project and obtain participants' permission for journalistic, photographic, or video release of information or images, if applicable.

It is recommended that faculty and students working on such projects complete the CITI training to ensure familiarity with regulations and the need to maintain confidentiality, obtain informed consent, etc.

It is also understood that the end result of the class project may be presented in the classroom to peers but may not be used for any publication or public presentation outside of the immediate classroom, if external presentation is then desired.

Faculty/Course Instructor Responsibilities:

Faculty and course instructors who require students to do classroom-based research projects assume responsibility for the conduct of those projects and assure that the guidelines outlined here are met and that research that falls outside of these criteria is submitted to the IRB for review.

Faculty and course instructors are responsible for the following:

1. Determine whether an assigned project involving humans can be classified as a course-related student project under the criteria above. The IRB office should be contacted for assistance if needed in making this determination.
2. Ensure that students understand and abide by ethical regulations when carrying out their assignments.
3. Review student class project proposals and consent procedures to ensure that the methods and procedures are ethical and appropriate.
4. Monitor student activities during data collection to ensure that the rights and welfare of participants are adequately protected.

In addition, the faculty and course instructor must ensure that all recruitment materials and surveys/questionnaires/interviews include the following information to be disclosed to the participants:

- The students are identified as Touro students (specify the school/department) who are performing the activity to fulfill a course requirement. The specific course should also be listed.
- The name of the supervising faculty member to contact for questions.
- The persons who have access to the individual data and/or summarized results are identified (e.g., instructor only, additional students in the class).
- Participation is completely voluntary and confidential.

In general, standard research practices that are reviewed by the IRB such as obtaining informed consent, ensuring confidentiality, and limiting risks to participants, should be employed and are the responsibility of the faculty member/course instructor.

- **Faculty Advisor Approval**

Faculty advisors must indicate approval of students' applications in the Mentor system before the review process can begin. Before indicating approval in Mentor, faculty advisors are required to read and sign the application protocol.

Human subjects may include non-Touro populations as well as Touro students or staff. For example, if a faculty member seeks to conduct research with students enrolled in a Touro course.

The IRB has the authority to approve, require modifications to, or disapprove all research activities as specified by both federal regulations and University policy.

Touro University New York Institutional Review Board (TouroNY-IRB) exists to provide protection for human subjects who participate in research. The main focus of the IRB is to review applications to identify the risks which may exist for potential research participants. Those risks are evaluated in relation to the potential outcomes to ensure that the study's benefits outweigh the risks. The recruitment strategies are also reviewed to ensure the application of the ethical principles of justice, autonomy, and respect to the person.

More specifically, the Touro University New York 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) Ensure that participants will be given an accurate and fair description of any risks or discomforts and any anticipated benefits; and
(6) Provide continuing oversight for progress reports and protocols for ongoing research studies.
(7) 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 obtain informed consent, 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.

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."[3]

The IRB usually approves research for a period of one year, which is the maximum allowed.[4] 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 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 (for example a fieldwork or ethnographic study in which the nature of the questions to be asked is not determined until the study is initiated).

Amendments

Changes to on-going projects generally **require** approval by the IRB **prior to implementation**. PIs are encouraged to consult with the IRB to determine the form and content of any proposed amendment.

A proposed amendment to the original project **should be submitted in a timely manner**.

Usually, an amendment takes the form of a memo in which the PI details the nature of and rationale for the proposed changes to the contents of the originally approved project. Particular attention ought to be paid to any change in risks to subjects, especially if there are any potential new risks. The memo must cite the Board approved project number, the date of the original approval, and the title of the project.

- Very modest proposed changes frequently are managed as an "administrative" amendment. These amendments normally are adjudicated quickly.

[3] Federal Policy Sec. 46 111(a)(2)
[4] Federal Policy Sec. 46 109(e)

- More substantive amendments may require a more detailed memo and a fuller level of IRB review. PIs ought to consider how the possible lengthier review process might affect implementation of their project plan.

- Additionally, PIs of approved Exempt projects should be sensitive to any proposed changes that might eliminate the project's Exempt status. This situation might be particularly likely if there are changes regarding risk to subjects.

Proposed amendment memos are to be submitted via Mentor.

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.**[5] The IRB has the authority to observe or to require a third party to observe, the consent process and the research itself[6] 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.[7]

Research Covered by Touro University NY's IRB

Any human subject research that involves the use of Touro time, facilities, resources and/or students is covered by these IRB policies. The word "research" refers to a systematic investigation designed to develop or contribute to generalizable knowledge.[8] Activities sponsored by an outside agency that utilize Touro resources are considered to be under the auspices of both Touro and the outside agency. In this case, approval must be obtained from the IRBs for the protection of human subjects of both Touro and the outside agency. TouroNY-IRB only reviews research proposals submitted by a principal investigator (PI) who is affiliated with Touro.

