



# Investigator Guide

Human Subjects Research

2008

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# First Things First

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## CHAPTER 1 - BEFORE YOU BEGIN

*...You might have some of the following questions about human subjects research.*

### **Why would my research require review?**

The University has negotiated a Federalwide Assurance (FWA) with the federal Office for Human Research Protections (OHRP). According to the terms of this assurance, it is the University's responsibility to ensure that the rights and welfare of research participants, or *human subjects*, are adequately protected in research conducted under its auspices. Federal laws require this protection, and in order for the University to fulfill its responsibility, all human subjects research must receive appropriate review and approval. For more information regarding OSU's FWA, see [Federalwide Assurance \(FWA\)](#).

### **Where do the requirements come from and how do I know which apply?**

All research conducted by OSU faculty, staff, or students that is determined to be human subjects research is subject to Department of Health and Human Services (DHHS) regulations and the terms of the University's FWA. The Food and Drug Administration (FDA) regulations may also apply to human subjects research conducted by OSU investigators. When research involves the use of protected health information, Health Insurance Portability and Accountability Act (HIPAA) requirements must be followed. Depending on the type of research conducted, the requirements of one or more of the applicable regulations may apply.

Many faculty, students, and staff throughout the University conduct research involving human subjects. All activities that involve research with human subjects (as defined by the federal regulations) – including those performed in support of an OSU honors' thesis, master's thesis or doctoral dissertation – are subject to Institutional Review Board (IRB) review or exemption. However, faculty, students, and staff also conduct other types of scholarly or scientific inquiry involving interactions with people that do not require IRB review. To comply with federal regulations, state laws, and University policies, investigators must be aware when their work requires IRB review or exemption. A designated Administrator in the Office of Responsible Research

Practices (ORRP) is available to make project-specific determinations concerning the need for IRB approval for activities that may be human subjects research. An ORRP Administrator will review the proposed project, consult the applicable regulations and University policies, and notify the Principal Investigator (PI) about any study specific requirements.

## **What is an IRB?**

Institutional Review Boards were established by the federal government to protect the rights and welfare of human subjects participating in research. IRBs are responsible for ensuring that physical, psychological, legal, economic, and social risks to research participants are minimized and that the risks associated with the research are in line with the importance of the research and/or the knowledge to be gained. IRBs also ensure that research participants receive complete information about the nature of the research and any associated risks, as well as participants' rights as research subjects, in a manner they can understand. At OSU, human subjects research is reviewed by one of three University IRBs, depending on the nature of the research – Behavioral and Social Sciences, Biomedical Sciences, or Cancer – or an external IRB, Western IRB (WIRB).

IRBs review human research activities to ensure that the University, affiliate institutions, and investigators are compliant with the ethical standards and regulations governing human subjects research. The primary regulations are codified in the Code of Federal Regulations (CFR) from the US Department of Health and Human Services (45 CFR 46) and the Food and Drug Administration (21 CFR 50; 56).

## **What is (the) ORRP?**

The Office of Responsible Research Practices is an administrative unit of the Office of Research that provides a range of services supporting the University's animal, human, and biosafety research programs and members of the University research community. Staff members assist faculty, staff, and students seeking committee approvals to conduct human subjects and animal research; provide educational programming in support of the responsible conduct of research; and support the operations of the University's Institutional Animal Care and Use Committee (IACUC), Institutional Biosafety Committee (IBC), and IRBs.

The ORRP staff provides the following services for faculty, staff, and students involved in human subjects research:

- Assistance with general questions about human research review procedures
- Assistance with study-specific questions

- Pre-screening of Board submissions for completeness to facilitate the review process
- Determinations about whether human subjects research meets the criteria for IRB review or exemption
- Attendance at meetings to provide support to IRB members
- Preparation and distribution of IRB correspondence to investigators
- Coordination and delivery of educational programs
- Responses to researcher, community, and research participant questions and concerns.

Although ORRP staff members work very closely with the various review boards, they are not IRB members and cannot act on behalf of the Boards. Only the IRB has the authority to review and approve non-exempt research.

The ORRP staff is committed to delivering excellent customer service. Consult the ORRP staff directory at [Contact Us - ORRP](#) for specific staff member contact information. The office is interested in suggestions for service improvements and is available to resolve customer service concerns.

For more information about ORRP or other units within the Office of Research at OSU, including links to other research resources, programs, and reports – see [Office of Research](#).

## CHAPTER 2 - THINK ABOUT THE PURPOSE OF YOUR PROJECT

...So that you can help determine whether you are performing human subjects research.

### How do I know if I am doing human subjects research?

Research projects involving human subjects require either review and approval by an IRB or a determination that the research is exempt. The first question a researcher should consider with respect to IRB review is whether the research project fits the definition of *research*, and if so, whether it also involves *human subjects*. In light of the responsibility to protect human subjects and the potential regulatory consequences of not obtaining IRB review and approval, investigators should err on the side of caution and consult with ORRP when uncertain whether a study constitutes human subjects research.

The following sections provide regulatory definitions to consider when determining whether a project involves “human subjects research,” as well as some examples. In addition, the federal Office for Human Research Protections provides “Chart 1: Is an Activity Research Involving Human Subjects?” at [Human Subject Regulations Decision Charts](#).

### Question 1 – Is it Research?

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\(d\)](#)). 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.”

“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, marketing studies, or contracted-for services. This definition of research generally does not include journalism or political polls. However, some of these activities may include or constitute research in circumstances where there is an intent to contribute to generalizable knowledge.

Some examples of common activities that are **not** considered “research” as defined by DHHS regulations:

**Data collection for internal departmental, school, or other University administrative purposes.**

Examples: teaching evaluations and customer service surveys. Service surveys issued or completed by University personnel for the intent and purpose of improving services or programs of the University or for developing new services or programs for students, employees, or alumni are not considered to be research, as long as there is no intent to generalize the findings, and the privacy of the participants is protected, confidentiality of individual responses are maintained, and survey participation is voluntary. This includes surveys by professional societies or University consortia. Note: If at a future date, an opportunity arose to contribute identifiable or coded survey data previously collected for an administrative purpose to a study with an intention to produce generalizable knowledge, IRB review may be required before the data could be used in the new project.

