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Common Practices

Audiotaping and Videotaping

Principle

To ensure that the confidentiality of individuals' participation in research is maintained

Practice

- A. The HSIRB requires that researchers maintain their research data for a period of at least 3 years after the study has ended.
- B. If possible, the HSIRB prefers that researchers transcribe videotapes/audiotapes and maintain transcriptions as opposed to the actual videotapes/audiotapes. These tapes should then be destroyed after transcription. This method provides additional protections for participants' confidentiality.
- C. If researchers intend to keep tapes instead of destroying them after transcription, a statement should be included in the consent form indicating that they will be maintaining the tapes for a period of at least 3 years. This statement should include an assurance that the tapes will be locked in a secure location where there is limited access to individuals other than the researchers.
- D. If researchers intend to use the tapes for anything besides the research, they must obtain participants' express consent. Furthermore, the researchers must have participants complete a Western Michigan University release form.

Informed Consent Process

Principle

To ensure that participants have sufficient information about a research study in order to make an informed decision regarding whether or not to participate

To provide participants with researchers' contact information for questions or comments

Practice

- A. Before researchers can use individuals as participants or information about them in a study, the individuals must give their informed consent. For exceptions to obtaining informed consent, see Waiver of Informed Consent section.
- B. A consent form including the project title, description, researchers' contact information, research procedures, perceived benefits/risks, and any additional information that might be relevant in understanding the research study should be provided for interested individuals to review if they are considering participating and to sign if they would like to participate. One copy should be signed and returned to the researcher. An additional copy should be given to individuals to keep. In anonymous research, an informed consent document may include the statement: "Returning the questionnaire indicates your consent to participate."
- C. If an individual is not capable of giving his or her consent, a proxy's permission and the individual's assent must be obtained, or it is the responsibility of the researcher to exclude the person from participating in the study.
- D. Researchers should give special consideration and employ protections to ensure that informed consent is obtained when working with vulnerable populations (e.g., prisoners, elderly, individuals with cognitive impairments, children, etc).
- E. Examples of some typical sample consent forms can be found at <http://www.wmich.edu/research/compliance/hsirb/consent.html>

Waiver of Informed Consent

Principle

To outline circumstances under which the HSIRB may grant a waiver of consent.

Practice

- A. The requirements for waiver of some or all elements of consent can be found under the Code of Federal Regulations for Protecting Human Research Subjects (45 CFR 46.116(d))
- B. An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent, provided the IRB finds and documents that:
 1. The research involves no more than minimal risk to the participants;
 2. The waiver or alteration will not adversely affect the rights and welfare of the participants;
 3. The research could not practicably be carried out without the waiver or alteration; and
 4. Whenever appropriate, the participants will be provided with additional pertinent information after participation.
- C. It is important to note the standard of meeting “impracticable” circumstances is very high. Impracticable does not refer to inconvenience or difficulty in obtaining a participant’s consent; rather, impracticable refers to the inability of the investigators to carry out the research if consent is required.
- D. In addition to waiving consent altogether, under special circumstances, the HSIRB may waive the requirement of documented informed consent as illustrated in code (45 CFR 46.117(c)). An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all participants, if it finds either:
 1. That the only record linking the participant and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Participants should be asked whether they want documentation linking them with the research. In this instance, the participant’s wishes will govern whether documented informed consent is necessary.
 2. That the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

In cases where the documentation requirement is waived, the IRB may require the investigator to provide participants with a written statement regarding the research.

Incentives for Participants

Principle

To ensure that incentives are commensurate with the time commitment, inconveniences imposed, and socioeconomic status of the participants.

Practice

- A. Incentives are enticements that encourage individuals to participate in research. Incentives may include but are not limited to: money, prizes, gift certificates, food, extended vacation time, academic rewards such as extra credit, and access to desired resources/information. Incentives should not be confused with benefits. Potential benefits are incurred as a result *of* participating in a particular research study, whereas incentives are used for encouraging persons *to* participate. Monetary payments or other forms of remuneration are not considered benefits that one accrues by participating in a study; rather they are considered to be incentives to participate.
- B. Researchers should not employ incentives so strong that they take away a person's voluntary choice to participate in the study.
- C. It is important for researchers to be mindful of how financial incentives can be unduly influential or even coercive to individuals, especially those who are economically or educationally disadvantaged. Economically disadvantaged persons include those persons who struggle to provide basic necessities for themselves and their families or communities. Therefore, the use of financial incentives for research participation is a special issue with these individuals. Medical care, remedial education, and financial payments are common incentives in research but to a person who is economically disadvantaged, seemingly nominal inducements may be powerfully coercive.

Responsibilities of HSIRB Committee Members

Principle

To ensure that members understand their roles and responsibilities as committee members. Furthermore, it is essential for members to uphold the integrity of the HSIRB by representing the HSIRB appropriately to investigators/colleagues/etc.

Practice

- A. It is the responsibility of each member to attend all meetings. If a member has a conflict and is unable to attend a meeting, he or she should contact the research compliance coordinator. The person should provide enough of an advanced notice so that appropriate accommodations for their absence can be made.
- B. Members should be prepared to discuss each agenda item. It is essential that each member review the topics for discussion in order to provide helpful feedback/comments.
- C. Members should use their areas of expertise and offer specific information regarding areas in which they are knowledgeable.
- D. When considering approval status for a protocol, members should be familiar with approval criteria as well as the standards outlined in the Belmont Report.
- E. Members must maintain the confidentiality of information contained in protocols they review.
- F. If a member foresees a potential conflict of interest, he or she should address this issue with the chairperson as soon as he or she becomes aware of it. If a conflict of interest is established or if a member feels conflicted, the member should remove him/herself from the review process for that particular item.
- G. It is the responsibility of each member to withdraw their membership when they are no longer interested or capable of committing their time/knowledge to the HSIRB.
- H. Members will not communicate directly with sponsors or investigators regarding protocol decisions or pending decisions about the protocol unless they have obtained the express permission of the HSIRB chairperson. However, board members might be willing to provide valuable advice during the process of developing a protocol.

