**IRB definitions (Is it Research? And definitions of exempt, expedited and full)**

Priority concern is research using human subjects, which is designed, conducted, supervised or directed by a faculty member. All research studies using human subjects are required to have some level of review (Even exempt studies need to be reviewed by the IRB Office). Exempt does not mean “no review”.

All undergraduate and graduate student generated research involving human subjects will be reviewed and will comply with all university and federal guidelines. Case studies are classified as research if there is a systematic implementation of an intervention with the intent to produce generalizable information. Activities that are primarily designed for teaching students how to conduct research may not necessarily qualify as research. Student projects that are not research are not subject to these policies.

These policies and procedures apply only to the use of human subjects for research and do not apply to the activities of the faculty and staff in the execution of their other professional duties. Activities such as local quality assurance, program evaluation and quality improvement that do not have a goal of producing generalizable information may not be research.

**Is it research? What is research? Research contributes to generalizable knowledge.**

- Research is designed in advance.
- Research utilizes a systematic approach.
- Defined purpose of contributing to generalizable knowledge.

Research - a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge. To be considered research, the activity must be characterized by systematic investigation AND the primary goal is to develop or contribute to generalizable knowledge.

DHHS regulations define research as “a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102(d)). FDA regulations define clinical investigation as "any experiment that involves a test article and one or more human subjects" as described in 21 CFR 50.3 (see Definitions for further details). Activities that meet either definition constitute research for the purposes of FHSU policy.

As described in the Belmont Report, “...the term 'research' designates an activity designed to test a hypothesis [and] permit conclusions to be drawn...” Research is usually described in a formal protocol that sets forth an objective and a set of procedures to reach that objective.” Thus, Research can encompass a wide variety of activities, including: experiments, observational studies, surveys, tests, and recordings. Studies assigned an Investigational New Drug (IND) number or an Investigational Device Exemption (IDE) by the FDA are by definition research that requires IRB review. (21 CFR 56.103) “Research” generally does not include such operational activities as: defined practice activities in public health, medicine, psychology, and social work (e.g., routine outbreak investigations and disease monitoring in public health); 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 clear advance intent to contribute to generalizable knowledge

with a scientific protocol. Intent to publish is one possible indication of intent to contribute to generalizable knowledge.

**Does it involve human subjects?**

A human subject – “means a living individual about whom an investigator (whether a professional or student) conducting research obtains (1) data through intervention or interaction with the individual including observational research”, or (2) identifiable private information. Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes." 45 CFR 46.102(f)(1) and (2).

The FDA defines a human subject as “an individual on whom or on whose specimen a device is used” (21 CFR 812.3) or “an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may either be a healthy human or patient.” (21 CFR 50.3 (g))

*“Identifiable private information*" 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)).

Although there is no definition of “identifiable” information in the Common Rule, HIPAA provides a list of 18 identifiers, the removal of which renders a data set deidentified for the purpose of determining if a human subject is involved.

*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 any other mode of communication.

*Private information* includes observation of behavior when an individual can reasonably expect that no observation is taking place, or information for specific purposes (such as a health care record) that individuals can reasonably expect will not be made public. Thus, approaches involving only existing records or human specimens or observations may still constitute human subjects research requiring IRB approval. The IRB will make this determination.

Simple observational studies of public behavior (including television and internet chat rooms) do not involve human subjects as defined, because there is no intervention or interaction and the behavior is not private. Also, studies based on data collected for nonresearch purposes may not constitute human subjects research if individual identity is not identifiable. Examples include programmatic data such as service statistics, school attendance data, crime statistics, or election returns. Studies based on data that are individually identifiable data but also are *publicly available* may not constitute human subjects research [45 CFR 46.101(b)(4)]; however, the term “publicly available” is intended to refer to record sets that are readily available to the broad public, such as death certificate.

**Review Categories**

There are three levels of review, primarily based on level of risk and subject characteristics, and are subject to changes in federal, state or university policies. The review categories are: exempt, expedited, and full review.

**Research That Requires Full IRB Review**

Full IRB review is required for all research involving greater than minimal risk to subjects. This responsibility cannot be delegated. Full IRB review may be necessary for the following protected groups including: fetuses, pregnant women, human in vitro fertilization, prisoners, children, elderly, and psychiatric patients. Depending on the type of research or target population, some groups may be vulnerable to coercion or undue influence, or have impaired capacity to make decisions and require additional safeguards. The researcher shall design subject selection and consent procedures that will protect the rights and welfare of all subjects.

