Yo San University
Institutional Review Board Manual
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Chapter 1: Guiding Principles

Individuals who interact with human subjects for research purposes are ethically obligated to protect the privacy, safety, welfare, and rights of those human research subjects. Methods used to assure these protections include appropriate recruitment procedures, informed consent processes, and analyses of the risks to the subjects relative to the benefits of the research. The Belmont Report (1979) was the first published report to address human research ethics and safety.

1.A. The Belmont Report: Guiding Principles

In 1974, the National Commission for the Protection of Human Subjects was formed in the United States. The Commission was charged with identifying basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines for conducting research within those principles.

A *human subject* is a living individual about whom an investigator (whether professional or student) conducting research obtains:

Data through *intervention* or *interaction* with the individual, or

Identifiable private information. (45 CFR 46.102(f))

One outcome of the Commission's work was *The Belmont Report* (1979), which responds to concerns across the medical community about research studies where subjects—many of whom were poor, uneducated, and/or developmentally disabled—had been placed at serious risk and sometimes seriously harmed. The researchers conducting these studies may have intended to benefit society; however, the ways in which participating subjects were treated created a public outcry.

The Belmont Report describes and expands on three ethical principles identified by the Commission:

- Respect for persons

- Beneficence
- Justice

After *The Belmont Report* was issued, the U.S. Department of Health and Human Services (HHS), the National Institutes of Health (NIH), and the Office for Protection from Research Risks (now known as the Office for Human Research Protections, or OHRP), introduced Part 46, "Protection of Human Subjects," to Title 45, "Public Welfare," of the Code of Federal Regulations (CFR), providing specific guidelines and definitions for researchers. Revised Part 46, "Protection of Human Subjects," became effective June 23, 2005.

1.B. Respect for Persons

The Belmont Report describes two key aspects of the principle of respect for persons. This principle leads directly to the requirement for informed consent and the important concept that some individuals (members of protected populations) require additional considerations from researchers. Respect for persons requires that a researcher must:

Acknowledge each subject as an autonomous person by,

- Providing a thorough informed consent process,
- Allowing subjects to decline to participate in some research activities,
- Allowing subjects to refuse to respond to some questions,
- Allowing subjects to withdraw from the research at any time,
- Protecting subjects' privacy and confidentiality
- Protect any subjects who have diminished autonomy.

Under the principle of respect for persons, researchers must provide each potential subject with all information he or she needs to make an informed decision about participating in a research project. Researchers may not withhold any information that might affect that decision, even if researchers are unable to obtain participants for their studies. Researchers must ensure that potential subjects have ample opportunity to ask any questions they may have about the study. (See "Informed Consent.")

To be able to provide realistic information about potential risks and likely benefits, researchers are expected to be thoroughly knowledgeable of their field of study and the related findings of other researchers.

The investigator must make clear to participants that they may decline to participate, that they may refuse to participate in any individual aspect of the study, that they may refuse to answer any question(s), and that they may withdraw from the study at any time, for any reason. Conversely, participants must also be informed that the investigator may terminate an individual's participation in a study, or may terminate the study itself at any time.

Investigators are expected to make every effort to ensure confidentiality and safety of participants. When assuring confidentiality is not possible, potential participants must be informed in advance.

Researchers are required to take all possible precautions to ensure the safety of any participants who are members of a protected group, as these individuals may lack—for a variety of reasons—the capacity to make an informed decision and/or are in circumstances that make them particularly vulnerable. (See "Protected Populations.")

1.C. Beneficence

The *Belmont Report's* principle of beneficence requires researchers to ensure and secure the well-being of their subjects; it speaks to the concept of benefits and risks. The principle of beneficence stems from the principles of medical ethics of the Hippocratic Oath: (1) do not harm, and (2) maximize possible benefits, but it is equally applicable to studies in other fields. Researchers may not intentionally injure any person during the conduct of a study, no matter what benefits might be realized as a result.

The principle of beneficence was and continues to be controversial in the research community. Some researchers argue that research that does not directly benefit participants should never be permitted, while others believe that anticipated future benefits to the larger community (through knowledge gained from a study) can be an acceptable justification for some risk to participating subjects. These opposing interpretations of the principle of beneficence can force researchers to make difficult choices.

Yo San University's IRB has chosen to follow the most commonly held interpretation of the principle of beneficence: participants in a research project do not always have to benefit directly from their participation, as long as a strong likelihood exists that the study will benefit others. The IRB's determination of whether a proposed study exhibits the principle of beneficence will rely on analysis of potential risks and likely benefits.

Benefits must always outweigh risks. The IRB will approve studies that will not directly benefit participants only when the level of risk is minimal. Conversely, if a proposed study presents more than minimal risk, the IRB will not approve it unless subjects are likely to benefit directly.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (45 CFR 46.102(i))

As with the principle of respect for persons, the researcher's expertise is an important factor in analyzing risks and benefits. A researcher needs to be thoroughly familiar with similar research studies before a risks versus benefits analysis of her or his proposed study is possible. If a researcher is unaware of what other researchers have done, he or she may needlessly place subjects at risk. As an example, to place subjects at risk in the investigation of a drug or medical procedure that has already been thoroughly tested is ethically and professionally unacceptable.

1.D. Justice

The third ethical principle established by *The Belmont Report*—justice—governs how benefits and burdens of research are shared. Injustice occurs when benefits of research are denied to participating subjects or when burdens of research are imposed unduly. Recruitment methods must be designed to assure fair selection of subjects based on clearly identified and justifiable inclusion and exclusion criteria.

The principle of justice was the subject of some of the earliest reflections on the ethics of research. Considerable concern focused on medical research that all too often used subjects who were "charity" patients or prisoners when the benefits of the studies, such as improved treatment methods or more effective medications, went—at least initially—only to the more fortunate members of society.

Researchers should always carefully consider the principle of justice as they determine who will be participants in their studies. Researchers may not select subjects from a class of persons (e.g., welfare patients, prisoners, homeless persons, the mentally challenged) only because those individuals are more easily accessible or likely to be more easily persuaded to participate. To ensure that the principle of justice is observed in a study,

investigators may limit participation to a specific class of persons only if the research is directly related to and likely to benefit that class of persons.

Chapter 2: Informed Consent

The Nuremberg Code sets forth fundamental principles for conducting research involving human subjects. The code stresses the importance of voluntary consent to participate, labeling it "essential." Informed consent is also a focus of The Belmont Report, especially as it relates to the ethical principles of respect for persons and beneficence.

All Yo San University research involving human subjects must include an appropriate and effective informed consent process. An informed consent form is typically a component of that process. According to the Office of Human Research Protections of the U.S. Department of Health and Human Services:

> Informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether to participate as a research subject. Informed consent is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act.

In most studies, the informed consent process will include a form—a written explanation of the proposed study that is provided to and signed by each prospective subject as part of the discussion of his or her possible participation. The IRB has developed a recommended outline of components to be included in an informed consent form (see 2, C below). Although researchers may choose to use a variety of formats, the informed consent process must include all elements required by the IRB.

In designing the informed consent process for a study, researchers should be guided by information in this manual as well as by the ethical standards of the discipline of the profession of Traditional Chinese Medicine/Acupuncture.

2.A. Subject Anonymity, Confidentiality, Identification, and HIPAA

One decision researchers must make when designing a research project is how they will protect the identities of their subjects. They need to decide whether subjects will be anonymous, whether their identities will be kept confidential, or whether subjects will be identifiable.

Anonymity

Anonymous means that the researcher cannot link the data to the participant. To ensure subject anonymity, the researcher will not know the names of participants or any personal characteristics that might reasonably lead the researcher or anyone else to discover their identities. Person-to-person interviews are not anonymous because the researcher knows the participant's identity. Always, depending on the methodology, reasonable assurance of anonymity can be expected for some of the following data collection methods and instruments:

- Surveys
- Questionnaires

Researchers may not promise anonymity to potential subjects if they cannot reasonably expect to achieve it. They are expected to take appropriate steps to assure subject anonymity during the study. For example:

- For a paper survey or questionnaire, make sure that the population is sufficiently large and that the instrument does not include questions that might reveal a subject's identity. Instruct participants not to write their names on the survey.
- For surveys or questionnaires conducted over the Internet, use appropriate technology to make sure responses cannot be traced to their sources. (See "Research Using the Internet.")

Even in the best-designed projects, anonymity can be breached. If a participant's identity becomes known, the researcher must immediately advise the individual and then take appropriate action to protect him or her by maintaining confidentiality. The participant should be given the option to withdraw from the study. The researcher may also decide to withdraw the participant from the study. In either case, all data resulting from that individual's participation must be destroyed and not used in the data analysis, writing of the findings, or final product. In extreme situations, such as when a subject has been harmed as a result of loss of anonymity and other participants also appear to be at risk, halting the study entirely and destroying all collected data may be necessary.

Confidentiality

Confidential means that the researcher may be able to identify a participant's data but will not reveal the participant's identity to anyone else. Because subject anonymity is not always possible or desirable, researchers may prefer to design a study for which they can

reasonably ensure subject confidentiality. A researcher may or may not know a subject's identity, but he or she must design the study in such a way that no one else will know or can reasonably be expected to determine a subject's identity. Methods used to ensure subject confidentiality include:

- Securing study data and records and limiting access to them
- Assigning codes, aliases, or pseudonyms to subjects and destroying code books after data are analyzed
- Reporting research results only in aggregate form
- Using masking techniques in reporting research results so that subjects cannot be identified by personal characteristics
- Modifying voices and/or images on audio- or videotapes to avoid subject identification

Subject Identification

For some studies, such as historical and biographical studies, identification of subjects by name may be integral to the study and expected of studies in the field. In studies in which audio- and/or videotapes or other visual images of participants will be included in the findings, subjects are readily identifiable, even if their names are not used.

If subjects' names will be used or they can be readily identified, the researcher must fully inform potential participants during the informed consent process. If a researcher will be using audio- or videotapes, or taking photographs, obtaining a signed release form is required. Potential participants must also be informed about planned uses of these materials and who will be likely to see them. For example, a videotape may be used in a professional presentation or as part of a public recruitment campaign to inform potential enrollees about an exercise program. For some other projects, if identifying a subject is unlikely to cause harm, revealing subjects' identities may be acceptable, especially if the benefits of the study are likely to be enhanced. Researchers are, of course, required to advise potential participants if their identities will be revealed and include an analysis of any risks resulting from their participation.

HIPAA and Research Activities

Most social / behavioral studies involving human subjects operate under the Common Rule (45 CFR Part 46, Subpart A). The Health Insurance Portability and Accountability Act (HIPAA), Privacy Rule, issued August 14, 2002 (compliance date, April 14, 2003), establishes conditions under which protected health information (PHI) may be used or

disclosed by covered entities for research purposes. HIPAA privacy regulations cover any situation involving personal medical information contained in insurance-related transactions. Medical information not involved in an insurance-related transaction is not covered. Insurance information not containing personal medical or health information about a person is also not covered.

Covered entities are health plan providers, health care providers, medical billing services, community health information systems, health care providers who transmit PHI electronically, etc. PHI includes individually identifiable health information, in any form, received or created as a consequence of providing healthcare services or health plan benefits (including demographic information). PHI may be included in health care provider notes, test results, genetic information, medical conditions, diagnoses, treatments, and medication lists.

The HIPAA Act of 1996 mandates resulted in significant changes in laws and regulations governing the provision of health benefits, the delivery and payment of healthcare services, and the security and confidentiality of individually identifiable, protected health information in written, electronic, or oral formats.

Researchers planning to use and access health care information from a covered entity are required to do the following to obtain authorization:

- Present valid authorization forms signed by the individual (patient).
- Obtain approval of an institutional review board or privacy board for the covered entity in addition to Yo San University's IRB.
- Obtain approval for access to and use of a limited data set.
- Verify that their research use is allowed without authorization for the following reasons:
    - Subjects are deceased.
    - The data required do not identify the subjects (all personal identifiers have been removed from the data set).
    - The researcher is employed by the covered entity and is preparing to do the research.

2.B. Indirect and Third-Party Participants

Researchers are ethically obligated to avoid doing harm. Without appropriate protections, a study could possibly harm someone not otherwise affiliated with the study. For example, unless the study will involve biographical or historical research, the researcher should adopt a "no-names" policy in reporting on the research. If a subject mentions a nonparticipant by name, the report should not include that name. Avoiding unintended harm to nonparticipants is also important for the researcher's own protection.

If a study participant provides information about another person—such as a spouse, relative, friend, co-worker, or social acquaintance—the individual is known as a third party. A third party is not considered to be a human subject of a study unless and until the researcher obtains information about the third party that is both private and individually identifiable. When this situation occurs, the Common Rule then applies and requires that the researcher either obtain the informed consent of the individual or destroy the data identifying the third party. If certain criteria are met, the subject's informed consent may be waived. For example, the Common Rule states that information collected must be individually identifiable such as name, address, other contact information, social security number, and identifiable photographic images.

Relationships identified only by association—spouse, father, mother, sister, friend, social contact, etc.—are not usually considered readily identifiable information. Readily identifiable is the primary criterion. Possibly or potentially identifiable information through which someone could ascertain the identity of a third party (e.g., the father of the subject) by piecing together bits and pieces of information requires time and effort unless the third party's full name or other identifying information is also collected. Information that requires such effort is generally not considered readily ascertainable.

2.C. Informed Consent Process: General Requirements

A well-designed informed consent process will include all the following basic elements. If any of these elements are not applicable to the study, the researcher should explain why in IRB application.

- A statement that the study involves research.
- A statement of who is responsible for the research, including the name and telephone number of the principal investigator.
- An explanation of the purpose of the research.

- A description of the procedures to be followed.
- The expected duration of the subject's participation.
- A statement regarding any procedures that may be experimental, if any.
- A description of any reasonably foreseeable risks or discomforts to the subject. If none, a statement regarding no foreseeable risks should be included in the consent form.
- A description of any benefits to the subject or to others which may be reasonably expected from the research. If no benefits, a statement regarding no expected benefits should be included in the consent form.
- A statement disclosing appropriate alternative procedures or courses of treatment, if any, that may be advantageous to the subject.
- A statement describing the extent to which confidentiality of records identifying the subject will be maintained.
- A statement that participation is voluntary, that refusal to participate involves no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits.
- Contact information for persons who will answer pertinent questions about the research and research subjects' rights and whom to contact in the event of a research-related injury.