Nutritional Supplements or other ingested/topically administered substances Research

Principle

To ensure that the substances/supplements administered to participants have been assessed for various risks, quality control issues, and safety precautions. Before submitting the protocol to the HSIRB, researchers should investigate and provide the information outlined below.

Practice

- A. Researchers should provide a brief description of the substance/supplement and cite relevant literature supporting some of its purported effects.
- B. Researchers should list the manufacturer of the substance/supplement and, if available, where the supplement is manufactured. Address the manufacturer's reputation as a maker of a particular substance/supplement. Are they well known and respected or have they had negative consumer reports, regulation violations, etc.?
- C. Researchers should state any known/potential risks or adverse reactions/purported effects due to the substance or supplement use. This information should provide a rationale supporting the supplement as reasonably safe for the type of use required in the study. Relevant references addressing these concerns should be cited as well.
- D. Researchers should provide a list of references of research studies in which the substances/supplements have been used with human participants. Information should include
 - Reference citations
 - Sample size
 - Demographic information (age, gender, health/fitness status)
 - Dosages of substance/supplement used
 - Any reported adverse reactions/effects due to the substance/supplementIf no human participant studies are available, this should be noted and any relevant animal research studies cited.
- E. Some databases collect information from professionals and/or consumers pertaining to adverse effects reported from using various substances/supplements. Furthermore, these sites list the warnings for several substances/supplements and also allow one to search for a particular substance/supplement to obtain information regarding adverse effects. Helpful potential resources include:
 - NIH Office of Dietary Supplements (<http://dietary-supplements.info.nih.gov/>)
 - FDA MedWatch Database (<http://www.fda.gov/medwatch/index.html>)
 - FDA Center for Food Safety and Applied Nutrition (<http://www.cfsan.fda.gov/%7Edms/ds-warn.html>)
 - SupplementWatch.com (<http://www.supplementwatch.com>)

Common Practices

Internet Research

Principle

To ensure the appropriate use of information obtained from participants as well as provide the maximum level of confidentiality possible for participants involved with research via the Internet

Practice

- A. Informed consent documents must address the potential limits to confidentiality associated with Internet research.
 - A potential limit to confidentiality that researchers should address concerns the lack of discreteness that participants may encounter when submitting responses over the Internet. For instance, persons passing by a computer station may be able to easily read a participant's responses that would typically not be observable in a paper and pencil format. Thus, researchers should make participants aware of the possibility that their answers may be "on display" for individuals passing by their computer terminal to see.
 - Companies often have tracking systems that monitor employees' emails. It is important for potential research participants to be aware that their participation may not be entirely confidential if they are receiving and/or submitting responses over a monitored email system.
 - Consent documents should include a 'limits to confidentiality' statement similar to the following:

"This project has been approved by the Western Michigan University Human Subjects Institutional Review Board. Approval of this project only signifies that the procedures adequately protect the rights and welfare of the participants. Absolute confidentiality cannot be guaranteed due to the limited protections of Internet access including..."
- B. To protect confidentiality, researchers should use software designed to de-identify email responses. The software system *SurveySaid* can be employed, as it eliminates the return addresses connected to emails before the researcher sees the participants' responses. For more information about developing web surveys go to <http://www.wmich.edu/itc/web-surveys.html>. The ITC department sponsors a workshop each semester in developing on-line surveys. To see the schedule, go to <http://www.wmich.edu/itc/workshops>.

Common Practices

Benefits Section

Principle

To describe benefits to society as well as benefits to those who participate in the research

To assist reviewers in risk assessment.

Practice

- A. Benefits are incurred as a result *of* participating in a particular research study. For example, increased self-growth, greater eye-hand coordination, improved social skills, etc. are potential benefits that an individual may experience as a result *of* participating in a particular study. Benefits should not be confused with incentives, which encourage individuals *to* participate. Monetary payments are *not* considered to be benefits of a study.
- B. Researchers should include a statement listing any anticipated benefits/contributions to the field of study they are investigating. It is important to state the potential benefits, as this assists HSIRB committee members in assessing the risk/benefit ratio.
- C. Include a statement describing any anticipated benefits to individuals participating in the study. If there are no foreseeable benefits, mention this as well.
- D. For all benefits, word the language of promised benefits using “may” rather than “will”. It is important that participants have a clear understanding that, although certain benefits are possible as a result of participation, it is not guaranteed that they will experience the anticipated benefits.
“Benefits you *may* experience as a research participant in this study include...”

Common Practices

Focus Groups

Principle:

To address the confidentiality concerns associated with information disclosed in a group setting including the information participants may gather about other participants.

Practice:

Researchers should include a separate confidentiality clause to impress upon participants that what others say in the focus group is confidential and should not be repeated outside the focus group. (e.g., “All information discussed in the focus group is confidential and I will not discuss the contents of the discussion or information about other participants outside of the focus group”; or “My signature below indicates that I agree not to discuss outside of this focus group any comments made by the other participants.”) This clause should come after the signature line for the consent document, and a second signature line should be provided for this statement. In addition, researchers should also inform potential participants that they cannot guarantee confidentiality.

