

Effective Date: May 14, 2008

To: SDSU Faculty

From: Human Research Protection Program

Re: Student Use of Existing Data – IRB Review Process

The IRB recently revised the submission and review process for student research that specifically involves use of data collected under an IRB approved protocol(s). This pertains only to SDSU students working in an SDSU research center, laboratory or institute.

Rationale: A student research assistant (RA) involved in the collection of human subjects data and/or with valid access to coded data associated with your IRB approved study may request access to the data for use in a thesis or dissertation. Presently, the student completes an “Existing Data” protocol for IRB verification of the exempt status. The SDSU IRB recently reviewed this process and determined that it was not responsive to federal regulations and proposed the following changes to enhance compliance and streamline existing procedures.

Revision: In lieu of the student submitting a separate protocol for use of existing data, the principal investigator of the primary study will modify his/her protocol to include the student’s proposed analysis.

1. Principal Investigator submits a modification to the primary study protocol.
2. Modification includes a brief description of the student’s research question, plan for data analysis, study title, student’s name and email contact information.
3. Upon IRB approval of this amendment, correspondence will confirm approval for the student’s use of data from the primary study. This documentation can be used by the student to enroll in 799A.

There are several advantages for faculty mentors. By modifying an approved protocol to permit the student’s use of existing data, the investigator will no longer be asked for a letter of authorization allowing access to the data nor be asked to review and sign the Faculty Sponsor Assurance form to verify the student’s work complies with federal, institutional and departmental policies. Another advantage is that the protocol modification documents all student research activity within the protocol rather than in separate documentation under the student’s name.

Please note: All research assistants should presently be listed in the approved protocol. To update this list, go to the “Personnel Changes” section of the modification form and provide a summary of the student’s responsibilities, qualifications and relevant experience.

If you have any questions pertaining to this correspondence, please contact the IRB office at 619-594-6622 or irb@mail.sdsu.edu.