Northland Community and Technical College

IRB HUMAN SUBJECTS RESEARCH REVIEW PROTOCOL

PART I. Cover Sheet.

Original Submission ____ Proposal Modification: ____ Renewal: ____

IRB USE ONLY

Date Received: ________ Approval Date: _________ Protocol Number: ________
Signed ____________________ Reapproval Date: ______________

This application is to be submitted to and approved in writing by the IRB prior to the initiation of any investigation involving human subjects, data or material.

A. Principal Investigator

Name: ____________________________ Title: ____________________________
Department/Program: ____________________________ Telephone: ______________

Sponsor (if PI is a student):

Name: ____________________________ Title: ____________________________
Department/Program: ____________________________ Telephone: ______________

Project Title: _______________________________________________________________

Beginning Date: ___________ Ending Date: ______________

Parts II and III of the protocol must be completed in detail for board review. Please submit either six copies for review or an electronic version that has all signatures on it. Attach all relevant materials.

D. Statement of assurance: I/we have read the Northland Community and Technical College Policies and Procedures for Research Involving Human Subjects, and will comply with the informed consent requirement. Further, I/we will inform the IRB if significant changes are made in the proposed study.

_________________________ __________________________
Signature of PI Date Signature of Sponsor Date
Part II DESCRIPTION OF STUDY

A. Research question. Beginning on a second page, provide a brief statement of the question(s) being asked and the supporting rationale. For example: "The study is designed to determine if conformity is related to perceptions of group strength. This project is based on the social impact theory of group influence which suggests that social influence will increase as a function of perceived 'strength' among the group members. Perceived strength in this study is being defined by the expertise of the members." Notice that the statement is brief and expresses not only the research question but the theoretical rationale behind the question. Some projects will undoubtedly require a bit more explanation, but a complete literature review is not necessary for IRB review purposes.

B. Hypothesis(es). Provide a clear statement of the research hypothesis(es) as related to the rationale and theory behind the study. For example: "Higher levels of conformity will be observed for groups that have undergone a preliminary cohesion enhancement." Stating hypotheses in the null form is of little help to reviewers.

C. Subject Selection.

1. Number of subjects:
2. Human subject pool:
   a. Describe relevant features of the subjects you will be using (e.g. sex, race, or ethnic group; age range; general state of mental and physical health; etc.).
   b. Note the relevant affiliations of your subjects (e.g. institutions, hospitals, general public, etc.).
2. If human subjects are children, mentally incompetent, or other legally restricted groups:
   a. Explain the necessity of using these particular groups.
   b. Describe any special arrangements to protect their safety.

D. Procedures.

1. Describe your recruitment procedures and any material inducements given for participation.
2. Note the location of the study. Be as specific as possible.
3. Describe all personnel, including names and affiliation with NCTC (and any other relevant affiliations).
4. Describe the information to be gathered and the means for collecting and recording data. If previously collected data is to be used, describe both the previous and proposed uses of these data.
5. Provide a step by step description of everything subjects will be asked to do in your study.
6. Note the title and source of instruments (i.e. personality scales, questionnaires, evaluation blanks, etc.). Include copies of original instruments.
Part III HUMAN SUBJECTS PROTECTION

A. Potential Risks you can anticipate for subjects.

1. Describe immediate risks, long term risks, rationale for the necessity of such risks, alternatives that were or will be considered, and why alternatives may not be feasible.
2. Describe any potential legal, financial, social or personal effects on subjects of accidental data disclosure. Though the potential for disclosure may be extremely remote, if a fire or bombing exposed your data, how would it affect subjects?

B. Expected benefits for subjects (if any) and/or society:

The IRB is required to insure that the potential risks to subjects (however minimal) are clearly justified by the potential benefits of the research both to the subjects and to the current state of theoretical knowledge on the topic. You can assist this process by providing a statement clarifying the potential for new knowledge resulting from the study as well as any benefits directly to the subjects. Stating that "more research is needed on this topic" will be of little help. Please explain why more research will be a benefit.