Minimizing Coercion in Research

Principle

To ensure that potential sources of coercion are minimized to the extent possible so that individuals can freely choose to participate or not participate

Practice

- A. In situations where a power differential exists between the researcher and participant (e.g., employer/employee; teacher/student; parent/child), researchers must make certain that their influence regarding the individual's decision to participate or not is minimized. Persons who are in a subordinate relationship to researchers may experience a loss of autonomy because of that relationship. Students, employees, and patients may fear a loss of grades, work benefits, or maximal health care when if they refuse to become research participants. This means that they are subject to undue coercion, even if researchers do not intend to be coercive. The researcher may have to go to extra lengths to assure the participant clearly that the participant's participation is voluntary, that the participant may withdraw from participation at any time, and that grades, employment, or health care will not be affected by the participants' choice to participate or not.
- B. One way to minimize coercion is by maintaining the anonymity of those individuals who chose to participate and those who elected not to participate. For example, researchers could have all individuals, regardless of participation or not, turn in a survey (either completed or left blank) so that the researcher has no knowledge of which individuals participated.
- C. If earning extra credit is an incentive for participation, teachers should have alternative options available for students to select if they do not wish to participate. These alternative options should be commensurate with the time commitment/effort required for participation in the research study.
- D. It may be helpful for a disinterested party to administer the questionnaire, etc. to reduce the possibility of coercion.
- E. Coercion can be reduced by making it clear that individuals can change their minds, quit, withdraw, or not reply to questions after they have agreed to participate.
- F. Also see "University Students as Participants" section.

Common Practices

Use of Existing Student Records

Principle

To protect students' privacy and confidentiality

Practice

- A. Use of existing student records is permissible when the researcher has legitimate access to the records. Another individual (not the researcher) should remove all identifiers from the records before granting the researcher access to the desired information.
- B. If de-identification is not possible, the students must give consent for their records to be used for research purposes. If the students are minors, their parents may be required to give permission.

University Students as Participants

Principles:

To avoid undue influence or perceived coercion

Practice:

- A. Persons in a subordinate relationship to researchers may experience a loss of autonomy because of that relationship. Students may fear a loss of grades, access to University services, benefits, employment, etc. if they refuse to be research participants. This means that they are subject to undue coercion, even if researchers do not intend to be coercive. Proposed research using any participants who are in direct subordinate relationships to investigators is scrutinized by the IRB. Making it clear that individuals can change their minds, quit, withdraw, or not reply to questions after agreeing to participate can reduce coercion. The researcher is obligated to assure the participant clearly that participation is voluntary, that the participant may withdraw from participation at any time, and that grades, employment, access to University services, benefits, etc. will not be affected by their choice to participate or not.
- B. The Board will approve giving course credit or extra credit to students who participate in research as long as other equivalent options are available to the students and risks related to self-identification of having qualified and/or taken part in a particular study are addressed.
- C. If students are under the age of 18, parental permission is required for them to participate in the research study.
- D. Researchers should avoid using their own students as participants whenever possible. When not possible, students should be protected from having their instructors know whether they have participated and the results of their participation until after grades for the semester in which they were students of the instructor are submitted to the university.
- E. All students can be given a package with an anonymous consent document, an envelope and alternate activity materials that they can work on if they choose not to participate. All students then hand the materials in at the end of the session. If possible, it may be helpful for a disinterested party to administer the questionnaire, etc. to reduce the possibility of coercion.
- F. Use of existing student records is permissible when the researcher has legitimate access to the records and someone other than the researcher has removed all identifiers from the records. If de-identification is not possible, the students must be contacted & must give permission for their records to be used for research (See point C above).

Research and Recruitment of Participants in Classroom Settings

Principle

To protect the privacy and confidentiality of students as well as minimize potential sources of perceived coercion

Practice

- A. In order to reduce potential sources of coercion due to power differentials, if the researcher is the professor he or she should consider having a research assistant or student distribute the research study information.
- B. When recruiting participants in classrooms, researchers should not ask students to write their names, ID numbers, or telephone numbers on sign-up sheets, as this infringes on their right to privacy and confidentiality. Instead, researchers could distribute a sign-up sheet with check boxes next to available participation times. Individuals can indicate the session they will attend without revealing their interest in the study or their personal contact information.
- C. Researchers should avoid using their own students as participants whenever possible. When not possible, researchers should wait until the end of the semester after grades are submitted to begin analyzing the data. Students who consent to participate can include a signed consent document in an envelope to be sealed until after grades have been submitted. This method protects students from having their instructors know whether they have participated or not.
- D. When surveys are administered in a classroom setting, giving consent forms and surveys to all students is important, as this allows all individuals to make their own informed decision about participating. If consent forms are to be signed and returned, a second copy should be provided so they will have access to contact information after the study is over.

Common Practices

Participant Recruitment and Advertising

Principles:

To fully inform potential participants about the research study prior to consent

To minimize coercion

Practice:

- A. As part of the review process, the HSIRB reviews all research documents and activities that bear directly on the rights and welfare of the participants of the proposed research. These include the protocol, research instruments, consent documents, and recruitment documents and methods.
- B. Direct advertising (i.e., advertising that is intended to be seen or heard by prospective participants) includes, but is not limited to, newspapers, radio, television, bulletin boards, and the Internet/world wide web. Not included are professional communications between health professionals and bona-fide media news stories. Direct advertising for study participants is considered the start of the informed consent and participant selection processes. Advertisements must be reviewed and approved by the HSIRB. The HSIRB reviews the advertising to assure that it is not unduly coercive and does not promise benefits beyond those outlined in the consent documents and the protocol.
- C. When advertisements are to be taped for broadcast, the HSIRB must review and approve the wording for the final taping.
- D. No claims should be made, either explicitly or implicitly, that the experimental procedure is safe or effective for the purposes under investigation, or is known to be equivalent or superior to any other procedure. Advertising for recruitment into studies should not use terms such as "new treatment" or "new procedure" without explaining that the procedure is investigational. Advertisements should not promise "free treatment" when the intent is only to say participants will not be charged for taking part in the investigation. Advertisements should state the amount that participants will be paid but should not emphasize the payment as a reason to participate. Studies in which participants' names are entered into a drawing must include the relative chance one would have of winning the drawing.
- E. Any advertisement to recruit participants should be limited to the information the prospective participants need to determine their eligibility and interest. When appropriately worded, the following items should be included:
 1. the name and address of the investigator(s) and/or research facility
 2. the condition under study and/or the purpose of the research

