

	Policy: Conduct of Human Subjects Research by SPHHS Students Without Prior IRB Approval
	Approved by: Kimberly Horn, Associate Dean of Research
	Date: 1/21/14

Rarely, the SPHHS Dean’s Office becomes aware of research involving human subjects being conducted by students without IRB review, approval or exemption. Student investigators or their faculty advisors/instructors may report to the IRB or the SPHHS Dean’s Office themselves about unapproved human subjects research in which they are involved. Alternatively, reports may be received from chairs, faculty, staff, subjects, and anonymous persons. Reports may be communicated verbally or in writing. Once the Dean’s Office receives such a report, the Associate Dean of Research (or designee) will promptly contact the academic advisor/instructor and the student investigator to discuss the reported concerns. At this point, SPHHS will require that the student investigator and advisor/instructor immediately suspend the research while the situation is assessed. The Associate Dean of Research also will inform the Director of the IRB (or designee in the case of the IRB Director’s absence) to request an assessment, and will keep the IRB, as well as the relevant department chair(s), aware of reports and results of the discussions with the advisor/instructor and the student investigator.

If the IRB Director determines that no infraction of institutional IRB policy has occurred, no further action will be taken. When the advisor/instructor, student investigator and Associate Dean for Research are so notified by the IRB in writing, the work on the project will be allowed to resume. If the IRB Director determines that an infraction of institutional IRB policy has occurred, the Associate Dean for Research will request that the advisor/instructor, student investigator, and the relevant department chair(s) be notified in writing by the IRB of the actions that must be taken. Depending on the outcome of the assessment, a number of possible actions might be taken by SPHHS, ranging from capitalizing on teachable moments to students, to steps to assure that the research is in compliance with institutional IRB policies, to discontinuing the research in question.

If the research has been completed, or if the IRB has determined that the research may not move forward, or if the student and the advisor/advisor *do not plan* to continue the research, the student and the advisor/instructor are required to document as fully as possible the research that was conducted without IRB review. This documentation is submitted to the Associate Dean for Research within 7 days of notification, and should include: (a) a description of the procedures that were followed; (b) the number of subjects studied; (c) results of the study (if known); and (d) the reason(s) that IRB review/approval was not originally sought. The information will be forwarded to the IRB Director for review including applicable attachments, such as surveys, consent forms, interview or focus group questions, a listing of variables obtained, etc.

If the IRB determines that it is possible for the research to go forward and both the student and the advisor/instructor want to apply for IRB approval for the research, the SPHHS will permit the student (with advisor/instructor approval) to submit a protocol to the IRB within 7 days of notification. Once a protocol is received and reviewed by the IRB, it will be processed in the usual manner. If an **exemption is granted** the study may resume. When a protocol requires **expedited or full review**, it will be reviewed within the normal IRB timelines. It is the position of SPHHS that **data collected prior to IRB review, regardless of the subsequent determination, should not be disseminated in scholarly publications or presentations outside of GW. However, if the IRB determines that the particular student project at issue does not constitute human subjects research or is exempt, any data that was originally collected and intended for purposes other than generalizable knowledge (e.g., within a GW course or classroom context) may be used for those purposes only.**

Acknowledgment: This policy was adapted from the Office of the Institutional Review Board | The University of Texas Health Science Center. Refer to: <http://research.uthscsa.edu/irb/withoutreview.shtml>.