

The University of Scranton



Department of Occupational Therapy and Physical Therapy

Department Review Board Guidelines

Approved _____
Date

IRB Chair _____
Margarete Lieb Zalon, Ph.D.

The Department of Occupational Therapy and Physical Therapy (OT/PT) has been granted permission to establish a Department Review Board for the protection of human research participants by the University of Scranton Office of Research Services (ORS) and the Institutional Review Board (IRB). The Occupational Therapy/Physical Therapy Department Review Board (OT/PT DRB) reviews research proposals submitted by Department of OT/PT faculty/professional staff, students and other entities requesting collaborative research relationships with the Department of OT/PT and/or its faculty, professional staff and/or students.

The purpose of the OT/PT DRB is to safeguard the rights and welfare of all human participants in research conducted under the auspices of the Department of OT/PT at the University of Scranton. Research involving animal subjects does not come under the charge of the OT/PT DRB and must be submitted for review to the Institutional Animal Utilization and Care Committee (IAUCC).

The purpose of the OT/PT DRB is accomplished through the assurance that research approved by the OT/PT DRB exposes participants to no more than minimal risk (IRB Policies & Procedures Section 5.02 & 5.03) and that subject confidentiality (Appendix C – HIPAA Compliance) is strictly maintained. The OT/PT DRB follows all the policies and procedures established by the University of Scranton ORS and IRB. The ORS and IRB shall be the final authority on any issue that cannot be resolved by the OT/PT DRB or exceeds its mandate. The IRB Policy and Procedure Manual shall be used to identify any policies and procedures not found in the OT/PT DRB Guidelines.

Introduction

Department of OT/PT faculty, professional staff members, and students are actively engaged in human research that assesses the effect(s) of various occupational and physical therapy interventions, professional practices and educational methods. These interventions may include, but are not limited to, the use of physical agents, therapeutic exercise, purposeful activities and occupation-based activities, and other health-promoting modalities and methods.. In addition, research is carried out to assess the effects of various disease processes, developmental disorders and traumatic conditions. Moreover, research conducted by faculty, professional staff members, and students may qualitatively and/or quantitatively examine the nature and meaning of occupation and activity.

The types of research normally conducted in the Department of OT/PT may include, but are not limited to: tests and measures of musculoskeletal, neuromuscular and physiological functions, integumentary/anthropometric characteristics, as well as physical, psychological and social functions that underlie the development or redevelopment of occupational role performance that fall within the respective scopes of practice for licensed Occupational Therapists and Physical Therapists within the Commonwealth of Pennsylvania. Additionally, the consequences of educational practices, professional standards and policies may be studied to determine their effectiveness and acquire normative data.

The methods used may include experimental, quasi-experimental, methodological, developmental, correlation, historical, surveys, case studies/reports and other appropriate methods of research.

All research conducted by faculty, professional staff, students and others collaborative partners will have a Department of OT/PT faculty sponsor. All Department of OT/PT faculty/professional staff members are licensed Occupational or Physical Therapists, trained in assessment procedures and are well qualified to assess risk and insure that proposed research does not expose the human participants to risk beyond that encountered by patients, clients and students in everyday life.

The OT/PT DRB members will use the *Guide for Physical Therapist Practice*, 2nd. ed. (APTA, 2003), the *Guide to Occupational Therapy Practice*, 2nd ed.(AOTA, 2008), *The Occupational Therapy Practice Framework*, 2nd ed. (AOTA, 2008) and the *ACSM Guidelines for Exercise Testing and Prescription*, 6th. ed. (American College of Sports Medicine, 2000) as references for determining the extent of risk involved in occupational and physical therapy interventions and research protocols.

Ethical Standards

All research conducted in the Department of OT/PT by its members or under its sponsorship at another location must be reviewed by the OT/PT DRB, its designated reviewer, the IRB or IAUCC as deemed appropriate.

The OT/PT DRB is guided by established ethical principles involving the use of humans as research subjects. These principles, which are included in the IRB Policy and Procedure manual, have been set forth by the *National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research*.

The guides for the establishment of these principles are:

The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research [*The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979, 2001*].

Protection of Human Subjects [*Code of Federal Regulations – 45 CFR, revised November 13, 2001*].

The Guide for Professional Conduct and Code of Ethics [*American Physical Therapy Association, 23314 – 1488*].

The Guiding Principles are:

- Respect for persons

- Informed consent
- Beneficence
- Assessment of risks and benefits
- Justice
- Equitable selection of subjects

Membership

The Department of OT/PT Chair will annually appoint a full-time faculty member or the Director of Clinical Education (DCE) to chair the OT/PT DRB. The appointment of the chair will normally occur at the beginning of the fall semester and continue for the duration of that academic year. Should it become necessary to replace the OT/PT DRB Chair during the normal period of appointment, the Department of OT/PT Chair will appoint a replacement within 10 days of the vacancy.

