The University of North Carolina at Chapel Hill abides by federal rules governing the research process. One of the fundamental requirements is the use of an Institutional Review Board or IRB for all research involving human subjects. This document explains in general terms what is meant by research and human subject research, when and why a proposal needs to be reviewed, and how the process specifically works at the School of Government. For further information please see the home page for the UNC Office of Human Research Ethics at https://research.unc.edu/offices/human-research-ethics/index.htm.

**What is research?**

For purposes of this discussion, research is gathering and analyzing information to be used to increase general knowledge, such as data that are analyzed and discussed in an article and published in academic journals or presented at conferences. An example of research would be a study of performance measurement use in North Carolina counties presented at the annual conference of the Association for Budget and Financial Management or legal research for publication in the Harvard Law Review. It is not work for individual SOG clients or client groups when that information is not intended to be used for wider dissemination. That would usually be considered consulting or advisory work. An example of consulting or advisory work would be an evaluation of an animal control program for Alamance County, analyzing various court administration statistics for the Administrative Office of the Courts, or legal analysis of new statutes for N.C. public health lawyers. Later, however, if there is further analysis with the goal of publishing a paper in an academic journal, the work from that point is considered research.

**What is human subject research?**

In general, human subject research is research that gathers private personal information on or about individuals. Examples would include a person’s income, health status, educational background, address, job experience, political views or family status. It is not research on a process or organization or that uses publically available information. Examples of research that is not considered human subject research would include paperwork requirements for purchasing land, performance measures for a department, the organizational structure of public health departments, the history of capital punishment, local crime statistics or individuals’ criminal records (because they are public information). If you ask people for factual information about these things, it is not human subject research – while you are gathering information from individuals, it is not about the individuals.

However, it is important to note personal opinions are always considered private personal information, and thus human subject research. Examples would include clients’ opinions about a reorganization of a public health department or citizen’s views of a police department. You can learn more about what qualifies as human subject research at http://research.unc.edu/offices/human-research-ethics/faq/general/index.htm.

**When does a research proposal need to be reviewed?**

SOG work or MPA research papers sometimes concern human subject research. Such research must be approved by the UNC Chapel Hill Institutional Research Board (IRB). When a proposal is first formally
submitted, the IRB contacts Tom Thornburg, Senior Associate Dean at the SOG. The proposal must be approved by Thornburg as the official representative of the SOG before it will be even considered by the University level IRB. To simplify Dean Thornburg’s task, the SOG has an internal pre-review IRB committee to help students and faculty assure they are complying with campus policy. Maureen Berner (Acting Chair), Willow Jacobson, and Leisha Dehart-Davis currently compose this committee. If you think you have a project or proposal that involves human subject research, you should contact one of these faculty members. In addition, the proposal will need to be reviewed by Georgia Allen, Assistant Dean for Information Technology, for any data security considerations. The proposal will need to be pre-reviewed by the internal SOG committee and Dean Allen, and recommended for approval by both to Dean Thornburg, before it can be considered by the central campus IRB.

Student papers written for MPA courses are normally not subject to IRB review; however, if a student intends to extend the course work so it can be eventually used in a publication, the student should consult with the SOG IRB.

**Why does human subject research need to be reviewed?**

The review process exists to ensure risk to participants in human subject research is minimized, and that participants are fully informed of risks and benefits and still consent to participate. It also guarantees participants are aware of their rights before, during and after participation. In the end, however, the IRB process sets a high standard for ethics in research, a standard the SOG and the University are required, and proud, to uphold.

**Why is there a separate pre-review for data security?**

In addition to human subject research issues, there is heightened campus interest in data security. Everyone on campus is required to annually acknowledge familiarity with data security steps. There may indeed be personal liability to students and employees for failing to follow data security requirements. For students that may mean an Honor Court charge; for employees that may mean discipline up to dismissal. In any particular research proposal, there may be data security issues. IRB review of each proposal culminates in a statement about security measures that will be required for the research project. When those requirements are known, security issues can be addressed. Georgia Allen, the School’s Assistant Dean for Information Technology, will help students and employees understand how to meet data security requirements through the pre-review stage and with any remaining questions as a result of University level IRB review. We recommend the student going over the rest of the proposal with a member of the IRB committee first before going to Dean Allen for her data security approval. Everyone at the University is expected to be current and comply with data security procedures.

**How does the internal pre-review IRB process work at the School of Government?**

The main University IRB process is entirely on-line. The information page and the entry point can be found at [http://research.unc.edu/offices/human-research-ethics/online-submission/index.htm](http://research.unc.edu/offices/human-research-ethics/online-submission/index.htm). The following are the typical steps in the process:

1. If not already certified, the primary researcher, called the principal investigator, and any other research team members, complete on-line ethics training at UNC, obtaining certification.
Training information is found at http://research.unc.edu/offices/human-research-ethics/researchers/training/index.htm. Researchers must be certified before the University IRB will approve a proposal. If a student is the primary researcher on a paper, the name of a faculty advisor will need to be listed on the IRB form. This advisor will need to have completed the UNC IRB on-line training as well, or have provided proof of certification from another university.

2. The researcher composes a proposal in the online proposal submission tool, but does not formally submit the proposal.
   1. The researcher should send Berner a pdf of the proposal and provide electronic copies of any attachments.
   2. Berner, or some other combination of the committee, reviews the proposal and provides feedback for improving the chance of approval.
   3. If needed, the researcher makes changes in the on-line proposal system (still not submitting it at this point) and sends Berner a revised pdf of their proposal. The researcher also sends a PDF to Allen for review regarding data security issues.
   4. This back and forth review process continues until the SOG pre-review committee and Allen are willing to recommend to Thornburg the proposal be approved. At that point, Berner and Allen contact Thornburg with their recommendation for approval. The researcher is cc’d on those messages or has otherwise confirmed Berner and Allen recommendation for approval.
   5. The researcher formally submits the proposal online.
   6. Thornburg receives a message from the University IRB requesting his approval of the proposal. In line with the SOG pre-review committee and Allen recommendations, he will approve the online submission.
   7. The IRB will review the full proposal, and contact the researcher with information on approval or changes needed.
   8. From this point, the researcher works directly with the University IRB Committee.
   9. The SOG pre-review committee is available to assist with any additional questions.

If you have any questions regarding IRBs, please contact Professor Maureen Berner at mberner@sog.unc.edu.