**Independent contract for activities carried out for an external agency.** Examples: personnel studies, cost-benefit analyses, customer satisfaction studies, biological sample processing (for a fee and not for authorship or other credit), public park usage, IT usage, and software development.

**Quality improvement projects.** These are not generally considered research unless there is intent to contribute to generalizable knowledge beyond the use of the data derived from the project internally to improve or alter the quality of care or the efficiency of an institutional practice. If the data is to be re-examined or reanalyzed and/or new information surfaces that could be used to contribute to generalizable knowledge, an application must be submitted for IRB review or exemption. Any individual who is unsure whether a proposed quality improvement project would be considered research (as defined above) should contact ORRP for guidance.

**Consultant activities.** Such activities are not considered research when consultants do not obtain, receive, or possess the identifiable private information of research participants. Other examples (that are not research) include performing commercial services for investigators and informing prospective participants about the availability of research. Note: The examples above are not an all-inclusive listing. See the following website for further information [\*Engagement of Institutions in Research\*](#).

## Question 2 – Does it Involve Human Subjects?

A **human subject** is defined by DHHS 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\(f\)\(1\)\(2\)](#)).

### Relevant Definitions

**Living individual** refers to data/specimen(s)/information collected from live subjects. Cadavers, autopsy specimens, or specimens/information from subjects now deceased are not living individuals and are not human subjects.

**Intervention** includes physical procedures, manipulations of the subject or the subject's environment for research purposes.

**Interaction** refers to communication between the investigator and the subject. This includes face-to-face, mail, and phone interactions, as well as other modes of communication.

**Individually identifiable** means the identity of the subject is or may be readily ascertained by the investigator or the investigator's staff, or is associated with the information.

**Private information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Examples of private information include medical or academic records or personal journals.

Some activities and materials that do **not** involve “human subjects” as defined above:

**Observational studies of public behavior.** These studies, including television and, in some cases, Internet chat rooms, do not involve human subjects when there is no intervention or interaction with the subjects, and the behavior is not assumed by the subjects to be private.

**Studies based on data that are publicly available but individually identifiable.** Use of these data does not constitute human subjects research, provided that the record sets are freely available to the

broad public. Note: Investigators should contact ORRP if they are uncertain as to whether the data qualifies as “publicly available.”

**Data sets without individual identifiers.** Example: publicly available census data. Also, studies based on data previously collected for non-research purposes do not involve human subjects when individuals are not individually identifiable (e.g., data such as service statistics, school attendance data, crime statistics, or election returns).

**Coded private information or biological specimens.** Uses of data or specimens that are were not collected for the currently proposed project do not involve human subjects when the data/specimens cannot be linked back to the individuals from whom these were obtained. However, when the holder of the data/specimens (or anyone else) has access to the identity of the individuals (e.g., names, addresses, record numbers), the research can also be said not to involve human subjects if the investigator enters into an agreement with the data/specimen provider that prohibits the identity of the subjects from being released to the investigator under any circumstances. Note: When an “Investigator Agreement” of this type is used, investigators must seek verification from ORRP that the project does not involve human subjects. See [Guidance on Research Involving Coded Private Information or Biological Specimens](#) for more information.

## **Research and Human Subjects as Defined by FDA Regulations**

Both “research” and “human subjects” are defined differently in Food and Drug Administration regulations, which apply to research supported or regulated by FDA. Studies involving drugs, medical devices, foods and color additives, dietary supplements (with a nutrient content or health claim), infant formulas, and electronic products (e.g., microwaves, cell phones) are FDA-regulated.

FDA regulations define a **clinical investigation** as “any experiment that involves a test article and one or more human subjects” that is either:

- Subject to the requirements for prior [data] submission to the FDA, or
- Intended to be submitted to (or held for inspection by) the FDA as part of an application for a research or marketing permit.

A clinical investigation may also be referred to as *research*, *clinical research*, or a *clinical study*. A non-clinical laboratory study is not considered to be a clinical investigation ([21 CFR 56.102\(c\)](#)).

A **human subject** is defined by FDA regulations as “an individual (a healthy individual or patient) who is or becomes a participant in research, either as a recipient of the test article or as a control.” A human subject also includes an individual on whose specimen an investigational device is used ([21 CFR 56.102\(e\)](#)).

## Human Subjects Research at OSU

Activities in any of the following categories are considered to be **research involving human subjects** and must comply with federal regulations and OSU policies for the protection of human subjects:

- Studies that collect data through intervention or interaction with individuals. Examples include: surveys, interviews, focus groups, audio or videotaping, blood drawing, invasive and noninvasive measurements and specimen collections.
- Studies that involve investigational or approved drugs (other than an approved drug used in the course of medical practice).
- Experiments testing the safety or efficacy of medical devices (**including in vitro diagnostics**).
- Studies using individually identifiable private information (even if the information was not collected specifically for the study in question).
- Studies that use bodily materials such as cells, blood, urine, tissues, hair, and other specimens (even if one did not collect these materials for the study). However, such research does not involve human subjects when the materials/data are coded and the investigator (via formal agreement) does not have access to the coding systems, as described above.
- Studies that produce generalizable knowledge about categories or classes of subjects from individually identifiable information.
- Studies that use human participants to evaluate environmental alterations. Examples include: habitat modifications to a person’s living or working space and test environments.

For additional examples, see the OSU HRPP Policy at: [Policies and Procedures at OSU](#).

## How do I get a written determination about the review requirements?

If an investigator is unsure whether the project is research involving human subjects, the PI should complete a determination request form (currently the exempt application) and submit it to an ORRP Administrator for review. The designated ORRP Administrator will make one of three determinations and will notify the PI as follows:

- The proposed activity **is not** research involving human subjects and may be conducted without further IRB review or exemption; or

- The proposed activity *is* research involving human subjects and meets the criteria for IRB exemption; or
- The proposed activity *is* research involving human subjects and requires IRB review.

Upon receipt of complete information, determinations regarding review requirements are usually made within five business days. Projects determined to be research involving human subjects require documented IRB approval or exemption, as described below, before starting any research activities, including advertising, recruitment, and pilot studies. “Retroactive” IRB approval or exemption is not permitted under federal regulations and University policy.