The OT/PT DRB Chair will annually appoint a minimum of (4) four additional OT/PT Department faculty to the OT/PT DRB: (2) two members from OT and (2) two members from PT. Should it become necessary for an OT/PT DRB member to be replaced during the normal period of appointment, the OT/PT DRB Chair will appoint a replacement within 10 days of the vacancy.

In addition, the OT/PT DRB Chair may appoint consultants, with expertise in areas not ordinarily possessed by the regular member of the OT/PT DRB, to review proposals and render opinions and/or recommendations. However, the expert consultants do not count as one of the minimum (5) five members of the OT/PT DRB and do not formally vote on the proposals they review.

The OT/PT DRB Chair, OT/PT DRB members and Form A reviewers are required to recuse themselves from review of any proposal in which they are listed as investigators or sponsors. In these cases the OT/PT DRB Chair will appoint a replacement from the alternate pool. If several members of the OT/PT DRB and alternate pool are listed as investigators or sponsors, making it impossible to attain a quorum, the proposal will be sent to the IRB for review.

Quorum

Attendance of a majority, but not less than (3) three, members of those eligible to vote constitutes a quorum.

A minimum of (3) three affirmative votes is required for approval of any proposal review by the OT/PT DRB. University IRB policy and procedures require that the vote of the DRB members present be unanimous. If not, the proposal must be sent to the IRB.

Meetings

OT/PT DRB meetings will be scheduled monthly during the academic year as needed. The OT/PT DRB Chair can convene meetings more frequently if the need arises. The dates, time and location of OT/PT DRB meeting as well as the dates of IRB meetings will be posted in a prominent and visible location in the Departments of Occupational Therapy and Physical Therapy. The OT/PT DRB Chair may call for a summer or intersession meeting if so desired, but is under no obligation to do so. Therefore, it is the responsibility of investigators to submit proposals to the OT/PT DRB *at least ten (10) days prior* to a regularly scheduled meeting. No assurances can be made regarding the availability of OT/PT DRB members for special meetings.

The OT/PT DRB Chair or a designee may review proposals covered under Form A without review of the full board. Reviews of Form A proposals should normally be completed and returned to the investigator(s) **WITHIN 10 (ten) days** of receipt. Results of Form A reviews will be documented by the OT/PT DRB Chair or designee and submitted to the IRB Administrator within 10 days of a decision. Form B proposals require full review by the OT/PT DRB and all proposals covered under Form C must be submitted by the investigator(s) directly to the IRB and are subject the IRB Policies & Procedures.

Records

Documentation of DRB actions will include:

- Names of principal investigator(s), mentor(s), and/or sponsor(s) if applicable,
- Title of the protocol,
- Type of application – e.g., faculty research, faculty led course assignment, student conducted course assignment, student independent research, etc.,
- Course number if applicable,
- Category - Form A or Form B,
- Results of review, and
- Evidence that all investigators (faculty, students, and research assistants) have completed an approved human subjects education program in accordance with IRB guidelines.

Procedure for Submission of Applications to the PTDRB

Potential investigators should:

- Obtain a copy of the OT/PT DRB Guidelines from the OT/PT DRB Chair or Department of OT/PT Chair.
- Read the guidelines very carefully.
- Complete Form A or Form B with the accompanying application and documentation including the Informed Consent Form to be used.
- Submit 5 (five) copies of the Form B application to the OT/PT DRB Chair at least ten (10) days prior to a regularly scheduled OT/PT DRB meeting (meeting dates will be

posted at the beginning of each semester) or request a special meeting *in writing* to the OT/PT DRB Chair for a meeting that is more than one month from a regularly scheduled meeting (there is no assurance that special meetings can be scheduled, so plan accordingly), or submit 2 (two) copies of the Form A application and documentation to the OT/PT DRB Chair at least 10 (ten) days prior to the requested decision date.

Procedures for Review

Unanimous agreement of the OT/PT DRB members eligible to vote at a meeting is required for approval of a Form B application.

Form A applications may be reviewed as noted above.