The informed consent process should include:

- Recruitment materials that explain clearly the research study and what subjects will be asked to do during the study.
- A single, consistently used process for obtaining informed consent from each subject and/or the subject's legally authorized representative prior to the subject's participation in the research.
- An informed consent form and/or oral presentation in language understandable to and age-appropriate for the subject and/or the subject's legally authorized representative.
- Provisions for answering all questions posed by potential subjects to assure that they understand the study and the part they will play in it.
- Sufficient time for subjects to consider and decide whether to participate without feeling pressured or rushed.
- A consent process free of coercion or undue influence.
- A clear explanation that participants may withdraw at any time, choose to not answer questions, or refuse to perform certain tasks, and that no negative consequences will ensue.

2.D. Informed Consent Documentation

Documenting the informed consent process for every participant is critically important for the protection of subjects and researchers. For most studies, this documentation will mean a consent form to be signed by each person agreeing to participate and by the researcher or the researcher's representative.

Two general types of informed consent forms may be used—comprehensive and abbreviated. The type selected will depend on the study and the participants. Regardless of the type of form, the informed consent process must include all required elements.

Informed Consent for Protected Populations and Special Circumstances

Some studies may call for more than one signed informed consent form. In studies involving children or adults who have cognitive impairments, for example, researchers will need to obtain the assent of the subject and the consent of the subject's parent(s), guardian(s), of legal representative(s). (See "Informed Consent with Children" and "Protected Populations" for information about studies involving children and other protected populations.)

Informed Consent in Pilot Studies (Tests)

Researchers planning a pilot study or test prior to engaging in a full study will need to obtain separate IRB approval for the pilot test. An informed consent process for a pilot test must clearly identify it as a pilot study. Risks and benefits for pilot tests are likely to be different from those related to an actual study and must be disclosed in the informed consent process. Once the pilot test is completed, the researcher will need to submit a second application for the full study; the proposal should include findings from the pilot test.

Informed Consent with Focus Groups

Focus groups are sometimes used to obtain feedback on services and to test new ideas. A focus group is essentially a group interview from which the researcher will collect information, and thus requires IRB review and an informed consent process. The application to the IRB for conducting a focus group will need to include the questions to be asked as well as an informed consent process and form. Focus groups may be conducted effectively online as well as face-to-face. For more information about conducting an online focus group, see "Research Using the Internet."

2.E. Comprehensive Written Informed Consent Form

A comprehensive written informed consent form will include all the following elements:

- General information about the proposed study
- An explanation of the purpose(s) of the research, including a statement (when applicable) that the researcher is conducting the study as part of her or his degree program. Students should identify the degree program they are enrolled in at Yo San Univeristy, Los Angeles, California.
- The expected duration of the subject's participation
- The expected frequency of participation (e.g., how many times will a subject be expected to visit the research site or be interviewed)
- A description of the procedures that will be followed
- Identification of any experimental procedures involved
- A description of reasonably foreseeable risks or discomforts to the subject, or a statement that no risks or discomforts are anticipated
- A description of foreseeable benefits to the subject and/or others that may be reasonably expected from the research
- A disclosure of appropriate alternative procedures or courses of treatment that might be advantageous to the subject
- A description of any compensation to subjects, or a statement that no compensation will be given
- A statement of the extent, if any, to which confidentiality of records identifying the subject will be maintained
- Contact information for the researcher (name, address, telephone number, e-mail address)
- Contact information—typically the dissertation chair, faculty advisor, or supervisor—for subjects to obtain answers to any pertinent questions about the research, subjects' rights, and/or reporting study-related injury (name, address, telephone number, e-mail address)
- **Note**: With the exception of university employees and others conducting research studies on behalf of the university, the contact information should be the researcher's own work or home address or telephone number and that of another person qualified to answer questions about the study such as the faculty advisor or course instructor. YSU's general telephone number and address should not be listed on the consent form.
- A statement that participation in the research is voluntary and that refusal to participate will not result in any penalty or loss of benefits to which the subject is otherwise entitled
- A statement that the subject may discontinue participation at any time without penalty

- A statement that participants may decline to answer any questions
- A statement that all data collected in any form on a subject will be destroyed if a subject withdraws from the study
- A statement that participants are entitled to receive an abstract or a summary of the research after its conclusion
- A statement that participants have the right to receive a copy of the informed consent form

A comprehensive written informed consent form may also include any or all the following elements:

- An explanation and description of any compensation and/or medical treatments that will be offered if injury occurs (for research that involves more than minimal risk)
- A description of the circumstances under which the subject's participation may be terminated by the researcher without regard to the subject's consent
- A description of any consequences likely to result from a subject's decision to withdraw from the study
- A description of procedures for termination of participation that includes a statement that all collected data will be destroyed
- A statement that a treatment or procedure may involve risks to the subject that are currently unforeseen
- A statement that significant new findings developed during the research will be provided to the subject, when such information might relate to the subject's willingness to continue participation
- The approximate number of subjects involved in the study
- A disclosure of any financial interest the researcher may have in the outcome of the study

2.F. Abbreviated Written Informed Consent Form

An abbreviated written informed consent form is a simple written statement that all the elements of a comprehensive informed consent form (as outlined in "Comprehensive Written Informed Consent Form) have been provided to potential subjects in non-written form. The purpose of an abbreviated written informed consent form is to document the granting of consent in projects where the researcher has made an oral presentation of informed consent elements to the subject. Abbreviated written informed consent forms are appropriate only for studies involving minimal risk where all the following requirements will apply:

- The researcher will prepare and adhere to a script that presents all elements required of informed consent.
- The form will be signed and dated by each subject or her/his legal representative.
- The researcher will sign and date each form as well as the written script of the oral presentation.
- A witness not otherwise affiliated with the research will be present at every oral presentation.
- The witness will sign and date each form as well as the written script of the oral presentation.
- The researcher will provide each subject and the witness with a copy of the signed, dated, and witnessed abbreviated form and the written script of the oral presentation.

An abbreviated informed consent form must include, at a minimum, all the following elements:

- Project name and dates
- Names of the principal researcher and any other researchers
- Contact information (address, telephone number, e-mail address) for the principal researcher in the event of questions or concerns
- A statement that the subject has been provided with complete and accurate information about the project, followed by a signature/date line(s) for the researcher or the researcher's representative (if a representative is making the presentation)
- A statement of the subject's consent to participate, followed by signature/date lines for the subject
- A statement of verification that the subject appears to have made an informed decision and has received a written description that matches the oral presentation, followed by the signature/date line(s) for the witness
- A statement of consent to participate on behalf of the subject, followed by signature/date line(s) for parents and/or guardians or legal representatives (if applicable)
- A statement that subjects are entitled to receive an abstract or a summary of the study after its conclusion
- A statement that the subject may withdraw from a study at any time for any reason without penalty
- A statement that subjects may decline to answer any question

- A statement that all data collected in any form on a subject will be destroyed if the subject withdraws from the study
- A statement that subjects have the right to receive a copy of the abbreviated informed consent form and presentation script

2.G. Informed Consent with Children

Research projects involving greater than minimal risk according to 45 CFR 46.406 (no prospect of direct benefit, but likely to yield generalizable knowledge about a subject's disorder or condition) and 46.407 (not otherwise approvable but presents an opportunity to understand, prevent, or alleviate a serious health or welfare of children problem) are prohibited. Research involving no more than minimal risk to children may be approved only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents, guardians, or legal representative as set forth in 45 CFR 46.408 (taking into account age, maturity, and psychological state when determining a child's capability for providing assent).

In general, permission should be obtained from both parents before a child is enrolled in research. In some cases, however, permission from one parent is acceptable. Consent from one parent is permitted if a parent is deceased, unknown, incompetent, not reasonably available, or if one parent has legal responsibility for the care and custody of the child. In the absence of a parent or parents able to give consent, consent may be given by a child's legal guardian or legal representative.

The informed consent process for studies involving children requires special care on the part of the researcher. (See "Protected Populations" for information on children as a protected population.) In the State of California, all persons of the age of eighteen (18) or more, who are under no disability, are capable of contracting and are of full age for all purposes. Researchers are required to secure the assent of each child under the age of 18, as well as the consent of the parent(s), guardian(s), or legal representative, provided that the child has sufficient reasoning ability to express the child's wishes; i.e., the child is capable of even limited understanding of what he or she is being asked to do. Researchers in other locations need to be aware of the age of majority of children to assure that assent is obtained in accordance with the application state, country, or local laws.

The IRB does not stipulate the minimum age for which a child must be asked for assent—in some cases, the age and the informed consent process will need to be

determined individually. A child who cannot read may still be capable of assent if the study is presented verbally or visually.

In accordance with OHRP guidelines, the IRB does not stipulate whether the child's assent should be sought before or after seeking consent of a parent or guardian. In general, however, parental, guardian, or legal representative permission should be obtained before seeking permission from the child, particularly in studies involving more than minimal risk. This decision will often be dictated by the study design. For example, for a study involving minimal risk that will occur in a school setting, seeking assent from the children first may be best. If they agree, they are sent home with a request for parent, guardian, or legal representative permission. If the children's assent is obtained first, however, researchers need to make clear that the children cannot participate unless their parents, guardians, or legal representatives also agree—in all cases.

Making separate presentations to the child and the parent, guardian, or legal representative is advisable whenever possible. Combined presentations could result in the child feeling obliged to participate because the parent has agreed. Researchers need to make clear to the parent / guardian / representative that, ultimately, the decision to participate is the child's and that they should not pressure their child into assenting.

When developing an appropriate written assent form for children, take care to use age-appropriate language. In some cases, consulting with an expert in language comprehension abilities (such as a teacher) for the age group under study may be appropriate. Studies that involve children in a broad age range (e.g., age 5 to 12) may require multiple consent forms to avoid "talking down" to the older children. (See sample child assent forms.)

2.H. Informed Consent with Individuals Having Diminished Capacity and Prisoners

Studies that will involve adult participants who have diminished capacity to understand the implications of the study, and thus make an informed consent, will need an informed consent process very much like that used for minor children. Special rules apply to prisoners as subjects, who are, by definition, in circumstances where ability to freely consent can be considered questionable. See "Protected Populations" for information about studies involving these protected populations.

2.I. Informed Consent in Special Circumstances

Studies that will involve subjects with special communication requirements such as individuals who speak a language other than English, who are illiterate, or who have no spoken language will need an adapted informed consent process and informed consent form. Individuals with visual impairments also require special accommodation in the consent process. If potential subjects will be selected from the general population, consider setting eligibility requirements for study participants that would eliminate the need for adapting informed consent to meet an individual's special communication needs.

If an interpreter is required, she or he may also serve as a witness, as long as the interpreter has no other affiliation with the study. All circumstances described below require adaptation of the informed consent process before meeting with potential subjects. A description of the process must be included in the application to the IRB:

- **Non-English Speaking Subject**: When a potential subject speaks a language other than English or has limited ability to understand or read English, the informed consent form and all accompanying materials must be in the subject's language. Researchers who are not fluent in the subject's language will need an interpreter for the presentation of informed consent and throughout the research project. Both an English translation and a native language informed consent form and related materials must be included when submitting an application for IRB approval. The IRB may require independent review of the form and materials to verify that the translation is accurate.
- **Non-speaking Subject**: When a potential subject comprehends written English but has no spoken language (such as an individual who communicates with American Sign Language), a standard, written informed consent form may be used. However, a qualified interpreter / ASL signer should be present during the informed consent process and throughout the research project if the researcher is not fluent in the subject's preferred language.
- **Visually Impaired Subject**: A verbal presentation may be made to a potential visually impaired subject in the informed consent process, but the informed consent form (and any accompanying print materials) must also be translated into Braille. If the subject does not read Braille, excluding him or her from the study may be necessary.
- **Illiterate Subject**: An abbreviated written informed consent form accompanied by a scripted oral presentation is the best approach for the informed consent process for a potential subject who is illiterate or has very limited reading ability. A witness must be present to attest to the presentation of informed consent and to the subject's apparent understanding of it.

2.J. Informed Consent in Authority Relationships

Researchers in positions of authority or perceived authority with potential subjects should take extra precautions in the informed consent process so that potential subjects do not feel coerced into participation. Authority relationships include, but are not limited to, teacher / student, therapist / patient, and/or priest / parishioner. Authority relationships are also inherent to all protected populations with the exception of pregnant women. Additional precautions in the informed consent process and for protected populations are needed.

Researchers who are likely to be perceived as being in a position of authority should always present potential subjects with equivalent alternatives (equivalent for-credit activities, alternative but equivalent treatment options, etc.) so that they know they will not suffer any negative consequences if they choose not to participate. The researcher should also be extremely careful when interacting with subjects, both during the informed consent process and during the study, so that subjects will not feel pressured or coerced. (See "Students Used as Research Participants.")

2.K. Waiver of Subjects' Signatures in Informed Consent

An informed consent process that does not call for subjects to sign an informed consent form may occasionally be acceptable to the IRB. The researcher should determine ahead of time whether to request to waive subjects' signatures. All subjects must be treated the same—either get signatures from all subjects or do not get signatures from any subjects. Unless the IRB has approved an informed consent process through which the researcher will not get subjects' signatures, any person who agrees to participate but refuses to sign the consent form may not be included in the study. The IRB will not accept possible difficulty in securing subject consent as a valid reason for waiving the requirement for signed informed consent forms.

The IRB will typically waive the signature requirement for studies involving surveys (written, online, or conducted by telephone), where the subject's responses to the survey questions constitute implicit consent. An informed consent process is still required: an introductory note, a cover letter, or an oral presentation that contains all the elements of informed consent is required.

The IRB may also waive the requirement for subjects' signatures if the researcher makes a convincing case that (1) the only record linking the subject and the research would be

the consent document and that the principal risk would be potential harm resulting from a breach of confidentiality. Each subject should be asked whether she/he wants documentation linking the subject with the research, and the subject's wishes will govern; or that (2) the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

If the informed consent documentation requirement is waived, the researcher must provide potential subjects with an informed consent form; it would simply not include a line for the subject to sign.

