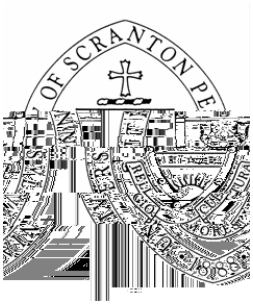
The University of Scranton



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-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 lesl >>BDCD ( )Tj EMC ET /Span <6/TT2 1 Tf 0 -2.32 TD ( )Tj EM

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: 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 4(n i)1(o)-8(C t)-2hnse so t s(g)10(i)-22(ous)]TJ (ous)]TJ (ou

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**