1. What is a “human subject”?

The Code of Federal Regulations at 45 CFR 46.102(f) defines “human subject” as “a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.”

2. What is “human subjects review”?

“Human subjects review” is an institutional and governmental required evaluation of certain proposed projects and investigations to ensure their compliance with ethical standards for the protection of human research subjects by treating them humanely, maintaining their dignity, and preserving their rights. Federal, state and university regulations require that the use of human subjects in research be reviewed and approved by an Institutional Review Board. See http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm for federal regulations and http://www.regent.edu/academics/academic_affairs/faculty_handbook.cfm for the Regent University policy on the Protection of Human Subjects in Research. Presently, Regent is using school-based Human Subjects Review Boards (“HSRB” or “Board”) for this purpose.

3. What is considered “research”?

The Code of Federal Regulations at 45 CFR 46.102(d) defines “research” as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”

4. Does my study require review?

If you are a faculty, staff, or student at Regent University and your research involves the use of human subjects (either directly or through records or other data) and you intend to externally disseminate the results (e.g., via publication, presentation, grant application, etc.) then your research requires human subjects review.

5. What about course assignments that involve surveys or other contact with human subjects?

Assignments which are part of normal, typical coursework that are not intended for dissemination are not required to undergo HSRB review; however, faculty are responsible for informing students of proper procedures regarding the conduct of such research and for monitoring the work done by students. Human subjects data collected in such class assignments may not be used in future publications or presentations. There will be no ex post facto approval of such activities to legitimize turning these studies into approved human research.

6. What about program or institutional improvement surveys or similar efforts?

Surveys or other data collection efforts for the purpose of program or institutional improvement and are not intended for dissemination are not required to undergo HSRB review; however, such efforts must be conducted in an ethical manner that includes appropriate participant protections. Human subjects data collected in such internal improvement efforts may not be used in future
publications or presentations. There will be no ex post facto approval of such activities to legitimize turning these studies into approved human research.

7. Does all research go through the same review process?

The depth of the review process is dependent upon the type of research that you are proposing. HSRB reviews are classified as exempt, expedited, or full board review. Each of these categories requires a submission to the Human Subjects Review Board, although the review time and procedures vary.

8. How do I know in which category (exempt, expedited, full) my application belongs?

The HSRB application has a checklist to help you determine in which category your application belongs, although the HSRB will review your submission and make the final determination of the application type. The criteria used to determine exempt review are found in 45 CFR 46.101 and expedited review in 45 CFR 46.110. These are available online at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm.

9. How do I begin the review process?

Complete a Human Subjects Review Board Application form online and submit it to your school’s Human Subjects Review Board Chair (details at www.regent.edu/irb). Be sure to include all relevant information (grant proposals, consent forms, questionnaires, test instruments, advertisements, debriefing statements, contact letters, etc.) in accordance with the requirements of your research category. If you are a student working under the guidance of a faculty member (e.g., sponsored research, thesis, or dissertation), you must secure the approval of your faculty advisor before submitting your application to the board.

10. What will happen to my application?

When the Human Subjects Review Board receives your application, it will examine your proposal to determine whether it warrants exempt, expedited, or full board review. After completing the review process, the HSRB will reply with a letter of approval, request for further information or revisions, or a letter of rejection. The Board reviews the proposed purpose, procedures, and subject populations to be used and determines if the benefits of the activity outweigh the risks to subjects. Issues considered in this analysis include ensuring that risks to the subjects are reasonable in relation to anticipated benefits, selection of subjects is equitable, informed consent is properly sought and documented, adequate preparation is taken to protect the privacy and confidentiality of subjects, and adequate provisions are made for the ongoing monitoring of the subjects’ welfare.

11. Is a research request ever denied?

Yes. If the HSRB determines that the risks of a proposed activity outweigh the benefits or that the proposed research is not in alignment with the guidelines found in 45 CFR 46 for the protection of human subjects in research, it will reject the application. However, in most situations, the HSRB will present the concerns to the researcher and provide an opportunity for modifications rather than simply denying the request.

12. How long does this process take?
The estimated review timeframes are one week for exempt reviews, two weeks for expedited reviews, and one month for full board reviews.

13. When can I begin data collection?

You will receive a letter from the Board responding to your application, and you are required to wait for approval before beginning any research.

14. How do I change my research after it has been approved?

You must notify the HSRB if you wish to change your research. You can make minor and administrative changes by submitting a written summary describing the proposed changes. Substantial changes in the focus, procedures, or subject population of the research may require submission of a new or revised application.

15. How long is approval valid?

Approval is good for one year. If you will be collecting data after the one-year anniversary of your approval, you will be required to submit a renewal request using the HSRB Application to secure an additional twelve-month extension. You may repeat this process for as many years as necessary just as long as you don’t substantially alter your original research request.

16. Do I need to submit anything to the HSRB after the research has been completed?

Yes; please submit a final report using the Research Final Report form at www.regent.edu/irb.

17. Is training available?

Yes, the Regent University HSRB website (www.regent.edu/irb) has information about online training as well as additional resources related to human subjects in research. In addition, the National Institutes of Health Office of Extramural Research offers free self-paced online training at phrp.nihtraining.com. You must complete human subjects research training prior to submitting an application.

18. Whom do I contact if I have more questions?

If you have additional questions, please contact your School’s Human Subjects Review Board Chair, the Chair of the University Human Subjects Review Board Committee, or the HSRB website at www.regent.edu/irb.