## CHAPTER 3 - YOUR PROJECT REQUIRES REVIEW

*...What you are proposing is human subjects research, but now what?*

### **What type of review is required for my project?**

Projects that involve human subjects research may receive one of the following three types of review: exempt, expedited, or convened (full Board) review, as explained below. Studies involving minimal risk (or less) will generally receive exempt or expedited review. For studies that involve greater than minimal risk, IRB review by the full Board will be conducted. Student investigators should consult with their faculty advisors or ORRP staff if they are unsure of which review is required.

### **What is exempt research?**

Exempt research is research involving human subjects that is “exempt” from the requirements for initial and continuing IRB review and other provisions of the federal regulations. For research to be exempt, it must also fit into one (or more) of the categories described below.

### **Exempt Categories**

#### **Category 1**

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on regular and special education instructional strategies or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Category 1 exemption is limited to the study of “normal” educational practices conducted in commonly accepted settings such as elementary, secondary and post-secondary schools. Exemption does not apply to normal educational practices occurring outside of the traditional setting for those practices. Also, radically new forms of instruction, randomization of participants, and/or deception are not considered normal educational practices and cannot be considered for exemption. Physical education studies cannot be considered as exempt if the study involves exercise that has been altered for the purposes of the research. In addition, elements of risk may preclude exemption and necessitate IRB review (e.g., if there is intense exercise involved).

## Category 2

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; AND 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.

**Note:** The exemption under Category 2 does **not** apply to research involving survey or interview procedures or observation of public behavior when children are the subjects of the activity, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

If the data collected could harm participants in any way, additional measures to protect confidentiality of the data are required, and such research will generally require IRB review. For example, questions regarding sexual preference or illegal behavior could reasonably place subjects at risk if responses were known, and therefore, cannot be exempt from IRB review if there is any way to identify the respondents. This kind of research should contain an unsigned consent form (or recruitment script or letter) that clearly describes the risks of the research. In some studies, even when the data collected are anonymous the potential for social stigma of an identifiable group can make IRB review a requirement. Surveys that contain invasive questions that may cause participants to experience emotional distress or discomfort while answering are also not exempt from IRB review, even if the data are collected from participants who remain anonymous. Research employing cognitive or diagnostic tests is not exempt if the testing is psychologically invasive and could potentially cause the participant some discomfort or distress.

## Category 3

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under Category 2, IF the human subjects are elected or appointed public officials or candidates for public office, OR federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Exempt category 3 represents an extension of exempt category 2, but without the same level of oversight of the participants' right to privacy. Category 3 is used for public officials and candidates for public office or when a federal statute protects confidentiality when personal identifiers are maintained.

## Category 4

Research, involving the collection or study of existing data, documents, records, 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.

### Relevant Definitions

**Existing** refers to the date of exempt determination. The data, documents, etc. must be in existence (i.e., “on the shelf”) before the study is determined to be exempt from IRB review. Data or specimens that come into existence after the date of exempt determination cannot be included in exempt research.

**Publicly available** refers to materials that can be accessed by anyone, without special permission. If data are not publicly available, then it is considered *private* information.

Research involving data or specimens is exempt under Category 4 when the data/specimens obtained from private sources are in existence before the exempt application is reviewed, provided that the information is recorded by the investigator without subject identifiers or codes that can link the data/specimen to its sources (persons). Proposed use of private data that has not yet been generated or collected (i.e., not *existing*) is not exempt and requires IRB review. If the study involves some data or specimens that are existing and some that are not, the project also requires IRB review. Similarly, research is not exempt when it involves privately held data/specimens that retain linked codes that could identify the subjects. Activities involving use of publicly available data (regardless of whether the subjects are identifiable) or data/specimens from decedents are not human subjects research. Data or specimens obtained from a repository or bank are generally not considered to be publicly available.

### When Data or Specimens Include Protected Health Information (PHI)

Access to protected health information requires specific permission for its use (i.e., HIPAA authorization) from the individual whose PHI is accessed for research purposes, or a waiver of authorization granted by the Privacy Board. Requests for waiver of HIPAA authorization are reviewed by the OSU Privacy Board, following a determination that the research is exempt. To be considered “de-identified” under the HIPAA Privacy Rule, 18 identifiers – including identifying dates (e.g., date of birth) and zip codes – must be removed from the recorded data. Exempt research involving PHI must meet the requirements of both human subjects protection regulations and the HIPAA Privacy Rule regarding identifiable information.

## **Category 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; procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs.

Category 5 is allows research on public benefit or service programs such as welfare, unemployment, Medicaid, and Social Security. The research is performed at the request of or with permission of a federal agency. Exempt category 5 allows the use of coded and/or identifiable data that are routinely compiled by the public office that administers the program even though the participant might consider the data private. Vulnerable populations, such as children or decisionally impaired adults, may be studied in category 5. It is essential that data be well protected against breaches of confidentiality. All ethical considerations still apply when dealing with participants.

## **Category 6**

Taste and food quality evaluation and consumer acceptance studies if wholesome foods without additives are consumed; OR if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the US Department of Agriculture.

Exempt category 6 is limited to taste and food quality evaluation studies that do not involve consumption by the participant of any type or volume of food that has any potential risks, such as indigestion or vitamin deficiencies. The consumption of food should constitute reasonable eating behaviors. Studies that involve consumption of alcohol or vitamins or supplements such as protein powder, creatine, and glucosamine chondroitin sulfate do not qualify as exempt studies.

## **Additional Information Regarding Exempt Research**

At OSU, research meeting any of the following conditions will receive IRB review (regardless of whether the research would otherwise be exempt):

- Research involving prisoners (with the exception of emergency uses)
- Research that is greater than minimal risk, involves coercion, undue influence, deception, or any practice that does not follow the ethical principles described in the Belmont Report

- Research in categories 1-5 (even if it would otherwise qualify for exemption) that is subject to FDA regulations.

## **How is exempt research reviewed at OSU?**

Exempt research requires submission of an exempt application. A designated ORRP Administrator will review the completed application and associated materials (e.g., recruitment script, data collection form, etc.) to determine if the research fits one (or more) of the categories described above and will notify the PI of the results of the review. The PI will receive email notification that:

- The research is exempt and may be conducted without IRB review, indicating the category under which the determination was made; or
- The research is not exempt and requires IRB review, with an explanation as to why the proposed study does not meet the exempt criteria; or
- The proposed activity is not research involving human subjects and may be conducted without further IRB review or exemption.