C. Deception used in gathering data.

Justify and support the use of deception in the project, particularly if subjects are being provided with any untruthful or misleading information. Realize that not providing complete information is minimally deceptive. Provide a detailed written description of the debriefing process.

D. Safeguarding Subjects' Identity.

1. What uses will be made of the information obtained from the subjects? What elements of your project might be openly accessible to other agencies or appear in publications?
2. What precautions will be taken to safeguard identifiable records or individuals? How will confidentiality of data be protected?

E. Informed consent.

Please refer to additional guidelines with respect to informed consent and sample consent forms if you have additional questions. Submit a copy of the consent form, survey questions, script for approaching candidates, and all materials used in the recruitment, selection and participation of subjects.

If the study involves children, the informed consent form must be signed by the child’s parent or guardian. However, the IRB usually requires that a second form be signed by the child as well, so that s/he understands as completely as possible the research which is being performed. This second form may be written in simpler language to match the age and understanding of the subjects.

When a signed consent form is required, a copy must be made available to the subjects. At the very least (e.g. when completion of the instrument serves as giving consent) subjects must be given a form identifying the researcher by name, address, and phone number, and including these statements:
Some researchers might meet this requirement by detaching the signature portion of the consent form and giving the rest to the subject. Others might print a separate card or sheet with the required information for distributing to subjects.

For simple surveys, written consent is not required.
CONSENT FORM
[Insert Title of Study]
[Insert NCTC IRB number]

You are invited to be in a research study of [Insert general statement about study]. You were selected as a possible participant because [Explain how subject was identified]. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

This study is being conducted by: [Name of PI, department (indicate College affiliation)]

Background Information
The purpose of this study is: [Explain research question and purpose in lay language]

Procedures:
If you agree to be in this study, we would ask you to do the following things:
[Explain tasks and procedures: subjects should be told about video or audio taping, assignment to study groups, length of time for participation, frequency of procedures, etc.]

Risks and Benefits of being in the Study
The study has several risks: First, [Risk]; Second, [Risk] (Risk must be explained, including the likelihood of the risk)
(If there are significant psychological risks to participation, the subject should be told under what conditions the researcher will terminate the study)

The benefits to participation are: [Benefit(s)] (If no benefits, state that fact here.)

Compensation:
You will receive payment: [Include payment or reimbursement information here.] (If subjects receive class points or some other token, include that information here. Explain when disbursement will occur and conditions of payment. For example, if monetary benefits will be prorated due to early withdraw.)

Confidentiality:
The records of this study will be kept private. In any sort of report we might publish, we will not include any information that will make it possible to identify a subject. Research records will be stored securely and only researchers will have access to the records. (If tape recordings or videotapes are made, explain who will have access, if they will be used for education purposes, and when they will be erased.)

Voluntary Nature of the Study:
Participation in this study is voluntary. Your decision whether or not to participate will not affect your current or future relations with the University of Minnesota [or with other cooperating institutions, insert names here]. If you decide to participate, you are free to not answer any question or withdraw at any time with out affecting those relationships.

Contacts and Questions:
The researchers conducting this study are: [Name of researcher] and [Name of researcher]. You may ask any questions you have now. If you have questions later, you are encouraged to contact them at [Location], [Phone number], [E-mail address]. (If the researcher is a student, include advisor’s name, telephone number and e-mail address here.)
If you have any questions or concerns regarding this study and would like to talk to someone other than the researcher(s), you are encouraged to contact [Name of Dean], [Title of Dean] or David Christian or , the Co-Chairs of the Institutional Review Board. These people may be reached at Northland Community and Technical College, 2022 Central Ave NE, East Grand Forks, MN, 56721, (218) 773-4635 or Northland Community and Technical College, 1101 Highway One East, Thief River Falls, MN 56701, (218) 681-0701.

You will be given a copy of this information to keep for your records.
Statement of Consent:

I have read the above information. I have asked questions and have received answers. I consent to participate in the study.