Research, or related activities that involve the use of human subjects that are conducted by Touro 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 Touro should seek permission of their respective Dean. Research conducted by students within an established Touro course and in which the only participants are other students in the same course are not covered by these policies (see above). 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.

[5] Federal Policy Sec. 46 103(b) (5)
[66] Federal Policy Sec. 46 109 €
[7] Federal Policy Sec. 46 113
[8] Federal Policy Sec. 46 102(d)

Research in which the students in a course interact with participants outside of the course (for example 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 Touro have the normal legal protections provided by Touro if their activities have IRB approval and if they are working within the scope of their employment or Touro affiliation. If these conditions have not been met, Touro will not be in a position to protect Touro investigators performing research with human subjects.

Projects that meet the federal definitions of human research may not be started until the review is complete and the primary investigator has received notification of approval and a date stamped consent form.

If a research project involving human participants has been initiated prior to receiving IRB approval, study participants could be exposed to unnecessary risks, and their rights to sufficient information, fair recruitment, and a voluntary choice may be limited. In addition, failure to obtain this approval could pose liabilities for the researcher, as well as the University. Federal regulations and IRB policy require that serious or continuing instances of noncompliance be reported to the Institutional Official of Touro University, the Office of Human Research Protections, as well as funding or other applicable agencies. Conducting a human research project that does not qualify for an exempt status without IRB approval is considered to be an act of serious noncompliance. **In those instances where the IRB has determined that noncompliance has occurred, a report will be sent to the Office of the Senior Vice President for Research Affairs, at which time the seriousness, as well as the specific circumstances of the events, and welfare of participants are considered. Suitable corrective actions will be proposed, and a determination made as to whether the data collected may be utilized.**

IRB COMMITTEE MEMBERS

The membership composition of the IRB follows the mandate of the Revised Common Rule[9]

The combination of expertise, experience, and diversity among its members allows each Board to maximize collective knowledge and sensitivity to appropriate community values. In turn, that aggregate competency helps promote respect for the advice and determinations each Board provides in order to safeguard the rights and welfare of human subjects.

The majority of members of the IRB consists of faculty members from across the University who reflect a broad spectrum of academic disciplines. The IRB is also required to have at least one scientist and one non-scientist and at least one external member who has no ties to Touro. Moreover, if the IRB determines that additional expertise is needed to be able to evaluate a

[9] Sec. 46, 107 IRB Membership

specific proposal, the IRB may invite an individual with that competence to assist in the proposal review (although that individual may not vote).

Board members pursue their ethical and legal obligations with all due diligence, coupled with a spirit of collegiality. Members recognize that at a primarily instructionally-focused institution like Touro—an institution whose research footprint is now expanding—assisting an investigator to build awareness of the ethical and practical issues surrounding the conduct of research with human subjects is a valuable and constructive educational role that benefits not only the researcher, but the University community as a whole.

IRB SUBMISSION AND MEETING SCHEDULES

The IRB holds regularly scheduled meetings during the course of the academic year (September through June). Meetings focus on discussing any Non-Exempt proposals that require full Board review and/or general business regarding oversight of human subjects research protections at the University. While no regularly scheduled meetings are held during summer months, the IRB will conduct ad hoc meetings when circumstances arise requiring full Board action.

Proposals that are likely to require full Board review must be submitted to the Board approximately two weeks prior to a scheduled IRB meeting. Once submitted, all proposals undergo an initial informal review to assess the completeness of the submission. Only after proposals are deemed complete are they distributed to Board members for review and formally placed on a meeting agenda for discussion.

Application Procedures

Investigators must create a protocol and submit their application electronically to the IRB via Sitero Mentor. The protocol must include specific reference to any attachments (for example consent forms, tests, interview questions) that are needed, and must be included with the electronic submission. Certification of completion of human subjects training (CITI) must be included for all named persons on the protocol (see below).

When submitting a protocol 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. Protocols 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.

Please know that the Touro IRB committee makes every effort to review the Touro IRB protocols as promptly as possible.

Who may be a Principal Investigator?

A Principal Investigator must have the technical competence and substantive capabilities (scientific, administrative, and otherwise) to carry out a sponsored project. The following individuals are eligible to serve as principal investigators on proposals submitted to outside funding agencies in support of research, training, or other sponsored activities at Touro.