On average, requests for exemption are reviewed and determinations made within five to seven business days of receipt of a complete application. When the use of protected health information in exempt research is proposed, subsequent review by the Privacy Board is required. Up to two additional weeks may be required for Privacy Board review. Research activities may not begin until documentation of the exempt determination is received and, when applicable, notification that waiver of HIPAA authorization was granted by the Privacy Board.

Exempt research projects do not “expire” and do not require continuing review. Exempt studies are to be conducted as proposed. To ensure that revisions continue to meet the exempt criteria, a new application for exempt determination is required prior to initiating any changes in the research. If a project is changed in such a way that it no longer meets exemption criteria, IRB review and approval will be required.

The application for exemption from IRB review is located at: [Exempt Research](#).

## **What is involved in IRB review?**

In accordance with OHRP and FDA requirements, the IRBs review human subjects research proposals to ensure that risks to potential participants have been minimized and the potential for benefit has been maximized before research is conducted. The IRB also ensures, when applicable, that human subjects will only participate in

research after providing legally effective informed consent. Investigators may not solicit participants or begin data collection until obtaining approval from the appropriate IRB or documented concurrence that the research is exempt.

To approve a given research project, the IRBs must make the following (regulatory) determinations:

- *Risks to subjects are minimized: (i) by using procedures that are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.*
- *Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research).*
- *Selection of subjects is equitable. In making this assessment the IRB takes into account the purposes of the research and the setting in which the research will be conducted, as well as any special concerns or regulatory requirement when the research involves vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.*
- *Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116.*
- *Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117; or, if requested, that the research meets the requirements for any waivers or alterations.*
- *When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.*
- *When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.*
- *When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.*

Upon review, the IRB will notify investigators of one of the following actions:

**Approval** – The application is complete, risks to participants are minimal or minimized, and the procedures are appropriate. The IRB gives approval for the research to be conducted.

**Modifications Required** – The application is complete, but there are administrative or minor issues/changes that must be addressed before the project is approved. A letter detailing these required modifications will be sent to the principal investigator. Upon satisfactory response to the contingencies, following IRB review and approval, the investigator will be notified that the research may be initiated.

**Deferred** –Applications that are found to have deficiencies (unreasonable risk to participants, unclear procedures, serious omissions, ethical issues, or major contingencies) will be deferred. Note: questions or unresolved issues involving the regulatory criteria for approval described above will result in deferral. The investigator is sent a memorandum listing the concerns that must be addressed for review to proceed. The investigator’s response is reviewed by the IRB and can be approved, require modifications (as above), or be deferred again until all issues are satisfactorily addressed.

**Disapproval** – Applications that are found to have risks outweighing the potential benefits to participants and/or society will be disapproved and the research will not be allowed. This action can only be taken by the full Board at a convened meeting, and investigators will be sent a rationale for the disapproval. An investigator may request that the IRB reconsider the disapproval, but institutional administrative officials may not override this decision.

## **How do expedited and convened (full Board) reviews differ?**

### **Expedited Review**

Federal regulations specify conditions under which research may be reviewed by the IRB using “expedited review procedures.” Under the expedited review procedure, IRB review is carried out by the IRB Chairperson or by one (or more) experienced IRB member(s) designated by the Chair. Note: When performing expedited review, a reviewer may exercise all of the authorities of the IRB except that the reviewer may not disapprove the research. The standard OSU IRB application, requirements for protocols, recruitment materials, informed consent (or its waiver, alteration, or exception), etc., apply regardless of the type of review performed – expedited or convened.

Research activities that meet both of the following conditions may be reviewed using expedited review procedures:

- The research presents no more than minimal risk to human subjects, AND

- The research involves only procedures listed in one or more of the allowed categories below (Note: Categories 1-7 apply to both initial and continuing IRB review):

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period, and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period, and collection may not occur more frequently than 2 times per week.
3. Prospective collection of biological specimens for research purposes by noninvasive means.  
**Examples:** (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications).  
**Examples:** (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography,

electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the DHHS regulations. This listing refers only to research that is not exempt.)
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the DHHS regulations. This listing refers only to research that is not exempt.)
8. Continuing review of research previously approved by the convened IRB as follows:
  - a. Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
  - b. Where no subjects have been enrolled and no additional risks have been identified; or
  - c. Where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption, where categories 2 through 8 do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

**Note:** The specific circumstances of the proposed research must be considered when determining whether an activity listed above involves minimal risk.

The expedited review procedure may not be used for:

- Research where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal
- Classified research involving human subjects

- Research involving prisoners.

## **How is expedited research reviewed at OSU?**

Pre-screening by ORRP staff includes a preliminary determination about whether the application meets the criteria for exempt, expedited, or convened review. If the research qualifies for expedited review, the IRB Chair and/or a designated experienced IRB member will review the submission. The IRB member(s) will complete the review and take action outside of the convened IRB meeting. The reviewer may approve the research, require modifications in the research before approval, or refer the submission to the full Board for further review. A protocol is referred to the full Board when the reviewer believes that the research does not meet the criteria for expedited review or approval. Investigators may not begin research activities until documentation of IRB approval is received. The expedited review process (from submission to approval) takes an average of 4 to 8 weeks.

IRB forms can be accessed at [IRB Forms](#).

## **Convened (Full Board) Review**

Projects that involve more than minimal risk, do not fit into one or more of the specified categories, or otherwise do not meet the criteria for expedited review must be reviewed by the full Board at a convened meeting where a majority of the IRB membership is present, including at least one member whose primary interests are non-scientific.

Examples of projects requiring review by the full Board include the following:

- Studies involving prisoners
- Studies involving investigational drugs or devices
- Studies involving x-ray, surgery, or other medical procedure requiring general anesthesia or sedation
- Studies including information that may be disclosed requiring mandatory legal reporting (e.g., child/elder abuse, HIV infection, etc.)
- Studies involving deception, when withholding information or debriefing raises the risk level of the study beyond minimal
- Studies involving populations requiring additional protections because of cultural, economic, or educational vulnerability
- Studies performed in populations different from the one(s) in whom risks have been identified and the possibility of unknown or increased risk exists (e.g., studies in children involving drugs previously tested only in adults).