Signature:_____________________________________________________ Date: ________________

Signature of parent or guardian:____________________________________ Date: ________________
(If minors are involved)

Signature of Investigator:_________________________________________ Date: ________________
INFORMED CONSENT

I. General Requirements.

No investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

- A. Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:
  - 1. A statement that the study involves research, an explanation of the purpose(s) of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
  - 2. A description of any reasonably foreseeable risks or discomforts to the subject;
  - 3. A description of any benefits to the subject or to others which may reasonably be expected from the research;
  - 4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
  - 5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
  - 6. For research involving more than minimal risk, an explanation as to whether any compensation is provided 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;
  - 7. 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; and
  - 8. 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 to receive for participation up to point of their termination.
B. Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

- 1. 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.
- 2. Anticipated circumstances under which the subjects' participation may be terminated by the investigator without regard to the subjects' consent.
- 3. Any additional costs to the subject that may result from participation in the research.
- 4. The consequences of the subject's decision to withdraw from the research, and procedures for orderly termination of participation by the subject.
- 5. 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.
- 6. The approximate number of subjects involved in the study.

C. The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

- 1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
  - (i) programs under the Social Security Act, or other public benefit or service programs;
  - (ii) procedures for obtaining benefits or services under those programs;
  - (iii) possible changes in or alternatives to those programs or procedures; or
  - (iv) possible changes in methods or levels of payment for benefits or services under those programs; and
- 2. The research could not practicably be carried out without the waiver or alteration.

D. The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

- 1. The research involves no more than minimal risk to the subjects;
- 2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- 3. The research could not practicably be carried out without the waiver or alteration; and
- 4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
• E. The informed consent requirements in these regulations are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

• F. Nothing in these regulations is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.
Institutional Review of Human Subject Research Conducted at Northland Community and Technical College

All research involving human subjects at NCTC must have prior approval of the Institutional Review Board. This includes research conducted by employees and students of NCTC and outside researchers. The scope of the Institutional Review Board's (IRB) charge is broad. Generally, any College research that uses humans, human tissue, surveys of human subjects, or human subjects' records requires IRB review, irrespective of its funding source.

Scope of review

IRB review and approval is required for any research involving human and live animals subjects that:

- is conducted by College faculty, staff, or students;
- is performed with or involves the use of facilities or equipment belonging to the College;
- involves college students, staff, or faculty;
- satisfies a requirement imposed by the College for a degree program or for completion of a course of study; or
- is certified by a dean or department head to satisfy an obligation of a faculty appointment at the College, including clinical or adjunct appointments.

Research conducted by students--the faculty responsibility

Independent class projects, research projects, and similar exercises must be independently submitted to the IRB by the student-researcher. However, when students conduct research as part of a course of study, a faculty member ultimately is responsible for the protection of the subjects, even if the student is the primary researcher and actually directs the project. Advisers shoulder the responsibility for students engaged in independent research, and instructors are responsible for research that is conducted as part of a course.

During the design of a project, advisors and faculty members should instruct students on the ethical conduct of research and help them prepare applications for IRB approval. In particular, students should:

- understand the elements of informed consent,
- develop a readable consent form
- plan appropriate recruitment strategies for identifying subjects,
- establish and maintain strict guidelines for protecting anonymity and confidentiality, and
- allow sufficient time for IRB review and completion of the project.

As assurance that the College's guidelines will be followed, the adviser or instructor is required to sign the student's application for IRB approval.
After IRB approval, faculty members should take an active role in ensuring that projects are conducted in accordance with the IRB's requirements. Meeting periodically with students to review their progress is one way to meet this responsibility.

**Research conducted in college courses**

Courses in research methods and class assignments that involve research with human subjects require IRB approval even if the class exercise does not seem to qualify as "true research": when, for example, the results are not intended for publication, will not advance work in another area, or will not contribute to generalizable knowledge. The IRB reviews research for risk assessment and provisions for informed consent.