ELIGIBLE FACULTY:

Professors

Associate Professors

Assistant Professors

Instructors

ELIGIBLE NON-FACULTY INDIVIDUALS

Students*

Research Scientists

Associate Research Scientists

Assistant Research Scientists

Research Associates

Emeritus Faculty members are also eligible to serve as Principal Investigators, conditional on the availability of university resources, and subject to the approval by the Dean of the School submitting the proposal.

*Student PI's must also have a Supervising PI who is a full-time faculty member.

CITI Training

Every application must be accompanied by proof of completion of the Collaborative Institutional Training Initiative (CITI) courses on working with human subjects. The courses are free to all Touro researchers. All members of the research team who have access to identifiable confidential data must complete CITI courses, including PIs, Co-Investigators, and when appropriate, research assistants and consultants.

The CITI curriculum includes required and supplemental modules, as well as modules on Conflict of Interest. The training is offered in two concentrated areas, biomedical research, and social-behavioral research. The area of training must be relevant to the study purpose and field of study. The CITI completion certificates must be current and are not due to expire during the duration of the study (if less than one year).

If the research team includes someone who is not faculty, staff or student at Touro University, this person also needs to complete the same CITI training modules either at their home institution or through Touro. If their home institution does not offer CITI training, they can add Touro NY as an affiliate organization to take the required courses. Researchers should refer to the Touro University website for a list of required CITI courses and for assistance with CITI.

Depending on level of risk and subject demographics, a study proposal will fall into one of three review categories: exempt, expedited or full board review. The pre-protocol diagnostic survey in the online Sitero Mentor system guides researchers towards the appropriate level of review. The IRB chair, vice chair, or designee will then review the submission level and either confirm or request change to another level.

Exempt Reviews

The IRB is responsible for reviewing research proposals and verifying exemption, confirming that these projects are low risk. Exempt applications do not have deadlines and will be reviewed on an ongoing basis. Initial review of an exempt protocol generally occurs within two weeks of submission. Principal investigators are notified via email of any areas for clarification or needs for revision. The timeline for completion of the review will depend on how many revisions are required; therefore, investigators should allow sufficient time between their initial submission and start date of their project.

The IRB Chair, Vice Chair, or designee will verify that the research is in a category appropriate for exemption, as listed below, and that the application meets all the requirements. Once an exempt application is approved, unless there are amendments to the protocol, the investigator does not have additional reporting requirements to the IRB. However, the investigator must respond to the annual check in email and report on the status of the study as requested.

Exemption Categories

Category 1: Research involving normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.

Category 2: Research involving the use of educational tests, surveys, interviews, or observation as well as the collection of potentially sensitive or harmful identifiable information from adults if adequate provisions for protecting privacy and maintaining confidentiality are in place.

Category 3: Research involving benign behavioral interventions (brief in duration, harmless, painless, not invasive, not offensive or embarrassing) with adults (e.g., solving puzzles under various noise conditions). Information collected (verbal or written responses, data entry, observation of subject including audiovisual recording) can be identifiable. Deception is allowable when subjects are prospectively consented in advance. Does not permit data collection via physical procedures (blood pressure, EEG, FitBit).

Category 4: Secondary research use of identifiable private information or identifiable biospecimens collected either retrospectively or prospectively. No consent is required as long as 1 of 4 criteria are met (e.g., publicly available information, information recorded such that subjects cannot be readily ascertained).

Category 5: Public benefit and service programs and research and demonstration projects conducted or supported by a federal department or agency.

Category 6: Taste and food quality evaluation and consumer acceptance studies if certain criteria are met.

Category 7: The storage of identifiable biospecimens and identifiable private information. Broad consent is required.

Category 8: Secondary analysis of identifiable biospecimens and identifiable private information. Broad consent for the storage, maintenance, and secondary research use must be obtained.

Although some exempt categories allow for self-exemption or limited IRB review, the Touro University NY IRB does not allow faculty or students to utilize self-exemption. All exempt studies are reviewed; therefore "limited review" does not apply.

Expedited Categories:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
    a. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
    b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
    a. (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or
    b. from other adults and children [2], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.
3. Prospective collection of biological specimens for research purposes by noninvasive means.
    Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with

accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
   Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject=s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)
8. Continuing review of research previously approved by the convened IRB as follows:
   a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
   b. where no subjects have been enrolled and no additional risks have been identified; or
   c. where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Expedited Reviews The IRB Chair, Vice Chair, or designee will confirm that the research is in a category appropriate for expedited review (45 CFR 46.110) and that the research involves no more than minimal risk for the research subjects. Research is considered as "**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.[10]

There are no deadlines for expedited review submissions; however, investigators should plan sufficient amount of time for review and possible revisions. If applications are incomplete or completed without sufficient detail, the length of review could be extended, delaying the start of a project.