2.L. Waiver of Informed Consent Process

Studies without an informed consent process are rarely acceptable to the IRB. Difficulty in obtaining subjects is not an acceptable reason for eliminating the informed consent process. Studies for which the IRB may agree to waive an informed consent process include:

- Some studies of normal educational practices, curricula, or classroom management methods in an educational setting
- Some non-intrusive, naturalistic observational studies

2.M. Clandestine / Deceptive Research

A clandestine research study is one in which subjects do not know that they are participating in a research study, as in the Humphrey's Tearoom Trade project. In a deceptive project, such as Milgrim's Shock Psychology study, subjects know they are participating in a research project, but they are not told its true purpose.

Because clandestine and deceptive research preclude true informed consent, studies of this type will rarely be acceptable to Yo San University's IRB. A researcher who is designing such a project will need to make an extremely strong case for the reason for the design and provide strong assurances of subject safety, guided by the following statement from The Belmont Report:

> *A special problem of consent arises where informing subjects of some pertinent aspect of the research is likely to impair the validity of the research. In many cases, it is sufficient to indicate to subjects that they are being invited to participate in research of which some features will not be revealed until the research is concluded. In all cases of research involving incomplete disclosure,*

such research is justified only if it is clear that (1) incomplete disclosure is truly necessary to accomplish the goals of the research, (2) there are no undisclosed risks to subjects that are more than minimal, and (3) there is an adequate plan for debriefing subjects, when appropriate, and for dissemination of research results to them. Information about risks should never be withheld for the purpose of eliciting the cooperation of subjects, and truthful answers should always be given to direct questions about the research. Care should be taken to distinguish cases in which disclosure would destroy or invalidate the research from cases in which disclosure would simply inconvenience the investigator.

2.N. Debriefing

Researchers should be prepared to provide subjects with information about the findings of the study after it has ended, including any previously undisclosed information about the study. Note that this usage of the word "debriefing" departs from the standard meaning of debriefing, which is obtaining rather than imparting information.

A debriefing may also be provided after study participants have completed an online questionnaire, interview, or survey. This type of debriefing may also serve as a vehicle for thanking the participants for participating in the study.

Chapter 3: Protected Populations

The federal government has specific regulations for research that involves a subject or subjects who belong to any one of the four groups known as protected populations:

1. children
2. persons with mental illnesses or developmental disabilities
3. prisoners
4. pregnant women, fetuses, and neonates (newborns)

Researchers intending to involve subjects who are members of a protected population in a study are required to abide by the applicable guidelines in "Protected Populations."

Because most of the studies supported by Yo San University are in the area of the medical sciences, the researcher should thoroughly review Office of Human Research

Protections / Department of Health and Human Services guidelines that pertain to medical sciences.

3.A. Children

Children are considered to be protected because their youth may make full understanding of the risks and benefits of a study impossible, making them unable to make a truly informed decision. Recognizing that regulations may vary from state to state and country to country, the IRB defines a child as any individual under the age of 18. If a study will occur in an area where different legal definitions exist, the researcher should incorporate this information into the proposal if he or she is seeking a waiver of requirements for this protected population.

If the subjects of a study will be children, the researcher is expected to respect each child as an autonomous being. Consequently, the researcher must secure the assent of each child as well as the consent of the child's parents / guardians or legal representatives. If a child cannot read, the consent process will need to be adapted to provide the information orally. Documentation of the child's assent and the consent of parents or guardians must follow the guidelines for informed consent.

Each class of subjects that one might consider to be incompetent, such as young children, should be considered on their own terms. "Respect" requires giving them the opportunity to choose whether to participate to the extent they are able to make a decision.

Researchers are not required to obtain a child's assent if the child is incapable of providing it. Each individual child's ability to assent must be determined. In other words, researchers cannot assume that all children below a certain age are unable to assent. Even a very young child may be capable of understanding what is proposed and thus can agree or decline to participate. In rare instances, a child's assent may not be required if the intervention or procedure is likely to benefit the well-being of the child directly and is available only in the context of the research. This situation occurs most frequently in biomedical research.

In determining whether children are capable of assenting, the IRB will take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate.

When interacting with children, use language the child can understand and present concepts in a way the child can grasp. Researchers should also take care that the child does not feel pressured by the researcher as an adult (authority figure) or by the child's parent, guardian, or legal representative—other authority figures.

In studies that involve more than minimal risk, obtain consent from both parents, if possible. (See "Studies with Children—More than Minimal Risk.") For minimal risk studies, consent from one parent is sufficient. Consent from one parent is also permitted if a parent is deceased, unknown, incompetent, or not reasonably available, or if one parent has legal responsibility for the care and custody of the child. In the absence of a parent or parents able to give consent, consent may be given by a child's legal guardian or legal representative.

Children who are wards of the state or of any agency, institution, or other entity may participate in research only if the study (1) is related to the children's status as wards, or (2) will be conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards (that is, the fact that an individual subject is a ward is incidental). In these situations, researchers must provide for the appointment of an advocate for each child who is a ward. The advocate is in addition to the child's guardian or legal representative, and he or she must have the background and experience necessary to act in the best interests of the child for the duration of the child's participation in the research. An individual may serve as advocate for more than one child; the advocate may not be associated in any way with the proposed research, the researcher(s), or the child's guardian organization. (See 45CFR46, Subpart D.)

3.B. Studies with Children—More than Minimal Risk

Research that involves no more than minimal risk to children may be approved only if the IRB determines that adequate provisions are made for soliciting the assent of the children and the permission of their parents, guardians, or legal representative, according to 45 CFR 46.408 (See "Informed Consent with Children.")

In studies with children that involve more than minimal risk, researchers should obtain consent from the parent, guardian, or legal representative before obtaining assent from the child, unless the requirement for obtaining parental, guardian, or legal representative

permission can be waived.

When research is conducted under the following two conditions, permission should be obtained from both parents, unless one parent is deceased, unknown, incompetent, not reasonably available (e.g., lives in another state or country, or is incarcerated), or when only one parent has legal responsibility for the custody and care of the child. (See "Informed Consent with Children" and "Children" under "Protected Populations.")

The Yo San University IRB will approve studies that can reasonably be expected to pose more than minimal risk to children only if one of the following two conditions applies:

- The study has a reasonable prospect of direct benefit to individual subjects. In such cases, the relationship of anticipated benefit to possible risk must be at least as favorable to the subject as benefits presented by available alternative approaches.
- The study has no prospect of direct benefit to individual subjects, but the potential risk is only slightly greater than minimal. In such cases, the intervention or procedure will be comparable to what might be encountered in actual psychological, social, educational, or medical situations. If subjects will not benefit directly, the study must be reasonably likely to yield generalizable knowledge about the subjects' disorder or condition that is of vital importance for understanding or ameliorating it.

3.C. Persons with Mental Illnesses or Developmental Disabilities

Persons who have a mental illness or a developmental disability are particularly vulnerable subjects because their illness or disability is likely to hinder their ability to make informed, voluntary decisions. Their circumstances may also increase the likelihood of harm. This possibility is particularly true with behavioral research that involves persons with certain types of mental illnesses.

In studies that will involve subjects who have mental illnesses or developmental disabilities, researchers should obtain and follow specific guidelines designed for these subject groups by the American Psychological Association (APA).

The informed consent process for studies involving persons with mental illnesses or developmental disabilities should be carefully designed to fit the level of the subjects' ability to comprehend and voluntarily give consent. In some situations, the researcher

will need the consent of a subject's legal guardian or legal representative. In every instance, a patient advocate is required. The advocate must have the background and experience necessary to act in the best interests of the subject for the duration of her or his participation in the research. An individual may serve as advocate for more than one subject. The advocate may not be associated in any way with the proposed research, the researcher(s), or the subject's guardian organization (if applicable).

3.D. Prisoners

Because of their incarcerated status, prisoners (or someone who becomes a prisoner during the course of a study) are under special constraints that may affect their ability to make voluntary (not coerced) decisions about participating as research subjects. Studies involving prisoners may not present more than minimal risk. Prisoners may be asked to participate as subjects only in certain types of studies. Prisoners may participate in studies of the following:

- Possible causes, effects, or processes of incarceration and/or of criminal behavior
- Prisons as institutional structures
- Prisoners as incarcerated persons
- Conditions particularly affecting prisoners as a class
- Practices—innovative or accepted—that have the intent and reasonable probability of directly improving the health or well-being of the individual subject

The IRB may approve research involving prisoners if any possible advantages for the prisoner through her/his participation, when compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in the prison, are not of such magnitude that the prisoner's ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired. In order words, the advantages of receiving special treatment should not lead to a prisoner consenting even if the research is not in his/her best interest.

If a research study participant becomes a prisoner during the course of a study, the researcher must notify the IRB immediately. The IRB will review the research proposal again to determine whether the subject should remain in the study, whether the IRB has sufficient representation for evaluating a study involving a prisoner, and whether appropriate protections are provided for the prisoner.

3.E. Students Used as Research Participants

When faculty or student researchers plan research projects involving students enrolled in classes taught by the researcher, the researcher must assure that participation is voluntary, that students are fully informed of the purpose of the study, and that an informed consent process is included. Coercion—unintentional or otherwise—is not acceptable. Researchers must provide a good scientific reason, rather than convenience, for conducting research with their own students as participants. The research should be relevant to the class subject matter, and participation in the study should be a part of the learning experience for the students.

Researchers presenting good reasons for involving their own students in their research studies, should ask someone else to obtain informed consent and collect the data—distribute and pick up surveys and questionnaires or other instruments. If another person is not available to assist with the research, the researcher should devise other methods for obtaining informed consent and collecting data. These methods should include details about how the researcher will not be able to determine which students participated until final grades are determined. These procedures should be presented in the informed consent form.

Acceptable recruitment methods include posting notices about the study in several locations within the school, distributing flyers to the general student population or to a specific student group, or using both posters and flyers. If personal discussions about a study occur, someone other than the researcher should conduct them. Any student who feels coerced to participate in a research project should contact the IRB Coordinator.

Extra Credit and Alternative Activities

A researcher may give students extra credit for participating in a research study if students who do not participate are given an alternative activity so that they are also able to earn extra credit. Participation in alternative activities must also be free of coercion. The option to withdraw at any time without consequences, such as grades, should be included in the informed consent form. If a student withdraws from the research study, extra credit should still be given.

Other Considerations

If student records are used as a basis for research, all personally identifying information must be removed from the records. School districts and/or individual school policies may

dictate how researchers may obtain database and other student records for research purposes. Researchers must obtain approval to conduct their research in their school and/or school system

3.F. Pregnant Women, Neonates, and/or Fetuses

Pregnant women, neonates (newborns), and/or fetuses are protected by federal regulations as subjects of studies that pose a potential risk to the physical well-being of the woman, the neonate, and/or the fetus. Such projects must be consistent with the federal guidelines established by the OHRP. (See 45CFR46.204 and 46.205.)

For studies that do not pose physical risk to subjects, such as many social and behavioral science research projects, pregnant women are not considered to be protected. As an example, a study that compares some behavioral characteristic of women with children and women who have no children would not usually require special protections for any pregnant women who might be study participants.

3.G. Elderly Persons and Persons with Physical Illnesses or Impairments

The federal government does not require special protections for elderly persons or persons with physical illnesses or impairments because age and/or physical limitations do not mean that an individual is incapable of making an informed decision about participation in a study.

Studies involving elderly persons or physically ill or physically impaired individuals do, however, require researchers to be aware of and sensitive to the potential for additional risk related to a subject's physical limitations or differences.

When working with these subjects, researchers may also need to adapt their informed consent process to meet subjects' special circumstances. If, for example, a study includes elderly persons, the researcher should be prepared for the likelihood that a subject will have hearing difficulties or a visual impairment. (See "Informed Consent in Special Circumstances.")

Chapter 4: Institutional Review Board

Yo San University's IRB reviews and approves applications and is responsible for developing and communicating IRB guidelines and procedures. The authority of the university's IRB extends to all research involving human participants as subjects conducted under university auspices, conducted by any individual or groups of individuals who are affiliated with the university, including:

- **Students**: Full-time, part-time, and casual or transient students enrolled in academic programs or courses offered by Yo San University are required to obtain IRB approval for any research involving human subjects that is a component of the student's academic program or course.
- **Full-Time Faculty and Staff**: Full-time Yo San University employees (faculty and staff) must obtain IRB approval for any proposed research involving human subjects to be conducted under university auspices, including research conducted while on approved (paid or unpaid) personal or sabbatical leave. The policy for ownership of intellectual property will apply.
- **Part-Time Faculty and Staff**: Less-than-full-time Yo San University employees (faculty and staff) must obtain IRB approval for any research involving human subjects to be conducted under university auspices or for which the researcher will use her / his affiliation with the university to obtain external funding.
- **Other Researchers** who are not Yo San University employees or students, but who propose to conduct research on behalf of the university (e.g., consultants, members of the Board of Trustees, alumni/ae members) will be required to obtain approval from the university's IRB if in any way the research is sponsored by YSU, or at the conclusion of the research, the university will own the resulting data.

Researchers who are unclear as to whether their studies need to go to the IRB may contact the IRB Coordinator.

4.A. IRB Authority

Yo San University's Board of Trustees has empowered the IRB as the university's decision-making body with regard to research with human subjects. IRB determinations regarding proposed research are final—they may not be overridden or reversed by any individual or group. Researchers are obligated to abide by the IRB's decisions about their proposed studies. Researchers may appeal an IRB decision to the IRB. (See "Appeals of IRB Decisions.")

Yo San University will not condone, support, or accept any research involving human subjects that:

- Does not have the prior authorization of Yo San University's IRB, unless the requirement for such authorization has been waived by the IRB. (See "Waiver of Requirement for IRB Approval.")
- Has been approved by another institution's IRB but has not been approved by Yo San University's IRB;
- Has been denied approval by any officially constituted IRB (Yo San University's IRB or another IRB).

See "Failure to Submit an IRB Application" for information regarding consequences of engaging in research without IRB approval.

4.B. IRB Structure and Membership

Yo San University's IRB is registered with the Office of Human Research Protections (OHRP) of the U.S. Department of Health and Human Services. Committee composition is in compliance with 45 CFR 46.107. The YSU IRB includes not less than five members. Members have appropriate expertise and diversity in ethnic backgrounds, gender, and cultural backgrounds.