**Full and Expedited Reviews**

Research projects that include children, human tissue, live animals,

Expedited Reviews include:

1. Collection of blood samples by finger, heel, or ear sticks, or venipuncture as follows:
   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.
   b. From other adult and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected

**NCTC-IRB Composition**

The IRB consists of six faculty members (a co-chair and two members from each campus), an administrator, and two outside members (for non-expedited reviews). Others may be invited in cases where it is warranted. These guidelines are based upon Federal guidelines guiding IRBs (Penslar, 2001).
This application is to be submitted to and approved in writing by the IRB prior to the initiation of any investigation involving human subjects, data or material.

A. Principal Investigator: Justin Berry

Project Title: Incidence and Prevalence of Low Back Pain in Professional Orchestral Musicians

Beginning Date: 3/10/09   Ending Date: 3/10/10

Parts II and III of the protocol must be completed in detail for board review. Please submit five copies for review. Attach all relevant materials.

D. Statement of assurance: I/We have read the Northland Community and Technical College Policies and Procedures for Research Involving Human Subjects, and will comply with the informed consent requirement. Further, I/we will inform the IRB if significant changes are made in the proposed study.
A. Research question. This study will research the incidence and prevalence of low back pain in professional orchestral musicians. Although many studies have researched musculoskeletal disorders in professional musicians, no work has been performed on which instrumental musicians are more prone to low back pain.

B. Hypothesis(es). It is anticipated that musicians who sit for rehearsal, practice, and performance will have a higher incidence and prevalence of low back pain. For sitting musicians, it is anticipated that those musicians with a heavier instrument will have a higher prevalence and incidence of low back pain.

C. Subject Selection.

- 1. Number of subjects: Links to a survey on survey monkey will be sent to musicians in 50 professional orchestras throughout the U.S. and Canada.
- 2. Human subject pool:
  - a. Professional orchestral musicians

D. Procedures.

- 1. Describe your recruitment procedures and any material inducements given for participation. Each orchestra will be contacted regarding the study via phone and/or email. A link to the survey will be emailed to a contact at the orchestra with the link then forwarded to members of each orchestra.
- 2. 20 professional orchestras in metropolitan areas throughout the U.S. and Canada
- 3. Describe all personnel, including names and affiliation with NCTC (and any other relevant affiliations). Justin Berry, PT, DPT, MS, PTA Program Director
- 4. Describe the information to be gathered and the means for collecting and recording data. Incidence and prevalence of low back pain, number of hours of playing instrument per week, if pain has effected playing, and demographic information.
- 5. Provide a step by step description of everything subjects will be asked to do in your study. Complete survey
- 6. Note the title and source of instruments (i.e. personality scales, questionnaires, evaluation blanks, etc.). Include copies of original instruments. Included
Northland Community & Technical College

IRB HUMAN SUBJECTS RESEARCH REVIEW PROTOCOL
PART I. Cover Sheet.

Original Submission _____ Proposal Modification _____ Renewal ________

IRB USE ONLY

Date Received: ______ Approval Date: ______ Protocol Number: ______

Signed _________________________________ Reapproval Date: ________

This application is to be submitted to and approved in writing by the IRB prior to the initiation of any investigation involving human subjects, data or material.

A. Principal Investigator: ______ Justin Berry

Name

Program Director/Instructor

Title

Physical Therapist Assistant 218-793-2565

Department/Program

Telephone

Sponsor (if PI is a student):

Title

Department/Program

Telephone

Project Title: Interventions Performed By Physical Therapist Assistant Students During Clinical Education Experiences

Beginning Date: 3/15/09 Ending Date: 3/15/10

Parts II and III of the protocol must be completed in detail for board review. Please submit five copies for review. Attach all relevant materials.

D. Statement of assurance: I/We have read the Northland Community and Technical College Policies and Procedures for Research Involving Human Subjects, and will comply with the informed consent requirement. Further, I/we will inform the IRB if significant changes are made in the proposed study.

Signature of PI Date Signature of Sponsor Date
Part II DESCRIPTION OF STUDY

A. Research question. This study will study how often physical therapist assistant students perform and are educated on certain physical therapy interventions during their clinical education experiences. Questions will be asked regarding the following interventions: peripheral joint mobilizations, spinal mobilizations, and sharp instrument debridement.

