



REGULATORY BASIS FOR DETERMINING NOT HUMAN SUBJECTS (UPIRB ONLY)

I. HUMAN SUBJECTS RESEARCH

The Institutional Review Board (IRB) has been charged with the responsibility of reviewing and overseeing human subjects research conducted under the aegis of USC. Therefore, the first question with respect to IRB review of a project is a determination of whether the project fits the definition of human subjects research. In light of the mission to protect human subjects who are involved in research and the potential regulatory consequences of not obtaining IRB review and approval, **the investigator should choose to err on the side of caution and consult the IRB when he/she is uncertain whether the study is human subjects research.**

DEFINING RESEARCH

Federal Regulations define **research** as “a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge¹” (45CFR46.102(d)). Research is usually described in a formal protocol that sets forth an objective and a set of procedures to reach that objective.”

“Research” generally does not include operational activities such as defined practice activities in public health, medicine, psychology, and social work (e.g., routine outbreak investigations and disease monitoring) and studies for internal management purposes such as program evaluation, quality assurance, quality improvement, fiscal or program audits, or marketing studies. It generally does not include journalism or political polls. However, some of these activities may include or constitute research in circumstances where there is a clear intent to contribute to generalizable knowledge.

DEFINING HUMAN SUBJECTS

A **human subject** is defined by Federal Regulations as “a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.” (45 CFR 46.102(f)(1),(2))

Intervention includes physical procedures, manipulations of the subject, or manipulations of the subject's environment for research purposes. **Interaction** includes communication between the investigator and the subject. This includes face-to-face, mail, and phone interaction as well as other modes of communication.

Identifiable private information² “includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation is taking place,” (such as a public restroom) “and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a health care record).” (45 CFR 46.102(f)(2)) “**Identifiable**” means the information contains one or more data elements that can be combined with other reasonably available information to identify an individual (e.g. name/address).

* In analyzing a particular activity, it is important to focus on what is being **obtained** by the investigators. If the investigators are not obtaining data through intervention or interaction with living individuals, or identifiable private information about the individual, then the research activity does not involve human subjects.

Observational studies of public behavior (including television and internet chat rooms) do **not** involve human subjects as defined when there is no intervention or interaction with the subjects and the behavior is **not** private. Also, studies based on data collected for non-research purposes may **not** constitute human subjects research if individual identities are not identifiable (e.g. data such as service statistics, school attendance data, crime statistics, or election returns).

Studies based on data that are individually identifiable but are also publicly available may **not** constitute human subjects research. However, the term “publicly available” is intended to refer to record sets that are truly readily available to the broad public, such as Federal census data, labor statistics, and health statistics. An investigator should **not** assume information qualifies as “publicly available” merely because it has been posted on an electronic website and can be accessed without authorization.

¹ "Generalizable knowledge" is information where the intended use of the research findings can be applied to populations or situations beyond the studied unit.

² Researchers must take caution since disclosure of private information may place the subjects at risk of criminal or civil liability and/or damage their financial standing, employability, or reputation.

II. GUIDANCE ON RESEARCH INVOLVING CODED PRIVATE INFORMATION OR BIOLOGICAL SPECIMENS

The Office for Human Research Protections (OHRP) does not consider research involving **only** "coded"* private information or specimens to involve human subjects as defined under 45 CFR 46.102(f) if the following conditions are both met:

1. the private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and
2. the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:
 - a. the key to decipher the code is destroyed before the research begins;
 - b. the investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased (note that the HHS regulations do not require the IRB to review and approve this agreement);
 - c. there are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; or
 - d. there are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.

This guidance applies to existing private information and specimens, as well as to private information and specimens to be collected in the future for purposes other than the currently proposed research.

***Federal regulations define "coded" as:**

Identifiable information (such as name and/or address) that is replaced with a number, letter, symbol, or combination thereof, that would enable the investigator to readily ascertain the identity of the individual.

If you wish to continue, specify a title for the project below then click the **Continue** button. Otherwise, click the **Back** button.