## How is convened research reviewed at OSU?

Pre-screening by ORRP staff includes a preliminary determination about whether the application meets the criteria for exempt, expedited, or convened review. If the research does not qualify for exempt or expedited review, the protocol will be added to the next available meeting agenda, assigned to IRB reviewers, and materials sent out to all IRB members for review prior to the convened meeting date. A primary IRB reviewer is responsible for presenting the proposed research to the Board at the convened meeting. All members receive a copy of the submission materials – including (but not limited to) the application, recruitment materials, informed consent documents, and data collection instruments – and participate in the review and discussion of the proposed research at the meeting. Consultants may also be invited to assist in the review of research where additional expertise is necessary. After the meeting, minutes are drafted by ORRP staff and approved by the IRB Chair before Board actions are communicated to investigators. The convened review process (from submission to approval), on average, takes from 8 to 12 weeks.

IRB forms can be accessed at [IRB Forms](#).

For Board-specific meeting schedules, see [Meeting Dates](#).

## What OSU research is sent to Western IRB for review?

The Western Institutional Review Board is a commercial IRB under contract with the Ohio State University to review and monitor research projects that are industry-sponsored and industry-initiated. The proposed research must also meet the NIH definition of a *clinical trial*:

*A prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices)* [NIH Glossary of Terms for Human Subjects Protection](#).

According to this definition, biomedical research involving drugs, treatments, and devices, and behavioral research involving an intervention to modify behavior (e.g., diet, physical activity, cognitive therapy) are considered clinical trials. Also, studies to develop or evaluate clinical laboratory tests, such as imaging or molecular diagnostic tests, can be considered clinical trials if the test will be used for medical decision-making for the participant or the test itself imposes more than minimal risk. “Sub-studies” of clinical trials are also sent to WIRB for review.

The following types of studies are not sent to WIRB for review, even if these projects would otherwise fit the definition of a clinical trial:

- Planned emergency research
- Human xenotransplantation
- Gene transfer research
- Embryonic stem cell
- “Registries” involving access to OSU data and/or PHI
- Federally funded research (in whole or part)

### **What is the process for WIRB review?**

To submit proposed research to WIRB, the OSU Application for Protocol Review by WIRB should be forwarded to ORRP with all other required materials (e.g., WIRB application, protocol, recruitment materials, informed consent documents, investigational brochures, data collection instruments, etc.). Investigators must also meet University requirements to serve as PI on a research project reviewed by WIRB. Pre-screening by ORRP staff includes a determination about whether the application meets the criteria for WIRB submission, confirming that all investigators and key personnel have received appropriate training in human subjects research, and verifying that the informed consent form language meets University requirements. ORRP staff will fax a signed Authorization Form to the PI upon verification. After OSU authorization is given, the PI can submit protocol materials and the signed Authorization Form to WIRB. Materials submitted to ORRP will be kept on file by ORRP.

ORRP staff screens applications usually within two business days of submission. Timelines for Western IRB review varies. WIRB will notify the PI of its decision and will provide copies of all regulatory documents to the PI, sponsor, and ORRP. **Note:** Charges for WIRB review are based on a fee schedule maintained at WIRB, which varies depending on the type of review (initial, continuing review, amendment, etc.). For questions about WIRB submission requirements or to obtain WIRB’s current fee schedule, contact ORRP.

The OSU Application for Protocol Review by WIRB can be found at [WIRB - ORRP](#).

## CHAPTER 4 – ADDITIONAL CONSIDERATIONS

*...To keep in mind before submitting your research for review.*

### **Is there anything else I need to know before I begin?**

Investigators must submit a detailed explanation of the study, or research protocol, which describes recruitment procedures, the consent process, study procedures, data collection, method of analysis, etc., as well as provide the actual materials to be used with research participants (e.g., scripts, advertisements, forms, questionnaires, etc.). For more information about what to include in a research protocol for IRB review, see:

[OSU Guidelines for Writing a Research Protocol](#)

[NIH Guidelines for Writing Research Protocols](#)

### **Does the location of my research affect the required review process or submission materials?**

Location plays an important role in determining the risk level of the research and method of review. An OSU IRB may only approve human subjects research activities at locations for which the Board has an understanding of the local research context and the University has oversight mechanisms in place.

#### **OSU Performance Sites**

OSU maintains a list of approved research sites where OSU IRBs have both oversight of the personnel involved in research and knowledge of the local research context. The list can be found at [Research Performance Sites](#).

#### **Non-OSU Sites**

Use of non-OSU facilities (e.g., schools, nursing homes, businesses, etc.) may be requested for research activities. Limited use of outside facilities or involvement of non-OSU personnel who do not become “engaged” in the research (i.e., perform research activities involving human subjects) are permitted with OSU IRB review. However, when the facility or the facility’s personnel at the non-OSU site becomes engaged in the research (e.g., by recruiting participants, obtaining informed consent, collecting data, etc.), additional review requirements apply. When applicable, the external site’s IRB may oversee involvement of its personnel in the study. When the non-OSU site does not have an IRB or to avoid duplicative IRB

reviews, an OSU IRB may serve as the “IRB of record” with appropriate agreements in place and knowledge of the local context. In such cases, inter-institutional agreements, investigator agreements, or redesign of the project may be required to perform the research.

**Collaborations** – If non-OSU sites or personnel are to be engaged in the research, check with ORRP as soon as possible to determine if other agreements, approvals, etc., may be needed. For more information on engagement, see [Engagement of Institutions in Research](#).

