



Human Subjects Research and the Research Subjects Review Board

Exemption Determination

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Federal Regulations and Social and Behavioral Research



The Department of Health and Human Services (DHHS) and FDA regulations apply to research involving **human subjects**, but there are some categories of research that the regulations consider to be **exempt research**.

Policy 501: Levels of RSRB review



Protocol Initial Review

- Determine if project is **research***
- Determine if project meets definition of **human subject*** research
- Determine Investigator/University **engagement** level
- Can the research be approved as **exempt**

* by the federal definition



Does my project involve “RESEARCH”?



A project needs to involve **BOTH**

- A systematic investigation: a pre-planned study design including research development, testing and evaluation in the form of a protocol or study plan
- A contribution to generalizable knowledge: is knowledge that is expressed in theories, principles and statements of relationships that can be widely applied to our experiences and is usually created to share with others through presentations and publications and extended beyond a single individual or internal program

The assumption that academic publication or presentation equals research is incorrect.

Policy 301: RSRB scope and authority



What Is a Human Subject ?



Definition: a living individual about whom an investigator conducting research obtains:

- data through **intervention** (physical and manipulation) or **interaction** (communication or interpersonal contact with the individual), or
- **identifiable** private information*

*Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purpose by individual and which the individual can reasonably expect will not be public (e.g. medical, employment, and educational records)

Policy 301 RSRB scope and authority



What is and is NOT Human Subject Research?

Source Data (e.g. tissues/samples) was (or will be) collected by someone else for different purpose

Provided to PI by “gatekeeper” with no links or identifiers

Not Research involving human subjects (either prospective or retrospective)

Deceased Individuals

Research performed on individuals who have been declared legally dead and/or research involving the collection of tissues from deceased individuals is not subject to review and oversight by the RSRB.

Source Data (e.g. tissues/samples) was collected by someone else **OR** by the study team for different purpose

Provided to PI by “gatekeeper” OR someone on or associated with study team **with links and identifiers**

Research involving human subjects

Gatekeeper: individual not on the study nor associated with the study team of proposed project

Policy 301 RSRB scope and authority



Determinations of Research

1. Quality Improvement (QI) projects and Program Evaluations (PE)

These activities are intended to benefit the department, institution, organization or improve ongoing care or needs of patients as opposed to **contributing generating knowledge.**

2. Classroom projects

Aimed at replicating well-known effects to enable students to learn methods, or aim is inherently instructional rather than collection new knowledge. Intended to benefit students as opposed to **benefiting others or contributing generating new knowledge.**

3. Oral Histories projects

Uses method of gathering and preserving historical information through recorded interviews that gives a unique perspective on the topic at hand; a series of interviews offers a variety of particular perspectives on the topic and not routinely a **systematic investigation.**

4. Case Report or Case Series

Summary of clinical/educational data, including medical/social history and other relevant information for journals, abstracts or other publications. It is not the intent that the collection of information for case reports would constitute a **systematic investigation**

Policy 301: RSRB scope and authority



What determines UR investigator “Engagement” at UR?

- Obtain data about human research subjects through intervention or interaction with them;
- Obtain identifiable private information about human research subjects, through direct or indirect interaction;
- Obtain informed consent of human subjects for research;
- Conduct a clinical trial as defined in FDA regulations.
- Obtain funding for study

Policy 301: RSRB scope and authority



Activities that Do NOT involve UR investigator “Engagement”

- **Informing potential subjects** about research study (e.g., providing consent, contact info, or posting recruitment documents)
- Allowing another institution to **use UR facilities** for research
- **Obtaining private coded information** (data or specimens) of which the investigator is unable to ascertain identity.

Policy 301: RSRB scope and authority



Exempt Status Determination

RSRB considers **Regulatory** categories and **Institutional** standards.

- RSRB reserves the right to deny exemption requests if there is a concern for welfare of human subject

Exempt status determination

- “exempt “ from federal regulations NOT exempt from RSRB oversight and institutional policies

Minimal or No **RISK**

Research meets **one of six categories** of Exemption.

Policy 501: Levels of RSRB review



Most common of the Six Exempt Categories

Educational Research

- Typical settings of schools, colleges, teaching hospitals, etc.
- Normal education practices

Survey/interview/observational

- No children (unless public observation)
- Identifiable or Sensitive, not both

Secondary use of de-identified “and” pre-existing data

- De-identified none of 18 HIPAA obtained/abstracted
- Pre-existing data are “on-the-shelf” at the time the research is submitted to the RSRB

Policy 501: Levels of RSRB review (guidelines for determining exempt review)



Educational Exemption

- **Purpose:** Using qualitative methods the investigator seeks to investigate and explore what literacy identities students with learning disabilities construct and how the classroom contexts shape these identities.
- **Subjects:** 14 students (learning disabilities), 6 educational teachers.
- **Age:** Students: 11-14, Teachers: >18 yrs
- **Procedure:** Investigator will conduct classroom observations and take field notes all names will be removed. Teachers will complete interviews about experiences and interpretations for how schooling impacts students' literacy. Students interview questions focus on what literacy means to them and what is happening during the instruction in the classroom.
- ? Established educational setting, involving normal educational practices (instructional strategies, techniques, curricula, classroom management methods). May be applied to research involving children.