* Specify a title for this project: Contemporary change in small towns

I. Human Subjects Research Checklist

Human Subjects

1. * Does the study involve interaction or intervention with live human subjects?
Yes
(Though interaction or intervention may have occurred previously, specimen(s)/data/information were collected from live subjects. Cadavers, autopsy specimens or specimens/information from subjects now deceased is not human subjects).
2. * Is the collected information/data/specimen(s) obtained about the subjects?
No
3. * Is the collected information/data/specimen(s) private information? (Private is that which allows identity of individual to be associated with the information/specimen/data)
Yes

Research

1. * Is your study designed to produce generalizable knowledge?
Yes

2. * Is the study systematic? Follows step by step procedures organized according to interrelated ideas or principles evidenced by a research plan and objectives.
Yes

II. Coded Private Information or Biological Specimens

Research involving "coded" data or biological specimens is no longer considered human subjects research by the Office of Human Research Protection (OHRP) as defined under 45 CFR 46.102(f). Coded means there is a link that could allow data/specimen(s) to be identified with the individual from whom they were obtained. To qualify for this guidance, the link must not be available to the investigator. See the following for more information—
<http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>

1. * Is the collected information/data/specimen(s) received by the USC investigator linked (by a code) to the identity of the data/specimen?

No (Yes = the PI received the information/specimen with a link/code)
(No = the PI received the information/specimen without a link or code)

2. * Was the information/data/specimen(s) originally collected for the study being proposed?

Yes (Yes = the data/specimen was originally collected for the proposed study)
(No = the data/specimen was originally collected for another study)
(Maybe = not sure)

3. * Does the investigator have access to decipher the coded information/data/specimen(s)?

No (Yes = the investigator has access to the "key" and can readily link the information/specimen to the subjects)
(No = the investigator does not have access to the "key" and can not link the information/specimen to the subjects; or this question is Not Applicable).
(Maybe = not sure)

3. Study Description

Additional information (to determine whether or not your project qualifies as human subjects research or qualifies for special guidance on coded private information / biological specimen(s)):

- A. * Provide a brief (1 to 2 paragraph) description of the study in LAY LANGUAGE. This should not be a scientific abstract.

My dissertation will examine changes in small towns, as well as the cultural and environmental ramifications of these changes. I intend to refocus theories of urban change — typically focused on large cities — on small towns. To do this I must first create a literature that defines small towns both culturally and demographically. Using demographic data, as well as a review of popular media discussions of small town change, I will create a typology of contemporary small towns.

This typology will be the basis for a selection of seven small towns that I believe are representative of national change. My fieldwork will be conducted in these small towns, where I will use interviews, participant observation, content analysis, and landscape analysis to identify changes in both the form and character of these towns. The final, and most telling, aspect of my research will be to examine the conflicts resulting from these changes. Preliminary analysis suggests that these conflicts: over land use, economic vitality, and sense of community, are strongly tied to environmental and social concerns faced by many contemporary urban places.

- B. * Describe the subject population/type of data/specimens to be studied. (e.g. where and how were the data/specimens collected/obtained? What information besides the data/specimens itself is provided?)

I will be interviewing primarily elected officials for my research. I will also interview those employed in positions related to the town: town historian, the local newspaper editor, directors of chamber of commerce, etc.

I will not ask questions about the persons themselves, only about the town that I am studying: how has it changed in form (growing population, increased home construction, etc.) and character (more crowded, more metropolitan-feeling, etc.)

Participant observation will be at public meetings only. No private data will be collected on audience members. Landscape analysis involves the physical construct of the town, not its inhabitants.

C. * Provide a brief description of the design and methodology of the study.

The study will

- 1) define small towns through cultural representations (film, literature etc.)
- 2) define small towns through census data on "urban clusters"
- 3) create a typology of small towns through cluster analysis of census data and media content analysis (what subjects -- migration, the internet, etc. -- are the focus of newspaper articles on small towns)
- 4) use typology to select case study small towns (seven)
- 5) visit each small town and conduct interviews and reviews of local history to determine change and community reactions to these changes

D. Submit the survey or questions that the subjects will be asked (if applicable). This may be attached at the end of the application.

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