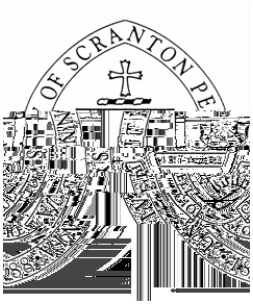
The University of Scranton



Department of Occupational Therapy and Physical Therapy

Department Review Board Guidelines

Approved _____ IRB Chair _____

Date 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 confidentially(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.

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),

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-

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.

Appendix A:

Appendix C: Vulnerable Participants

Children – Minors under the age of 18 years of age

Prisoners

Mentally Disabled

Pregnant women, fetuses, and neonates

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 alternat

Guidelines Approved by the IRB

Date	**Signature of IRB Chair**