Members of the IRB are appointed by the President, based on recommendations from Deans/Directors of the academic units. The IRB committee includes members with interests in scientific and medical disciplines as well as an unaffiliated, community member. Members serve two- or three-year renewable terms. The IRB operates independently of the university's academic programs. As an institution-wide entity, administratively, the IRB operates directly under the Office of the President.

The IRB is cross-institutional and not program specific. Most members are individuals with Yo San University faculty status, although qualified administrators may also be appointed. In most instances, IRB members hold an earned master's or doctoral degrees. The IRB may (but is not required to) have one member who is a student or an alumni/ae. The IRB coordinator, a voting member, is responsible for IRB operations and for providing assistance and advice to applicants.

4.C. Quality of Proposed Research

The IRB considers the quality of proposed research or the merit of a proposed study only in so far as it is related to ensuring the protection of the rights and well-being of human subjects. However, research design quality and merit are important in IRB members' analysis of a study's potential risks and likely benefits.

A poorly designed research project poses inherent risks to subjects. Studies that have little or no merit are unlikely to result in any benefit. An uninformed researcher may also pose a risk to subjects. During the evaluative review, IRB members consider evidence of the researcher's knowledge of research design, research methods, research ethics, and/or data analysis, and familiarity with the work of other researchers in the field or topic. Researchers should keep IRB criteria in mind throughout the development and implementation of their projects.

Students may submit applications to the IRB only after the proposed study has been approved through applicable academic review and approval processes. Following IRB review, if substantive changes to a project are required in order to meet IRB criteria for approval, the student may need to obtain academic approvals for planned revisions to the study.

IRB members are members of the community of scholars. The IRB may choose to make recommendations to improve a research project separate from its requirements for approval. Although researchers are not required to follow these recommendations—they will be clearly communicated as such—they should certainly be considered.

4.D. IRB Confidentiality

IRB members may not discuss a proposed research study outside the IRB review process. The IRB review process may, however, extend to consultation with individuals external to the IRB such as a student's faculty advisor or dean, or an employee's supervisor. The IRB may also, if necessary, engage a consultant to provide additional expertise needed to make a decision about a proposed study.

When IRB approval is requested for externally funded research or for research to be conducted in collaboration with another institution, the IRB may also communicate with those parties about the study. Such communication will typically be limited to sending copies of official IRB correspondence (e.g., approval letters).

4.E. IRB Conflict of Interest

To avoid conflict of interest or the appearance of conflict of interest, an IRB member who is affiliated with a research project submitted to the IRB for review and approval is recused from the discussion about and decision on the project. Such member may answer questions only and will not vote on approval of the research proposal.

4.F. Advice vs. Assessment

Each IRB member is available to provide general advice and information on IRB policies and criteria for research involving human subjects. An IRB member may not assess an IRB application prior to submission for consideration. Doing so would create a prior relationship or affiliation to the project that would require the individual to recuse her or himself from consideration of the research project.

4.G. IRB Records

The IRB maintains documentation of IRB activities and copies of all research proposals reviewed, reviews that accompany the proposals, approved sample consent documents, progress reports submitted by researchers, and reports of injuries, if any, to subjects.

Minutes of IRB meetings include attendance, actions taken, the vote on these actions; the basis for requiring changes in or disapproving research; and a written summary of the discussion of issues and their resolution.

Records of continuing review activities, modification of research studies, official IRB approvals, copies of all correspondence between the IRB and investigators, and statements of significant new findings provided to subjects are also maintained.

All IRB records, including records relating to research conducted, are retained for at least three years after completion of the research. IRB application and research proposal records are destroyed by shredding three years after the research has been completed or after the researchers have graduated, withdrawn, or are no longer registered and pursuing a degree program at YSU.

Unless otherwise noted, “IRB” refers to the full IRB.

Recognizing that some university employees may have other employment, these guidelines apply only to research projects related to employment by, or relationship to,

Yo San University.

OHRP guidelines allow the nonaffiliated member to be a graduate of the university, as long as the graduate has no other official relationship with the university such as membership in an alumni association.

IRB records are maintained in accordance with 45CFR46.115.

Chapter 5 – Need for IRB Review

Determinations about whether an activity constitutes research involving human subjects are made by the IRB Coordinator. Individuals seeking advice about whether their proposed activities constitute research should contact the IRB Coordinator. Investigators should provide sufficient information about the activity in writing to determine whether it represents human subjects research. .Following review, the IRB Coordinator may make one of the following determinations:

- The proposed activity is not research involving human subjects and may be conducted without IRB review or waiver;
- The activity is research involving human subjects and before it may be conducted, it must be submitted for IRB review and approval; or
- The information is incomplete, and clarification or additional information is needed to make the determination.

Completion of the review may require up to one week. Investigators will be notified electronically or in writing of the determination.

5.A. Requirement for IRB Review

Generally speaking, and unless the requirement has been waived by the IRB as outlined in ”Waiver of Requirement for IRB Approval,” or a class-related project is exempt from IRB review, the following individuals (or groups) who propose to conduct research that involves human subjects are required to obtain approval from YSU’s IRB prior to beginning their research:

- Students enrolled in a YSU academic program, when their proposed research studies are components of that program
- Full-time YSU employees (faculty or staff), when the research is to be conducted under university auspices (including research conducted while on paid personal or sabbatical leave)
- Less-than-full-time YSU employees (faculty or staff), when the research is to be conducted under university auspices, is funded or otherwise supported by the university, or when funding will be sought on the basis of their relationship to YSU.
- Individuals who are not YSU Students or employees, but who propose to conduct research on behalf of the university (e.g., consultants, members of the Board of Trustees, etc.).

5.B. Waiver of Requirement for IRB Approval

All researchers are expected to abide by IRB guidelines that describe the ethical conduct of research and protection of human subjects. Any researcher who is unclear whether his or her study needs IRB approval should contact the IRB Coordinator. All requests for waiver will be considered by the full IRB.

The IRB will not consider waiving the requirement for IRB review and approval for any research project that began after January 1, 2010.

5.C. Studies That Require IRB Approval

Research involving interactions with other humans designed to collect personally identifiable information from, about, or by them and research that involves analysis of existing personal data about other humans typically require IRB review and approval. The IRB will consider an application only after the proposed study has been approved through all applicable academic and/or administrative processes. In addition, each application to the IRB must be reviewed and approved by a dean, program director or supervisor, as applicable.

Title 45, Code of Federal Regulations, Part 46, "Protection of Human Subjects," defines human subjects (sometimes referred to as participants) as follows:

> *Human subject means 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 encompasses physical procedures by which data are gathered and manipulations of a subject or of a subject's environment are performed for research purposes.*
- *Interaction includes communication or interpersonal contact between investigator and subject.*
- *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, 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 medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or be associated with the information) in order for obtaining the information to constitute research involving human subjects.*

The need for IRB approval for some research, such as psychological studies, surveys, interviews, etc., is clear. IRB approval for other types of studies, such as those in which no direct interactions occur between the researcher and a subject, may be less clear. These studies must be handled individually. As a general rule, however, the following activities do not require IRB approval:

- Analysis of widely available existing data, such as Census or Department of Education data, that has been stripped of any identifying information.
- Analysis, by a YSU employee, of existing student or employee data, conducted as part of an institutional self-evaluation or program review.
- Collection of data or information about an organization or institution, through a survey or interview of an employee of that organization; in other words, the information to be collected is not personal to the survey respondent or interviewee.
- Teaching and student teaching, unless the activity will be used to investigate the effect on subjects of a new or experimental teaching model.

See "Class-Related and Other Research Activities" and "Research vs. Practice" for more information.

5.D. Teaching and Student Teaching

Students are not required to obtain IRB approval for teaching a course or for student teaching, unless the activity will combine research with practice, such as using teaching to investigate the efficacy of a new or experimental teaching method. (See "Research vs. Practice," "Students Used as Research Participants," and "Class-Related and Other Research Activities.")

5.E. Pilot Studies

Pilot studies or tests conducted prior to engaging in a full study require separate IRB approval. Because the purpose of a pilot study is to test an instrument or other methodological component, any direct benefits to participants are unlikely. In the informed consent process, prospective subjects must be informed that they are being asked to participate in a pilot study and what participation means in terms of potential risks and possible benefits. Once the pilot study / test is completed, the researcher will need to submit a second application for the full study; the proposal should include findings from the pilot test.

5.F. Oral Histories and Open-Ended Interviews

Oral history interviewing projects in general do not involve the type of research defined by the Office of Human Research Protections (OHRP) in that oral histories do not involve systematic research development and data collection procedures designed to produce generalizable knowledge as defined by the OHRP. However, some oral history projects are considered research and do require IRB review and approval. The IRB Coordinator will conduct an evaluation to determine whether an oral history or open-ended interview activity constitutes human subjects research. This evaluation involves the following steps:

1. Determine whether the activity constitutes research
2. Determine whether the research includes human subjects

If a project meets the following criteria, it is considered to be an oral history project and does not require IRB review and approval:

- The project involves open-ended interviews that are explicitly intended for preservation as a historical document.
- The project involves interviews conducted to document ONLY a specific historical event or the experiences of individuals with no intent to draw conclusions or generalize findings as defined in 45 CFR 46.102(d). (Example: Creating oral history audio recordings of war veterans for a history museum or archives depository. The intent for creating the audio recordings is NOT to draw conclusions, inform policy, or generalize findings.)
- The project involves oral history participants (also known as “narrators”) that are not anonymous individuals selected as part of a random sample for the purposes of a survey. Individuals are selected

because of their unique relationship to the topic, and the questions are gradually developed and open-ended.

- The oral history interviews are conducted in accordance with the Oral History Evaluation Guide "Principles and Standards and Evaluation Guidelines."
- Oral history projects involve interviews in which individuals being interviewed fully understand the purposes, potential uses, and their freedom not to answer questions. Participants / narrators are typically required to sign a release that addresses copyright and terms of access and reproduction (for interviews deposited in a library, museum, or archives), identification of narrators, and disposition of tapes and transcripts.

If a project meets the following criteria, it is not considered to be an oral history project and does require IRB review and approval:

- Systematic investigations involving open-ended interviews designed to develop or contribute to generalizable knowledge. (Example: Open-ended interviews of war veterans to document their experiences to draw conclusions about their experiences, inform policy, or generalize findings.)
- Open-ended interviews conducted to create an archives to provide a resource for other researchers. Because the intent is to create a depository of information for other investigators to conduct research, the project constitutes research under 45 CFR 46 and requires IRB review and approval. (Example: Open-ended interviews conducted with descendants of a specific person(s) to collect data for future research.)

5.G. Class-Related and Other Research Activities

The requirement for IRB approval is not limited to "capstone" research projects—dissertations, theses, and culminating studies. Because the IRB is registered with the Office of Human Research Protections (OHRP), Yo San University has agreed to take necessary measures to protect human subjects in all types of research projects, conducted under its auspices, in which information from, by, or about a human may be involved. This commitment includes class-related research projects.

"Class Projects" refers to class-related research activities that involve human subjects, and the results of these studies will not be published or used in any way beyond the class or course requirement. The "class" may be a seminar, workshop, methods course, an internship, independent study, or other non-capstone activity. Although not typically assigned class projects, internship research projects involving human subjects require

IRB approval.

Instructors have primary responsibility for ensuring that the rights and welfare of human subjects are not violated during class-related research projects. Instructors' responsibilities include communicating to students the ethical principles for protecting human subjects, reviewing student class project applications, and monitoring their consent procedures and research activities. Any adverse incidents must be reported to the IRB Coordinator within 48 hours. (See "Unanticipated and Adverse Events" for reporting information.)

Typical purposes of class-related learning activities that will not be published and do not require IRB approval include the following:

- The activity is intended as experiential learning, and the primary goal is to gain experience and/or greater understanding of some aspect of research ethics, design, and/or methods by conducting interviews, administering a survey, leading a focus group, and so on. Questions developed for these types of activities are directed toward the learning process not the individuals being interviewed, completing a survey, or participating in a focus group. However, an informed consent process is still necessary.
- The learning activity is an integral component of a course of study (e.g., student teaching or classroom observation in an educational program, or clinical practicum placements in a clinical program).

Such learning activities do not constitute research because their purpose is not to develop or contribute to generalizeable knowledge (i.e., the results will not be published or otherwise disseminated beyond the learning environment).

A faculty member planning a course, seminar, academic residency, independent study, or workshop during which students will engage in exercises involving human subjects should consult with the IRB Coordinator well in advance of the proposed start date to determine whether IRB approval is required. If the proposed activity will occur within the learning environment (such as students interviewing one another), faculty are expected to include information about the activity in the course syllabus or course description so that students will be informed prior to registration for the course. The IRB Coordinator will answer any questions when instructors and/or students are unsure whether an activity needs IRB approval.

Guidelines for Class Research Projects Exemption

Research projects conducted by students for courses, seminars, independent studies, workshops, or academic residencies must adhere to the following requirements in order to obtain an exemption from IRB review and approval.

- No Minors. Minors or any other vulnerable populations, such as pregnant women, neonates, prisoners, children, individuals who lack the capacity to consent, non-English speaking individuals, and so on, may not be included in the project. Exception: Projects conducted in established or commonly accepted educational settings, involving normal educational practices such as work on regular and special education instructional strategies, or work on the effectiveness of, or the comparison among instructional techniques, curricula, or classroom management methods.
- No More than Minimal Risk. Minimal risk means no more than the potential participants would normally encounter in their daily lives or during the performance of routine physical or psychological examinations or tests. Studies of any illegal activities or studies requiring collection of private information that could put participants at risk through a breach of confidentiality are prohibited.
- No Deception. Potential participants must be fully informed and given the opportunity to voluntarily consent to participate. Deception is prohibited.
- No Publication. Data from class projects approved under this exemption cannot be used for any type of publication, presentation, or for thesis/dissertation/ culminating study research. Data may be used only for the methods course, seminar, workshop, or non-capstone report.
- No Videotaping. Audio taping is allowed only if the recording is erased upon transcription or no later than the end of the current term.

Class Projects for Publication

Instructors may obtain blanket IRB approval for assigned class projects that do not meet the above requirements and do not qualify for an exemption from IRB review—results may be published, used in a professional presentation, or included in a thesis, dissertation, or culminating study—by submitting the Instructor Application for Class Projects to the IRB Coordinator. The instructor will also prepare an Informed Consent Form Outline template for students to customize for their projects. The consent form must include a statement indicating that the results of the study may be published in a [dissertation, thesis, or culminating study] as well as a future journal article or used in a future professional presentation. Classroom presentations are not considered to be professional presentations. Instructors will review these consent forms before they are

submitted to the IRB Coordinator for approval. Students will also submit interview questions, surveys, and questionnaires to the instructor prior to submitting them to the IRB Coordinator for these class projects. Stuents are not required to submit separate IRB applications when the instructor obtains blanket approval for class research activities.