Expedited reviews are assigned a member of the committee and are typically reviewed within 14 days. The length of the review process depends on the need for revisions; therefore, investigators should ensure that a thorough and professional application is submitted to reduce the length of time for completion of the review.

Expedited reviewers submit their findings to the IRB Administrator, who will then notify the PI of any revisions or clarification needed. All revisions are reviewed by the same IRB committee member. Once the reviewer agrees that the application meets all the requirements and is ready for approval, the Chair or Vice chair will then perform a final review and notify the IRB Administrator of the final determination. The IRB Administrator will then finalize the review process and notify the PI of approval.

IRB approval means that the study protocol has been reviewed and the research may be conducted at Touro University as proposed. The IRB Chair or Vice chair will send a certificate of approval to the principal investigator via notification from Mentor. Approval is effective as of the date on the notification. The certificate of approval will include the requirements for reporting adverse effects and submitting an application for continuing review. Expedited level projects can be approved for up to one year. At the end of that year, investigators must either formally terminate their study or request continuing review.

Immediately following approval, PDF consent forms will be generated within the Sitero Mentor online protocol management system with the stamped approval date. Principal investigators can find their approved/stamped PDF consent forms on their protocol page and should use the approved stamped forms to obtain written consent prior to data collection. Investigators must use the stamped PDF consent forms only. No other consent forms may be used to obtain consent. Any changes to the consent form must be submitted to the IRB as an amendment. If approved, the revised form will be stamped, dated, and sent as PDF back to the investigator.

Full Review

[10] Please see Federal Policy Sec. 46 102(i)

Research that requires a full committee review is determined to involve more than minimal risk, and/or involves protected populations such as children, prisoners, or individuals with impaired decision making.

1.

Research is considered 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. Table 1 includes further descriptions of potential risks.

Table 1:

Possible 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. However, taking a blood sample could be a significant risk to a hemophiliac; if appropriate, 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 (for example by retaining audiotapes or videotapes no longer than is necessary to analyze the relevant information).**Social or 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 inappropriate sexual behavior. **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 linage 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 (for example 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***[11] 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 proceedings.[12] The certificate does not protect identifiable data that the participant may disclose about other people.

If researchers are collecting data where no one, not even the researcher, will be able to tell where or from whom the data came from, then the data is considered to be "anonymous." However, data which may be linked to an individual through use of codes, video/audio recording, or other identifiers would be considered to be "identifiable data." If a researcher promises to keep identities of participants secure and private, not disclosing these identifiers to anyone other than the research team, the data is considered to be "confidential."

Applications for full board review are due 2 weeks prior to the next scheduled IRB Committee meeting. Since these reviews are time and labor intensive, It is recommended that principal investigators (PIs) contact the IRB Chair when they are writing the protocol so the committee can be alerted to any upcoming full board reviews. Additionally, it is recommended that full board applications should be submitted the semester prior to the anticipated research start date to allow sufficient time for protocol development and review. Principal investigators should check the IRB calendar for specific submission deadlines.

IRB Decisions

(1) Approval: The research study is approved without any conditions.

(2) Approval Pending: The research study is approved pending non-substantial revisions.

(3) Deferred: The protocol requires substantive or complex changes it is recommended for approval. The IRB committee may vote to defer a final decision of approval or

[11] Public Health Service Act Sec. 301 (d)

[12] NOTE: The Federal Certificate of Confidentiality's precedence over state law has been upheld in the New York State Court of Appeals.

disapproval until the PI adequately responds to the IRB's concerns. Once the PI responds, the study will again be reviewed by a fully convened IRB.

(4) Disapproval: When criteria for approval is not met, even with substantive clarifications or modifications to the protocol and/or informed consent process/document, the IRB can vote to disapprove a protocol.

The IRB cannot approve a protocol under the following conditions:

(a) The IRB is unable to make the required determinations about research risks and benefits, the adequacy of privacy and confidentiality protections, or the adequacy of the informed consent process.

(b) The IRB is unable to specify changes to the research protocol that would allow the IRB to make these required determinations.

If disapproved, no proposed study procedures may take place, and the study may not be re-submitted for review.

(5) Tabled: If the IRB committee is unable to provide adequate review of a study due to lack of time, expertise, or quorum, then the review may be postponed until another full IRB meeting.

After the committee meets, the PI will receive electronic notification of the results of the IRB review. For any full review research protocol that is approved, the IRB will state the duration of approval, which shall not exceed one year.

Following approval, PDF consent forms will be generated within the Sitero Mentor online protocol management system with the stamped approval date. The PI can find the approved/stamped PDF consent forms on their protocol page and should use the approved stamped forms to obtain written consent from participants.