Common Practices

3. in summary form, the criteria that will be used to determine eligibility for the study
4. a brief list of participation benefits, if any
5. the time or other commitment required of the participants
6. the location of the research and the person or office to contact for further information

Common Practices

Research in Group Settings (e.g., classrooms, employee meetings, team meetings)

Principle

To minimize group pressure and other influences that may occur when questionnaires are distributed in the group format

Practice

- A. First obtain permission from the designated group leader(s) to distribute the questionnaire in their group setting.
- B. Make certain to account for issues of group pressure and coercion that may occur as a result of distributing the questionnaire in this setting. One suggestion to reduce undue group influence on an individual's decision to participate involves distributing the consent form and questionnaire/survey to all individuals in the group. Everyone should return a survey. Individuals choosing to participate would turn in completed forms, whereas those not interested in participating would return blank forms.
- C. In order to ensure privacy and confidentiality, the researcher should instruct individuals to place their completed or blank questionnaires face down or in a large envelope or box/container. This will also reduce group pressure to participate since others will not know whether an individual has responded to the questionnaire or not. Another option involves having everyone return completed or blank forms in a sealed envelope.
- D. Individuals who choose not to participate should have another activity available for them to engage in while others are participating (e.g., reading, homework, etc.)
- E. Explain to potential research participants that risks of participation may involve a loss of time that would normally be allotted for other activities and/or potential inconveniences in their typical group activities.

Common Practices

Studies that Include Gambling

Principle

To ensure that researchers are compliant with relevant state and federal regulations and that risks to participants are addressed and minimized.

Practice

- A. Researchers should be familiar and compliant with state and federal regulations governing gambling practices. For instance, a gaming license may be required in order to perform this kind of research. Federal and state policies should be thoroughly described in the protocol and appropriate references should be cited.
- B. One risk of introducing gambling techniques in a research study is the possibility that a participant may have difficulties with or concerns about gambling after participating. A referral list with contact information for agencies that provide appropriate assistance with this issue should be offered to all participants.

Consent for use of Data Collected Prior to HSIRB Application

Principle

Protections must be in place for individuals whose previously collected data will now be used in research. The protections for participants regarding already existing data should be commensurate with the protections for participants whose data has yet to be collected.

Practice

- A. Whenever possible, individuals must have the opportunity to give consent to have their data used for research purposes *prior* to the data being collected.
- B. Individuals must give their consent if data previously collected for another purpose will now be used for research purposes, especially if they never consent to have their information used for anything other than its original purpose.
- C. Public data information may be used for research without obtaining consent (e.g. census data.)
- D. Data that is not public record information must be stripped of all identifiers OR the researcher must get individual permission from each person whose data is being used. When creating or using a large database it may be impracticable to strip all identifiers. In these situations, computer access to the data should be protected by a password and identifying information should be removed after data collection is complete. In such cases, researchers should apply for a waiver of consent (See Waiver of Informed Consent section).

Excluding Potential Participants

Principle

To help interested individuals who are not chosen or who do not meet inclusion criteria understand why they were not selected for participation in a particular study.

Practice

- A. In order to address the potential reactions that interested individuals not selected for inclusion might experience, researchers should develop an oral script that they will use to explain why an individual was not chosen. For example:
“We appreciate your interest and willingness to participate in our study. Unfortunately the criteria for participants to be eligible for inclusion in our study include _____. However, you may wish to contact _____ to find out more about additional opportunities and/or information related to this particular area in which you have expressed interest.”
- B. Whenever possible, researchers should provide comparable alternative options/opportunities that individuals not selected for the study could seek out.
- C. If applicable to the particular area of investigation, contact information for appropriate health professionals should be distributed for individuals not included in the study. For instance, if individuals are excluded because their level of functioning or psychological distress is inappropriate for the study, researchers should have a list of health professionals that individuals may contact to receive additional assistance. This contact information should be provided to all participants, if applicable.

Common Practices

Preferred Items Assessment for Rewards

Principle

To employ appropriate and safe rewards for participants (rewards are often used in the course of psychology experiments with children)

Practice

- A. When using food as a reward for participants during an experiment make certain that potential choking items, as relevant for each particular age group, are excluded (e.g. nuts, hot dogs, smaller candies for young children).
- B. Exclude common allergens from the reward pool (e.g. products containing peanuts, strawberries, wheat, or soy) and find out specifically what the participants have adverse reactions to.
- C. Be sensitive to the appropriateness of individual reward items are sensitive and appropriate for the particular group of participants (e.g. consider age, culture, and other relevant factors in determining an item's appropriateness).

Common Practices

Sample Recruitment Procedures and Invitation Scripts

Principle

To ensure appropriate and non-coercive recruitment of potential participants

Practice

- A. Make it clear that the individual is being *invited* to participate (not “asked” or “requested”) in order to minimize chances that the individual feels pressured to agree to participate.
- B. Make certain that potential participants know they are being invited to participate in a *research* study.
- C. Explain to the potential participants why they, in particular, are being called for potential inclusion in the study (e.g., how and why did you obtain their number?)
- D. Provide a number for potential participants to call if they *might be interested in learning more about the study*. Please make it clear to potential participants that, by calling to receive additional information about the study, they are only expressing possible interest in learning more about the study and they are not committing to participate.

Snowball Sampling

Principle

To ensure that confidentiality is maintained and that potential participants do not feel coerced to participate when snowball sampling is employed.