Survey/interviews/tests/observation

- **Purpose:** explore the views of single mothers' of 3-to 5 year old children about daily routines and b) to explore potential barriers and facilitators for establishing and maintaining healthy everyday routines as described by mothers themselves.
 - **Subjects:** 24 mothers >18yrs with a preschool child
 - **Procedures:** Focus group (6-8) interviews asking about their everyday activities with their child, challenges, what helps to maintain activities or changes that could be made. No personal identities will be collected from the mothers about their child or themselves.
- ? *Anonymous testing, surveys or interviews of adults; non-identifiable testing, surveys or interviews of adults if information is not sensitive nature; observation of public behavior with no manipulation by investigator*



Survey/interviews/tests/observation

- **Purpose:** to identify the causes of elevated rates of binge drinking in members of fraternities and sororities in order to develop intervention strategies and policy changes to reduce its prevalence in Colleges and Universities.
 - **Subjects:** members of nationally recognized Greek organizations at the University of Rochester. Approximately 30 students.
 - **Procedures:** Two observations will be conducted, a social event sponsored by a Greek organization at local bar, the second will be a Greek-sponsored special event that is open to the entire university community located on the campus. Students enrolled will be interviewed including personal questions, the Greek organization, and feelings about the use of alcohol.
- ? *Anonymous testing, surveys or interviews of adults; non-identifiable testing, surveys or interviews of adults if information is not sensitive nature; observation of public behavior with no manipulation by investigator or potentially damaging.*



Secondary Use of Pre-Existing data

- **Purpose:** is to conduct a secondary data analysis designed to examine the effect of cigarette smoking on the mean severity of 12 common cancer treatment-related side effects at post-treatment.
- **Subjects:** Records will be obtained from the database called URCC CCOP XXXX. A total of 950 individuals.
- **Duration:** collected between January 30, 2001 and September 13, 2002.
- **Procedures:** none of the 18 HIPAA identifiers will be received or a code to allow the information to be linked to the original dataset.
- **Outcomes:** findings of the research within the year as part of a Thesis for a Master's of Public Health degree. In addition, data from this project will serve as a foundation for the development of R01-funded intervention studies that will be designed to improve quality of life and outcomes in cancer subjects.

? Data already been collected (on shelf) at time of submission, no on-going collection.

Recorded/abstracted that subjects cannot be identified, directly or indirectly or through linked codes.



Secondary Use of Pre-Existing data

- **Purpose:** to examine the effectiveness of the Healthy Living Center's (HLC) weight management program in reducing mean weight loss and achieving clinical significant weight loss (<5% from baseline) for all of those who enrolled in the 6-month program.
- **Subjects:** data from 275 participants records will be reviewed.
- **Duration period:** between February 2011 and July 2012
- **Procedures:** The information will be identified and abstracted from HLC weight management program database maintained by the PI, and will include health related information but will not contain any individual identifiers.

? Data already been collected (on shelf) at time of submission, no on-going collection.

Recorded/abstracted that subjects cannot be identified, directly or indirectly or through linked codes.



Retaining Identifiers

- If you assign a subject number to each observation in the data set, but maintain a separate list linking that number to the subject's name or other identifying information, even temporarily, the data set is **NOT de-identified**, and not **Exempt**
- Linking 2 databases: **NOT de-identified**
 - test scores to school record
- Recording names or maintaining address for follow-up: **NOT de-identified**