Informed Consent

As indicated in federal regulations for protection of human subjects (45 CFR part 46), investigators must obtain informed consent of the human subject or the subject's legally authorized representation.

For protocols at expedited or full board review levels, documented informed consent will consist of a written electronic consent form approved and stamp dated by the IRB and then signed and dated by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form. The signed consent forms shall be kept in the investigator's secured

and protected files. (Participant signed consent forms should be maintained by the investigator for 3 years.)

Informed consent is more than just getting participants to sign a form. It is a ***process*** that involves giving participants enough information so that they understand the research and its risks. The goal of the informed consent process is to provide sufficient information so that participants can make informed decisions about whether or not to originally participate in a study or to continue participation.

The process starts when investigators enroll participants in a study and is ongoing throughout the research project. Obtaining consent involves informing participants about their rights, the purpose of the project, the procedures that will occur during the study, and the potential risks and benefits of participation.

The informed consent document must be written in language easily understood by the participants (no higher than an 8th grade reading level). Additionally, participants must be given sufficient time to consider whether or not they will agree to participate. Within the process of informed consent, investigators must minimize the possibility of coercion or undue influence.

For participants not fluent in English, the consent process and document must be presented in a language (preferably native) understandable to them. If it is expected that participants who do not speak English will be enrolled in a study, translated documents should be made available.

Elements of Informed Consent – See https://www.hhs.gov/ohrp/regulations-and-policy/guidance/checklists/index.html

- A statement that the study involves research
- An explanation of the purposes of the research
- The expected duration of the subject's participation
- A description of the procedures to be followed
- Identification of any procedures which are experimental
- A description of any reasonably foreseeable risks or discomforts to the subject
- A description of any benefits to the subject or to others which may reasonably be expected from the research

- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
- An explanation as to whether any compensation and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained.
- Research, Rights or Injury**:** An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled

Additional Elements as Appropriate

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable.
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
- Any additional costs to the subject that may result from participation in the research
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
- A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.

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. 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 representatives with sufficient opportunity to consider whether or not to participate and that minimizes 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 parent's 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 parent's 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 in the case where 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[13] 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. They must be told that they can stop at any time without penalty. Each participant must provide informed consent prior to participation. The person who signed the consent form must be given a copy as a reference of the information conveyed.

A "short form" may sometimes be approved for the consent.[14] 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 alternative method to document consent may only be considered if:

[1313] Federal Policy Sec. 46.117

[14] Federal Policy Sec. 117(b)(2)

(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[15]

Furthermore, especially in studies which involve the collection of sensitive information (for example about 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[16]

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.

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 on 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

[15] Federal Policy Sec. 46 116(d)
[16] Federal Policy Sec. 46 117(c)

releases or appears to release the investigator, sponsor, institution, or their agents from liability for negligence.[17]

Application Procedures

IRB applications are forwarded to members of the IRB. While the IRB attempts to be as responsive as possible to all investigators, it may not be possible 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.

When an expedited review is appropriate, the IRB Administrator will assign the application to an IRB member for his or her's independent review. If that IRB member and the Chair agree, that an expedited review is permitted, the IRB Administrator will so inform the investigator and notify the IRB at its next meeting. If the reviewers do not agree on an action, the protocol will be considered ineligible for expedited review and will be placed on the agenda for the next meeting.

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 modification, 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 IRB Administrator may communicate these initial decisions via notification in Mentor 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,

[17] Federal Policy Sec. 46 116.

appropriate procedures must be used to minimize any risks, and the potential benefits of the research must outweigh the potential risks.

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.

How long does IRB approval last?

The duration of approval will be stated in the certificate of approval (i.e., electronic notification) from the IRB to the investigator. IRB approval of research is always for a limited period of time not to exceed one year from the date at which the research was approved. Principal investigators will receive electronic notification of pending expiration of IRB approval approximately one month before approval ends. This notification requires the investigator to submit a study termination report. The IRB chairperson reviews that report and sends electronic notification that the report has been accepted and the study has been closed for IRB purposes, specifying the date of closure.

What if my study ended?

The IRB will need a study termination report to be submitted in the Mentor system.

Requests for Extension

If the research extends 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 deadline of funding agencies. The IRB is not obligated to send a reminder notice to the investigator about this requirement.

Continuing Review is a federally mandated re-evaluation of an approved study that is required to be conducted at least once per year. Research projects determined to be Exempt or Expedited do not require continuing review. Otherwise, continuing Review is required until the Principal Investigator has completed all research-related interactions and interventions with participants or when the collection and analysis of identifiable private information, as described in the IRB-approved research protocol, has been completed.

