Whether you need to submit to the IRB hinges on the federal definition of “research.” “Human subject” and “principal investigator” are also important terms to understand. The PBPL due date for IRB submission is 11/21/18.

**Research** is defined as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to **generalizable knowledge**” (45 CFR 46.102(d)). Activities which meet this definition constitute “research” for purposes of the federal regulations that protect human research subjects, whether or not they are conducted or supported under a program which is considered “research” for other purposes.

A **human subject** is defined 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” (45 CFR 46.102(f)).

A **principal investigator** is required to oversee a student project in a formal sense. The student must prepare all of the documentation (e.g., consent and data protection procedures, interview guides, etc.). Jim Leitzen, Chad Broughton, and Sorcha Brophy can all serve as principal investigators in the Public Policy Studies program.

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**Student thesis projects do not need review if the following criteria are met: 1) data only used for learning purposes (internal course paper and/or presentations) and not intended to create or develop generalizable knowledge; 2) thesis not intended to be made publicly available (e.g., published, deposited into a library), presented at a conference, or pursued in further projects; 3) participants are clear on intended purpose of work and use of data, and 4) a faculty member oversees the ethical conduct of project activities.**

**Examples of additional activities that *do not* need review:**

- Information gathering interviews with experts focusing on facts about things, products, or policies and with no information *about* individuals collected (e.g., opinions, interpretations). Please check with the SBS IRB office (sbs-irb@uchicago.edu) if unsure whether review is needed.
- Journalism, oral history, biography.\(^2\) Generally speaking, if a project is limited to interviews that are only intended to document a specific historical event or the experiences of

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\(^1\) Email correspondence with Cheri Pettey, Director of Chicago SBS IRB. This document has been reviewed and approved by SBS IRB.

\(^2\) The final rule explicitly removes a category of activities consisting of certain scholarly and journalistic activities from the definition of research and the scope of the regulations. This category of activities concerns certain activities in various fields that focus directly on *the specific individuals about whom information are collected*. As described above, this category is removed from the definition in order to resolve long-standing debate and uncertainty about whether these activities are considered research in the sense of the regulatory definition. We believe that these activities *should not* be considered research in the context of the Common Rule, and that making this explicit in the final rule will help to resolve the uncertainty. In these activities, the ethical requirement is to provide an accurate and evidence-based portrayal of the individuals involved, and not necessarily to protect them from public scrutiny. For example, a biographer might collect and present factual information to support the biographer’s opinion about the character of an individual to show that the individual does not deserve the positive reputation he or she enjoys in society. These fields of research have their own codes of ethics, according to which, for
individuals, the project would not be considered human subjects research because it is not designed to be generalizable beyond the individuals, have predictive value, or lead to development/testing of a hypothesis. However, if using oral history as a data collection method where data will be analyzed to create or develop generalizable knowledge, then review would likely be required.

• Class projects and research practicums whose purpose is to provide training in research methods as part of the overall educational mission of a program and are not designed to contribute to generalizable knowledge.4

Undergraduate research that does need review:

• Research with children, prisoners, or other vulnerable populations.
• Studies about individuals that are meant to test hypotheses or otherwise contribute to generalizable knowledge about categories or classes of subjects from individually identifiable information.
• Studies using identifiable data, interactions, and/or interventions with human subjects for external purposes like publication, adding to policy knowledge, or for pilot/development work for a larger research project.

Two examples: 1) a student who intends to present and publish an article for an external scholarly audience (e.g., a journal) and plans to continue using the data for academic study beyond the thesis process would need review, while 2) a student who uses only key informant (e.g., expert) interviews to gather information on a policy question and will not further use the collected data or present or publish their paper (aside from what’s required for the class grade and internal thesis requirement—i.e., not contributing to generalizable knowledge or using in future academic studies) would not need review.

Consult the sources below to learn more. To submit to the IRB, go to: https://aura.uchicago.edu. Please contact sbs-irb@uchicago.edu with any questions or for assistance determining if your project needs review. If you intend to pursue IRB approval, you must submit your materials (which can require a significant amount of time to complete) by 11/21/18.

Sources
• https://sbsirb.uchicago.edu/page/does-my-research-need-irb-review-0

example, consent is obtained for oral histories (https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html)

3 https://sbsirb.uchicago.edu/page/does-my-research-need-irb-review-0
4 However, if, for example, a student is involved in an activity designed to teach research methodologies and the instructor or student wishes to conduct further investigation and analyses in order to contribute to generalizable knowledge, the design of the project has changed such that it meets the above definition of research and requires IRB review, and the IRB must at that time review the research (https://sbsirb.uchicago.edu/page/does-my-research-need-irb-review-0)