B. Hypothesis(es). PTA Programs are no longer allowed to teach the psychomotor aspect of these interventions in the didactic aspect of their curriculum. At the same time, these interventions can legally be performed by PTAs in most states. It is assumed that the number of students performing these interventions will be low.

C. Subject Selection.

- 1. Number of subjects: Links to a survey on survey monkey will be sent to PTA Program Directors throughout the United States at accredited programs in states where these interventions are legal to perform.
- 2. Human subject pool:
  - a. PTA Students who are at least 18 years of age.

D. Procedures.

- 1. Describe your recruitment procedures and any material inducements given for participation. PTA Program Directors will be emailed the survey link and will be asked to email the link to their students during their final clinical experience during the Spring 2009 Semester.
- 2. Accredited PTA Programs within the United States
- 3. Describe all personnel, including names and affiliation with NCTC (and any other relevant affiliations). Justin Berry, PT, DPT, MS, PTA Program Director
- 4. Describe the information to be gathered and the means for collecting and recording data. Survey asking if students have performed and have been educated on certain physical therapy interventions.
- 5. Provide a step by step description of everything subjects will be asked to do in your study. Complete survey
- 6. Note the title and source of instruments (i.e. personality scales, questionnaires, evaluation blanks, etc.). Include copies of original instruments. Included
Justin Berry

Professional Presentations:

Interventions Performed by Physical Therapist Assistants: A Regional Survey on Perceptions and Clinical Practice. (Poster) Berry JW, Benson RJ, Bowden, RG
American Physical Therapy Association Annual Conference & Exposition, Baltimore, MD. 6/09

Injury Type and Incidence Among Elite Curling Athletes During the 2008 World Men's Curling Championship. (Poster) Berry JW, Romanick MA, Koerber SM
Canadian Academy of Sports Medicine Injury Prevention Symposium, Vancouver, BC, Canada. 6/09

Perceptions of Physical Therapist Assistant Program Directors on the Education and Clinical Role of the Physical Therapist Assistant. Berry JW, McCartney C
American Physical Therapy Association Combined Sections Meeting, Las Vegas, NV. 2/09

The Use of Iontophoresis for the Treatment of Peyronie’s Disease. Berry JW.
American Physical Therapy Association Combined Sections Meeting, San Diego, CA. 2/06

The Effect of T’ai Chi Chih on Balance in the Elderly (Poster) Berry JW, Johnson, B
American Physical Therapy Association Combined Sections Meeting, San Antonio, TX. 2/01

Continuing Education Courses Taught:

● Evidence-based Cervical, Lumbar, & Shoulder Stabilization (12 hours)
  Deaconess Health Care, Bozeman, MT, 4/09
  San Juan College, Farmington, NM, 10/08

● Introduction to Manual Therapy (12 hours)
  Taught individually
  Aurora BayCare Medical Center, Green Bay WI, 9/08
  Spooner Physical Therapy, Phoenix, AZ, 6/08
  North Iowa Area Community College, Mason City, IA, 4/08
  Williston State College, Williston, ND, 4/08
  Meriter Health System, Middleton, WI, 11/07
  Mountain View Physical Therapy, Great Falls, MT, 6/07
  Deaconess Health Care, Bozeman, MT, 4/07

● Co-taught with Jim Cenova, PT, MPT, OCS, Cert MDT
  Momentum Physical Therapy, Fort Collins, CO, 6/07

● Co-taught with Kirk Hayes, PT, MPT, Cert MDT
  Oregon Orthopedic PT Study Group, Portland, OR, 1/07
  Therapeutic Associates, Bend, OR, 11/06
  Spooner Physical Therapy, Phoenix, AZ, 8/06
  North Iowa Area Community College, Mason City, IA, 3/06
  San Juan College, Farmington, NM, 11/05
  Rehab Authority Boise, ID, 8/05
  Williston State College, Williston, ND, 3/05
  University of North Dakota, Grand Forks, ND, 2/05

● Co-taught with Eldon Johnson, PT, MPT, CSC
  Kootenai Medical Center, Coeur d’Alene, ID, 10/06