

Institutional Review Board

Minutes of Regular Meeting

February 24, 2004

Members present: Brad Chase (School of Business), Bernadette Maldonado (Staff Rep.), Donald J. McGraw (Administration), Fr. Ron Pachence (Arts & Sciences), Jacqueline Rychnovsky (Graduate Student Rep.), Allen Snyder (School of Law) Annette Taylor (Chair, Arts & Sciences, Psychology Department).

Members Absent: Jane Georges (School of Nursing), Daniel Martinez (Undergraduate Student Rep.), Mary Scherr (School of Education).

1. Announcements/Minutes:

- The minutes of January's meeting were approved, 7-0-0, with the following modification to the 2nd full paragraph, 2nd sentence of page 3: "...from one standard of review to two."

2. Summary Reports, Continuation Reports, Modifications Pending and Approved, Full-Reviews, and Other Business:

A. Summary Reports:

None submitted.

B. Continuation Approvals:

None submitted.

C. Modifications Pending and Approved:

None submitted.

D. Expedited Review Actions:

2004-01-020

Dr. Cheryl Getz Fac Educ

"Learning to Lead: Knowledge and Awareness Gained in an Undergraduate Experiential Course."

Approved: 1/28/04

E. Exempt Reviews:

2004-02-021

Dr. Rick Olson Fac Engr.

"Pilot Study of the Effect of Pre-Lecture Reading on Student Learning."

Approved: 2/5/04

2004-02-022

Dr. Sue Lowery Fac Biol.

Ms. Diolinda Parsick Associate PI Biol.

"Science Survey for Current and Future K-6 Educators."

Approved: 2/6/04

F. SDSU/USD Joint Doctoral Program Reviews:

SDSU/USD Joint Doctoral Program

Michanne Hctor Doc Educ SDSU

Dr. Dana Grisham Fac Educ SDSU

"Investigating Collaborative Professional Development in Technology for Literacy Teachers."

Approved: 1/27/04

G. Full Reviews:

2004-02-023

Ms. Julia Ann Smith Doc Nursing

"The Efficacy of School-Based Support Groups on Adolescent Self-Esteem."

Motion to approve pending modifications by Dr. Taylor, seconded by Fr. Pachence, 6-1-0 with the following required modifications:

1. You describe your study as a quasi-experiment but there is no obvious (quasi-)manipulation, only a longitudinal retesting of self-esteem. With this design you cannot rule out multiple alternative explanations for changes (i.e., life events, differences in group dynamics). Please clarify the design or justify the lack of comparison groups. If your findings cannot be attributed to participation in the group then you should not be subjecting your participants to additional testing. This would be a violation of human subjects protections.
2. You ask for information on ethnicity and gender in the demographic questionnaire but there is no justification for this in the background and purpose for the research. Are you filling a gap? Is there a reason for collecting this information in the literature? There is a risk that with a small enough sample a breach of confidentiality could occur based on this information.
3. Sample size: you have not specified anywhere in the proposal your desired sample size, whether you are basing that sample size on quantitative needs for statistical power, availability of participants, or perhaps qualitative procedures. Please provide information on anticipated sample size and rationale.

Other modifications:

1. It appears that all 'group' members will be given the opportunity to participate in this study. Please clarify, and if not, please discuss any need for compensatory measures.
2. Please provide reliability and validity information for the measures you will be using, as well as permission to use.
3. Federal guidelines are that you must keep your data for 5 years in a safe and secure location, not just until the completion of the study.
4. What are you going to do with extremely low scores on the assessment measures, scores which might indicate immediate danger of damage to self (or others)? Clearly there are items on both measures that suggest such potential. Given your role as an employee of the school district, aside from your role as researcher, you need to provide a plan for dealing with that potential situation. Delineate whether there is a confidentiality issue from this perspective and what the guidelines would be for informing, or not, the parents. This should also be addressed in the consent and assent forms.
5. You need to include the standard language when working with children about needing to report any abuse information that might disclosed during the study.

6. A bibliography should be included with the proposal.
7. Assent & Consent forms:
 - a.) Make the Assent form, as you did the Consent form, in second primarily in person.
 - b.) Indicate on both forms the amount of time to complete all questionnaires (it is currently only on the Consent form).
 - c.) Make it clear that counseling will be available should the students become distressed on filling out the forms, or should you discover a need for such a referral based on assessment scores.
 - d.) Time frame for keeping data is 5 years.
 - e.) Make the Assent consistent with the Consent and change 'ethnicity' to 'ethnic background'.
 - f.) Change the contact paragraph, second sentence to read, "This study has been reviewed and approved by the University of San Diego's Institutional Review Board, Dr. Donald McGraw, administrator (619-260-4553).
 - g.) Remove the date of birth from the signature lines on the Consent and Assent forms.
 - h.) On the Consent form remove the word 'medical' from the first line, second paragraph, so it reads, "There are no known risks..."
 - i.) Clarify on the Consent form that the parents are to keep one copy, sign and return a second copy.
8. On the Demographic Data sheet the Date of Birth is an obvious identifier. Unless there is a specific reason, which you should elaborate in the proposal, replace with "Age."
9. You may want to change from using names to coded participant numbers. This will assure greater confidentiality and may increase the comfort level for your participants.

H. Other Business:

- Dr. Taylor reported on the status of Board action in response to the new IRB Policy amendment put into effect by the Fall 2003 Senate (see minutes of 1-20-04). She stated that a meeting took place in late January between Dr. Lazarus, herself, Dr. McGraw, and Dr. Schneider. Dr. Taylor stated that, as a result of that meeting and on the advice of Dr. Lazarus, she contacted Dr. Beth Dobkin, Chair of the University Senate, in order to discuss placing a Board motion on the Senate agenda for spring to amend the IRB policy amendment. Dr. Dobkin agreed to put the Board's motion on the Senate agenda. Dr. Taylor is in the process of creating the final draft of this motion and plans to distribute it to the Board for review upon completion. Dr. Taylor cautioned the Board that Fall Senate IRB policy amendment becomes governing policy in June if the Board's motion is not on the Senate floor for action well in advance of the semester's conclusion.

I. Adjournment:

- The meeting was adjourned at 1:30 pm.

Respectfully submitted,

Bernadette Maldonado
IRB Staff Representative/IRB Administrative Support