## **International Sites**

International studies often require additional safeguards to protect the rights and welfare of research participants. OSU investigators wishing to perform research in international locations must consider the language spoken/understood by potential participants, local customs or laws that might influence how the research is carried out, and possible risks due to social or political conditions. Investigators who will be conducting research internationally need to be prepared to gather and submit the Research in International Settings Appendix, which solicits the following information for IRB review:

- Description of where the research will be conducted (including geographic location and specific performance site, where applicable). Note: In some areas, government-issued research visas are required.
- Copy of local IRB or equivalent ethics committee approval, where applicable. Depending on the location, this may take the form of a letter of approval from an applicable IRB, local university department sponsoring the research, institutional oversight committee, or an indigenous council.
- Information about the local research context, including the current economic, cultural, political, or religious conditions of the area that may affect the conduct of the research, and a description of the investigator’s personal experience conducting research (or studying or residing) in the region.
- The language(s) in which consent will be sought from participants and the research will be conducted, as well as whether the investigator is fluent in this language or whether a translator will be required. If a translator will be used, it should be clear what limitations or risks, if any, this might present for participants, as well as how these potential problems will be overcome or minimized.
- Any local exceptions to the required consent process and, if so, how these will be addressed.
- Copies of the translated informed consent documents and study instruments, as applicable, including verification of the accuracy of the translation(s) by an independent expert.
- Any benefits to the local community that will remain with the community once the research is complete.
- If compensation is being offered, a description of its appropriateness for the setting.
- Procedures for data storage in the local setting and for transfer of data to OSU.

- If the research is federally funded, verification of the Federalwide Assurance for the international performance site.

## **What are my responsibilities as a researcher at OSU?**

All OSU investigators and key personnel must fulfill the University's requirement for education in human subjects protection by taking the web-based course licensed by the Collaborative Institutional Training Initiative (CITI). More information about this educational requirement can be found at [Training Requirements](#). Investigators may also be required to meet additional compliance requirements, including conflict of interest (COI) disclosure requirements. COI information can be found at [Conflict of Interest](#).

### **Principal Investigator**

This title identifies the individual primarily responsible for the oversight and conduct of the study, including all administrative aspects, and the study's adherence to relevant policies and regulations (institutional, state, and federal). Only one PI can be named for a project submitted to the IRB. The individual responsible for the conduct of the study (PI) must be a salaried, regular faculty member having at least a 50 percent University appointment. According to University policy, persons holding some University non-academic titles may also serve as principal investigators on projects directly related to the missions and responsibilities of their offices. At OSU, students may not serve as PIs on their own projects and must name a faculty advisor as PI. The principal investigator title, while a designation of institutional responsibility for the conduct of a study, does not necessarily represent principal authorship on resultant publications, which is a separate consideration agreed upon by members of the research team.

See [Qualifications for Service as a Principal Investigator](#) for further explanation of the requirements to serve as a PI at OSU.

### **Co-Investigator**

This title designates an investigator with an integral part in the research. Individuals do not need to meet the qualifications of PI to be named a co-investigator. For example, a master's or PhD student submitting dissertation or thesis research for IRB approval will be listed as a co-investigator, with the thesis or dissertation chair/advisor listed as the PI. Similarly, an undergraduate working on a senior or honors' thesis or other research project should be listed as a co-investigator on an IRB submission. Faculty members should be listed as co-investigators when they do not have primary responsibility for the conduct of the study.

## Key Personnel

This title designates personnel who play a more limited role in the research than a principal or co-investigator(s). Often, key personnel have little or no input on how the study is designed, but serve a critical purpose on the project, e.g., personnel hired to assist in data collection or analysis, or those responsible for the preparation of regulatory documentation.

## Are there any additional requirements for student researchers or their faculty advisors?

Student research projects are reviewed in the same way as any other human subjects research conducted by faculty or staff. Student investigators (after consultation with their faculty advisors) who are planning to conduct a research project involving human subjects must obtain either IRB approval or exemption prior to initiating *any* research activity/study procedures intended to produce generalizable knowledge. Undergraduate honors' research, master's theses, and doctoral dissertations are normally considered to produce generalizable knowledge. "Retroactive" IRB approval or exemption (e.g., for pilot data) is not permitted under federal regulations and University policy. Failure to seek approval for research before beginning may invalidate the study and/or result in noncompliance findings by the IRB.

OSU policy specifies that a student may not be a PI for human subjects research projects, as explained above. However, student co-investigators, under the guidance of faculty advisors, are responsible for:

- Completing the required human subjects education requirements
- Ensuring that the description of the research is accurate and complete prior to submitting to the IRB
- Obtaining IRB approval prior to initiation of the research
- Informing the IRB of all changes or additions to the previously approved study
- Submitting all required progress reports to the IRB
- Reporting to the IRB all unanticipated problems involving risks to subjects or others.

## Faculty Advisor Responsibilities

It is the responsibility of faculty advisors to help students determine when a project must be reviewed by the IRB and to guide students through the IRB submission process. When classroom research activities are designed or have the potential to be used by students beyond the classroom, it is the responsibility of faculty advisors to assist students in obtaining IRB approval or exemption prior to the initiation of any project involving human subjects. The faculty advisor ensures that student research projects are conducted

according to federal requirements, OSU policy, and the ethical standards of the relevant discipline. Faculty advisors must also fulfill the human subjects education requirements when serving as PI on student projects.

Faculty advisors who supervise student researchers are responsible for the protection of human subjects and are required to:

- Be familiar and discuss with students the ethical and regulatory requirements of human subjects research
- Determine whether projects require IRB review and assist students during the submission process
- Monitor student projects, giving special attention to maintaining participant protections, including privacy, confidentiality, and informed consent, minimizing risk, and voluntary participation and withdrawal
- Assure that ongoing IRB reporting requirements (e.g., unanticipated problems, continuing reviews) are met in a timely manner
- Oversee submission of the final study report to the IRB when the research is completed.