Practice

- A. Snowball sampling involves recruiting additional potential participants through contact information obtained from current participants. It is important for the researchers to inform participants that they will be invited to provide names of other potential participants that the researcher may wish to recruit. Make certain that the participants understand that they have the option of declining to provide this information.
- B. Several confidentiality issues may emerge when contacting participants through this method. Participants' written permission to disclose their identity to later recruits should be obtained first. This permission can be an adjunct to the consent form for participating in the study. For instance, the consent form could have a box where participants check if they are willing to provide contact information about potential recruits as well as checkboxes indicating or denying their permission for the researchers to reveal how they obtained the contact information of future potential participants. Depending on the nature of the study, it is possible for recruited participants to identify who nominated them as a potential participant (unless the participant has given permission for using his or her name with potential participants), so it is important to maintain the confidentiality of the original participant.
- C. Address coercion issues. New recruits may feel obliged to participate due to their relationship with the person who nominated them or the status of the nominator.
- D. To avoid some of the confidentiality and coercion issues, consider another method employed in snowball sampling. Have the current participant contact the potential recruit and give the potential recruit the *researchers'* contact information. The recruit has the option of contacting the researcher if they are interested, thus reducing pressure or coercion to participate.
- E. It is important for the researcher to determine whether participants could be recruited in other ways. For example, in some circumstances a flyer may be just as effective as snowball sampling.

Common Practices

Natural Behavior Observation Research

Principle

To ensure that the confidentiality of research participants is maintained and that researchers are as unobtrusive as possible.

Practice

- A. Natural behavior observation typically involves research in which the investigator has minimal or no interaction with the research study participants. Examples may include watching people's specific behaviors in public places and recording these observations. The researcher makes no attempt to interact with the participant and does not attempt to obtain identifying information from the participant.
- B. Since the research occurs in a public setting where there typically is no expectation of privacy, this type of research generally qualifies as exempt. The primary concern with this situation involves maintaining the person's confidentiality by obscuring identifying information as well as not publishing pictures since consent was not obtained.
- C. As much information as possible should be submitted to the HSIRB regarding what behavior will be recorded and how recording will take place. Checklists or grids may be helpful.

Participant Observation

Principle

To ensure that the confidentiality of participants is maintained

Also, it is important to recognize the necessity for an ongoing informed consent process during the study.

Practice

- A. Participant observation occurs when a researcher engages in interactions with the research participants while recording his or her observations. Essentially, the researcher becomes a participant in order to obtain information.
- B. It is important that researchers are cognizant of the risks that participant observation may generate. For example, participants may begin to feel an attachment to the researcher and, at the conclusion of the study, the participants may feel a sense of abandonment by the researcher. Moreover, the participants may feel resentful towards the investigator if they perceived that they have been “used” and exploited by the researcher as a means to obtain data. Thus, they may feel that they have forged a relationship with the researcher only to realize that the researcher may have had an underlying agenda in forming a relationship with the participant. When outlining the risks in this type of a study, the researcher should make certain that the aforementioned risks, as well as the protections for these risks, are addressed.
- C. In lieu of written consent, it may be possible for researchers to use audio-recordings/video-recording, when relevant, that indicate an individual’s willingness to participate. Justification for waiving written consent must be submitted.
- D. Informed consent should be a continual process throughout the duration of the study. For example, although persons may give their express consent for participation at the beginning of the study, it is important for the researcher to remind the individuals at different points throughout the study that they are participating in research. Since the researcher essentially becomes one of the participants, it is likely that some participants will “forget” that they are participating in research. Furthermore, reminding the participants that they are involved in a research study will help guard against some risks, such as abandonment, that they may encounter when the research terminates.

Sample Child Assent Scripts

Principle

To ensure that children's willingness or refusal to participate in a study is honored, and that children are not unduly influenced or coerced into participation.

Practice

- A. The guidelines for assent include the following: Generally, 2-6 year-olds should be given oral assent, 7-12 year-olds should be given written assent, and children over age 13 should be given written assent forms which may look quite similar to adult consent forms. As an example, psychology researchers at Western Michigan University have used the following criteria in assessing whether a child orally assents to participation in a study: (1) the child says "yes," "uh-huh," or some other phrase that the parent(s)/guardian(s) recognizes as willingness to participate, and (2) the child smiles, nods, or makes other gestures that suggest interest in participating in the experiment. Written assent for 7-12 year-olds should be put in simple and understandable language for this population, and written assent forms for children over 13 should be appropriately modified to their level of understanding (which may be quite similar to the written consent forms given to adults).
- B. Researchers must assure that they are familiar enough with the population to be able to determine when a child does not want to participate in a study (e.g., autism population).
- C. Researchers must make certain that the child is not being coerced or pressured to participate (e.g., by their parent(s), guardian(s), teachers, etc.).
- D. There is a sample assent form on the HSIRB web page <http://www.wmich.edu/research/compliance/hsirb/sample-assent.doc> that can be adapted for many protocols.

Transporting Participants

Principle

To protect the researchers, Western Michigan University, and other entities involved from liability should the participant incur an injury while being transported.

Practice

- A. Participants must be given a WMU release of liability form to sign if they are being transported during the course of the study. (Typically these forms are used when children are the participants. The forms must be signed by the parent/guardian).
- B. Include the name of the study as well as the researcher's contact information in the form. If you design your own release form, you should forward it to the WMU Office of Legal Affairs and General Counsel for approval.

Sample WMU Release of Liability for Transporting Children

I, _____, am the parent of _____ and I hereby agree to allow researchers from Western Michigan University (WMU) to transport my child from my child's home to _____ in order to participate in the research study called _____. Principal Investigator Name (Phone #), Co-Principal Investigator Name (Phone #).

I understand that transportation will be by automobile and I understand the risks associated with that activity, include, but are not limited to, property damage, personal injury, and death. To the fullest extent permitted by law, I hereby release, waive, discharge and agree to indemnify WMU, its governing board and members, its officers, directors, and employees as well the Human Subjects Internal Review Board and its members from and against any and all claims, injuries, damages, and losses regarding the transportation of my child that I or my child, or any other person acting of behalf of me or my child, may have. If any emergency medical procedures or treatment are required while my child is in the care of Western Michigan University, I consent to Western Michigan University employees, representatives, or agents taking, arranging for or consenting to the procedures or treatment in his/her/their discretion.