Reporting Changes to an Approved Application

Modifications

Investigators are responsible for ongoing requirements in the conduct of approved research. This includes obtaining prior approval from the IRB for any modifications of the previously approved research before implementing the proposed modification.

Changes that require IRB approval include:

- Change in the Number of Participants
- Consent Document Changes
- Funding Changes
- Personnel Changes
- Protocol Changes
- Recruitment Changes
- Study Site Changes

Making modifications to your current study may require additional changes to study procedures or to the study documents in Mentor, including the protocol, consent form, and recruitment materials. Only one Modification may be under review at any time (except changes in study personnel). Multiple changes may be bundled into one Modification submission. Minor modifications to approved research may undergo expedited review. More substantial modifications, especially those that change the risk-to-benefit ratio, may require review by a fully convened IRB which typically takes longer to process. Plan carefully if you bundle changes so as to not delay the review of a change that could be done under expedited review.

Documentation

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 modifications 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.

Mandatory Reporting

During the course of a research study, Unanticipated Problems Involving Risk to Subjects or Others and Non-compliance may occur and need to be reported to the IRB.

What must be reported to the IRB?

- Risk: Information that indicates a new or increased risk, or a safety issue.
- Protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm.
- Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm.
- Any changes significantly affecting the conduct of the research.

- Harm: Any harm experienced by a subject or other individual(s) that, in the opinion of the investigator, is unexpected and related or possibly related to the research procedures. Harms can include psychological, economic, legal, and other non-physical harms.

- Death of a Research Participant

- Reportable Non-compliance: Serious and/or continuing non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB that causes harm, increases the risk of harm, adversely affects the rights or welfare of participants or undermines the scientific integrity of the data, or an allegation of such non-compliance. Examples of Reportable Non-compliance include, but are not limited to, the following:

    - Human subjects research conducted without IRB approval.
    - Research personnel do not obtain written consent or assent for a study.
    - Enrollment of participants before IRB approval has occurred and/or after IRB approval has lapsed.
    - Continued treatment of participants after IRB approval has lapsed.
    - PI enrolls a participant that does not meet all of the inclusion/exclusion criteria. The criteria that were not met puts the participant at risk of harm.

    - Enrollment of children, prisoners, pregnant women and fetuses, without prior IRB approval.
    - Use of an unapproved consent form.
    - Use of unauthorized study personnel to conduct study procedures, obtain informed consent, or have access to identifiable participant information.
    - Assessment for any inclusion/exclusion criterion was not done prior to beginning of study procedures.
    - A procedure, treatment, or visit specified in the protocol is conducted outside of the required time frame and has clinical consequence; poses risk of harm to subject or others; and/or is thought to be impactful to the scientific integrity of the study.

- Researcher Error: Failure to follow the protocol due to the action or inaction of the investigator or research staff.

- Confidentiality: Breach of confidentiality, data breach, or data incident. For example:
    - Sharing identifiable information with a study sponsor or non-IRB authorized personnel
    - Sending communications to incorrect individuals (i.e. sending addressed recruitment letters to the wrong patient)
    - Misplacement/lost fully executed consent forms containing participant name

- Incarceration: Incarceration of a subject in a study not approved by the IRB to involve prisoners.

- Complaint: Complaint of a subject that cannot be resolved by the research team.

What should I do if I leave Touro University?

If you are planning to leave Touro University, you must notify the IRB Office. You may decide to transfer responsibility of your research to another Touro University researcher, close your research at Touro University prior to your move, or transfer IRB oversight of your research to another IRB. Regardless of which option you choose, you will need to develop a plan for transfer and a plan for informing research participants of your move if appropriate and how it affects them. IRB administrative staff will be able to advise you on what actions you will need to take.

Additional Information and Next Steps

As a final reminder, it is requested that all researchers inform the committee when their research has been completed. Additionally, we ask that researchers submit a copy of any paper or article which results from the study.

OPERATIONAL GUIDELINES

TOURO NY IRB - INSTITUTIONAL REVIEW BOARD

ARTICLE I. Name

The name of the committee shall be the Touro University NY Institutional Review Board (hereafter referred to as "TouroNY-IRB")

ARTICLE II. Objectives and Overall Goal

A. The object of the TouroNY-IRB activities is to ensure compliance with and fulfillment of 1) the policies contained in this document outlining the research protocol review for investigators and 2) All regulations and laws relating to the governance of the TouroNY-IRB, which have been promulgated by the United States, the State of New York, Touro University and its University System and any other appropriate governing authorities.

B. The TouroNY-IRB is charged with oversight of human subject research and review and approval of project applications involving human subject research.