Actions

The OT/PT DRB may:

1. Approve the application
2. Request specific changes and resubmissions by the investigator(s) for further review
3. Notify the investigator(s) of concerns the OT/PT DRB has concerns regarding the proposal and request that it be sent to the IRB in accordance with their policies and procedures
4. Notify the investigator(s) that the application does not meet the criteria for a Form A or Form B application and must be submitted on Form C directly to the IRB

Activities Excluded from OT/PT DRB Review

Applications must be submitted directly to the IRB for research:

- Involving risk to human subjects beyond everyday life (IRB Policies & Procedures Section 5.03)
- To be submitted for external funding or support
- Involving any vulnerable subjects (IRB Policies & Procedures Section 7.02, Appendix C), except for the use of pre-existing data with no identifiers
- Involving deception (IRB Policies & Procedures Section 5.05)
- Requiring waivers of any part of the informed consent (IRB Policies & Procedures Section 7.07.03), unless approval authorization is granted by the IRB for specific circumstances
- To be conducted by an investigator(s) from outside of, but involving, the University
- For which the IRB provides notice to the investigator(s) or department that the IRB is exercising its oversight responsibility and requires IRB review and approval
- For which an investigator(s) requests IRB review in addition to, or in substitution for, the departmental review process, even if this activity falls within the OT/PT DRB guidelines

Appendix A: Definitions

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

Investigators – All persons who contribute significantly to the design and implementation of a study protocol.

Research Assistant – Individuals who contribute to the implementation of a study. This includes interaction with subjects and/or access to subject data. Research assistants do not participate in the design and development of the study protocol.

Human Subject – A living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or the collection of identifiable private information.

Anonymous – Surveys, questionnaires, interviews, public observations, and pre-existing data are anonymous when no identifiers are recorded anywhere in the investigator's records, so that no individual can be connected with her/his responses or data.

Confidential – Information about research subjects that is collected and coded in a manner that only allows the investigator(s) to be able to connect the data with the subject.

Deception – Not informing subjects of all the aspects of a study so that the subject is not able to give full informed consent. Blinded studies are examples of deception.

No Risk Beyond Everyday Life – Defined in federal regulations as minimal risk. The probability and magnitude of harm or discomfort in the research are not greater in and of themselves than those ordinarily encountered in daily life or the performance of routine physical or psychological examinations and tests.

Appendix B: Categories of Review

Form A – Research involving Anonymous surveys/interviews/public observations/pre-existing data with no risk beyond everyday life.

Form B – Research involving no risk beyond everyday life and use of experimental procedures (other than surveys) or recording the identity of participants.

Form C – Research involving risk beyond everyday life, deception, and or vulnerable participants.

Appendix C: Vulnerable Participants

- Children – Minors under the age of 18 years of age
- Prisoners
- Mentally Disabled
- Pregnant women, fetuses, and neonates

Appendix D: HIPAA Compliance

HIPAA is an abbreviation for the Health Insurance Portability and Accountability Act, passed by Congress in 1996. Any research conducted under the auspices of the University of Scranton is subject to the HIPAA regulations. Private health information is defined as individually identifiable health information which is created or received by a health care provider, health plan, or health care clearinghouse. Such information relates to the past, present, or future physical health, mental health or condition of an individual. Private health information either identifies or could be used to identify the individual and has been transmitted or maintained in any form or medium (electronic, paper, and oral). Health information which includes identifiers is subject to the regulations contained in the privacy rule.

Information is considered de-identified if identifiers are removed and if the remaining health information could not be used alone, or in combination, to identify a subject. Identifiers are:

- names
- geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code and equivalent geocodes, except for the initial five digits of a zip code to 000
- all elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death, and all ages over 89
- telephone numbers
- fax numbers
- electronic mail addresses
- social security numbers
- medical record numbers
- health plan beneficiary numbers
- account numbers
- certificate/license numbers
- vehicle identifiers and serial numbers including license plate numbers
- device identifiers and serial numbers
- Web Universal Resource Locator (URL)
- biometric identifiers, including finger or voice prints
- full face photographic images and any comparable images
- internet protocol address numbers
- any other unique identifying number characteristic or code

Appendix E: Elements of Informed Consent

In clear and non-technical language which is appropriate to the subject, subjects must be informed of:

- the fact that the study is research
- the purposes of the research
- the expected duration the subject's participation
- the procedures to be followed
- any reasonably foreseeable risks or discomforts
- any benefits to the subject or to others which may reasonably be expected from the research
- appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject
- the extent, if any, to which confidentiality of data and privacy of subjects will be maintained
- for research involving more than minimal risk, whether any compensation and whether any medical treatments are available if injury occurs
- whom to contact for answers to pertinent questions about the research, subjects' rights, and 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.

When appropriate, one or more of the following elements of information shall also be provided to each subject:

- 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;
- The approximate number of subjects involved in the study.

Exculpatory language may not be included in any informed consent (oral or written). Subjects or their representatives cannot be made to waive or appear to waive any legal rights, or release or appear to release the investigator, sponsor, institution, or agents from liability for negligence.

Guidelines Approved by the IRB

Date

Signature of IRB Chair