## CHAPTER 5 – WHERE TO FIND WHAT YOU NEED

*...To further help you begin the research process.*

### Where do I find help and/or information about conducting research at OSU?

ORRP [www.orrp.osu.edu](http://www.orrp.osu.edu)

Forms: <http://orrp.osu.edu/irb/forms/>

Research Training: <http://orrp.osu.edu/irb/training/>

Education/help sessions: <http://orrp.osu.edu/irb/workshops/>

Walk-in help for student researchers & advisors: <http://orrp.osu.edu/news/detail.cfm?News=195>

Outreach for investigators: <http://orrp.osu.edu/irb/workshops/>

Office of Research <http://research.osu.edu/>

Research Foundation <http://www.rf.osu.edu>

PI Portal – Direct access to current awards and protocols for researchers: <http://www.eresearch.osu.edu>

Technology Licensing and Commercialization <http://tlc.osu.edu/>

Office of Research Compliance <http://orc.osu.edu/>

OSU:pro – Searchable database created to serve as a comprehensive, single-point resource of faculty and staff expertise and scholarly activity: <https://pro.osu.edu/index.cfm>

Graduate School <http://gradsch.osu.edu/>

Undergraduate Research Office <http://ugresearch.adm.ohio-state.edu/>

OSU Legal Affairs <http://legal.osu.edu/olaindex.php>

### Where can I access the major laws & regulations related to human subjects research?

#### 45 CFR 46 (“Common Rule”)

Code of Federal Regulations from the US Department of Health and Human Services:

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>

#### HIPAA

The HIPAA Privacy Rule is a federal law that generally prohibits health care providers (such as physicians or other health care practitioners, hospitals, nursing facilities, and clinics) from using or disclosing protected health information without written authorization from patients. Investigators intending to use or release any identifiable health information to others (e.g., sponsors, other investigators, collaborators) in connection with the research must indicate this in the IRB application.

PHI is health information transmitted or maintained in any form or medium that includes **ALL** of the three following parts:

- Identifies or could be used to identify an individual
- Is created or received by a healthcare provider, health plan, or healthcare clearinghouse
- Relates to the past, present, or future physical or mental health or condition of an individual; the provision of healthcare to an individual; or the past, present, or future payment for the provision of healthcare to an individual.

The full text of the Privacy Rule can be found at Office for Civil Rights (OCR) website:

<http://www.hhs.gov/ocr/hipaa>.

## **FDA**

21 CFR 50 and 21 CFR 56: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm>

FDA Information Sheets: Guidance for IRBs, Clinical Investigators, and Sponsors:

<http://www.fda.gov/oc/ohrt/irbs/default.htm>

## **Education**

Department of Education Protection of Human Subjects in Research:

<http://www.ed.gov/about/offices/list/ocfo/humansub.html>

## **FERPA**

The Family Educational Rights and Privacy Act (34 CFR Part 99)

<http://www.ed.gov/policy/gen/guid/fpco/ferpa/index.html> is a federal law that protects the privacy of student education records. The law applies to all schools that receive funds under an applicable program of the US Department of Education.

OSU Office of Academic Affairs statement on FERPA: <http://oaa.osu.edu/reports/FERPA.html>

## **PPRA**

Protection of Pupil Rights Amendment (34 CFR Part 98):

<http://www.ed.gov/policy/gen/guid/fpco/ppra/index.html>

## **Ohio House Bill 104**

[http://www.legislature.state.oh.us/bills.cfm?ID=126\\_HB\\_104](http://www.legislature.state.oh.us/bills.cfm?ID=126_HB_104)

<http://www.bricker.com/Publications/articles/907.asp>

## **Ohio Codes**

Ohio Revised Code: <http://codes.ohio.gov/orc>

Ohio Administrative Code: <http://codes.ohio.gov/oac>

## **International**

OHRP's links to international research resources: <http://www.hhs.gov/ohrp/international/>

*The International Compilation of Human Research Protections* is a listing of the laws, regulations, and guidelines that govern human subjects research in many countries around the world:

<http://www.hhs.gov/ohrp/international/HSPCompilation.pdf>

## **Other Helpful Links**

### **Community Based Research**

Community research group in Ohio (includes links to data sets):

<http://communityresearchpartners.org/14654.cfm>

National Community Research Groups: <http://www.mapcruzin.com/community-research/>

<http://www.loka.org/crn/index.htm>

### **Additional Links**

American Educational Research Association: <http://www.aera.net>

American Psychological Association: <http://www.apa.org>

American Society for Bioethics & Humanities: <http://www.asbh.org/>

Belmont Report: <http://ohsr.od.nih.gov/guidelines/belmont.html>

Centers for Disease Control and Prevention: <http://www.cdc.gov/>

Declaration of Helsinki (World Medical Association): <http://www.wma.net/e/policy/b3.htm>

Ethnographic Resources related to Folklore, Anthropology, Ethnomusicology, and the Humanities:

<http://www.loc.gov/folklife/other.html>

Gerontological Society of America: <http://www.geron.org/>

National Association of IRB Managers: <http://www.naim.org/>

National Association of Social Workers: <http://www.socialworkers.org/>

National Cancer Institute: <http://www.cancer.gov/>

National Council for the Traditional Arts: <http://www.ncta.net/>

National Institutes of Health: <http://www.nih.gov/>

NIH Bioethics Resources on the Web: <http://www.nih.gov/sigs/bioethics/>

Nuremberg Code: <http://www.dallasw.quik.com/cyberella/Anthrax/Nuremberg.htm>

Oral History Association: <http://www.dickinson.edu/oha/>

President's Council on Bioethics: <http://bioethics.gov/>

Public Responsibility in Medicine and Research: <http://www.primr.org/>

Secretary's Advisory Committee on Human Research Protections:

<http://www.hhs.gov/ohrp/sachrp/index.html>

Society for Research in Child Development: <http://www.srcd.org/about.html#standards>

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# Appendices

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## APPENDIX 1: SUBMISSION GUIDE

Prior to submitting a protocol for IRB approval, investigators may wish to use this guide for planning purposes to help determine whether all steps have been completed and all necessary submission information has been gathered and/or created. Note that this checklist should not be used as a substitute for familiarity with the official OSU IRB guidelines found on the ORRP website, which contain specific information about current submission requirements. This guide is intended to address materials often overlooked during the initial submission process.

### 1. All research submissions

- Have all investigators and key personnel completed the required CITI human subjects training?
- Does the application contain the signatures of the PI and Department Chair?
- Is protocol, proposal, or relevant section(s) of the thesis/dissertation attached?
- Does the project description, in lay terms, clearly discuss all procedures in which human subjects are involved?
- Is the purpose of the research described clearly?
- Are the participant population and size justified appropriately?
- Are frequencies of intervention and data collection methods described clearly for each type of participant?
- Do the protocol and participant materials describe how subjects will be identified in written reports?
  - Is the level of confidentiality, anonymity, and privacy of participation clearly described to participants?
  - If recordings will be made, does the application and participant materials explain how they will be handled, stored, transcribed, destroyed, and/or archived?
- Have consent forms been translated into appropriate language for non-native English speakers (as applicable)?
  - Have these translations been verified for accuracy by a person fluent in the language but not affiliated with the research?

- Are all supporting documents attached, including the following:
  - Copies of the consent, child assent, and/or parental permission forms or verbal scripts (as applicable)
  - Instruments (including data collection sheets, surveys, questionnaires, etc.)
  - Advertisements/flyers
  - Interview session scripts
  - Debriefing scripts/forms (as applicable)
  - Letters of support
  - Application appendixes
- Are potential conflicts of interest indicated?
- If a known conflict exists, do investigators have a conflict management plan in place?

## 2. Research protocols involving children

- Are child assent and parent permission forms attached?
- For research at day-care centers or schools, is a letter of support from the school principal attached?

## 3. Research protocols involving vulnerable populations (e.g., minorities, prisoners, pregnant women, elderly, economically disadvantaged, adults requiring a legally authorized representative)

- For pregnant women or fetuses, is documentation (e.g., prior research) provided for assessing potential risks to participants? Has Maternal Fetal Committee approval been granted (as applicable)?
- For prisoners, are risks comparable with those acceptable by non-prisoner volunteers?
  - Are the prison IRB or Ethics committee approvals attached?
  - Have the prison research criteria been met or addressed (see Prisoners Appendix)?
- Has a plan to minimize coercion been clearly defined?
- Have specific risks to the population been addressed and minimized?

## 4. Research protocols involving students

- Have students given voluntary, informed consent? Note: Student subject pool participants must be consented for each individual study (i.e., consent to participate in the student pool is not consent to participate in a specific study).

- If course credit or extra credit is offered as an incentive for research participation, is there a non-research alternative that allows students to gain the same credit if they do not wish to participate in research? Is this explained both in the application materials and participant materials?
- If incentives will be offered, does the consent form or script specify that the incentive will be given even if a participant withdraws? Incentives, including course credit, can be pro-rated, but cannot be based on study completion.
- If the investigators are doing research on their own students, is there a detailed description of how the possibility for coercion is minimized and/or a detailed plan to protect the identity of the students who choose to/not to participate in the research?

#### 5. Research protocols involving human biologic specimens

- Do protocol and consent form disclose the specific types of tests to be done, what type of information will be collected, what happens to the specimens at the end of the research, etc.?

#### 6. Research protocols at multiple sites

- Are letters of IRB approval or other agreements for each site attached?

#### 7. Deception research

- Have deception research criteria been met or addressed (see Waiver/Alteration of Consent Appendix)?
- Is justification for deception research provided?
- Has the Deception Appendix been completed?
- Is the participant debriefing process adequate (i.e., are subjects informed about the necessity/purpose of the deception)?

#### 8. Internet research

- Has permission been obtained from the list owner or administrator to recruit participants, use archived data, or post messages to the research site?
- Will encryption software be used and if so, how will participants be informed?
- What specific security measures will be employed (e.g., SSL encryption)?
- Are participants informed about the inherent insecurity of Internet/email data collection (as appropriate)?

## 9. Externally funded research

- Is grant or sponsor protocol attached? Note that the entire grant (including all face pages, budget info, etc.) must be submitted.
- If a grant is pending, is there a plan in place to update the IRB of the award via an amendment request?

## **APPENDIX 2: GUIDE TO WRITING A RESEARCH PROTOCOL/PROPOSAL**

To ensure an effective review by the Institutional Review Board, a full description of the planned research must be submitted with the Application for Initial Review. A research protocol/proposal provides the reader with background information of the problem under study, including the study rationale, a detailed plan for conducting the research involving human research participants, and a discussion of the potential importance of the research. Different disciplines and projects may not require all of the elements below. The outline below is only intended as a guide.

### **I. Objectives**

The purpose of the study (research questions and/or study objectives) should be clearly and succinctly stated. In experimental designs, objectives will be stated as hypotheses to be tested.

### **II. Background and Rationale**

Summarize and synthesize the available research (including published data) to provide justification for the study. Evaluate prior research for relevance to the research question under study. When the proposed research is the first of its type to involve human participants, the results of relevant animal studies must be included. Discuss the anticipated results and potential pitfalls. Describe the significance of the research, including potential benefit for individual participants or society at large. Discuss how public health and social welfare might be enhanced.

### **III. Procedures**

The procedures should include the following:

#### **A. Research Design**

The research design should be identified and should be appropriate to answer the research question(s) under study. Describe the type of research proposed (e.g. experimental, correlational, survey, qualitative) and specific study design that will be used (e.g. pre-test/post-test control group design; cross-sectional design; prospective longitudinal cohort design; phase III, double-blind, randomized control group design, etc.).

#### **B. Sample**

Describe the sampling approach. For experimental designs, include justification for sample size determination. Identify the procedures that will be used to recruit, screen, and follow study volunteers. Specifically define the study sample (number of participants to be enrolled, characteristics of participants to be included in and excluded from the research).

#### **C. Measurement/Instrumentation**

Identify the variables of interest and study endpoints (where applicable). Justify measurement techniques selected. Provide validity and reliability data for selected measures.

#### **D. Detailed Study Procedures**

Methods for study data collection and for avoiding/minimizing participant risks should be included. Include a timeline for participant evaluations and the duration of subject participation in the project. Identify the proposed safeguards for participant confidentiality (plans for coding data and for securing written and electronic participant records). Indicate how long personal information will be stored once the study is completed. Note: Methods will vary with the research approach used (qualitative, quantitative). The selected methods should be sufficiently described to justify the use of the approach for answering the defined research question. Methods should also be described in adequate detail so that IRB members may assess the potential study risks and benefits.

#### **E. Internal Validity**

Threats to internal/external validity should be considered. Describe measures that have been taken to avoid study bias.

#### **F. Data Analysis**

Specify the analytic techniques the researcher will use to answer the study questions. Indicate the statistical procedures (e.g., specific descriptive or inferential tests) that will be used and why the procedures are appropriate. For qualitative data, specify the proposed analytic approaches.

### **IV. Bibliography**

Include a reference list of literature cited to support the protocol statement.