ARTICLE III. Members

A. The membership of the TouroNY-IRB shall consist of no less than five (5) persons.

B. The members shall be appointed at the recommendation of the TouroNY-IRB Chair and approved by the Senior Vice President for Research Affairs. In making appointments to the TouroNY-IRB, reasonable efforts will be taken as necessary to achieve committee members who represent diversity in race, sex and professional qualifications.

C. At a minimum, to assure diversity, the membership of the TouroNY-IRB shall include, where possible:

1). Members whose primary concern is in the scientific areas, and;
2). Members whose primary concern is in a non-scientific area, and
3). At least one person who is not otherwise affiliated with Touro College and who is not a member of the immediate family of a person affiliated with the institution who may properly represent the community.

D. The TouroNY-IRB committee members will be appointed at the beginning of the academic year. A member may be reappointed for an unlimited number of terms.

E. If, for any reason, a member is unable to complete a full term of membership, the Chair may request the Chair of the academic department and / or Dean of the School where the retiring member came from to propose another member.

Article IX. Officers

A. The Senior Vice President for Research Affairs of Touro University and its University System shall appoint a Chair of the TouroNY-IRB. The Chair may be reappointed for an unlimited number of terms.

B. The Chair may recommend a Vice-Chair, who shall preside over meetings in the absence of the Chair. The appointment of the Vice-Chair must be approved by the Senior Vice President for Research Affairs. The Vice- Chair may be reappointed for an unlimited number of terms.

C. The Chair, or in the Chair's absence, the Vice-Chair may perform the duties prescribed by these guidelines.

D. Ex-Officio members of the Board may be recommended by the Chair, with the approval of the Senior Vice President for Research Affairs as appropriate. Attendance at meetings will be by invitation.

E. Other individuals may be appointed to carry out the activities of the TouroNY-IRB.

F. The Chair and Vice-Chair shall be members of the TouroNY-IRB.

Article V. Meetings

A. The TouroNY-IRB shall ordinarily meet at least once a month. The time, date, and place of the meeting shall be determined by the Chair or the Chair's designee and each member shall be notified in writing of the meeting schedule.

B. The Chair may call a meeting at another time, other than the scheduled monthly interval to handle any matter before the TouroNY-IRB. Each member shall be notified in writing of this special meeting.

C. A majority of the full membership of the TouroNY-IRB shall constitute a quorum which shall include at least one member whose primary concerns are non-scientific.

D. Determination of a quorum shall be subject to the following exceptions:

1). A number of members and alternates equal to a majority of the membership shall constitute a quorum;
2). Ex-officio members of the TouroNY-IRB shall not be counted toward the establishment of a quorum.

ARTICLE VI. Decisions of the TouroNY-IRB

A. Decisions by the TouroNY-IRB shall be by majority vote of members in attendance at the meeting. A member having significant conflicting interest in a matter before the TouroNY-IRB shall voluntarily recuse him/herself and shall not vote on that specific matter. When a member is restricted from voting because of a conflicting interest, said member shall not be counted in determining the number of votes needed for a majority, notwithstanding that the presence of said member has been counted to determine a quorum at the start of the meeting. Such member who has voluntarily recused him/herself due to a significant conflict of interest shall be officially absent from the room or the conference call or the internet conference meeting during both the deliberation and the vote.

B. Ex officio members shall have no voting rights on the TouroNY-IRB.

C. Voting shall proceed openly, after an opportunity for full presentation, discussion and debate, has been afforded. The Chair may call for a vote after he/she feels a full debate has occurred and all key issues have been discussed.

D. Business may be conducted by telephone or a video teleconferencing method with a majority of the TouroNY-IRB or its subcommittees in the meeting, even if it is conducted by alternate technology.

E. All of the business of the TouroNY-IRB shall proceed regardless of the methodology of the meeting whether in person or virtual (phone or video teleconference).

ARTICLE VII. Subcommittees

A. The Chair may, from time to time, appoint subcommittees or ask members to execute various duties related to the objectives and policies of the TouroNY-IRB including but not limited to the following:

1). Assisting the Chair in preparation of the agenda for regular meetings of the TouroNY-IRB

2). Performing periodic ongoing review of investigations previously reviewed by the TouroNY-IRB or any of its subcommittees, including review of terminated investigations;

3). Reviewing research proposals to determine whether such proposals may obtain expedited review by a subcommittee;

4). Performing expedited review of research proposals;

5). Assisting the Chair in reviewing modifications of previously approved research projects to determine whether such modifications warrant reconsideration of projects for action by the TouroNY-IRB or a subcommittee;

6). Reviewing reports of adverse and/or unexpected developments in previously approved research projects to determine whether such developments warrant reconsideration of a project by the TouroNY-IRB or a subcommittee;

7). Performing emergency review of research proposals when, in the opinion of the Chair, the employment of any other approval procedure may, because of the time required, seriously impair the mission of the University or the medical or other interests of any subject or potential subject of research;

8). Granting final approval to research proposals, upon a determination that conditions required for approval by the TouroNY-IRB or a subcommittee have been met.