Reminders: Secondary analysis

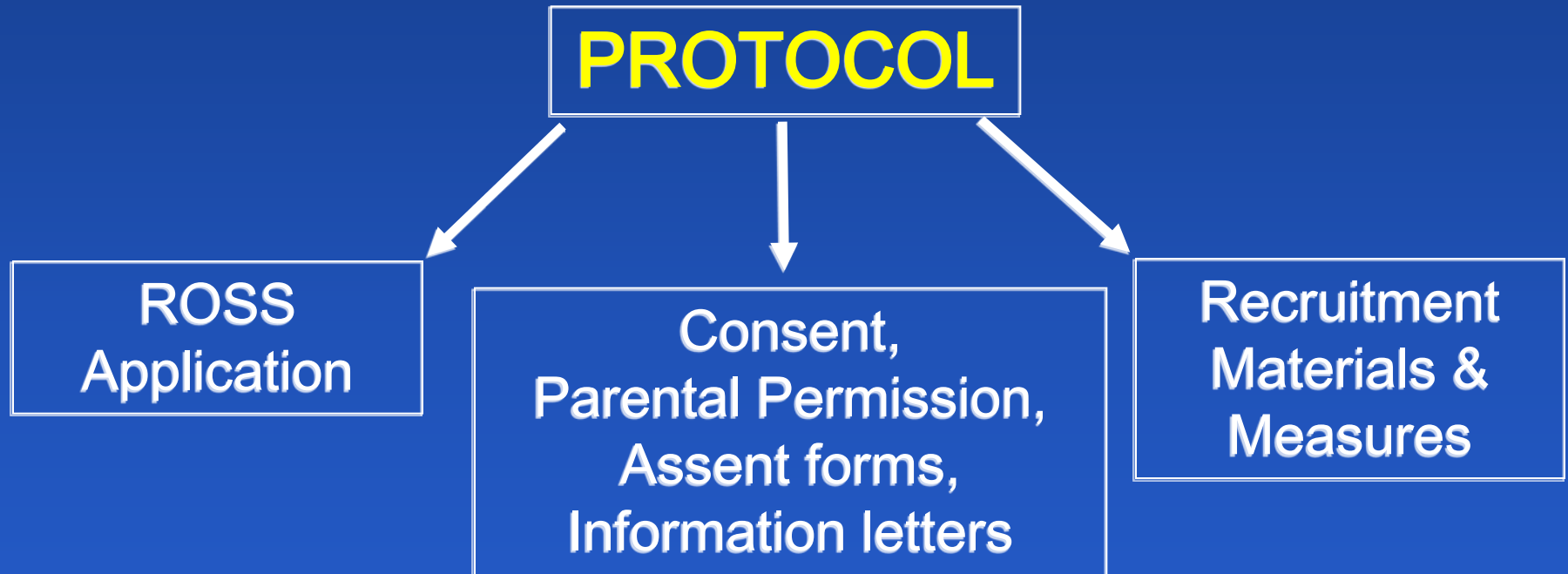
Definition: *Use of data that was collected by someone else for some other purpose.*

Same basic research principals that apply to primary data apply to secondary analysis:

- Development of a clear research question
- Study sample
- Appropriate measures
- Thoughtful analytic approach



Relating the Protocol, ROSS Application & Supporting documents



Purpose of the study is to learn more about the support women in South Africa receive from each other when someone is facing a health problem. Sixty women between ages of 20-45. *Investigators we will conduct the following:*

- *Recorded informal interviews: support received when faced with health problem*
- *Observation of daily life/routine activities (5-7 people): laundry, cooking, collecting water and interaction with other people in village*
- *Recorded Focus groups (4 people): availability of social support and potential avenues for strengthening social support.*

Potential Risk: discussion around subjects life experiences may be upsetting during the interview, subjects can refuse to answer the question or choose to end the interview.

Subject names and identifiable information of participants will never be used in the presentation or dissemination of study findings.

Level of Review? Exempt or Expedited



The purpose of the study is to examine the content around two theories of homophobia and sexuality. One theory is the attraction-based hypothesis showing that homophobia results from hidden/repressed same-sex attraction, and the other theory is attitude-based hypothesis.

The study will recruit 900 individuals who are 18 years of age and older who are (UR) undergraduates and Mechanical Turk (on-line) for individuals who live in the US.

Subjects will be asked to complete questionnaires about sexuality, and series of tasks. First task: Subjects are asked to use a computer to view words like “gay” and “straight” and to categorize them. Second task: Subjects are presented additional words (like arousing, erotic, attractive, etc.) and visual stimuli (consisting of series of images of nude images) and asked to categorize them. Internet-based survey instruments must be formatted in a way that will allow participants to skip questions . At the end of the survey subjects should be given the option of either discarding or submitting their data. Data collected over computer networks be transmitted in an encrypted format. The nude images embedded in the tasks can not downloadable.

Level of Review?
Exempt or Expedited



The aim of the study is to examine young children's judgments about different types of hypothetical moral transgressions as depicted in the context of different types of social relationships (good friend, acquaintance, disliked peer, bully, and older sibling). Children being studied will range from 4 to 8 years of age. Children will be presented with three stories depicting everyday types of moral rule transgressions. Children will be told very short (2-3 sentence) stories describing children their age committing moral transgressions involving physical harm (hitting or shoving), psychological harm (teasing or excluding from an activity), and unfair resource distribution (not sharing crayons during a group activity or giving an unequal snack).

Potential risk: The child may feel some psychological distress at hearing about transgressions and thinking about how potential victims will feel, but this is expected to be minimal.

Level of Review? Exempt or Expedited



The collection of data by a playground designer hired by the superintendent of schools about the physical dimensions of school playgrounds, presence of fencing, and the kinds of equipment currently provided.

Level of Review

Exempt or Expedited?



Ensuring a Timely Review

- Plan ahead
- REALLY think about...
 - logistics
 - access to the subject population
 - what data is NEEDED to answer your question
 - how will the data be analyzed
 - responsibilities of being listed at PI
- Respond to initial review changes in timely manner and within ROSS
- Use RSRB provided templates





Protecting human subjects should be a cooperative venture between the investigators, review boards, and institutions.

