GUIDELINE FOR DETERMINING HUMAN SUBJECT RESEARCH

According to OHSP Policy 301 Scope and Authority of the RSRB, at the request of an employee or agent of the UR, the RSRB has the authority to determine whether a project meets the criteria for human subject research. When the RSRB is consulted to discuss the proposed activity, or when a project is submitted for RSRB review, the RSRB staff makes the determination whether HHS or FDA criteria for review apply. Investigators, study teams and RSRB staff will follow the procedures below for making and confirming this determination.

1. **Complete Application in ROSS**
   Investigators who would like a formal determination by the RSRB regarding whether activity is human subject research will apply through the RSRB online submission system (ROSS).

2. **Assess Criteria for “Research”**
   Upon consultation regarding a proposed activity, or receipt of an application in ROSS, RSRB staff will consider the definition of “research” under the following HHS 45 CFR 46.102(d) definition. Projects that include FDA regulated activities will be reviewed under the FDA definition of research according to 21 CFR 56.102(c).

   **Research** is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. A "systematic investigation" is an activity that involves a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a question.

   **Generalizable knowledge** is knowledge that is expressed in theories, principles, and statements of relationships that can be widely applied to our experiences. Generalizable knowledge is usually created to share with others through presentations and publications and typically requires that the results or conclusions of the activity are intended to be extended beyond a single individual or an internal program (i.e., information gained will be shared with the greater research/professional/academic/lay community outside of a department or the UR). Examples include activities where there is an intent to publish the results in a peer-reviewed journal or to present at a regional or national meeting, as well as, theses or dissertation projects conducted to meet the requirements of a graduate degree.

3. **Assess Criteria for “Human Subject”**
   RSRB staff will also consider the definition of “human subject” under the following HHS 45 CFR 46.102(f) definitions. Applications that include FDA regulated activities will be reviewed under the FDA definition of human subject according to 21 CFR 56.102(e).
**Human subject:** 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.

**Intervention** includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.

**Interaction** includes communication or interpersonal contact between investigator and subject.

**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 purposes by an individual and which the individual can reasonably expect will not be made public (e.g., medical, employment and educational records).

4. **Reviewing Activities Generally Not Human Subject Research**

Examples of what typically isn’t research (Amdur & Bankert, 2006):

- **Medical practice:** Designed to enhance the well-being of a patient or others. Includes innovative therapy – still designed to benefit an individual patient, but “the desired outcome is to some degree unproven.”
- **Medical practice for the benefit of others:** Donating blood, for example, in which the goal “is to benefit a well-defined group of people in a predictable way.”
- **Public health practice:** Examples include surveillance (monitoring of diseases) and program evaluation (immunization coverage, or clinical preventive services such as mammography).
- **Outcome analysis:** “Projects in which medical records are reviewed to evaluate the outcome of medical treatment or the course of patients with a specific medical condition.” Results are not compared to an established standard [or publically shared outside a department/group].
- **Resource utilization review:** “Medical record review…conducted to evaluate the use of resources in a specific health care activity.”
- **Education:** Transferring information from one group of people to another – i.e., teaching.

Additional examples of activities that the RSRB may determine do not require additional regulatory oversight:

- **Case Reports:** A summary of clinical data, including medical history and other relevant information, that was collected initially for the purposes of analyzing and diagnosing the individual’s condition and/or for instructional purposes, is considered by the RSRB to be a ‘case report’ or ‘case study’. Because this information was not collected with any intent to test hypotheses or otherwise produce ‘generalizable’ knowledge, the activity does not meet the criteria for ‘research’ [45 CFR 46.102(d)], and ordinarily does not require RSRB oversight.

*Note: If any of the following is present, the activity is considered research rather than a case report:*
There is a plan to perform the treatment on some individuals but not on others.

Investigational drug(s) or device(s) are involved (off-label use of an approved drug or device is permissible).

There is a clear intent before treating the patient to use systematically collected data that wouldn’t ordinarily be collected in the course of clinical practice in reporting and publishing the case study.

There is intent to manipulate medications (even approved ones) to determine maximum effectiveness, or to test if they work consistently well.

Extra tests are conducted for the sake of reportability.

There is a protocol/study plan.

Separate sets of records or data sheets are maintained (particularly with identifiers).

The primary purpose is to answer a research question, not to provide care.

There is consideration that the treatment might yield a case series if it is effective in others (i.e., testing a hypothesis).

• **Program Evaluations**: Involve the systematic collection and analysis of information about the effectiveness of the program in order to make judgments about the program, improve program effectiveness, and/or inform decisions about future program development. The intent of these projects is to inform particular programs about that program’s effectiveness and needs rather than to contribute to generalizable knowledge, and, as such, are not considered research.

• **Quality Assurance and Quality Improvement (QA/QI) Projects**: These activities do not require RSRB oversight except when they involve “Research” as defined by the federal regulations. Precise definitions to permit the distinction between research studies and QA/QI projects have not been established. In general, QA/QI projects are focused primarily on improving patient care within a given patient care environment (e.g., hospital or health care organization) and, as such, the outcome of the project may not be generalizable to other patient care environments. Publication of a quality assurance project does not, per se, render that project “research”; however, if the outcome of a quality assurance project is published, attention should be given to avoiding the terminology “research” in the publication.

• **Research Methods Classes**: University Schools and Departments offer courses that require students to undertake projects in which other people are interviewed, observed, or otherwise serve as participants. The purpose of these courses is to train students and provide them with a closer view of social, educational, or psychological processes, and an opportunity to practice various research methods. Provided the data obtained will not contribute to generalizable knowledge or be published outside of the classroom (i.e., School or Department), the activities are not considered human subject research that require RSRB oversight.

• **Research On or Involving 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. (Note that the Federal Policy regulations governing human research subject protections defines a “Human Subject” 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.”)
5. **Determination of Review Status**

   RSRB staff may request additional information from the investigator or study staff in order to ensure an appropriate determination has been made as to whether the activity involves human subject research. At any point during the review process, RSRB staff may determine that the activity is human subject research, in which case additional reviews will be applied to determine whether the activity may qualify under an exemption category defined by the federal regulations, or that the research activity needs to be considered for additional board review (e.g., expedited review).

6. **Confirmation/Notification of Review Determination**

   The RSRB staff will review the activity to confirm that the activity falls under **Category A: Activities Being Conducted are Not Research**, or **Category B: Research Does Not Involve Human Subjects**. Upon confirmation of this review (e.g., via consultation or application through ROSS), the investigator will be notified (Note that formal notification may occur if an application was completed in ROSS).

   If Investigators or study teams have additional questions, contact the RSRB Office (585-275-3050). The RSRB staff may be able to address inquiries by phone; however, staff may need written materials and/or may need to discuss the proposal at a face-to-face meeting.

_Amdur, R. J., Speers, M., & Bankert, E. (2006). Identifying intent: Is this project research? In R. J. Amdur & E. A. Bankert (Eds.), Institutional review board management and function (pp. 101-105). Sudbury, MA: Jones and Bartlet Publishers._