Instructors' Responsibilities

Instructors are specifically responsible for the following:

- Submitting an IRB application and research proposal (Instructor Application for Class Projects) to obtain blanket approval for assigned class projects that will be published or used in future presentations. A blanket approval is valid only for the academic term during which the class project will be conducted.
- Assuring that students are trained in human subjects research ethics and in all Yo San University guidelines for conducting research involving human subjects.
- Completing review of student applications for class projects that will be published to ensure compliance with IRB guidelines before students submit their applications to the IRB Coordinator.
- Reviewing and approving student applications for class projects that will not be published and for retaining the paperwork for a period of one academic year. These applications are only for the use of the instructors – the IRB does not review them.
- Reviewing and approving all informed consent procedures for both published and not-published projects.
- Reviewing and approving all instruments, methods, and procedures prior to use by students. For published projects, interview questions and other study instruments will be submitted to the IRB Coordinator for review after the instructor has reviewed them.
- Ensuring that students obtain authorization for access to all study locations, including other institutions or agencies.

Informed Consent Form for Class Projects

The class projects consent form (Form 620 Class Projects Consent) is for use only in class projects that will not be published or used beyond the class environment. This form does not meet the minimum necessary federal standards for regular research. Consent forms used in research projects that will be published must include the necessary components found in Form 495 IRB Informed Consent Form Outline and include a statement about possible future publications and other uses beyond the class environment.

Internships

Research studies involving human subjects conducted during internships may not be assigned class projects. Researchers are required to submit IRB Application and Research Proposal and Informed Consent Form Outline to the IRB for review and approval before an internship research project may begin. Research to be conducted at a hospital, clinic or at another educational institution must be submitted to the IRB at those institutions and be approved by the students faculty advisor as well as approved by YSU's IRB.

5.H. Research Using the Internet

Ethical guidelines for research studies in which interactions with subjects occur via the Internet or e-mail are the same as for studies involving other modes of interaction. Internet-based studies must incorporate the principles of The Belmont Report and Title 45 CFR 46. Subjects' identities must be protected to the extent the researcher is able such as using a secure, password protected study Web site and installing security software on the researcher's computer. Studies must include an informed consent process. With appropriate preparation of the informed consent form, obtaining electronic agreement to voluntarily participate is possible. Research involving minors requires obtaining consent from parents, a legal guardian, or legal representative. Written consent (signatures) may be obtained by mailing or faxing an informed consent form or consent statement to the researcher. Telephone consent may be obtained for low risk studies. A face-to-face interview should be conducted to obtain parental consent for studies with minors that involve more than minimal risk.

When reviewing a proposed Internet-based study, the IRB will want to know how the researcher will

- Include an informed consent process;
- Ensure that a participant is in the desired age group and that he/she is not a minor—to the extent possible;
- Provide opportunities for potential participants to ask questions and fully understand what they will be doing in the study;
- Provide processes for subjects to withdraw from the study and to decline to answer any question(s);
- Secure all data collected;
- Provide assistance or treatment if subjects are harmed by their participation in a study;

- Ensure that intruders (hackers) will not be able to enter the study, intentionally or inadvertently;
- Provide a link to the online survey, questionnaire, focus group, or interview questions for review.

Researchers may, for example, design an online informed consent form with buttons for selecting "I Agree" and "I Do Not Agree," followed by a "Submit" button. Potential participants who click "I Agree" and "Submit" will be directed to the survey, questionnaire, focus group, or interview questions. If a potential participant clicks "I Do Not Agree," he/she should be returned to the study's home page or directed to a "Thank you for considering participation in my study" page. Other methods for obtaining consent may also be used. A link to "Exit This Study" should be provided to allow participants to withdraw at any point in the study.

Research Conducted in Online Communities

Conducting research in online communities, such as chatrooms, blogs, social sites, and gaming sites, requires researchers to respect members of the communities, their privacy, and their right to grant permission to conduct research within their communities. Researchers should take care to conduct research in online communities in such a way as to avoid damaging the reputation of researchers that would result in fewer opportunities for conducting research in online communities. Joining an online community for the purpose of lurking in the background while collecting information and quotes for a research study is unethical and would not be approved by the IRB.

A researcher may set up his/her own chatroom, for example, for a research study. Each person who joins the chatroom may be greeted with a statement about the research study. For a low risk study, the statement may be sufficient. For higher risk studies, obtaining informed consent from participants is needed.

Conducting Internet research involving sensitive topics, such as sexual orientation and activities or illegal activities, requires extreme caution to avoid the loss of confidentiality and release of a participant's personally identifiable information. The use of pseudonyms and other coding methods may be used and employed with protection of the link between the real names and the pseudonyms or codes.

Researchers need to determine from whom to obtain consent in online communities—the

site owner, a group's gatekeeper, an online personality, and/or individual participants. Sometimes consent is necessary from more than one party.

Documenting Online Sources

Many articles and reports are available on the Internet and provide good sources for literature reviews and bibliographies for culminating research projects—theses, dissertations, and culminating studies as well as for class-related research projects. Quotes and excerpts from online articles and reports must be properly cited, using the recommended style guide. Total duplication of a portion or of an entire online article or report is considered plagiarism, and it will not be tolerated. Using direct quotes from an online article or report without proper acknowledgment of the source is also considered plagiarism.

5.I. International Research

Research studies conducted in countries other than the United States must abide by all IRB criteria for approval. The same considerations associated with research involving minor children apply as well. Obtaining permission / approval from local, state, and or national officials may be necessary, and another IRB may be associated with the facility where the research study will be conducted. Consequently, researchers need to recognize that the amount of time required to obtain all relevant approvals may be lengthy and plan accordingly. A link to an International Compilation of Human Subject Research Protections on the OHRP Web site is accessible on the IRB Web site.

5.J. Research with Animal Subjects

Animal research projects are not within the scope of this manual.

5.K. Dual Review Authority

Studies for which review by another IRB is required must meet the criteria of both YSU and the other organization or institution. If the requirements for approval of the two IRBs are in conflict, the researcher should be prepared to negotiate a compromise. Studies for which multiple IRB approvals may be required include:

- Research conducted at a hospital, clinic or other treatment facility outside of the YSU campus Community Clinic.
- Research conducted at another educational institution
- Classroom-based research at another educational institution
- Research conducted in another country

Researchers should try to obtain approval from the external IRB before submitting the proposal to the Yo San University's IRB and attach the external IRB's approval to the application. If approval from the other IRB is not possible prior to submitting the application, YSU's IRB may consider and approve the study. However, it will withhold an approved start date until documentation of the other IRB's approval is provided.

5.L. Researchers' Responsibilities

Anyone associated with YSU (faculty, students, staff) proposing to conduct research with human subjects is responsible for reading the IRB guidelines and becoming familiar with The Belmont Report, federal regulations on the protection of human subjects, and the standards for research and ethical practices for the researcher's discipline or profession. Researchers are also responsible for:

- Becoming thoroughly familiar with research design and methods, data analysis, and reporting
- Designing studies that include appropriate protections for human subjects
- Taking all appropriate measures to assure confidentiality and security of all information obtained from and/or about subjects
- Adhering to applicable university policies, including submitting an IRB application and research proposal
- Complying with applicable federal, state, and/or local regulations

A researcher seeking IRB approval is responsible for:

- Review and knowledge of the YSU IRB Manual
- Obtaining approval for the proposed study from the appropriate faculty advisor, dean, program director and/or others, as applicable
- Preparing a complete, accurate, and timely application in accordance with the IRB guidelines
- Obtaining faculty advisor's or supervisor's approval of the application
- Responding to all questions or concerns the IRB may have regarding proposed research activities

A researcher conducting a study involving human subjects is responsible for:

- Adhering to the highest ethical standards applicable to the profession and/or field of study

- Notifying the IRB Coordinator immediately of any adverse events—physical, psychological, or social—resulting from a subject's participation in the study
- Providing all progress reports required by the IRB and university policy
- Submitting a request for continuation of IRB approval at least two months in advance of the expiration date of IRB approval
- Obtaining IRB approval before making any substantive changes to previously approved research
- Retaining records, documents, and informed consent forms for at least three years following the completion of the approved project or activity; researchers who conduct studies in compliance with specific professional associations, such as APA, may be required to retain study records for a longer period
- Destroying any link between participants' names and pseudonyms or codes immediately after the study is completed

5.M. Faculty Advisors' and Employee Supervisors' Responsibilities

Faculty members, deans or directors who advise students and supervisors of university employees, which include faculty and staff employees, proposing to conduct research involving human subjects are responsible for:

- Becoming familiar with IRB policies and procedures
- Submitting an IRB application and research proposal for all faculty and staff research projects that involve human subjects
- Ensuring that any student or employee who plans to conduct a study involving human subjects does not do so without IRB approval
- Providing appropriate advice and assistance in the design of the research and preparation of the application for IRB approval
- Ensuring that students or employee researchers have sufficient knowledge of research methods and ethics to engage in the proposed projects
- Reviewing the IRB applications and research proposals carefully to ensure they meet IRB requirements
- Providing appropriate oversight of ongoing research
- Ensuring that researchers conduct studies in accordance with IRB approval
- Notifying the IRB of any changes, unanticipated events, adverse incidents, concerns about ongoing research, or other study-related information

5.N. Failure to Submit an IRB Application

Although federal and YSU policies are clear that all research projects involving human subjects are to be submitted and approved prior to engaging in research activity, in rare

cases the IRB will agree to conduct a post-hoc review when research is in progress without prior IRB review and approval. The IRB Coordinator will first determine that the research is, in fact, either in progress or has been completed without prior IRB review and approval. Once this confirmation is secured, the following procedures will be followed:

- The principal investigator (PI) will submit a complete application to the IRB along with a short letter requesting a post-hoc review. The letter should include a rationale for submitting the protocol retroactively.
- The application will be considered by the full IRB.
- The IRB will review the methods used to provide for basic human subjects protections and identify any problems with the procedures. The IRB may require changes to areas still open to revision such as data analysis or protecting the privacy and confidentiality of existing data.
- Approval will not be granted retroactively for the stages of the project that have already been completed. However, for researchers whose projects have been initiated and/or are currently in progress, the IRB may provide approval only for those segments of the project that have not been initiated at the time of review. If a research study involving human subjects is conducted without IRB approval, data and results of that study will not count toward that student's degree program.
- The IRB will provide written comments regarding the research activities that involved human subjects and the degree of risk associated with the study. The IRB will communicate its findings to the PI, the faculty advisor, and to other appropriate individuals in the academic division.
- If the IRB finds serious problems with the human subjects protections and/or finds that the researcher(s) knowingly engaged in the study without IRB approval, the IRB Coordinator will conduct an investigation of noncompliance, and the findings of the investigation will be sent to the researcher in writing.
- If the IRB finds that an individual intentionally bypassed the IRB approval process, or that a study under way does not meet IRB criteria, then IRB approval will be denied. Because IRB approval for research with human subjects is mandated by institutional policy, any student that does not have IRB approval should not be considered to meet applicable degree requirements.
- If a student is engaging in a study involving human subjects without having first obtained IRB approval, the post-hoc process described above may be initiated.

- If a student has completed a study involving human subjects, and did not have IRB approval, then the work may not be accepted as meeting degree requirements.

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Chapter 6: Types of IRB Reviews

IRB reviews may be conducted by the IRB Coordinator, by another individual IRB member, or by the full IRB. The type of review will depend on the study. Researchers should become familiar with the types of IRB review to ensure that their applications are appropriately designed. The requirement for including an informed consent process applies regardless of the type of review. Review of an application will fall under one of three general types:

(1) review for exemption from IRB review

(2) expedited review

(3) full review.

The IRB may decline to consider a research study that has been completed without IRB review and approval.

6.A. Review for Exemption from IRB Review

The following examples are of studies that could be eligible for exemption from IRB review. Studies of the types discussed in Categories 1 through 4 are often used in social and behavioral research.

1. **Educational Practices**. Research conducted in established or commonly accepted **educational settings, involving normal educational practices** such as (a) research on regular or special education instructional strategies, **or** (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. **Educational Tests (1)**. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), **surveys, interviews, or observations of public behavior, *unless*** (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) any disclosure of the human subjects' responses outside the

research could reasonably **place subjects at risk** of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. [A survey returned without a subjects' name or any other identifier (an anonymous survey) may be considered exempt.]

3. **Educational Tests (2)**. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), **surveys, interviews, or observations of public behavior** that is not exempt under (2(b)) above if: (a) the human subjects are elected or appointed public officials or candidates for public office; or (b) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. **Existing Data or Records**. Research involving the study of **existing data, documents, records**, or pathological 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.

5. **Public Benefit or Service Programs**. Research and demonstration projects designed to study, evaluate, or otherwise examine (a) public benefit or service programs; or (2) possible changes in methods or levels of payment for benefits or services under those programs.

6. **Taste and Food Quality**. Evaluation and consumer acceptance studies conducted for the purpose of determining whether (a) wholesome foods without additives are consumed; or whether (b) 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 (FDA), or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Service of the U.S. Department of Agriculture (USDA).

Researchers must submit a summary of their research study and the Claim for Exemption from IRB Review to the IRB Coordinator. The IRB Coordinator will notify the researcher via e-mail regarding whether the study is exempt from IRB review.

6.B. Expedited Review

An expedited review process is used for certain kinds of research that involve **no more than minimal risk** but do not qualify for exemption and for relatively minor changes to previously approved research. To qualify for expedited review, the study must fit one or more of the following criteria. Studies that may qualify for expedited review include:

- Research involving materials (data, documents, records, specimens, voice, video, digital, or image recordings) that were **previously collected, or will**

be collected solely for non-research purposes (such as medical treatment or diagnosis).

- Collection of data from voice, video, digital, or image records made **for research purposes**.
- 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**.
- **Continuing review of research previously approved** by the convened (full) IRB as follows: (a) Where the research (i) 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.
- **Changes to studies previously approved** by the IRB, provided that the proposed changes do not result in more than minimal risk.