9). Continuous improvements of documents, processes and systems used by the TouroNY-IRB.

B. Subcommittees shall be composed only of TouroNY-IRB voting and non-voting members .

C. Subcommittees may be comprised of any number of TouroNY-IRB members including the Chair;

D. Subcommittees will take minutes of all meetings and shall report any recommendations as well as any actions taken at the next regular meeting of the TouroNY-IRB.

ARTICLE VIII. Action on Research Proposals

A. The TouroNY-IRB or any of its subcommittees shall review research proposals submitted to it and shall periodically conduct ongoing review of approved research projects.

B. Considerations will be given during the approval process by the TouroNY-IRB to determine the review frequency for the study.

C. The TouroNY-IRB may appoint a subcommittee to review amendments to and continuing reviews of projects approved by the Board. Such delegated review shall be deemed to be the review of the TouroNY-IRB upon report to and approval by the TouroNY-IRB.

D. The TouroNY-IRB may delegate review of research proposals which fall within the categories for expedited review as listed by the United States Department of Health and Human Services to a subcommittee established pursuant to the establishment for subcommittees listed in this document.

E. The TouroNY-IRB may delegate authority to one or more experienced members of the TouroNY-IRB to review research proposals to determine whether such proposals may be exempted from obtaining TouroNY-IRB or subcommittee approval. Such determination will be submitted to the TouroNY-IRB.

F. The TouroNY-IRB may delegate authority to the Chair or Vice-chair to review and approve certain kinds of research proposals which involve no more than minimal risk to the subject(s) or involve minor changes in previously approved proposals. Such review and approval may be conducted by the Chair or by one or more experienced members of the TouroNY-IRB designated by the Chair or Vice-Chair.

Article IX. Participation of Non-Members

A. The meetings of the TouroNY-IRB may be attended by persons who are not members with the consent of the Chair. A person who is not a member of the TouroNY-IRB shall, with the consent of the Chair, be permitted to express views or opinions and offer comments, explanatory or otherwise to the TouroNY-IRB.

B. Consultants with competence in special areas may also be invited to assist in the reviews and research issues which require expertise different from that available on the Board. All consultants are invited to participate with the consent of the Chair.

Article X. Procedure for TouroNY-IRB Meetings

A. The members of the TouroNY-IRB shall be furnished with advance copies of the agenda for its regular meetings.

B. The agenda shall be prepared by the IRB Administrator appointed for that purpose.

C. In addition to review of research proposals not delegated to a subcommittee for expedited review, the agenda shall include the following:
    1. Review of the minutes of the previous TouroNY-IRB meeting;
    2. Review of any other minutes as requested by a TouroNY-IRB committee member or the Chair;
    3. Review of previously approved research projects which have been modified or of the report of the subcommittee appointed to review such modifications;
    4. Review of previously approved research projects in which unanticipated difficulties have occurred or of the report of a subcommittee appointed to review such projects and difficulties;
    5. Ongoing review of previously approved projects or of the report of a subcommittee appointed to review such matters;
    6. Review of the report of any subcommittee appointed to perform expedited review;
    7. Review of the report of any subcommittee appointed to perform an emergency review;
    8. Review of terminated projects or of the report of subcommittee appointed to review such projects;
    9. Such other matters as the Chair or any member shall consider appropriate although the final decision rests with the Chair.

D. Whenever, in the opinion of the Chair and a majority of the members and alternates constituting the quorum of a meeting, delay in making a decision on a research proposal which will seriously impair the mission of the TouroNY-IRB, the University or the medical or other interests of a subject or potential subject of research, a decision may be reached on the proposal notwithstanding that the proposal has not been placed on the agenda.

Article XI. Minutes

A. The Chair or Chair's designee shall prepare, or cause to be prepared, minutes of each meeting. Minutes shall be made available to each member of the Board.

B. The Chair or Chair's designee shall preserve, or cause to be preserved, an archive of the minutes of the meetings through physical or digital means.

Article XII. Amendments

Amendments to these guidelines may be proposed by any member of the Board. The amendment may therefore be officially adopted by majority vote.

The Touro University New York's Policies and Procedures Manual for the Protection of H
Iuman Subjects was drafted (July 1, 2023) and finalized (January 19, 2024).

IRB Administrator	Date: January 22 2024
IRB Chairperson	Date: JANUARY 22, 2024
Senior Vice President of Research Affairs	Date: 01/24/2024