I have read this Release of Liability and I understand its terms and that it is a release.

Parent/Guardian Signature

Date

Permission Obtained By

Date

Common Practices

Sample WMU Release of Liability for Transporting Adults

Release of Liability

I, _____, hereby agree to allow researchers from Western Michigan University (WMU) to transport me from _____ to _____ in order to participate in the research study called _____ Principal Investigator Name (Phone #), Co-Principal Investigator Name (Phone #).

I understand that transportation will be by automobile and I understand the risks associated with that activity including, but are not limited to, property damage, personal injury, and death. To the fullest extent permitted by law, I hereby release, waive, discharge, and agree to indemnify WMU, its governing board and members, its officers, directors, and employees as well as the Human Subjects Internal Review Board and its members from and against any and all claims, injuries, damages, and losses regarding the transportation that me, or any other person acting on behalf of me, may have. If any emergency medical procedures or treatment are required while I am in the care of Western Michigan University, I consent to Western Michigan University employees, representatives, or agents taking, arranging for, or consenting to the procedures or treatment at his/her/their discretion.

I have read this entire Release of Liability and I understand its terms and that it is a release.

Signature

Date

Permission Obtained By

Date

Vulnerable Populations

Principle

To address the unique issues and concerns that vulnerable populations present as well as to protect these individuals from experiencing undue risk, coercion, distress, etc. as a result of participation.

Certain groups of persons are especially vulnerable research participants. They include:

- children and minors;
- pregnant women and fetuses;
- prisoners;
- persons with cognitive or emotional impairments;
- economically or educationally disadvantaged persons;
- members of minority groups;
- elderly persons; and
- persons who are in a subordinate relationship to researchers (such as students, employees, or patients).

In general, when an IRB is considering research with especially vulnerable participants, the IRB can approve research that is of minimal risk or will benefit participants directly. If the research involves more than minimal risk and does not benefit the participant directly, the study may be subject to approval by the Secretary of Health and Human Services.

Research with Children

Principle

Children cannot legally consent to their own participation in research so protections must be in place to ensure that appropriately designated persons are making decisions that reflect the interests of the child(ren).

Practice

- A. Children and minors are defined as persons who have not attained the legal age of maturity. In the State of Michigan, the age of maturity is 18.
- B. When children or minors are research participants, researchers must obtain both the permission of the parent(s) or guardian(s) (i.e., parental informed consent) and the assent of the child (i.e., the child's affirmative agreement to participate). Mere failure to object is not assent. Whenever possible, children must be invited to assent following parental consent.
- C. The IRB has the authority to waive the requirement of assent. Special DHHS regulations applying to children may be found in **45 CFR 46, Subpart D** (<http://www.med.umich.edu/irbmed/FederalDocuments/hhs/HHS45CFR46.html>)
 1. Research concerned with improving normal educational practice and being conducted in established or commonly accepted educational settings will receive an administrative review.
 2. It is recommended that letters from school principals document whether the proposed procedures are considered normal educational procedures at that school.
 3. Other studies using children as participants will be reviewed by the full board.
- D. The issue of coercion becomes especially relevant when working with children: It is important that children do not feel coerced into giving their assent. Situations that may engender coercion include group settings and circumstances where the researcher possesses some authority/power in influencing the child's assent to participate. In group settings, children may feel pressured to participate if non-participants are easily identified (see section on research conducted in group settings). Also, if the researcher is a teacher, parent, or some other potentially influential person in their life, precautions need to be employed so children feel free to deny their assent.

Common Practices

Research with Adolescents

Principles

To allow adolescents appropriate choice in participation and to protect confidential information while respecting parental rights

Justice and access to participating in research

The Society for Adolescent Medicine has issued a draft of Guidelines for Adolescent Health Research: A Position Paper of the Society for Adolescent Medicine.

Practice

- A. Parental permission may be waived only if all 4 conditions specified in 45 CFR 46.116(d) are met and documented by researcher. Note that the standard for impracticability is high.
- B. 45 CFR 46.116(d) Waiver of some or all elements of informed consent (<http://www.med.umich.edu/irbmed/FederalDocuments/hhs/HHS45CFR46.html>) An IRB may approve a consent procedure, which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent, provided the IRB finds and documents that:
 1. The research involves no more than minimal risk to the subjects;
 2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
 3. The research could not practicably be carried out without the waiver or alteration; and
 4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

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Research with Pregnant Women

Principles:

Minimizing risk

Justice and access to participating in research studies.

Practice:

- A. Researchers are responsible to identify participants who may be pregnant if pregnancy could reasonably constitute increased risk for the woman or the fetus.
- B. Researchers are to include women of childbearing age in research in which pregnancy does not increase the level of risk.
- C. Pregnancy encompasses the period of time from the confirmation of implantation until the expulsion or extraction of the fetus. A fetus is the product of conception from the time of conception until a determination is made, following expulsion or extraction, that it is viable.
- D. Viable as it pertains to the fetus means being able, after either spontaneous or induced delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heart beat and respiration. Nonviable refers to a fetus *ex utero* that is living but not viable. Dead fetus means a fetus *ex utero* that exhibits neither heart beat, spontaneous respiration, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord. In vitro fertilization means any fertilization of the human ova that occurs outside the body of a human female. Special DHHS regulations applying to pregnant women and fetuses may be found in **45 CFR 46, Subpart B**. No research may be conducted with pregnant women or fetuses unless the following conditions have been met:
 1. appropriate studies on animals and non-pregnant individuals have been conducted;
 2. the risk to the fetus is minimal, except where the activity is to meet the health needs of the mother or particular fetus, and the activity involves the least possible risk;
 3. individuals engaged in research will have no part in (a) decisions as to the timing, method, and procedures used to terminate the pregnancy, and (b) determining the viability of the fetus at the termination of the pregnancy;
 4. when the pregnancy is terminated, no changes in standard procedure will be introduced for the purpose of research if the changes cause greater than minimal risk to the mother or the fetus;
 5. no monetary or other inducements may be offered to terminate a pregnancy for the

Common Practices

purpose of research.