Other types of medical and clinical studies also eligible for expedited review include:

- 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. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risk associated with the use of the product is not eligible for expedited review.) (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 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.

- Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant 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.

- Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) Hair and nail clippings in a nondisfiguring

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.

- 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 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 (MRI); (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.

The expedited review process **may not be used** when identification of subjects and/or their responses would reasonably **place them at risk of criminal or civil liability** or be damaging to 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.

Studies must include procedures consistent with sound research design. The IRB will consider only risks and benefits that may result from participation in the study—distinguished from risks and benefits subjects might encounter if not participating. Finally, the IRB will not consider possible long-range effects of applying knowledge gained in the research (e.g., possible effects of the research on public policy) as among those risks / benefits that fall within its responsibility. (See "Criteria for Approval.")

Researchers must submit Application and Research Proposal Outline and Expedited IRB Review Form to the IRB Coordinator. An expedited review may be carried out by the IRB Chair or by one or more experienced reviewers designated by the Chair from among voting members of the IRB. The expedited review is not available for federally classified research involving human subjects. Federally classified research is restricted to individuals with United States government security clearances.

6.C. Full Review

Full IRB review is required for proposed research (or proposed changes to previously approved research) that might reasonably be regarded to pose some degree of risk (i.e., greater than minimal. (See "IRB Application Preparation and Submission.") If the answer is yes to any one of the following five questions, the research requires full review.

- Has previous research (researcher's own or others') indicated that this study presents a possible risk?
- Could participation in the study put a subject at risk for legal or civil liability, disciplinary action by an employer, invasion of their privacy in regard to sensitive aspects of her/his behavior (e.g., illegal conduct, drug use, alcohol use, sexual behavior), or have other adverse consequences, including embarrassment or other emotional distress?
- Will subjects be given drugs or other substances?
- Will the research involve intrusive procedures (physical, psychological, cultural)?
- Will the research involve subjects who have life-threatening physical conditions?

6.D. Review of Ongoing Research

The IRB conducts systematic reviews of previously approved, ongoing research with human subjects. As a condition of approval, the IRB may require the researcher to provide progress reports and/or a concluding report. If the IRB requires a progress report, the approval letter will include a submission date and an outline of the information the researcher is required to provide. The IRB may also decide, subsequent to approval, to require a progress report and/or concluding report.

- Progress Reports. Progress reports typically include a description of the project to date, the number of subjects recruited, the number of subjects who withdrew from the study, reasons for withdrawal, a

description of any changes to the research design, a description of any significant new findings, a description of any unexpected or adverse events, and a copy of the informed consent form in current use.

- Concluding Reports. Concluding reports provide a brief statement that all data have been collected, a summary of the project, and a description of how and where the researcher will communicate findings. It may include sections of the dissertation, thesis, culminating project, etc.

Researchers are responsible for submitting required progress and/or concluding reports on or before the date established by the IRB. If a researcher fails to do so, the IRB may suspend or terminate approval for the study. The IRB may also suspend or terminate approval if a progress or concluding report describes a study that is substantively different from what was approved by the IRB and/or unanticipated or adverse events were not reported to the IRB. (See "Modifications to Previously Approved Research" and "Suspension or Termination of IRB Approval.")

6.E. Continuation of IRB Approval

Twelve (12) months is the maximum length of time granted for initial IRB approval of a research study involving human subjects. IRB approval is intended to cover recruitment and data collection. If these phases are not completed within the approved twelve (12) months, obtaining continued IRB approval is required. IRB approval may be continued for an additional six (6) or twelve (12) months. Researchers are responsible for supplying information necessary for obtaining IRB re-approval of their research studies.

The IRB uses full IRB review procedures unless the research meets the expedited review criteria for continuing review. To approve the research, the full IRB will determine whether all requirements for the initial approval continue to be met (See "Criteria for Approval") Continued IRB approval for higher-risk studies may be limited to a maximum of six (6) months. If researchers do not obtain an official IRB re-approval, they are required to suspend their studies until they have received re-approval. If the IRB determines that a research study has continued beyond its approval ending date, the IRB will require the researcher to suspend the study until he/she has applied for and received IRB re-approval to continue. Studies continued beyond the original approval period, without IRB re-approval, are unapproved studies. Researchers who do not obtain re-approval but continue their studies will be in violation of YSU and IRB requirements.

An expedited review procedure may be used for the continuing review of research previously approved by the full IRB as follows:

- The research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects; **OR**
- No subjects have been enrolled and no additional risks have been identified; **OR**
- The remaining research activities are limited to data analysis.

To avoid interruptions to a study, a researcher should provide information needed to obtain re-approval at least two months in advance of the need for continued IRB approval. In most cases, the IRB Coordinator can approve a continuation of previously approved research. Continued review by the full IRB is required for studies originally reviewed and approved by the full IRB that do not meet the expedited review criteria for continuing review. (See Continuing Review / Request to Renew IRB Approval)

6.F. Modifications to Previously Approved Research

Researchers are required to obtain advance IRB approval for substantive changes in the research model, informed consent form(s), survey instrument(s), or nature of subjects. IRB approval of the research with the proposed changes will extend no more than twelve (12) months from the date the researcher proposes to implement the changes.

If a subject experiences an adverse or unexpected reaction or side effect, the researcher will be required to make changes to the study to avoid future, similar situations. When an adverse event occurs, proposed changes to avoid additional adverse events require full IRB review.

The request for approval of proposed changes to a previously approved should include the following:

- A description of any proposed changes to the protocol
- Copy (ies) of informed consent form(s), if they are to be changed
- A progress report that includes:
  - The number of subjects who have participated to date, whether they are active, completed, or pending, and the time frame for future participation

- Any unexpected events, adverse reactions, or side effects. If none, state none.
- Summary of the results to date

Submit the application and Continuing Review / Request to Renew IRB Approval Form, and Modification Request Form to the faculty advisor, dean , program director, or supervisor for review and signature before sending it to the IRB coordinator; it will not be accepted for consideration without these approvals.

6.G. Collaborative Research

A collaborative research project involves more than one researcher and may involve researchers affiliated with different institutions. Participating researchers and institutions share the responsibility for safeguarding the rights and welfare of human subjects and compliance with applicable regulations.

- Projects Involving More Than One YSU Researcher. The IRB application and review process for research studies involving more than oneYSU researcher is the same as the process for projects with a single researcher. Be careful to describe any differences in researchers' roles and responsibilities and to design an informed consent process that clearly identifies all researchers.
- Projects Involving Researchers Affiliated with Another Institution or Organization. When a YSU researcher engages in a study with someone from another organization or institution, the project should have a lead institution—usually the organization where the primary investigator is affiliated. Such projects typically require approvals from more than one IRB. When possible, students involved in collaborative projects as a component of their degree program should obtain the approval of the external organization's IRB prior to applying for approval from YSU's IRB. If prior approval is not possible, the IRB may approve the proposed study but will not permit it to begin until the student provides documentation of approval of the other IRB.

6.H. Certification of Research

External funding for a research study may require IRB certification of the project, even when no human subjects are involved. The IRB certifies projects through formal notification to the Office of Human Research Protections (OHRP) of the U.S. Department of Health and Human Services or to the applicable nongovernmental funding department / agency. For collaborative research involving more than one institution, only the IRB at the lead institution may file for certification with the OHRP. Proposed research for which

the principal researcher requests IRB certification must be reviewed and approved by the full IRB, even when it qualifies for review for exemption.

6.I. Suspension or Termination of IRB Approval

The IRB has the authority to suspend or terminate IRB approval of research involving human subjects for any of the reasons listed below. Researchers are obligated to halt their research immediately if they receive a notice of IRB suspension or termination of IRB approval.

The decision to suspend or terminate IRB approval of a research project may stem from the IRB's charge from the university's Board of Trustees, from the IRB's responsibilities to human subjects, from the obligations of an OHRP-registered IRB, from our commitment to the protection of human research subjects evidenced by a Federalwide Assurance, or from IRB policies and procedures. The IRB is required to and will suspend or terminate IRB approval for research if it determines that:

- Any portion of the research project is being conducted without IRB approval, when IRB approval is required
- IRB-approved research continues beyond the end date of IRB approval
- The research study is substantively different from what was approved by the IRB or
- Subjects of the research have been harmed as a result of the research

The IRB may suspend IRB approval of a research study based on information provided by someone other than the researcher. In fact, as a member of the academic community, researchers are obligated to notify the IRB Coordinator immediately if they have a concern about the conduct of research involving human subjects or the safety of those subjects. Notices of suspension or termination of IRB approval will be sent to other interested parties such as a faculty advisor, dissertation chair, dean, or funding agencies, if any. In emergency situations, such as when a subject has been harmed, the IRB Chair has the authority to suspend research. The IRB is not required to investigate or consult with the researcher prior to suspending IRB approval of a research study. In fact, in many cases, it will not do so. In emergency situations, notice of suspension of IRB approval may be made by telephone or e-mail.

This list is based on Title 45 CFR Part 46.101.

"Categories of Research that May Be Reviewed by the Institutional Review Board (IRB) Through an Expedited Review." Available from http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm.

Extracted from 45CFR46.110. Available from http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm.

The IRB may approve internal assessment research projects conducted by or on behalf of university administrative or academic units for up to 24 months. See "Class-Related and Other Research Activities."

Source: Guidance on Continuing Review, dated January 15, 2007, available at http://www.hhs.gov/ohrp.

Chapter 7: **IRB Application Preparation and Submission**

Applications for IRB approval must be submitted to the IRB Coordinator using the IRB application and research proposal outline. Applications must be error-free, meet all IRB requirements, and contain all information necessary for the IRB to make a determination. Applications that do not meet IRB requirements may not be accepted by the Coordinator. Official IRB decisions are communicated in writing by letter; only communications from the Chair of the full IRB, the IRB Coordinator, or the Coordinator's designee are considered official.

Students may not apply for IRB approval if the proposed study has not first been reviewed and approved through all applicable academic acceptance processes for their degree program.

Faculty and employees may not apply for IRB approval without first securing the approval for their projects from their supervisors. For internal assessment studies, the approval of the Dean or Program Director may also be required.

7.A. Contact with the IRB

Contacts with the IRB should occur through the IRB Coordinator. A researcher who has questions about his/her application should not contact any voting IRB member other than the Coordinator. Such contact might later cause the member to recuse her or himself from voting on approval of the application. The preferred method for communication with the IRB Coordinator is by e-mail.

7.B. Preparation for IRB Review

The researcher, in consultation with the IRB Coordinator, will determine which type of review is needed, based on potential risks to study participants. The three types of IRB review are: review for exemption, expedited, and full review. Decision trees may help researchers determine which type of IRB review is indicated. Researchers may also consult with the IRB Coordinator.

7.C. Time Allowance for IRB Approval

A properly prepared application that meets all IRB criteria for approval is the best assurance of timely IRB approval. Submitting an application at least two months before the desired beginning date for the study is strongly recommended.

A possible delay in the expected project start date is not considered sufficient reason to expedite IRB consideration of a study outside the normal meeting agenda. Waiting until receiving IRB approval before making final arrangements to begin the study is recommended. Researchers may need IRB approval before they can make arrangements and/or obtain approval from individuals responsible for the physical location of their studies such as a clinic, a homeless shelter, or a treatment center. Assuring that appropriate location officials, such as owners, administrators, and/or supervisors, have been contacted and have granted permission to conduct research in a specific location/room/building is an essential element of ethical research. Approval letters or e-mails from the appropriate officials or supervisors should be included with the application or submitted as soon as received. Researchers may not begin recruiting study participants until their IRB applications have been formally approved, and they have received the official approval letter from the IRB.

Studies are expected to begin within six months of the date that IRB approval is granted. Under special circumstances, the IRB will consider applications for which the start date is more than six months in the future. However, if a researcher makes any substantive

changes to his/her study in the interval between IRB approval and the start date, the researcher must submit an application for approval of those changes. (See "Modifications to Previously Approved Research.")

7.D. Application Preparation Requirements

Applications must meet all the following requirements to be accepted for consideration by the IRB:

- The application is complete, prepared according to the IRB Application and IRB Research Proposal Outline.
- The application includes all required documents / attachments, as outlined in the IRB Research Proposal Outline.
- The research proposal has been approved through appropriate academic procedures.
- The application has been reviewed and is accompanied by a written approval from a faculty advisor, dean, dissertation chair, or supervisor.
- The application is written at a level appropriate for college or professional work: It is free of typographic or grammatical errors. It is submitted via e-mail attachment (e.g., not handwritten).
- The descriptive section of the application is no more than 3-5 pages, double spaced, exclusive of attachments.
- The application is consistent, in terms of purpose statements, descriptions of risks and benefits, and so on.

7.E. Application for Full Review

An application for full review is a comprehensive description of a proposed research project. (See "Full Review.") It must include the following components:

1. A completed, signed (by faculty advisor, dean or program director, or supervisor, and researcher), IRB application and research proposal.

2. IRB application and research proposals submitted for full review by faculty and staff members are submitted first to their supervisors who must approve them before the application and research proposals are submitted to the IRB for review and approval.

3. The approval of a faculty advisor or supervisor, indicating that he or she has reviewed the application. Faculty advisor or supervisor approval may be in the form of a signature on the IRB application and research proposal outline, submitted by e-mail, in a pdf attachment, or in a letter attached to the application. Advisors and supervisors may also send an e-mail to the IRB Coordinator in

which they state that they have read and approved the application and research proposal.

4. A detailed description of the proposed research, exactly following the "Outline for Research Proposals." No items may be omitted: If one or more items are not applicable, include a statement to that effect (e.g., "participants will not be compensated.").

5. The application and research proposal page header or footer formatted so that it shows the researcher's name and the name of the proposed study on every page. Page numbering should show total pages (i.e., 1 of 5, 3 of 5, etc.).

6. All applicable supporting documentation such as informed consent form(s), scripts, survey instruments, recruiting media, etc.

7.F. Application for Expedited Review

Components of an application for expedited review are the same as for a full review. However, the description of the research will focus on establishing eligibility for expedited review and documenting that the proposed study poses no more than minimal risk to human subjects. (See "Expedited Review" and "Criteria for Approval.")