**Research Which May be Considered for Expedited Review**

An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the federal requirements. All of the authorities of the IRB may be exercised, except the reviewers may not disapprove the research. Expedited proposals must be discussed at the next IRB meeting.

Expedited review is appropriate for research that involves no more than minimal risk or for review of minor changes to previously approved research projects and protocols. The research proposal and protocols must be submitted to the IRB to determine that all of the following requirements are satisfied:

- risks to subjects are minimal;
- risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge;
- selection of subjects is equitable and non-coercive;
- informed consent will be sought from each prospective subject or the subject's legally authorized representative;
- informed consent will be appropriately documented;
- when appropriate, the research plan makes adequate provision for monitoring data collected to ensure safety of subjects; and
- when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Below is a list of types of research with human subjects that may be eligible for an expedited review:

1. Collection of hair and nail clippings in a non-disfiguring manner.
2. Collection of excreta and external secretions.

3. Collection of data from subjects 18 years of age or older using non-invasive procedures routinely employed in clinical practice.

4. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.

5. Anonymous voice recordings made for research purposes, such as investigations of speech defects.

6. Moderate exercise by healthy volunteers.

7. Study of existing data, documents, records, pathological specimens or diagnostic specimens.

8. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate the subject's behavior and the research will not involve stress to subjects.

9. Research involving manipulation of the subject's behavior which does not involve stress or risk.

Expedited review may also be appropriate for minor changes or requests for extensions in previously approved research during the period (one year or less) for which approval is authorized.

**Research That May be Considered Exempt from Full Review**

Some research may be exempt from university IRB review. The decision to exempt a study from IRB review must be made by someone other than the researcher. Exemptions are requested from the Research Compliance Office. (Note: If the human subjects are in the vulnerable subject population identified under FULL REVIEW, then Exempted Review does not apply.)

**If an exemption is requested, the researcher must identify the exemption by stating which of the following apply (For items 1-6, see 45 CFR 46.101 (b) (1) through (6))**

1. "Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curriculum, or classroom management."

*This exemption is limited to normal educational practices in commonly accepted settings. For example, random assignment to different instructional methods or involving a new strategy is not exempt.*

2. "Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey or interview procedures, or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation."

For example, research is not exempt if it involves subject identifiers and if disclosure of the data could have serious consequences for subjects. Additionally, surveys that contain invasive or sensitive questions that may cause discomfort and increase risk may not be exempt even in the absence of personal identifiers.

3. "Research involving the use of education tests (cognitive, diagnostic, aptitude, achievement), survey or interview procedures, or observations of public behavior that is not exempt under (2) if the subjects are **elected or appointed public officials** or candidates for public officials or candidates for public office, or federal statutes require without exception that the confidentiality of the personally identifiable information be maintained through the research and thereafter."

4. "Research involving the collection or study of existing data, documents, records, or pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects."

For qualify for this exemption, the research material must be de identified and exist prior to the research activity. If there is a code used to identify the subject, then the research is not exempt. Also note that HIPAA Rules may apply.

5. "Research and demonstration projects that are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate or otherwise examine public benefit or service programs; and" other items identified in the regulations. **Public benefit or service programs must be conducted under specific federal statutory authority (such as social Security benefits or Older Americans Act nutrition or social services).** There must be no significant physical invasions or intrusions upon the privacy of the participants.

6. "Taste and food quality evaluation and consumer acceptance studies" as described in the regulations.

This exemption is limited to studies that do not involve any type or volume of food that could cause risk. Consumption of alcohol, vitamins or food supplements is not exempt.

Some examples of exempt research may include (1) a survey, such as a mailed or phone survey, or (2) observation techniques with no intervention, or (3) with no risk to subjects and no identification of the subject. Studies that use questionnaires sent to adults are usually exempt if the study is described and the reason for the study detailed. The return of the questionnaire may be evidence of the consent of the subject as long as the subject remains anonymous. Telephone surveys may also be exempt.

Research that is classified as exempt is not subject to continuing review or the other requirements of 45 CFR 46. **Although the regulations do not require consent for exempt research, there may be ethical reasons to provide full disclosure and obtain consent.**

**Exempt does not mean “no review”!**