E. Research protocols must clearly describe and document:

1. any known or possible risks to pregnant women related to participation in the research
2. procedures for screening pregnant women from participating. Level of accuracy must be appropriate for the risk involved, and can range from self-report by potential participants to a blood or urine analysis.

Research with Prisoners

Principles:

Minimizing risk

Justice and access to participating in research studies.

Practice

- A. Prisoners are persons involuntarily confined or detained in a penal institution. The term encompasses individuals sentenced to such institutions under a criminal or civil statute, individuals detained in other facilities by virtue of statutes of commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. Special DHHS regulations applying to prisoners may be found in **45 CFR 46, Subpart C**. No research may be conducted with prisoners unless the following conditions have been met: the research examines (a) the possible causes, effects, and processes of incarceration and criminal behavior; provided that the research poses no more than minimal risk or inconvenience to the participants; (b) prisons as institutional structures or prisoners as incarcerated persons; (c) conditions particularly affecting prisoners as a class; or (d) practices (both innovative and accepted) having the intent and reasonable probability of improving the health and well being of the participants.
- B. The possible advantages of participation must not be of such a magnitude that they impair the participants' ability to weigh the risks against the benefits of participation.
- C. The risks must be commensurate with risks that would be accepted by non-prisoner volunteers.
- D. Participant selection must be fair to all prisoners.
- E. There must be adequate assurance that participation will not affect the prisoner's chance of parole, and the prisoner is informed of this fact in advance of participation.

Research with Persons with Cognitive or Emotional Impairments

Principles:

Minimizing risk

Respect for Persons Principle

Justice and access to participating in research studies.

Practice

- A. Selection of participants is a particularly important issue as it relates to persons with cognitive or emotional impairments. Research involving persons whose autonomy is compromised by disability or restraints on personal freedom should bear some direct relationship to their condition or circumstances. Persons who are institutionalized should not be chosen as participants simply because it is convenient to the researcher. Nevertheless, persons do not become incompetent when by virtue of entering a mental health institution. Their right and considered judgment to participate in research should be respected.
- B. Persons with cognitive or emotional impairments are those persons having a psychiatric or developmental disorder that affects cognitive or emotional functions to the extent that the capacity for judgment and reason is significantly diminished. Other persons, including those under the influence of or dependent on alcohol or drugs, those affected by degenerative brain diseases, those who are terminally ill, and those who have severe physically disabling handicaps, may be compromised in their ability to make decisions in their best interests. Persons with cognitive or emotional impairments may not be able to give legally valid informed consent. However, researchers have a responsibility to persons with cognitive impairments (1) to inform them about the procedures, risks, and benefits of the research to the extent that the participant can understand, and (2) to obtain affirmative assent before collecting their data.

Common Practices

Research with Members of Minority Groups

Principles:

Minimizing risk

Justice and access to participating in research studies.

Practice

For generalizability of research findings, investigators should include a diverse population. Therefore, investigators must provide a "clear and compelling rationale for their exclusion or under representation" of minority group members from research. On the other hand, members of minority groups should not be over-included in research out of mere convenience or availability. No group of persons should be asked to bear the risks of research when many groups will share the benefits of that research.

Common Practices

Research with Elderly Persons

Principles:

Minimizing risk

Justice and access to participating in research studies.

Practice

- A. Elderly participants are generally persons over the age of 65. Advancing age may place them at increased physical, cognitive, or financial risks. However, there is no specific age at which persons become high-risk participants. Researchers have the responsibility to determine the level of risk that research poses on an individual basis and to minimize risks accordingly. The use of age *per se* to define one's ability to consent is not valid as the principle of justice dictates the inclusion of older persons in the research enterprise.
- B. When older persons are cognitively impaired or institutionalized, the same protections apply to them that apply to persons with cognitive or emotional impairments and to children. They should not be used as participants merely because they provide a convenient sample. Instead, research involving elderly institutionalized persons should bear some direct relationship to their condition or circumstances. Furthermore, they should be informed and given the opportunity to assent to research, to the extent they are able, even if a guardian must provide informed consent for them to be participants.

Informing Participants and Consent Language

Principle

To ensure that participants are appropriately and fully informed about the study in which they are being invited to participate.

Practice

- A. Potential participants may have educational deficits, learning disabilities, or cultural backgrounds that limit communication with a researcher. It is the responsibility of the researcher to ensure that a participant is fully informed. This may include presenting material at an appropriate level, in an appropriate language, and via an appropriate medium (e.g., verbal or visual).
- B. If a participant does not fully understand what participating in the research study will entail, it is the researcher's obligation to exclude the potential participant from the study (see Common Practices for Excluding Potential Participants).
- C. Researchers should not exclude participants who need special accommodations for becoming fully informed. Instead, researchers should employ reasonable efforts to help these individuals understand the study so they have the option of participating after being fully informed in an appropriate manner.

Undergraduate Student Research (Class Projects)

Principle

Although undergraduate research might not be of the caliber to contribute to generalizable knowledge, protections must be in place for participants and students should learn appropriate HSIRB principles and procedures. Also, faculty and students of WMU may be more likely to participate in student research that has been reviewed by the HSIRB office.

Practice

- A. Faculty should complete a class project registration form at the beginning of the semester (see below).

Western Michigan University
Human Subjects Institutional Review Board
Class Research Projects with Human Subjects

Please complete the following at the beginning of the semester and send a copy to the HSIRB office:

Class:

Semester or session:

Instructor:

Department:

Telephone:

E-mail:

Overview: As a class research project students will be asked to [describe assignment].

If data will be collected about human participants, please assure that the following are covered in class. These are the criteria for IRB approval according to the Code of Federal Regulations, 45 CFR 46.111:

- Participant selection and recruitment processes
 - Equitable
 - Lack of coercion
 - Risks to Participants
 - Minimization of potential risks
 - Risks reasonable in comparison to benefits
- Protection for participants
 - Informed Consent
 - Documentation of informed consent
 - Monitoring for participant safety as appropriate
 - Privacy for participants
- Confidentiality of data

Common Practices

Additional protections for vulnerable populations

Please include a class list.

Please complete the following once information is available:

Projects: For students collecting data about Human Participants, please complete the following to the extent possible. Projects for which data is intended for publication, thesis or dissertation (including pilot studies) will probably need individual reviews.

Name 1

Project title

Purpose, hypothesis, or research question

Intended use of data (e.g. in-class use only, publication, first step in thesis or dissertation)

Name 2

Project title

Purpose, hypothesis, or research question

Intended use of data (e.g. in-class use only, publication, first step in thesis or dissertation)

Etc.

- B. When class projects are identified, faculty should send summaries of the projects to the HSIRB office to register the projects.
- C. Students distributing cover letters or consent forms should have these forms stamped as registered with the HSIRB office.
- D. When faculty members indicate that student-collected data will be used for in-class purposes only, they are to assure that results, particularly of potentially sensitive data, will not be shared with colleagues, other students, or administration. This can be done through confidentiality agreements—signed by student researchers and, in cases in which students present their findings to the entire class, by all students who hear the presentations. This process would be similar to that recommended for focus groups.
- E. If there is any possibility of the data or aspects of the study being used for thesis or other independent study, students should complete an HSIRB application before recruiting participants. A supervising faculty must be listed as the principle investigator.
- F. Data on human participants collected by students as both class projects and as part of a faculty's research agenda must be addressed with full applications to the HSIRB, listing the faculty as the PI and students as SIs.
- G. Approval of a class project does not mean approval for graduate college purposes.

Common Practices

Graduate Student Research (thesis or dissertation)

Principle

Student theses or dissertations are considered research for HSIRB purposes.

Practice

- A. All graduate theses and dissertations involving human participants must be reviewed by the HSIRB. If the HSIRB decides that the protocol does not meet the HSIRB criteria for research with human participants, the HSIRB chair will send a letter to the principal and student investigator documenting this decision.
- B. The graduate student must be listed as the student investigator and the principal investigator must be a full-time staff or faculty member (not adjunct) at Western Michigan University.

Common Practices

Undergraduate Student Research (Honors Theses)

Principle

If your honors thesis involves collecting data from or about people, you and your advisor must obtain approval from the Human Subjects Institutional Review Board (HSIRB) before you contact any participants.

Practice

Instructions for applying for HSIRB approval are on line at the HSIRB website (http://www.wmich.edu/research/compliance/hsirb/hsirb_1.html). Honors students should obtain an HSIRB Packet from the Honors College or the HSIRB office, and the student and his/her advisor should carefully follow the instructions and the timetable in the packet.

Protocols with Multiple Data Collection Points Over Time

Principle

To ensure that the participants' rights to discontinue participation at any time without penalty.

To ensure that participants' right to being fully informed throughout their participation.

Practice

- A. Participants must be clearly informed that participating in data collection at one point does not obligate them to participate in later data collection.
- B. Depending on the time since the previous data collection point, the Board might request that participants be given an additional copy of the consent document prior to participating in subsequent data collection procedures.
- C. Scripts should be included in the protocol outline for invitations to participate in subsequent data collection.

Submission of Required Revisions following Review by HSIRB

Principle

A complete and corrected protocol must be submitted to ensure accuracy and clarity regarding what has been approved by the HSIRB. HSIRB will renew the revised protocol with the same level of thoroughness required for initial reviews.

Practice

- A. Researchers should submit a cover letter, which specifically addresses each comment on the revision letter that the HSIRB has sent to the investigator. If the investigator believes that the revision is not warranted, he/she should provide a clear rationale detailing why they did not incorporate the requested revisions.
- B. The entire revised protocol must be submitted. Revisions should be clearly marked with a method such as highlighting or a change in font. Revisions in consent documents should also be clearly marked, and a second unmarked copy of the consent documents should be included for HSIRB stamping and final use in the research.
- C. For minor revisions, a numbered and dated page can be submitted, stamped by the HSIRB and noted as replacing a prior page. The original shall then be dated according to submission date and stored in the rear of the protocol file.

Common Practices

Use of Identifying Information

Principle:

Protection of confidentiality both within the research and in terms of identity theft.

Compliance with HIPAA regulations.

Practice:

- A. Social security numbers should not be used as participant identifiers
- B. Use of any part of social security number for identification means that the data is not anonymous
- C. Other descriptors such as age, job title and location could be used to identify participants in particular situations and must be treated as identifiers. Some strategies for protecting confidentiality include: not collecting or not reporting a certain level of detail; concealing or changing descriptors; or reporting only aggregate data. If descriptors are used, it is important to make it clear to potential participants that consumers of the research findings could identify participants.

Evaluation and Research

Principles:

To fully inform potential participants about how data collected from them is to be used

To avoid using evaluation data for research purposes without participants' informed consent

To protect confidentiality of data

To allow researchers to use anonymously collected data

Practice:

- A. Evaluation becomes research at the moment when the investigator begins to think the data might be used in a professional presentation or publication. HSIRB review is required at this point.
- B. Benefits of the research do not include benefits of participating in the program, since one could participate in the program and not consent to have his/her data used for research.
- C. In general, researchers should include a statement in their proposal that there is no expected additional benefit to participants for having their evaluation data used in research. In the consent process and the consent form, help participants to understand the components of the evaluation separately from the components of the research. Participants would not consent to the evaluation but they would consent to having their data used for research.
- D. If there is any possibility of the data or aspects of the study being used for a thesis, dissertation, or other independent study, students should complete an HSIRB application before recruiting participants. A supervising faculty must be listed as the principle investigator.