7.G. Application for Review for Exemption from IRB Review

Components of an application for review for exemption include a summary of the proposed research project as well as Form 626 Claim for Exemption from IRB Review. (See "Review for Exemption from IRB Review.")

7.H. Outline for IRB Research Proposals

All applications submitted for IRB consideration must include a description of the proposed research following the IRB Research Proposal Outline to assure standard formatting. Use the bold face items on the Research Proposal Outline as headings and incorporate information described in the outline. If any item is not applicable, it should not be ignored—include a statement that the item does not apply to the research study. Do not include the "notes" or lettered items in the proposal—they are meant to help during preparation of the document. Proposals should be **no longer than 3-5 pages, double-spaced, not including attachments**.

7.I. Method for Application Submission

Applications may be submitted only to the IRB Coordinator at YSU. Electronic submissions are preferred and strongly encouraged. If electronic submission is not possible, an application may be submitted on paper. Applications that include

attachments available only on paper, such as externally developed questionnaires, the attachments may be submitted on paper. Electronically submitted applications should be in MSWord. Hard copy applications should be submitted on 8.5" by 11" paper, printed on one side only. Faxed applications are strongly discouraged because the quality of the document may be lost.

Electronic signatures are acceptable for electronically submitted applications. If e-signatures are not available, the signed signature page of the application may be sent or faxed separately. Faculty advisors, deans, dissertation chairs, and supervisors may indicate approval of an application by signing it before it is submitted, in a separate letter, a pdf document, a fax, or an e-mail to the IRB Coordinator.

Electronically submitted applications should be sent to the IRB via the published email address. Printed applications should be clearly marked "**Attention: Institutional Review Board**" to ensure prompt delivery. Students and Faculty should not send their IRB applications to their academic program office.

Chapter 8: The IRB Review Process

The full IRB reviews research proposals involving **more than minimal risk** to human subjects. Individual IRB members and the IRB Coordinator review proposals for exemption from review and expedited reviews. Centralization of IRB records and operations, with a designated IRB Coordinator, ensures that the IRB is able to fulfill its responsibility for tracking and oversight of ongoing research.

8.A. Application Submission Process

All applications should be submitted to the IRB Coordinator. The Coordinator will conduct a desk review to determine whether the application meets general IRB criteria with regard to format and content. IRB review is not scheduled until an application is accepted by the Coordinator.

If an application is not acceptable, the Coordinator will contact the researcher (usually by e-mail), outlining the requirements for acceptance. These requirements range from simple clarifications or additions to a total revision of the proposal and/or attachments. All revisions should be highlighted to facilitate the review process.

8.B. IRB Meetings and Meeting Procedures

IRB meetings are held on an as needed basis. Meetings are called by the Chair as necessary. A quorum is required for every meeting: A majority of IRB members constitutes a quorum, which includes a nonscientific member. Agreement of the majority of the quorum is required for official determinations on issues requiring approval of the full IRB.

The IRB Coordinator reviews each application received. Once accepted for review, the Coordinator places acceptable applications requiring full review onto the agenda for the next IRB meeting, and sends the applications to IRB reviewers.

Applications for studies that qualify for review for exemption or expedited review are assigned either to an individual IRB member or to the IRB Coordinator. Reviews for exemption and expedited reviews are conducted in the order received and accepted. The Coordinator provides a summary of all exemption and expedited reviews to the IRB on a monthly basis.

8.C. Time Frame for IRB Review

No application submission deadlines apply to IRB applications. Applications requiring review by the full IRB will be scheduled for the next available meeting. Applications for full review should be submitted at least one month prior to the convened IRB meeting to allow for the Coordinator's review. Applications are mailed to IRB members before the monthly meeting.

Within 3 to 10 working days after an application is received, the Coordinator (or Coordinator's designee) will complete a desk review to determine whether the application is acceptable (i.e., meets IRB criteria with regard to format and general content

8.D. Official Notification

Informal notifications of IRB decisions may be made by e-mail. However, researchers may not begin their projects, including recruitment, until they have received the official approval / notification letter from the IRB Coordinator.

Official, written notice of all IRB decisions will be made within 3 to 7 working days of the decision. All official notices will be sent by the IRB Coordinator (or Coordinator's

designee), in the form of a letter on university letterhead. See IRB Determinations for the range of decisions available to the IRB.

8.E. IRB Determinations

A research proposal may be approved, conditionally approved (revisions, corrections, or changes may be required), deferred for revision (the proposal is not ready for IRB review or needs additional work), referred for review by an expert in the research area (if such expertise is not available on the IRB), or denied.

8.F. Approval

If an application meets all IRB criteria, it will be approved. The researcher will receive an official notification letter on letterhead from the Coordinator, which will stipulate the duration of IRB approval—typically twelve (12) months from the proposed or approved start date of the study—and any required progress or concluding reports. The researcher may begin the research project after receiving the official approval letter.

Criteria for Approval

1. Risks to subjects are minimized: (i) By using procedures consistent with sound research design that 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.

2. 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 will 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). The IRB will consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3. Subject selection is equitable. The IRB will take into account the purposes of the research and the setting in which it will be conducted and will pay particular attention to special problems of research involving vulnerable populations such as children, prisoners, pregnant women, mentally disables persons, or economically or educational disadvantaged persons.

4. Informed consent must be obtained for each prospective subject or the subject's guardian, or legally authorized representative, or waived, in accordance with IRB guidelines.

5. Informed consent must be appropriately documented in accordance with IRB guidelines.

6. Proposed research procedures should make adequate provisions to protect the privacy of subjects and maintain the confidentiality of data.

7. When some or all 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 steps must be included to protect the rights and welfare of these subjects.

Approval Time Frames

The approval time frame for expedited studies is one year from the date of approval. For research studies reviewed by the full IRB, the approval period starts on the date the IRB approved the study or on the date the IRB Coordinator determined that explicit conditions required by the IRB were approved. The expiration date is defined as the first day on which the study is no longer approved without continuing review and approval by the IRB. The expiration date is calculated as the date the IRB approved the study or approved the study with explicit conditions, plus the interval of approval (maximum of one year). The approval period ends the day before the expiration date. For example, if the full IRB approved a study with explicit conditions on 10/15/2010, and the Coordinator confirmed that the conditions were met on 10/22/2010, the approval period is 10/22/2010 to 10/20/2011, and the expiration date is 10/21/2011.

Expiration Notices

The IRB Coordinator sends researchers e-mail notices 60 days prior to the expiration of IRB approval. Notices list the study title, IRB ID number, and the approval and expiration dates. Researchers are required to respond to inform the IRB regardless of whether they have completed or will complete all recruitment of subjects and all data collection prior to the expiration of IRB approval. If IRB approval for a research study expires, all research activities are to cease, including recruitment, acceptance of participants, interventions and interactions with current participants.

8.G. Conditional Approval

If the IRB agrees that a project is generally acceptable but needs minor modifications to meet all criteria for approval, it will be conditionally approved. Conditional approval is given when the IRB requires minor changes, such as clarification of a specific item or minor changes to the informed consent process (e.g., modification of language, correction of typographic or grammatical errors). The official notification letter or e-mail message

from the IRB Coordinator will stipulate conditions of approval.

Researchers may not begin their research projects until they have met those conditions and have received official notification of IRB approval. Conditional approval will also result if a study meets all IRB criteria but requires review by another IRB. Full approval will not be made until the researcher has furnished documentation of approval by the other IRB. Responses to a vote of conditional approval are reviewed by the IRB Coordinator.

If an application is conditionally approved, the researcher must meet the conditions for approval within the time frame stipulated by the IRB Coordinator in the notification letter, typically 30-90 days. If the researcher does not respond within that time frame, the Coordinator may place the application on inactive status. The researcher must request reactivation if he/she wants further consideration of his/her application.

If a researcher's revision does not respond appropriately to the IRB's conditions for approval, the Coordinator will advise him/her of the remaining conditions to be met and a time frame for response. If the second revision does not meet conditions for approval, the Coordinator will refer the application for review by the full IRB with a recommendation for denial.

8.H. Deferral of Approval for Revision

The IRB will defer approval when the committee determines that it needs more information before it can review the study adequately. The committee may request substantive changes or additions in order for an application and research proposal to meet criteria for approval. The official notification letter from the IRB Coordinator will stipulate all conditions for eventual approval. The notification letter may also include a deadline for submission of the revised application, typically 30-90 days. If the researcher does not meet the deadline, the Coordinator may place the application on inactive status. After the application is placed on inactive status, the researcher must submit a new IRB Application and Research Proposal Outline if he/she wants IRB approval for a study involving human subjects.

If an application is deferred, the researcher has two options: (1) respond to the IRB's requirements and resubmit it, or (2) withdraw the application. If the researcher chooses to withdraw the application, she/he should notify the Coordinator immediately.

A response to deferred approval will first be reviewed by the IRB Coordinator to determine whether responses were made to all IRB requirements. The Coordinator will then forward the response to the same IRB member who conducted the initial review or to the full IRB if the initial application was reviewed by the full IRB.

This second review may result in any of the following determinations: approval, conditional approval, deferral for revision, or denial. If approval is deferred for revision a second time, the next review will have only two possible determinations: approval or denial (or referral with a recommendation for denial).

8.I. Referral of Review

The IRB may refer the review of some research proposals for the following purposes:

1. Review for expertise, or
2. Review for denial of IRB approval.

Referral of Review for Expertise

An individual IRB reviewer will refer review to the full IRB when related expertise is needed to make an informed decision about a proposed study. All referred reviews are made by the full IRB. If an application is referred for review for expertise, the notification letter from the IRB Coordinator will explain the reason for referral. The review will not occur until an appropriate reviewer has been identified.

Referral of Review for Denial of IRB Approval

An individual IRB reviewer must refer review to the full IRB if he/she believes approval should be denied, as only the full IRB has the authority to deny approval. If an application is referred for review with a recommendation for denial, the notification letter from the IRB Coordinator will outline the reasons for the recommendation. The researcher will then have the option to officially withdraw the application, revise it, and resubmit it as a new application. If a researcher chooses to withdraw the application, he/she should notify the Coordinator immediately.

8.J. Withdrawal of an Application

A researcher may choose to withdraw an application if he/she receives a decision of conditional approval, deferral of approval for revision, or referral for denial. (Researchers may also withdraw their applications for other reasons, such as a decision to make

substantive changes, or to postpone start of the study.) The IRB Coordinator may place an application on inactive status if a researcher fails to meet submission deadlines established through either conditional approval or deferral of approval for revision.

8.K. Denial of IRB Approval

Only the full IRB may deny approval. Denial of approval will occur only after due and careful consideration. The IRB will deny approval if any one of the following situations apply:

- The proposed study places subjects at risks that appear to outweigh the likely benefits and/or value of the knowledge to be gained.
- The proposed research raises serious ethical questions.
- The proposed study is insufficiently developed or articulated for the IRB to determine the level of possible risk to human subjects.

If the IRB denies approval of a proposed research project for any reason, the researcher may design a new project or redesign the project so that it will meet IRB criteria for approval of research with human subjects. IRB review of new or revised applications following denial may include consideration of the previously denied project.

8.L. Researcher Participation in Reviews

Researchers may interact with the IRB only through the IRB Coordinator. Researchers should not initiate contact with individual IRB members about their projects. Although the IRB chair may contact researchers, individual IRB members should not contact a researcher regarding submitted IRB applications and research proposals. Communications between the IRB Coordinator and a researcher will be documented and placed into the researcher's IRB file.

If an application will be reviewed by the full IRB, the Chair may choose to ask the researcher to join the meeting via phone to respond to questions about the application. Although researchers are strongly encouraged to agree to such participation, because their involvement may help the IRB in its evaluation of their projects, their participation is not a requirement for approval. If a researcher is invited to join an IRB meeting, he/she is expected to abide by the meeting rules and to leave the meeting when asked to do so.

8.M. IRB Consultants / Advisors

In rare circumstances, the IRB Chair will bring in a temporary member or engage a

consultant / advisor to inform its decisions. The Chair's decision, which may have financial implications, will be made only in consultation with the IRB Coordinator, and it may require approval from the university's chief academic officer.

An IRB member may refer review for expertise. If appropriate expertise does not exist among IRB members, this option allows the IRB Chair to locate a reviewer with expertise appropriate to a proposed project. In such cases, the individual would serve as a temporary, nonvoting consultant / advisor to the IRB.

In most cases, consultant / advisors will be chosen from YSU faculty and administration. However, if an appropriate consultant / advisor is not among the university's faculty or staff, the IRB Chair may (1) recommend that an external consultant / advisor be engaged, or (2) refer the application to the full IRB with a recommendation for denial. In the latter case, the IRB's denial would be made on the basis that the university lacks the expertise to provide appropriate academic support and assessment of the proposed study.

If a project submitted for review involves the participation of prisoners as subjects and for which federal funding will be sought, the IRB is required, under federal regulations, to have a voting member who is either a prisoner or prisoner representative by reason of background or experience. Because arranging for this temporary IRB member may take some time, researchers planning such projects should notify the IRB Coordinator well in advance. (See "Informed Consent Documentation.")

Financial considerations related to engaging an external temporary voting member or consultant / advisor can have an effect on the IRB's decision. To prevent the appearance of conflict of interest, any costs related to engagement of an external member of consultant are the responsibility of the IRB. Consultants / Advisors may not be paid by the researcher.

8.N. Appeals of IRB Decisions

Researchers may appeal conditional approvals, deferrals of approval for revision, and denials if they disagree with the conditions or reasons stipulated by the IRB for the decision. Appeals must be submitted to the IRB Coordinator, in writing, within thirty (30) working days of the date of the official notification letter from the Coordinator. Appeals will be considered by the full IRB at a regularly scheduled meeting. An appeal is not

considered justification for calling an emergency IRB meeting.

Appeals will be considered only if they include substantive revisions to the original application and/or significant clarification or additional information. The researcher must respond directly (item by item) to the reasons for the IRB's decision—conditional approval, deferral of approval, or denial of approval. The IRB will not consider appeals submitted on the basis of resulting delay in completing degree requirements, nor will it accept disagreement with the IRB's findings as a valid ground for appeal.

If an appeal is denied by the IRB, the researcher may not appeal to the IRB again. The researcher may choose to pursue other published formal university grievance or appeal options. Researchers should keep in mind, however, that decisions made by the IRB, as a Board of Trustees-mandated body, may not be overridden by academic or institutional officials.

Chapter 9: Researchers' Obligations

Chapter 9 – Researchers' Obligations

Researchers are obligated to submit an IRB application and research proposal for IRB review and approval before conducting a study involving human subjects. They may begin their research projects only after they have received official notification of IRB approval. Researchers are obligated to adhere to the ethical standards applicable to their profession, and to researchers in general. As members of the university community, researchers are obligated to abide by applicable institutional policies and procedures. Researchers are also obligated to ensure the safety and well-being of human participants in their studies and to abide by the policies and procedures established by the IRB and all they entail.

9.A. Required Approvals

Researchers are required to obtain all necessary approvals to conduct their research projects in their selected facilities and locations. For example, researchers planning to conduct research projects in public and private hospital or clinic systems often are

required by the central administration of the hospital or clinic to obtain approval for specific locations.

Researchers employed at institutions of higher learning will need to verify whether their institutions have an IRB, ethics committee, or other research-approval process that must approve their research projects in addition to YSUs IRB. Some higher learning institutions require YSUs IRB to approve a research study before their research committee will approve the study for their employee.

Researchers employed in government agencies, hospitals, clinics, business organizations, and other professions need also to inform their employers of any planned research projects and obtain appropriate approvals if they plan to conduct any portion of their research projects at their places of employment.

Which approval should be obtained first may depend on the researcher's employer. Approval letters from employers may be submitted after YSUs IRB approves a research project. Employer approvals must be submitted to the IRB prior to the initiation of any portion of a research project.

9.B. Required Reporting

The official notification of approval letter from the IRB may stipulate requirements for a progress report and/or a final report on a study. Researchers are responsible for submitting required reports by the date stipulated. The IRB may suspend or terminate IRB approval a study if the required reports are not submitted as required.

The IRB may also require unscheduled reports on studies in progress. Researchers who receive a notice from the IRB Coordinator requiring such a report should respond by the stated submission deadline, or the IRB may suspend or terminate approval of the study.

9.C. Continued, Modified, and Delayed Studies

Researchers are required to supply information to the IRB, at least two months in advance, for continuation of IRB approval for previously approved research and for any proposed, substantive modifications to previously approved research. (See "Continuation of IRB Approval" and "Modifications to Previously Approved Research.") Researchers should also notify the IRB Coordinator if they need to change the start and/or end dates of their studies. Changes to study dates may be approved by the IRB Coordinator.

Substantive modifications must be reviewed and approved through applicable IRB processes. Continuation of IRB approval for studies approved under the expedited review process may be approved by the IRB Coordinator. Studies approved by the full IRB may be granted continued approval by the full IRB if they do not meet the expedited review criteria for continuing review.

Because research studies may not continue beyond the end date of IRB approval, and substantive changes may not be instituted without approval, requests for approval of changes should be submitted to the IRB Coordinator well in advance of the institution of substantive changes.

Researchers are required to submit a Continuing Review / Amendment Form if their studies are not completed by the expiration date of original IRB approval. If IRB approval has expired, a researcher is required to suspend her/his study until obtaining IRB re-approval.

9.D. Unanticipated and Adverse Events

An unanticipated or unexpected event that occurs during a research study may result in a delay or interruption of the completion of the study. Examples of unanticipated or unexpected events that may occur during the course of a research study include the loss or theft of a laptop or file folder containing study data that contain subjects' personal identifiers; a participant, or the researcher, is injured as a result of an accident; a participant, or researcher, contracts a serious illness; or the researcher's or research assistant's computer hard drive containing all study data crashes. Such incidents must be reported to the IRB Coordinator within 48 hours of their occurrence. The researcher needs to submit a plan for overcoming the delay caused by the event, especially when participants' personally identifying information is no longer secure.

An adverse event is any substantive, undesirable, or unintended experience resulting from research that does or is likely to have a harmful effect on an individual subject or group of subjects. An adverse event may be an experience that the researcher anticipated as a risk but that has occurred more frequently or is more serious than the researcher thought likely.

Regardless of whether the harmful experience is physical, psychological, social, legal, economic, or other, it must be substantive / serious. Quite often the harm is a matter of

degree. In a study that includes subject interviews, an unanticipated, unexpected, or adverse event has not occurred if a subject becomes angry about one or more questions. An adverse event has occurred if that anger is great enough to result in a harmful physical or emotional response such as a heart attack, severe asthmatic episode, or clinical depression. Researchers are required to suspend their research if they see or hear of an adverse event or events during the course of their studies. Researchers must report the event(s) to the IRB Coordinator, in writing, as soon as possible, but no later than 48 hours. An Adverse Event Report should include the following:

- A description of the event, including the researcher's immediate response (such as removal of the participant, referral of the participant to counseling, etc.)
- A description of the process used to suspend the study, including copies of communications about the suspension to participants in the study
- A description of any action the researcher will take to resume the study, if possible

An adverse event may necessitate changes in a study to prevent re-occurrences. If the changes are substantive they should, of course, be submitted to the IRB for review and approval. All requests for IRB approval of changes submitted as a result of an adverse event will require full review because the event constitutes evidence that the study poses potential risk to participants.

If a subject dies, even if the death does not appear related to the subject's participation in a study, the researcher must immediately suspend the study, and he/she must report the death to the IRB Coordinator, by telephone or e-mail, within 48 hours. The researcher must follow that report with a written report within ten (10) working days. If the death is clearly unrelated to participation in the study, the Coordinator will reinstate approval.

9.E. Notification of Unapproved or Harmful Research Activities

As a member of the university community, researchers are obligated to notify the IRB Coordinator immediately if they have a concern about the conduct of any university-sponsored research involving human subjects and/or the safety of participants in a study. (See "Suspension or Termination of IRB Approval.")

The IRB has the authority to suspend or terminate IRB approval of research with human subjects conducted by a YSU student, faculty, staff member, or consultant for any of the

reasons listed below. The IRB's decision to suspend or terminate a study may result from notification of concern about the study by someone other than the researcher. In such cases, the researcher will be advised of the concerns and have the opportunity to respond to them. The IRB is under no obligation to identify the individual who notified the IRB.

A researcher is obligated to immediately halt the research if he/she receives a notice of IRB suspension or termination of IRB approval. The IRB will inform appropriate academic and administrative personnel, including the university's dean or the appropriate program director, whenever the IRB suspends or terminates IRB approval of a research study.

A decision to suspend or terminate IRB approval of a study is mandated by the IRB's charge from the university's Board of Trustees, by its responsibilities to human subjects, and by its obligations as an OHRP-registered IRB. The IRB is required to and will suspend or terminate IRB approval of research in all the following cases:

- Research under way without IRB approval
- Research continuing beyond the end date of IRB approval
- The research study is substantively different from what was approved by the IRB
- A study in which a subject or subjects have been harmed as a result of their participation
- A study in which a subject dies

Chapter 10 – Internal Assessment Studies

Yo San University may authorize or support formal and informal internal assessment studies that directly or indirectly involve human participants. The most likely forms of such studies are focus groups, interviews, pilot tests, questionnaires, and surveys.

The term "internal assessment" is used to describe a wide range of information and data gathering efforts conducted by a college, center, administrative unit, committee, or individual. Assessment activities that do not require IRB approval include:

1. Evaluation, by an authorized employee, of students' academic work or records when the activity is conducted as a component of an academic program model or for purposes of assessment of learning outcomes or program review
2. Collection / analysis / reporting, by an authorized employee, of individual or aggregated student or employee data contained on the AS400 for the purposes of reporting to external agencies
3. Review / evaluation, by an authorized employee, of an individual or aggregated employee data or records for purposes of performance evaluation
    - If, however, any of the above-mentioned items occur with the intent to publish findings outside the university, IRB approval will be required.

Glossary

anonymity: The condition achieved when the identities of subjects are confidential, or when the researcher does not know their names or any characteristics that might reasonably lead the researcher or anyone to discover their identities. The researcher cannot link the data to the participant.

autonomy: The personal capacity to consider alternatives, make choices, and act without undue influence or interference of others. Potential subjects have the right to decide whether to participate in the study, to decline to answer specific questions or engage in certain activities, and to withdraw from the study at any time.

***Belmont Report (The)*:** A statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1979. The report was developed in response to concerns about research studies in which subjects had been placed at serious risk and sometimes seriously harmed. It describes three ethical principles: (1) respect for persons, (2) beneficence, and (3) justice.

beneficence: An ethical principle discussed in the Belmont Report that entails an obligation to protect persons from harm. The principle of beneficence can be expressed in two general rules: (1) do not harm; and (2) protect from harm by maximizing possible benefits and minimizing possible risks of harm. Researchers may not harm subjects. The risks and benefits of participating in a study must be clearly identified and explained to

potential subjects. Researchers may not intentionally injure any person during the conduct of research, regardless of any possible benefits that may result.

benefit: A valued or desired outcome; an advantage. Something of positive value to the health or well-being of subjects. Benefits can be known, probable, or possible outcomes.

children: Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. Generally the law considers any person under 18 years old to be a child.

- Assent means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.
- Guardian means an individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care.
- Parent means a child's biological or adoptive parent.
- Permission means the agreement of parent(s) or guardian to the participation of their child or ward in research.

clandestine research: A study in which subjects do not know they are participating in a research study. Example: Tearoom Trade project.

classified research: See federal classified research.

cognitively impaired: A condition of having either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders, or dementia) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests.

confidentiality: A condition that results when research participants' identities or characteristics are not revealed as a result of a study. The researcher may be able to identify a participant's data but will not reveal the participant's identity to anyone else.

Common Rule: The Federal Policy for the Protection of Human Subjects is referred to as the "Common Rule." The HHS regulations incorporate the Common Rule as Subpart A of 45 CFR 46.

co-researcher: A co-researcher may be a collaborator at YSU at another institution. In action research studies, participants are sometimes referred to as "co-researchers."

debriefing: A process through which subjects are given previously undisclosed information about the research project following completion of their participation in the research. (Note that this usage, which occurs within the behavioral sciences, departs from the standard meaning in which debriefing is obtaining rather than imparting information.)

deceptive research: A study in which subjects know they are participating in a research project, but they are not told its true purpose. Example: Milgrim's Shock Psychology study.

exempt/exemption (review for exemption): Research projects determined to meet exemption criteria are designated as "exempt" from the federal regulations for the protection of human subjects, as allowed by the regulations. Even though federal approval criteria and consent elements may not apply, ethical codes still apply. A class-related project may receive an exemption from IRB review if the project meets certain requirements.

expedited review: Review of proposed research by the IRB chair or a designated voting member or group of voting members rather than by the entire IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research [45 CFR §46.110].

federal classified research: Research, knowledge of the procedures, and results of which, is restricted to individuals with United States government security clearances.

focus group: A group (usually of six to ten people) convened to discuss a specific topic, conduct an evaluation, or test new ideas, etc. It usually involves group interviews.

full board review: Review of proposed research at a convened meeting at which a majority of the IRB members are present, including at least one member whose primary

concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting [45 CFR §46.108].

HIPAA Privacy Rule: The Health Information Portability and Accountability Act (HIPAA), Privacy Act, establishes the conditions under which protected health information (PHI) may be used or disclosed by covered entities for research purposes. PHI includes information such as physician / psychologist notes, test results, genetic information, medical conditions, diagnoses, treatments, and medications.

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. See intervention and private information.

informed consent: A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence [45 CFR §46.116; 21 CFR 50.20 and 50.25].

interaction: Communication or interpersonal contact between investigator and subject.

intervention: (1) Physical procedures by which data are gathered (for example, venipuncture) and (2) manipulations of the subject or the subject’s environment performed for research purposes.

justice: An ethical principle discussed in The Belmont Report requiring fairness in distribution of burdens and benefits; often expressed in terms of treating persons of similar circumstances or characteristics similarly. Injustice occurs when benefits of research are denied to participating subjects or when burdens of research are imposed unduly.

minimal risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

pilot study (test): A mini version of a full-scale study and the pre-testing of a particular research instrument such as a questionnaire or interview questions. Also known as a feasibility study.

practice: An intervention or action designed to enhance the well-being of an individual, having a reasonable expectation of achieving that goal. Practice may include testing, diagnosis, teaching, preventive treatment, therapy, etc.

principal investigator (PI): The scientist or scholar with primary responsibility for the design and conduct of a research project.

prisoner: Any individual (minors or adults) involuntarily confined or detained in a penal institution. Individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing are included. Individuals in hospitals, alcohol / drug treatment facilities, work-release, or at-home detention programs are also included.

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 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 medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

protected health information (PHI): Individually identifiable health information such as physician / psychologist notes, test results, genetic information, medical conditions, diagnoses, treatments, and medications.

purpose: The purpose of a study is to find an answer to the research question. For students, fulfillment of degree requirements is also a purpose.

research: (1) A systematic investigation (i.e., the gathering and analysis of information), including research development, testing, and evaluation, designed to develop or

contribute to generalizable knowledge. In social and behavioral research, the contribution may be to add to the current literature of the topic of the research. (2) An active, diligent, and systematic process of inquiry aimed at discovering, interpreting, and revising facts, intended to produce a greater understanding of events, behaviors, or theories. (3) A collection of information about a particular topic.(2)

respect for persons: An ethical principle discussed in The Belmont Report requiring that individual autonomy be respected and that persons with diminished autonomy be protected. Each potential participant has the right to decide whether to participate, to refuse to participate in some activities or respond to some questions, and to withdraw at any time for any reason.

risk: The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk." Risk can be a known, probable, or possible outcome. (See also minimal risk.)

surveys: Studies designed to obtain information from a large number of respondents through written questionnaires, telephone interviews, door-to-door canvassing, or similar procedures.

third parties: Persons, such as relatives, friends, social acquaintances, or spouses, who are not participants in a research study but who may be discussed by a study participant. The third party becomes a human subject if and when the researcher obtains information about her/him that is both private and individually identifiable. The Common Rule then applies and requires informed consent of the subject. If certain criteria are met, the subject's informed consent may be waived.

Title 45 CFR Part 46: The section (Part 46) of Title 45 (Public Welfare) of the Code of Federal Regulations that addresses protection of human subjects.

variable (noun): An element or factor the research is designed to study, either as an experimental intervention or a possible outcome (or factor affecting the outcome) of that intervention.

voluntary: Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity.