

# UConn

UNIVERSITY OF CONNECTICUT

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## Office of the Vice President for Research

Research Compliance Services

### IRB Researcher's Guide

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## Introduction

The following documents provide investigators and students with information that will be helpful for meeting the standards set by the UConn IRB policies and by the Federal Regulations for the protection of human subjects in research. The topics appear in alphabetical order.

## Guidance for Data Security and Internet-Based Research Involving Human Participants

Computer- and internet-based methods of collecting, storing, utilizing, and transmitting data in research involving human participants are developing at a rapid rate. As these new methods become more widespread in research in the social, psychological, and social sciences, they present new challenges to the protection of research participants. The Institutional Review Board (IRB) reviews computer- and internet-based research protocols using the same considerations and standards of approval of research under 45 CFR 46.111 and 21 CFR 56.111 as all other research activities. All studies including those using computer and internet technologies must (a) ensure that the procedures fulfill the principles of voluntary participation and informed consent, (b) maintain the confidentiality of information obtained from or about human participants, and (c) adequately address possible risks to participants including psychosocial stress and related risks.

The purpose of these guidelines is to help researchers plan, propose, and implement computer- and internet-based research protocols that provide the same level of protection of human participants as more traditional research methodologies. The guidelines are comprised of requirements and recommendations that are consistent with the basic IRB principles applied to all research involving human participants. UITS has developed a [Glossary of Terms](#) related to data security, which may be helpful for researchers and students.

### Internet Based Research

#### Recruitment:

- Computer-and internet-based procedures for advertising and recruiting potential study participants (e.g., social media, internet advertising, e-mail solicitation, banner ads) must follow the [IRB guidelines for recruitment](#) that apply to any traditional media, such as newspapers and bulletin boards. All advertising and recruitment material must be reviewed and approved by the IRB prior to implementation.

- Investigators are advised to review the University’s policy on [Use of Official Email Lists](#) prior to soliciting participants by email. If you plan on using LISTSERVs at UConn, please contact [list moderators](#) for individual list policies regarding solicitations for research.

## Data Collection and Security:

- All laptops, iPads, tablets, portable media such as USB drives, or devices that are used to collect or store personal identifiable information (PII) for research purposes must use encryption.
- Any data that are collected from human participants over computer networks and are transmitted over the Internet must be in [encrypted](#) format. This helps insure that any data intercepted during transmission cannot be decoded and that individual responses cannot be traced back to an individual respondent. UITs and Research Compliance Services encourage the use of [Filelocker](#), Office 365, [encrypted email](#), encrypted USB drive, or secure FTP to transmit sensitive data containing PII. Filelocker is an encrypted web-based application that is used to provide short term secure storage and an encrypted transport of files both across campus and anywhere with web access.
- The level of security should be appropriate to the risk. For most research, standard security measures like whole disk encryption and secure socket layer (SSL) (commonly used for secure websites) will suffice. However, for sensitive data additional protections should include certified digital signatures for informed consent, or de-identifying data to ensure anonymity. [The Office for Human Research Protections](#) (OHRP) has additional guidance for obtaining informed consent electronically.
- For international research, investigators are cautioned that encryption standards vary from country to country and that there are legal restrictions regarding the export of certain encryption software outside US boundaries.
- Internet-based survey instruments must be formatted in a way that will allow participants to skip questions if they wish or provide a response such as “I choose not to answer.” Also, at the end of the survey, there should be two buttons: one to allow participants to discard the data and the other to submit it for inclusion in the study. Finally, if applicable, online surveys must include mechanisms for withdrawal. For example, if a participant decides to withdraw, there should be a mechanism for identifying the responses of a participant for the purposes of discarding those responses.
- Researchers working with children online are subject to the [Children’s Online Privacy Protection Act](#) in addition to human subjects regulations. Researchers are prohibited from collecting personal information from a child without posting notices about how the information will be used and without getting “verifiable parental consent”. For minimal risk research written permission may be

obtained by paper, mail, or fax. If the research is more than minimal risk, parental permission should be obtained in a face-to-face meeting.

### **Online Data Collection Software:**

The UConn Office of Institutional Research & Effectiveness (OIRE) has obtained a license from [Qualtrics](#) as an on-line data collection tool. Faculty members, students, and staff with an UConn Net ID and password are able to utilize Qualtrics. Use of SurveyMonkey, Psychsurveys, and other online survey tools is also permitted for minimal risk studies that do not involve the collection of sensitive data. As noted above, data must be transmitted in a secure format. The level of encryption used by the online survey tool must be described in the IRB study protocol.

The use of on-line survey software should be administered by a professionally trained person with knowledge in computer and internet security. Access to the server should be limited to key project personnel. The server should receive frequent, regularly scheduled security audits.

### **Data Storage/Disposal:**

- If a server is used for data storage, personal identifying information should be kept separate from the data, and data should be stored in encrypted format [Social Security Numbers](#) are not permitted to be used as an identifier.
- It is recommended that competent data destruction services be used to ensure that no data can be recovered from obsolete electronic media.
- Researchers must adhere to the UConn Information Security Office's [Confidential Data Security Standard Policy](#), and [Data Storage Guidelines](#).

### **Informed Consent Process For Internet-Based Research:**

- For anonymous internet-based surveys, include "I agree" or "I do not agree" buttons on the website for participants to click to indicate their active choice of whether or not they consent to participate. For anonymous surveys sent to and returned by participants through email, include the IRB's [information sheet template](#) and inform participants that submitting the completed survey implies their consent.
- If the IRB determines that written consent is required, the consent form can be mailed or emailed to the participant who can then sign the form and return it via fax or postal mail.
- Researchers conducting web-based research should be careful not to make guarantees of confidentiality or anonymity, as the security of online transmissions is not guaranteed. A statement in the informed consent form indicating the limits to confidentiality is required. The following statement

may be used: “Your confidentiality will be maintained to the degree permitted by the technology used. Specifically, no guarantees can be made regarding the interception of data sent via the Internet by any third parties.”

Source material for this policy guidance was provided by the Pennsylvania State University and the University of Georgia IRBs. The UConn IRB gratefully acknowledges this support.

In addition, the IRB would like to acknowledge information provided by Jason Pufahl, Chief Information Systems Security Officer for UConn.

**Additional Resources:**

[UConn Security Policy Manual](#)

[UConn Password Standards](#)

[Information Security Office Security Tips](#)

[Information Security Office Confidential Data Handling Suggestions](#)

*January 2017*



## Security Tips

<http://security.uconn.edu/policystandards/standards/security-best-practices/>

## Confidential Data Handling Suggestions

<http://security.uconn.edu/policystandards/data-security-checklist/>

In addition, the IRB would like to acknowledge information provided by Jason Pufahl, Chief Information Systems Security Officer for UConn.

*January 2015*

## Informed Consent

See also the IRB Policies and Procedures on Informed Consent.

“Informed consent is more than just providing a prospective participant with a form to sign. Informed consent is a process” that stems from the requirement for Respect for Persons one of the three most important principles of conducting research with human participants. (See the Belmont Report: Respect for Persons). The informed consent process is an interaction between the prospective participant and the Principal Investigator, student investigator or other designated qualified, key personnel (hereafter referred to as the “PI”). During the process, the research study is explained to the participant so that the participant can make an informed decision about whether or not to participate in the research study. This common sense process involves having a conversation with the prospective participants to ensure that the participant understands the research study and the reasons why the study is being conducted as well as the risks and benefits of the research. The conversation must allow the participant sufficient time to ask questions and to consider whether to participate in the study. This conversation must also take place in a setting that affords a sufficient level of privacy for the participant. The informed consent process is most often documented by the use of an IRB approved and validated informed consent form. The person obtaining consent must be trained in human subject protection, have an in-depth knowledge about the research study and be able to answer all questions posed by the participant.

Before beginning the conversation, the PI should discuss with the participant whether any special provisions will be needed for the consent process to take place. For example, hearing impaired individuals may want a sign language interpreter present or individuals with dyslexia may prefer to have the document read to them. The informed consent process should also be specific to each participant population and must take into consideration the participant’s native language, level of education, and maturity. Non-English speakers, educationally disadvantaged and minors are among the populations considered to be vulnerable. The IRB will look to see that the PI has taken this into consideration throughout the consent process.

Informed consent is an on-going process and this is particularly important for longitudinal studies. The PI should be available to answer participants questions at all times. In certain circumstances, it may be appropriate to remind participants of the purpose of the study and to remind them of the study procedures that will take place in the future. For example, longitudinal studies that require completion of multiple assessments over several weeks or several months should be accompanied by a brief informed consent document, not necessarily one that must be signed, to explain the research and the study procedures that must be completed at the point in time the assessment is to be completed.

The informed consent process should also take place in person. The IRB may, for extenuating circumstances or minimal risk studies, consider the possibility of obtaining consent by phone or fax.

## When Consent Must be Obtained

Consent must be obtained prior to any involvement of the participant in a study.

All consent forms must include instructions for the participants as to whom to contact regarding research related questions, the PI/research team members, research related injuries (if applicable) and how to contact the IRB regarding their rights as a research participant.

In general, participants must consent to any screening procedures as well as to participation in the study. The PI may choose to use two different forms or to use one form that includes both phases. Participants are considered enrolled at the time of signing the consent form. Participants must be informed that they may be withdrawn if it is determined that they do not meet inclusion criteria. Participants who did not meet the screening criteria are to be reported as withdrawals from the study at the time of continuation. Note that there are certain exceptions to obtaining consent prior to screening. Please contact the IRB Office for more information.

Consent from individuals other than the participant may need to be obtained if investigators seek information about people who are not principals to the research (“secondary participants”). These people could be members of the principal participant’s family, friends, sexual partners, co-workers, etc. Such individuals may be participants in their own right, even if the investigator never has any contact with the individual. The federal regulations define a human participant not only as someone with whom the investigator interacts, but also as someone about whom the investigator seeks information.

## Requirements of Informed Consent

As explained in the federal law that governs research with human participants, the informed consent process and document must contain certain required elements. Most of the elements involve basic, common sense information - information that most people would want to know in any situation before deciding to participate.

Consider the following scenario involving a decision to go to see a movie. It begins with your friend inviting you out for the night. The purpose of going out would be to see a movie. Your friend will naturally explain the procedures for the evening; suggesting the name and location of the movie and the time to leave so you will be able to go out to dinner but make it to the movie in time to see the previews. You may be hesitant about going out because you have had a tense day at work and you consider that one of the benefits of going out would be a relaxing evening. Even if the evening is relaxing, you consider that a possible inconvenience (or risk) may be giving up the time to do something else. Of course, the deal is even sweeter when your friend insists on paying for the movie so that you don’t have to worry about any economic considerations for the evening. After weighing the fun you’ll have going to the movie versus staying home or doing something else, you decide to go to see the movie. You have made a voluntary decision to go to see the movie. Of course, this example is not research but it illustrates that the elements of the informed consent process are really common sense and that providing these elements for consideration enable people to make an informed decision about

whether or not to participate. For a complete explanation of the required elements of the informed consent process refer to the informed consent document templates and the policy and procedure document .

## Standard Consent and Documentation

The informed consent process is most often documented by use of an IRB approved, validated consent form. Consent must be obtained from individuals who are at least 18 years old (or who, under their state’s laws are emancipated individuals) and who are competent to give informed consent. The PI must make a practical assessment of the participant’s capacity to understand the research, weigh the risks and benefits and make an informed decision about whether to participate.

Consent will most often be documented using a full length standard signed consent form that lists the required elements of consent. The participant (or the participant’s legally authorized representative) and person obtaining the consent (PI or delegate) must sign and date the form prior to study participation. The PI must provide the participant (or the participant’s legally authorized representative) with a copy of the signed and dated document.

When it is feasible, the PI or his/her delegate must sign and date the form in the presence of the participant. Written consent may not be necessary or appropriate in certain studies, such as surveys, interviews and other minimal risk research or in research where the participants are to remain anonymous. In these cases, the investigator should prepare an Information Sheet appropriate for the study. An Information Sheet is similar to a consent form; it contains the same required elements but omits the signature section.

The IRB has prepared a number of informed consent templates. The templates should be used; however, the IRB will consider alternative formats (e.g. letter format) on a case-by-case basis. The PI must explain why the Templates are not feasible for this research in the documentation of consent section of the IRB-1 or in the informed consent section of the IRB-5. The templates also provide guidance and suggested language that may be used to inform participants about the research study, the requirements for participation and the participants’ rights and responsibilities.

- 1.) The consent document must be written with language that is understandable
- 2.) It should include plain conversational language, at an 8th grade reading level, similar to the level used in popular magazines and newspapers to the participant population.
- 3.) Jargon and field specific terms should be avoided or if unavoidable must be defined.
- 4.) It must also be written in the second person (e.g., you are invited to participate, your child will be assigned, etc.). The IRB has tips on writing for lay audiences and Microsoft Word has a tool to assess readability. The consent document should be prepared with a font that is easy to read such as Times Roman, Arial, or Garamond and use a font size no

smaller than 12 point. Instructions that accompany the informed consent templates also have additional suggestions for preparing the consent form.

### **Waiver of Consent or Alteration to Elements of Consent**

In some circumstances, the IRB may waive or alter the elements of informed consent. A complete waiver of consent is most often granted for research studies that involve the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens (45 CFR 46.101(b) or those studies that are conducted by or subject to the approval of state or local government officials such as an evaluation of Medicare programs (45 CFR 46.101(b)(5)). When a complete waiver of consent is granted, the PI does not prepare a Consent Form or Information sheet and the participant is not told that his/her information is being used in a research study. To request a waiver of consent, the PI must complete the appropriate section of the IRB-1 and IRB-5 protocol applications. The PI must explain why the research could not practically be carried out without the waiver.

In certain circumstances, the IRB may grant a partial waiver or alteration of certain required elements of the informed consent process. The two most frequent examples of when such waivers or alterations are granted are when the research involves use of deception or use of “implied consent,” for example, via the return of completed, frequently anonymous, surveys. The IRB may also grant a waiver for use of deferred consent in which the research activity begins and consent is obtained later (e.g., for research on classroom instructional techniques.)

In all cases the IRB is required to find and document justification for any alteration to the requirements of consent.

### **Assessment of Participant’s Understanding of the Research and Consent Process**

As described earlier, the PI must make a practical assessment of the participant’s capacity to understand the consent discussion in order to be certain that the participant can give informed consent. This must be done in all circumstances even for minimal risk studies with participants who are not considered to be vulnerable. Such an assessment is also useful in order to gauge whether the participant may be able to understand and carry out the research procedures. The PI can facilitate this process by asking the participant open-ended questions that ask for explanations rather than closed ended answers that can be answered by a “yes” or “no” answer. For example: “Please tell me in your own words what we’re going to ask you to do?” vs. “Do you understand the procedures?”

### **Informed Consent Requirements with Use of Deception in Research**

The use of deception in research (e.g., participants are initially misinformed deliberately for purposes of the study) raises special issues that the IRB will review closely. One consideration is whether the deception is necessary. A PI proposing to use deception must justify its use in the procedures section of the IRB-1. Federal regulations prohibit the use of deceptive techniques that place participants at greater than minimal risk. The IRB may modify the informed consent process for research involving deception

when participants are not placed at risk. However, potential participants should be advised in the consent form that the information they are given is not complete and that they will be debriefed after the research procedures are completed.

The debriefing should include a detailed description of the ways in which deception was used and the reason why deception was necessary in order to carry out the research. The investigator is responsible for ensuring that the participant leaves the research setting with an accurate understanding of the purpose of the research and why deception was used. The debriefing process, including any written materials, should be provided to the IRB as a part of submitted protocols. The following statement, or some similar statement, must appear in every consent form/information sheet for studies involving deception:

“Research designs often require that the full intent of the study not be explained prior to participation. Although we have described the general nature of the tasks that you will be asked to perform, the full intent of the study will not be explained to you until after the completion of the study. At that time, we will provide you with a full debriefing which will include an explanation of the hypothesis that was tested and other relevant background information pertaining to the study. You will also be given an opportunity to ask any questions you might have about the hypothesis and the procedures used in the study.”

## **Requirement for Witness Signature on the Consent Form**

It is possible to conduct an oral presentation of informed consent information in conjunction with providing 1) a short form written consent document stating that the elements of informed consent have been presented orally and 2) a written summary of what is presented orally. This procedure is most often used when a witness to the informed consent process may be required for certain vulnerable populations (i.e. educationally disadvantaged, illiterate or non-English speaking individuals or when the study is complex in nature. For example, the IRB may require that the entire consent process be witnessed by a research participant advocate, a representative of the IRB, research study personnel, a primary caregiver or other appropriate individual.

## **Consent of Participants Not Fluent in English**

For participants not fluent in English, the consent process and document as well as study related documents (e.g., survey instrument, medical release forms) must be presented in a language (preferably native) understandable to them. If it is expected that participants who do not speak English will be enrolled in a study, translated documents should be made available. The IRB must review and approve all foreign language versions of the consent documents. The IRB recommends the use of one of two methods for translation. If one of the two recommended methods is not feasible, the IRB will accept certification from the PI that he/she or a member of the research staff translated the document and that the translation is accurate. This should be explained in the documentation of consent section of the IRB-Policies and Procedures document.

The informed consent process must also be conducted in a language understandable to the participant and may therefore require the use of a translator or sign language interpreter. In most cases, the translator may be a family member or friend of the participant, an employee of the institution or may be hired by the PI. The IRB will determine whether a professional translator is required on a case-by-case basis.

## **Re-Consenting Participants**

Common sense and IRB requirements dictate that participants must be re-consented if there have been developments that may affect a participant's willingness to continue to participate. To continue the movie analogy given above, such developments may be a discovery that the movie may be scarier for the participant than anticipated or that the movie is sold out and another must be selected. Re-consent more commonly occurs in biomedical studies, but may occur in social and behavioral research in cases where participants in an on-going study are asked to provide consent for their data to be used for another research purpose or in cases where the PI has a need to retain data (de-identified) indefinitely. In most cases, re-consent can take place at the participant's next regularly scheduled visit. In some circumstances, depending upon the level of risk and the nature of the information to be conveyed to participants, the PI or the IRB may require that participants need to be contacted immediately.

It should be noted that minor participants who are actively participating in a research study when they research the age of majority should be re-consented as adults at their next regularly scheduled visit.

## **Assent from Children or Decisionally Impaired Individuals**

In the State of Connecticut only individuals who are 18 years old (the age of majority, Conn. Gen. Stats. §1-1d) or older, may legally consent to participate in research. This legal authority may be withheld from some classes of individuals with limited decision-making or cognitive ability. Further, some individuals voluntarily give over this authority to another through a power of attorney or a health care proxy. Individuals who do not have the authority to consent to participate in research must still provide their "assent," which may be in writing, oral or in some circumstances, by action or behavior, e.g., with very young children.

Assent is a knowledgeable agreement to participate in the project. It differs from "consent" which is recognized as being granted from an individual with the legal authority to do so. Children cannot legally give consent; however, they can provide assent. Adequate provisions should be made for soliciting the independent, non-coerced assent from children or cognitively impaired persons who are capable of a knowledgeable agreement. In cases where assent is obtained from a child or cognitively impaired participant, permission must also be obtained from parents or legally authorized representatives. In accordance with the ethical principal of respect for persons, if the person from whom assent is sought refuses, the person should not be enrolled, even if the parents or legally authorized representatives give permission. Alternatively, if the person from whom assent is sought agrees to participate, the person may not be enrolled if the parents or legally authorized representatives do not give permission. In rare

circumstances, depending on the nature of the study and the age and circumstances of the child or decisionally impaired person, the IRB may waive the requirement for permission from parents or legally authorized representatives.

The IRB will determine whether one or both parents must sign a parental permission form. The IRB may find that permission from one parent (or legally authorized representative) is sufficient for research involving no greater than minimal risk or for research involving greater than minimal risk but holding out the prospect of direct benefit to the participant.

As a general guideline, if the participant is 12 years of age or older, the child signs and dates an assent signature line on the parental permission form and a parent or guardian signs the same form. Note that the language used to describe the consent form has changed. Parents give their permission, not their consent, for their child to participate. In certain circumstances, the PI may propose or the IRB may require that a separate assent statement is necessary. For example, the PI may wish to reinforce the voluntary nature of participation and the nature of the study with minor participants in studies taking place at a school where the parents have already given permission of the minor participant to participate in the study.

If a separate assent form is required, both the form and the assent discussion with the participant should be in a language especially tailored for participant, i.e., age appropriate and should describe the following:

- Explain why the study is being conducted;
- Describe what will happen and for how long or how often;
- State it is up to the child/individual to participate and that it is okay to say no;
- Explain if it will hurt and for how long and how often;
- Say what the child's/individual's other choices are;
- Describe any good things that might happen;
- Say whether there is any compensation for participating; and,
- Ask for questions.

The assent form should be limited to one page. Illustrations might be helpful and larger type makes it easier for some individuals to read. In studies involving older children or adolescents it may be possible for the child to read and indicate their written assent on the assent form.

If the child is between 7-12 years of age, and the study is a therapeutic trial, the parent signs the parental permission form and the child participant does not have to sign. If the study is not a therapeutic trial, the parents or guardians sign the parental permission form and the participant signs an assent statement that is either included at the end of the parental permission form after the signature lines or as a separate document.



If the child is less than 7 years of age, the parent or guardian signs the parental permission form, the participant signs nothing. No written assent statement is required; however, the PI should provide a script that will be followed to describe the study to participants. However, the PI or person obtaining consent must document in the study record that the child was willing to participate.

## **Considerations for Informed Consent for International Research**

Field research done outside of the United States, especially in non-western societies or places where the participants do not speak English, poses some problems in obtaining written documentation of informed consent. In these situations, it is sometimes impossible, for a variety of reasons, to obtain written consent. If that is the case, the PI must provide the IRB with a statement of the reasons why it should waive written consent, and also provide an acceptable alternative method of obtaining oral consent, which is appropriate to both the participants and their culture (refer to Ethnographic Research section).

If the participants may be economically or educationally disadvantaged, the investigator should pay particular attention to these issues and ensure that appropriate safeguards have been implemented.

## **Informed Consent Requirements for Research with a Certificate of Confidentiality**

A certificate of confidentiality protects the participant's confidentiality by protecting identifiable research records from subpoena. The certificate goes beyond the consent form in ensuring confidentiality and anonymity. Without the certificate, researchers can be required by a court-ordered subpoena to disclose research results (often as part of a criminal investigation of the participants). Regardless of a study's funding source or whether it is funded, Certificates of Confidentiality are issued by the National Institutes of Health (NIH) and other Department of Health and Human Services (HHS) agencies. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in civil, criminal, administrative, legislative, or other proceedings, whether federal, state, or local.

The IRB has prepared language to explain Certificate of Confidentiality requirements in the consent form. Either this or similar language must be used when the PI obtains a Certificate of Confidentiality.

## Guidance for Use of Deception in Research

The IRB recognizes that the uses of deception or incomplete disclosure in research are valuable research techniques. However, the use of such techniques raises special issues that the IRB will review closely. Deception occurs when participants are deliberately given false information about some aspect of the research. Incomplete disclosure occurs when participants are not given information about the real purpose or the nature of the research.

## Justifying the Use of Deception in the IRB-1 Protocol Application

Federal regulations prohibit the use of deceptive techniques that place participants at greater than minimal risk. An investigator proposing to use deception or incomplete disclosure should justify its use in the IRB-1 protocol application. Address the following when preparing the IRB-1:

- In the procedures section, justify use of deception and explain why deception is necessary to achieve the goals of the study. Explain if alternative methods not involving use of deception were considered and why these methods are not being used (Sloan & Hull, 2006).
- In the procedures section, explain the process to debrief participants. Explain when participants will be debriefed and who will debrief them. Provide copies of the debriefing statement that will be given to participants and the script that will be used by the researchers to orally explain the study (see below for guidance regarding the debriefing).
- In the risk section, explain if use of deception is likely to cause the participant psychological discomfort (i.e., stress, loss of self-esteem, embarrassment) while the deception is taking place. Explain how this risk will be minimized during the experiment and after the experiment is complete (i.e. full debriefing) (Sloan & Hull, 2006).
- Complete the waiver of consent section. When participants are not given complete information about the study in the consent document, the IRB must waive certain required elements of the consent process (i.e. an explanation of the purpose of the research, a description of the procedures involved, etc.). See below for additional information.

## Informed Consent Requirements with Use of Deception in Research

Potential participants should be advised in the consent form that the information they are given is not complete and that they will be debriefed after the research procedures are completed. Address the following when preparing the consent form/information sheet:

- In the “Why is this study being done?” section, provide a truthful and accurate explanation of the purpose of the study to the extent possible, without priming participants or by giving too much of the study away.
- Include the following statement in the “What will I be asked to do?” section, “Some research requires that the full purpose of the study not be explained before you participate. We will give you a full explanation at the end of the study.” Please note: the last sentence can be further customized to say, “We will give you a full explanation as soon as you complete the study.”

## Debriefing Requirements for Use of Deception in Research

The debriefing is an essential part of the informed consent process and is mandatory when the research study involves use of deception. The debriefing provides participants with a full explanation of the hypothesis being tested, procedures to deceive participants and the reason(s) why it was necessary to deceive them. It should also include other relevant background information pertaining to the study (see below).

### The Federal Debriefing Requirement

When required elements of informed consent are waived or altered by the IRB, in accordance with criteria provided in the regulations, participants must be debriefed at the end of the study, when appropriate. When a research study involves use of deception, the IRB must find that:

- the research involves no more than minimal risk to participants
- the waiver or alteration will not adversely affect the rights and welfare of the participants;
- the research could not practicably be carried out without the alteration or waiver; and
- when appropriate participants will be provided with additional pertinent information regarding participation.

As indicated above, the debriefing must occur “when appropriate.” It may be inappropriate when: Debriefing regarding the deception may cause more harm than the deception itself. For example, if a student is selected for participation in a study based upon certain physical characteristics (i.e., weight), it might not be appropriate for the debriefing to describe that aspect of the selection process.

The timing of the debriefing is also an important consideration. Generally, the IRB expects that participants will be debriefed immediately following their participation in the study. However, it is possible that an immediate debriefing may compromise study results. Participants who have completed the study might tell others about it. If they have been debriefed and have been debriefed may share that information with prospective participants, thus compromising the scientific validity of the study. The IRB recommends the use of the following strategies to handle this situation.

If participant names and contact information are collected as part of study procedures, debriefing information can be sent when the study is completed via mail, email or by phone.

If participant names and contact information are not collected researchers can:

- Give participants a URL where they can get debriefing information and a date upon which it will be available.
- Have each participant address an envelope to themselves before they leave the study session and send them debriefing information when the research is completed.

In most cases, the IRB expects that participants will be given a debriefing statement to take with them after the study is complete and after participants have been given an oral debriefing (script) immediately following completion of the study. Both the debriefing statement and the debriefing script must be reviewed and approved by the IRB.

The process to debrief participants must be explained in the IRB-1 protocol application. Address the following elements:

- Indicate who will debrief participants. The IRB expects that this person is a member of the research team, someone knowledgeable about the research and the deception. If the research is student directed (i.e. related to graduate studies, master's thesis or doctoral dissertation), the IRB expects that the student researcher will debrief participants.
- Indicate when participants will be debriefed. Again, the IRB generally expects that participants will be immediately debriefed after they complete the study. Any delay in debriefing must be explained and justified.
- Provide a rationale for any elements of the deception that will not be revealed to participants.

At a minimum, the debriefing statement must include the following:

- Label the form as "Debriefing Statement"
- Study title
- PI name and contact information for follow-up questions
- Student researcher's name and contact information, if applicable, for follow-up questions.
- Thank participants for taking the time to participate in the study
- Explain what was being studied (i.e., purpose, hypothesis, aim). Use lay terms and avoid use of jargon.
- Explain how participants were deceived
- Explain why deception was necessary in order to carry out the research
- Explain how the results of the deception will be evaluated
- If the study involves use of audio or videotaping an individual participant, give the participant an opportunity to withdraw his/her consent for use of the tapes and, potentially, withdraw from the study all together, after the true purpose of the study is revealed. The IRB suggests that participants be given at least 48 hours to make this decision and provide contact information for

whom participants should contact regarding their withdrawal from the study. This option must be given to participants even if they were video or audiotaped during a focus group or during an experiment involving other participants. If a participant decides to withdraw, the PI must use video editing tools to make an individual who withdraws unidentifiable. If tools are not available, the PI cannot use the video or audiotape.

Consider adding the following, additional elements, to the debriefing statement:

- Provide references/website for further reading on the topic
- Emphasize that it was not the gullibility of the participant but rather the skill of the experimenter that is responsible for the success of the deception (Sloan & Hull, 2006).
- If the study did not involve use of audio or videotaping but involves sensitive topics, it may be appropriate to give participants an opportunity to withdraw their consent to participate.

In addition to the elements included in the debriefing statement, consider adding the following elements to the oral debriefing that takes place after the participant has completed the study:

- Relate the research to something participants may have learned in class (methods or theory)
- Explain anticipated or observed results so far
- Offer to provide them with the study results

## **Debriefing as an Educational Tool**

Finally, the IRB suggests that the debriefing also be used as an educational tool, even when the study does not involve use of deception. Participants should be given a simple, clear and informative explanation of the rationale for the design of the study and the methods used. Ask for and answer participant's questions.

Sloan, L and Hull, J. 2006. Deception of Research Subjects 2nd Edition. In E. A Bankert and R. J. Amdur (Eds.), Institutional Review Board Management and Function (210-215). Sudbury, Massachusetts: Jones and Bartlett Publishers.

Source material for this policy guidance was provided by the Duke University IRB and the Stanford University Psychology Department. The UConn IRB gratefully acknowledges this support.

*January 2009*

## Guidelines for Developing Good Research Documentation Habits

The importance of accurate documentation to the quality of medical care given to patients is unquestioned. It is such an accepted element of patient risk reduction in hospitals and in court rooms that the corresponding maxim is: "If it's not written down, it didn't happen." NYU Medical Center website reminds its employees that in addition to its importance in providing a chronological description of patient care, and communication to other health professionals, "proper documentation also facilitates:

- If an adverse event occurs, you will have a record of what transpired prior to and of the incident.
- Appropriate compliance and quality review evaluations.
- Collection of data that may be used for research and education."

These concerns also apply to research with human subjects, whether it is conducted in a hospital setting where the chart is a legal document or elsewhere. It is common sense that accurately recording information is essential for providing accurate research data.

## Basic Principles of Documentation

- Entries need to be legible. If your handwriting is not readable, PRINT.
- Date and sign or initial each entry you make at the end of the entry/page.
- Document immediately after you complete a procedure; details never so clear later on.
- Write complete entries; use standardized abbreviations only.
- Don't document something for someone else.
- Don't sign a document for someone else.
- Maintain the confidentiality of the record you are creating. Re-file subject files; don't leave them open in common rooms where casual observers like other graduate students may view them.
- Don't discuss subject information outside the research team.

## Making Corrections

Mistakes happen; if you make a mistake, correct it right away.

Do: Draw a single line through the incorrect entry: ~~120/80~~ error 120/60 CAM / \*5/21/07 (\*if a different date) so that you can still read it.

Write "error" immediately after it and initial it.

\*Preferably, you realized your mistake right away and are correcting it the same day. If not, you should also include the date you are making the correction.

Do not: Scribble over the entire original entry so that it is impossible to read.

The implication may be made that you wanted to hide something.

Do not alter or go back and correct entries. The more corrections in a record the less reliable a record appears to be; the more time that goes by the less reliable a correction appears to be.

## **Ethnographic/Naturalistic Research**

Ethnographic research presents special challenges to investigators as it can be difficult to accurately describe the nature of the ethnographic research within the confines of the IRB-1 or IRB-5 protocol application forms. Therefore, we have created a separate form for submission of qualitative or ethnographic research, the IRB-9 form. The IRB appreciates that ethnographic research has the following special characteristics (Arwood, T., and McGough, H., 2007 PRIM&R SBER Conference):

- It is experiential
- It is interactive
- It is not easily bounded by time and place
- It is often exploratory
- It morphs easily and often (new questions emerge during research)
- The boundaries between normal activities and communication and data collection are blurred

In order for the IRB to understand these special characteristics and the nature and scope of a particular ethnographic research project, the following issues should be addressed in the IRB application form, if applicable to the research.

## **Participant Population**

The kinds of people who will be involved in the research should be described. If there are different groups or categories of people, the groups and the approximate number of participants in each group anticipated to be enrolled must be described. If an exact number of people to be enrolled are unknown, a range should be provided. An amendment should be submitted to the IRB when/if actual numbers exceed those estimates.

## **Description of Procedures**

- The length of time to be spent at the field site(s) should be described. If unsure, an approximate length of time should be provided (e.g., one year, two summer months, etc.). An amendment should be submitted to the IRB when/if actual dates exceed those estimates.
- The research techniques that will be used to conduct the research (such as participant observation, interviews, focus groups, use of public, private governmental or other records, administration of test, etc.) should be described. The topics or research domains to be covered as well as what will be observed (such as individual behaviors, community rituals, societal norms, etc.) should be described. This will help the IRB get a sense of what will be learned from and about the participants in the research.



- Explain how the maximum number of participants is determined or what criteria will be used to determine when data collection is completed.
- The research site(s) or location(s):
  - Explain where the research will be conducted and explain why this particular research setting was chosen.
  - Has the researcher conducted research at this site or with the population previously? If so, briefly describe the topics and duration of your previous research.
  - Is local governmental or community permission to conduct research required at any of the sites? If so, explain how you will obtain this permission. If there is formal documentation of this permission, attach it to the application form or indicate when it will be received and forward to the IRB.
  - Will you work with local collaborators (interviewers, interpreters, translators, guides, etc.)? If so, please explain who these collaborators are and how they will be involved in the research. Will they need to obtain local ethics committee approval for their role in the study?
  - Many countries have the expectation that foreign scholars will collaborate with local scholars and institutions. Explain whether this applies to your research and if local IRB or other type of ethical review board approval will be obtained.

## Risks and Inconveniences

Risk of harm in ethnographic research is usually limited to what may result from invasion of privacy, stigmatization, or breach of confidentiality. Harm may happen to individuals and to the groups or communities to which they belong.

- Identify the risks of harm that may result from this research.
- Describe the steps you will take to minimize the risks of harm. If harm occurs, what plans do you have to manage it?
- If there are different risks of harm for different groups of participants, please identify the risks for each group. Sometimes this cannot be known in advance of entering the field. If unanticipated problems occurrence research has begun, the incidents must be reported to the IRB. When appropriate, the study can be modified to address any issues that arise.

## Benefits

- Is it possible that individuals who take part in your research can reliably expect a direct benefit from taking part? If yes, describe.

- Describe the anticipated benefits of this research for the community you will study, for your profession, or for society in general.

## Confidentiality

- Describe how you will find out how people in this setting feel about the fact that you will write articles about them. Will you consult with the people from whom you collected data before you publish?
- Are any portions of the research material you may collect not publicly available and expected by community standards to be private? If yes, describe the materials that are private and explain (1) how you will store the private information or materials while you are in the field so that the confidentiality of the data is protected; (2) explain how you will store the private information or materials after you leave the field so that confidentiality is protected; (3) explain whether you will retain information that could lead to identification of the research site and explain any negative consequences this could have; (4) explain if you will record any direct participant identifiers (such as names or contact information) that could be linked to the private research material.
- If you will record identifiers (# 4 above) explain why and describe how you will protect against disclosure of this information or explain why this is not necessary. If you will retain the identifiers linked to the data, explain (1) how long the identifiers will be kept, (2) how confidentiality will be maintained during this period, (3) who will have access to data (such as sponsors, advisors, government agencies, etc.). In each case, explain whether they will have access to study data with identifiers or only to coded data with no access to the identifying study code. If identifiers will be maintained indefinitely, explain why. For example, do you intend to re-contact participants or communicate with them over a long period of time, or is the data identifiable by its nature (recordings, genealogies, etc.). Explain how you will protect the data from a breach of confidentiality or why this is not necessary.
- If you will retain data that may place participants at risk for criminal or civil liability or be damaging to their financial standing, employability or reputation, please explain. It may be advisable to obtain a federal Certificate of Confidentiality.
- The IRB acknowledges that sometimes it is not possible or desirable to maintain anonymity. For example, when a researcher works with a small group of people only found in a particular region with whom others have worked. In order to advance ethnographic knowledge about the group, their identity must be made known.
- Sometimes individuals or whole communities do not want to remain anonymous. If this is the case, please describe why. If there are differences in the community about this, describe how this will be handled.

## Consent Procedures/Process

- Explain how you will introduce yourself as a researcher to potential participants. If you already know them, please explain the circumstances.
- How will you inform people about your research and obtain their consent to participate? If you plan to use an oral consent process and to work informed consent procedures into your introduction to a group, or the beginning of an interview, please provide a general script or a list of points you will cover.
- Describe how people in this setting let you know if they don't want to talk with you.
- Identify who is responsible for giving consent in the research setting (for instance, if a tribal council or community leader provides consent for the entire group). Sometimes the consent process can be multi-layered in community settings. Be sure to describe what the full process is in the setting in which the research will take place.
- Describe how you will handle situations in which group consent is provided, but individuals do not want to participate and vice versa.

## Does Evaluation Require IRB Review?

Research studies involving human subjects require IRB review. Evaluative studies and activities do not. It is not always easy to distinguish between these two types of projects and projects frequently have elements of both. Therefore, the decision about whether review is required should be made in concert with the IRB.

**If you think that your project is limited to evaluative activities and therefore not subject to IRB oversight, please contact the IRB office at 6-8802 to discuss.**

Research studies are defined by Federal Regulation as:

Systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Evaluative studies are defined as:

Systematic collection of information about the activities, characteristics and outcomes of programs to make judgments about the program (or processes, products, systems, organizations, personnel, or policies), improve effectiveness, and/or inform decisions about future program development.

Below are elements that are common to evaluation and research projects. This list is not intended to be comprehensive and not all elements are required in order for a project to be considered research or evaluation. Rather, this list of elements can be used to assist faculty in determining whether an activity involves research requiring IRB review.

Common Elements	
Evaluation	Research
Determines merit, worth, or value	Strives to be value-free
Assessment of how well a process, product, or program is working	Aims to produce new knowledge within a field( <i>designed to develop or contribute...</i> )
Focus on process, product, or program	Focus on population ( <i>human subjects</i> )
Designed to improve a process, product, or program and may include:  -needs assessment  -process, outcome, or impact evaluation	May be descriptive, relational, or causal

-cost-benefit or cost-effectiveness analyses	
Designed to assess effectiveness of a process, product, or program	Designed to be generalized to a population beyond those participating in the study or contribute broadly to knowledge or theory in a field of study ( <i>designed to develop or contribute to generalizable knowledge</i> )
Assessment of program or product as it would exist regardless of the evaluation	May include an experimental or non-standard intervention
Rarely subject to peer review	Frequently submitted for peer review
Activity will rarely alter the timing or frequency of standard procedures	Standard procedures or normal activities may be altered by an experimental intervention
Frequently, the entity in which the activity is taking place will also be the funding source	May have external funding
Conducted within a setting of changing actors, priorities, resources, and timelines	Controlled setting (interaction or intervention) or natural setting (observation which may or may not include interaction or intervention)

**Informed by:**

Coffman, J. (2003). Ask the Expert: Michael Scriven on the Differences Between Evaluation and Social Science Research. The Evaluation Exchange, 9(4). Retrieved January 8, 2012 from <http://www.hfrp.org/evaluation/the-evaluation-exchange/issue-archive/reflecting-on-the-past-and-future-of-evaluation/michael-scriven-on-the-differences-between-evaluation-and-social-science-research>

National Center for Justice Planning. (2012) Research and Evaluation Overview. Retrieved on November 28, 2012 from <http://www.ncjp.org>

National Institutes of Health (2012). Evaluation Basics. Retrieved on November 28, 2012 from <http://www.nigms.nih.gov/Research/Evaluation/>

Oklahoma State University Institutional Review Board. IRB Toolbox. Program Evaluation: When is it Research? Retrieved on November 28, 2012 from <http://compliance.vpr.okstate.edu/irb/irb-toolbox.aspx>

Patton, M. Q. (1997). Utilization focused evaluation: The new century text. Thousand Oaks, CA: Sage.

Scriven, M. (1991). Evaluation thesaurus (4th ed.). Newbury Park, CA: Sage.

U.S. Government Accountability Office. (2005). Performance Measurement and Evaluation. Retrieved January 8, 2012 from <http://www.gao.gov/special.pubs/gg98026.pdf>

Source material for this policy guidance was provided by Oregon State University. The UConn IRB gratefully acknowledges this support.

## **Focus Group Policy Guidance**

When research involves the use of focus groups to obtain data, the participants should be given information before the focus group takes place regarding what the topic is, who the other participants / stakeholders may be, where the group will meet, and how long the session will last. It is particularly important to inform participants ahead of time when sensitive topics will be discussed (e.g., sexuality, substance abuse).

### **Informing Participants about Other Participants**

In the consent form and during the consent discussion, participants should be informed of who may participate in the focus group. Ideally this would be done during the recruitment phase, throughout the consent discussion and in the consent form. A participant may decide that he/she does not want to participate based on the expected other participants in the group.

Example: A focus group to discuss substance abuse and availability of drugs might possibly include participants who are current and former drugs users and members of law enforcement. Because of the sensitivity of the topic, participants should be told that it is possible that law enforcement officers may take part in the group. This must also be clearly stated in the consent form. However, until the focus group actually takes place, it is not possible to know whether members of law enforcement will actually be present. Therefore, before the discussion takes place, members should be informed who is present in the focus group and given a choice as to whether they would still like to participate.

### **Confidentiality of the Information Shared in Focus Group Settings**

In the consent form and during the consent discussion, participants should be informed that the information shared in the focus group session should not be shared with anyone outside of the group, and that the confidentiality of anything they choose to say during the session cannot be guaranteed. If the focus group is being audiotaped, participants should be instructed to maintain their privacy and confidentiality, and that of the people they talk about, they should not use names.

### **Informing Participants about the Focus Group Topic**

In the consent form and during the consent discussion, participants should be informed of the topic that will be discussed during the focus group session. The IRB expects the PI to fully disclose the exact nature of the focus group topic area in the consent form and as part of the consent discussion. However, the cultural context must be taken into consideration when addressing this issue. The PI must provide a justification for not fully disclosing the topic, such as the one provided in the example below, in the IRB-1 protocol application. For more information on the use of deception in research, please refer to the section on *Guidance for Use of Deception in Research on page 18* of this document.

Example: A research study being conducted in Nepal involved running a series of focus groups to obtain village residents' views on sex trafficking. The PI indicated that it would be counterproductive to explain the exact nature of the focus group topic since sex is considered a taboo subject in the local culture. The

PI felt that by clearly stating sex trafficking as the topic, it would change the dynamics of the group and make the discussion difficult. The PI further indicated that she felt the topic of sex trade would come up spontaneously in the interview if the indirect prompts were provided. The IRB agreed to give the PI latitude on this matter, and agreed to allow the purpose of the study and the specific topic to be discussed to be described obliquely in the consent form. This was acceptable since participants were debriefed at the end of the session, and provided with the specific purpose of the study.

## **Audio- or Videotaping the Focus Group**

In cases where the focus group session will be audio- or videotaped, the PI must disclose use of recording devices in the consent form and as part of the consent discussion. When the focus group meets, the PI should again disclose this to each member of the focus group, and ask if they agree to be audio- or videotaped. If being taped is a requirement of participation in the focus group, this must be stated in the consent form. If a member of the focus group objects to being taped, the PI can excuse the participant from the group, or agree not to audio- or videotape the session. Video editing tools that blur or block individual participants may also be used, and described in the protocol application. Participants should be given the opportunity to withdraw their consent AFTER the focus group session has ended. All of these specifics regarding videotaping must be clearly stated in the consent form.

## **Focus Groups Conducted in Developing/Traditional Societies**

PIs must use special care in conducting focus group sessions in developing countries and in vulnerable communities. It is crucial that the PI thoroughly understand the structure of local governments and local communities in order to gain permission from a representative of the community to conduct research. As a first step, the IRB suggests that the PI obtain permission from the mayor, a tribal elder, or from a tribal council. In some cultures, it is inappropriate for men and women to be invited to discuss some or all topics in one group. Sensitivity to and knowledge of local culture must be demonstrated by the PI in the IRB application.

Please refer to *Ethnographic/Naturalistic Research* on page 24 of this document for more information regarding Ethnographic/Naturalistic Research.

## IRB Responsibilities of Research Investigators

### Responsibilities of Principal Investigators

The IRB holds the PI responsible for the overall management of an approved study. Management of the study encompasses the ethical, technical, administrative, and fiscal elements of a project. The PI may delegate certain tasks, but retains ultimate responsibility and accountability. Principal investigators are required to:

- Acknowledge and accept their responsibility for protecting the rights and welfare of human research participants, including the equitable selection of research participants, ensuring that risks to participants are minimized, and that the risks are reasonable in relation to anticipated benefits,
- Fulfill the training requirement for the protection of human participants in research (CITI on-line training modules, [www.citiprogram.org](http://www.citiprogram.org)), and to understand the ethical standards and regulatory requirements governing research activities with human participants,
- Supervise all study personnel and ensure that all personnel abide by the ethical principles of respect for persons, beneficence and justice, as outlined in the Belmont Report,
- Ensure that all study personnel are knowledgeable of, and conduct the study in accordance with the approved protocol (including approved amendments),
- Ensure that all research activities have IRB approval and other approvals required by the institution before human participants are involved, and implement the research activity as it was approved by the IRB,
- Report any real or potential conflicts of interests of the PI or any study personnel in compliance with conflict of interest policies and management plans,
- Obtain informed consent from participants before participants are involved in the research, and document consent as approved by the IRB. A copy of the IRB-approved informed consent document must be used. Participants must be provided with a copy of the form after it has been signed, unless the IRB has specifically waived this requirement. Documented evidence of informed consent of the participants or their legally authorized representative is to be retained in a manner approved by the IRB. The consent process involves two required elements: 1) a discussion of the study by the person obtaining consent and the participants, and 2) an opportunity for participants to read the consent form. Please note that it is never appropriate to forgo the discussion, even if participants will then read the consent form. Participants must be given the opportunity to have the consent form read to them if they have difficulty reading,



- Maintain written records of IRB reviews, decisions, research records and informed consent documents,
- Obtain IRB approval for and notify the sponsor (if applicable) of any proposed change to the research protocol prior to its implementation, except when necessary to eliminate apparent immediate hazards to the participants,
- Obtain re-approval by reporting progress of approved research to the IRB, in the manner prescribed by the IRB, but not less than once per year,
- Promptly report to the IRB any adverse events, protocol deviations or other unanticipated problems involving risks to participants or others. PIs should not undertake any action with an external funding agency regarding an unanticipated problem or noncompliance without first contacting the IRB Chair, the AVPR or the ADRC in order to determine the correct course of action,
- Verify that IRB approval has been obtained from all participating institutions in collaborative activities with other institutions, and that continuing review by other institutions is maintained,
- Ensure the confidentiality and security of all information obtained from and about human participants, and the privacy of participants is maintained,
- Use the most current version of IRB forms and document templates, which can be downloaded from the IRB website,
- Oversee the budget and expenditures related to the study to ensure that adequate resources are available, including staff, equipment supplies, storage space etc., to conduct the study at the University and any other performance site for which the PI is responsible,
- Ensure charges assessed to insurance carriers are for procedures for illness or injury directly resulting from the research procedures of the study, if applicable,
- Provide the IRB with audit or inspection reports or findings issued by regulatory agencies, cooperative research groups, contract research organizations, the sponsor or the funding agency,
- Communicate, when applicable, the investigator's plans to meet with representatives of the community from which individuals will be recruited, about community concerns, values and expectations,
- Maintain, when applicable, accurate records on the receipt, use and disposition of excess drugs/devices,

- Conduct the study in compliance with internal policies and regulations including 45 CFR 46 and 21 CFR 50 – Protection of Human Participants, 21 CFR 312 – Investigational New Drug Application and 21 CFR 812 – Investigational Device Exemptions; with Good Clinical Practices and, when applicable, 21 CFR 210 – Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs and 21 CFR 211 – Current Good Manufacturing Practice for Finished Pharmaceuticals.

## **Responsibilities of All Key Personnel**

The IRB holds all study personnel (including PI and co-investigators) responsible for meeting certain obligations. Study personnel are required to:

- Fulfill the training requirement for the protection of human participants in research (CITI on-line training modules, [www.citiprogram.org](http://www.citiprogram.org)), and understand the ethical standards and regulatory requirements governing research activities with human participants,
- Comply with applicable IRB policies and procedures,
- Document contact with participants, e.g., obtaining informed consent or informing participants of changes that may affect their willingness to continue participating,
- Provide a thorough explanation of the study in lay terms to the participant during the consent process,
- Provide the participant with an opportunity to ask questions and have them answered when obtaining informed consent and throughout their participation,
- Understand the appropriate use of an investigational intervention (drug or device) as described in the protocol, investigator brochures, product information/drug labeling, and various other available sources such as newsletters, safety alerts, or communications from sponsors, if applicable,
- Be familiar with and follow the adverse event and protocol deviation reporting requirements.

## Normal Educational Practices

### What type of research study qualifies for exemption?

Federal regulations allow specific categories of human subjects research to be exempt from continuing IRB review (45 CFR 46.101(b)). Category 1 applies to research conducted in schools and other education settings:

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

Although the regulations do not address a maximum risk level, it is implicit within the concept of exempt research that there must be very little, if any, associated risk. Please note that survey research involving children is not exempt, nor is observation of a minor's public behavior unless the investigator does not participate in the activities being observed. (Institutional Review Board Management and Function, Bankert & Amdur, 2006).

Research exempted as normal educational practice is often conducted in public school settings which may demand that specific steps be followed in order to comply with additional state and federal laws. Although the definition in the regulations is fairly straightforward, it can create a conflict with other regulations that the IRB is obligated to follow, such as Subpart D of 45 CFR 46, FERPA (Family Educational Rights and Privacy Act), and PPRA (Protection of Pupil Rights Amendment). Subpart D specifically deals with children as a vulnerable population and most protocols that qualify for normal educational practice deal with children. If the IRB determines that a research study does not qualify for exempt status, then the extra protections for minors under Subpart D apply. Additionally, FERPA restricts researchers' access to student records without written permission from parents. However, within FERPA [20 U.S.C. 1232g(b)(1)(F)], there are conditions under which student records can be disclosed without parental consent: "Organizations conducting certain studies for or on behalf of the school". Investigators must contact each institution and follow that institution's FERPA policy, in addition to the requirements of UConn IRB. Finally, PPRA outlines 8 categories of protected information for survey responses and requires that parents be afforded the right to inspect surveys before they are given to students (for more information on FERPA and PPRA, see the link at the end of this section).

### What is an educational setting?

45 CFR 46 does not specify that normal educational practice takes place in schools only. The IRB defines an educational setting as any setting where an educational experience takes place. For example, a public

school, an after-school club or program, a Boy or Girl Scout meeting, a professional development seminar for school district personnel, or a postsecondary education setting.

## Who are the research participants?

The participants should include those involved in the educational experience, which most likely will include the teacher(s), student(s), and possibly the administrator(s). Participants that are indirectly involved in the educational experience may be included in the study, but they may not be exempt under normal educational practice, thus requiring additional consent procedures. For example, interviewing a principal may require that you use a consent form because this occurs outside the classroom and may not be considered normal educational practice. Participants can include populations with special educational needs, though the IRB will require demonstration of the investigator's credentials to work with these vulnerable populations as well as clear explanation of any additional procedures to minimize risks specific to working with this population. For example, if a child is significantly cognitively delayed, obtaining assent may not be appropriate, and the investigator must describe what steps will be taken to ensure that appropriate cues are taken from the child that may indicate an unwillingness to continue with study procedures.

## What is normal educational practice?

As noted above, the regulations define normal educational practice as "(i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods."

The IRB considers educational time to be a valuable commodity, and thus, the design of a research study that will be carried out in an educational setting should be developed with this in mind. At the minimum, the research should not waste student educational time, and may offer benefit to the individual and/or classwide educational experience. The IRB will consider the proposed methodology for the study in light of both time requirements and likelihood of benefit in order to determine whether it qualifies as normal educational practice. In all cases, the IRB will need to assess risks to all proposed participants in the study to determine the level of review required.

In some cases, it may be helpful if the PI can provide a letter verifying that the appropriate school administrator (e.g., principal, superintendent, school board) considers the proposed research study to be normal educational practice. (See Appendix A for an example).

Normal educational practice research that may qualify for exemption

- Development of assessments related to educational activities. The time commitment required to complete assessments should be described and may not exceed reasonable limits. The protocol design should clearly describe how results will be shared back with the school staff to assist in their instructional decisions as well as potential risks that might be associated (i.e., Will

students' grades be affected by their scores on the assessments? Will results be shared at the individual student level or in aggregate? How will the data be used by the school?).

- Research with instructional methods or classroom / school activities which may include pre and post testing, surveys, interviews, and/or observations. For example, if you are studying a new writing technique and you want to ask the students what they think about the writing technique, this could qualify for exemption. However, if you want to ask the students questions that are beyond the writing technique, the IRB may approve the study using the expedited review mechanism, because the questions may not qualify as normal educational practice. In all protocols, it is most helpful to the IRB if you clearly justify the necessity for using the chosen methods for collecting data and specify what data will be collected (via testing or survey instruments, interview questions, and/or observation protocols).
- Collecting data specific to teacher and/or student current knowledge, beliefs, or attitudes towards learning, or data about how these change over time. These studies may be descriptive in nature and may even be longitudinal. Interviews, observations, and surveys must include questions and subject matter that fall within the scope of the educational activity being studied.
- Data collection using videotape, audiotape, and/or photography will be eligible for exempt status only when the materials are accessible only to the researchers and they are destroyed after coding specific to the proposed research. Video and audio taping that is intended for other uses, such as presentation at meetings, publication, or education of graduate students, may not be eligible for exempt status. Please justify the necessity for using these methods for collecting data and specify exactly what will be collected. If the information collected can identify an individual person (i.e., student, staff member), it may be necessary to document signed consent using a consent form. In addition, if the materials will be used in a presentation or publication, it may be necessary to obtain specific permission from parents to do so.
- Obtaining samples of student work or scores may be eligible for exemption if FERPA regulations are met.

### **Examples of research eligible for exemption under normal educational practices in a commonly accepted educational setting:**

Example 1 – A researcher is interested in implementing an elementary school art education curriculum designed to help students develop visual vocabulary. The curriculum involves asking children to sort cards with reproductions of various Western artists as well as additional related activities. The basic curriculum has been widely used in school settings for over 15 years. The researcher is interested in adding some contemporary artists and those from other cultures to examine whether there are any differences in children's ability to make discriminations based on visual elements. These additions will not add significant time to the curriculum already being implemented and the assessments used in the

study are typical of both length and content of current classroom assessments. Results of the study will be shared in aggregate form so that teachers can determine the benefit of including these curriculum modifications in the future.

Example 2 – A middle school department of science teachers begins using graphic organizers to improve instruction of English language learners. The school has an existing relationship with the local university to partner on projects of collaborative interest. Thus, the school contacts researchers to ask for assistance in developing appropriate procedures for evaluating the hypothesized improved instructional practices. Researchers plan to use the resulting data in aggregate form for purposes related to presentation and publication as well as providing individual data to teachers to inform their instructional practices.

**Examples of research NOT Eligible for exemption under normal educational practices in a commonly accepted educational setting:**

Example 3 – A researcher wants to determine whether providing tangible reinforcement or verbal reinforcement will lead to greater increases in appropriate behavior and decreases in problem behavior for students identified with a serious behavior disorder. Individual students will be chosen for participation from classrooms of the same grade in consultation with the teachers. The students will be as closely matched for age and nature of the disorder, and then randomly assigned to an intervention condition. For example, one student will receive tangible reinforcement, one will receive verbal reinforcement, and the third will be the control.

Example 4 - Researchers are interested in developing a new assessment for math skills that involve both scoring of written prompts as well as responses involving use of manipulatives. It is expected that a new standardized, norm-referenced product will result. According to the school, the planned assessment is aligned with current curriculum and will not require students to respond to questions that would be unfamiliar. However, the development process entails having students respond to more assessment items than would be expected. In addition, in order to validate the new assessment, additional tests not currently used in the school will be administered for comparison, thus extending total testing time and number of items beyond what would be considered normal educational practice.

## **Obtaining Parental Permission and Child Assent**

In research with minors, even if a protocol does qualify as normal educational practice, the IRB generally requires that parents be notified about the study via a letter sent home with the students (waiver of parental permission with notification). In some cases, it may be appropriate for the letter to be generated from an appropriate school official (e.g., principal) in conjunction with the PI (see appendix B for one example). As noted on the IRB-1 form, to justify waiving parental permission, the IRB must find and document the following:

- The research involves no more than minimal risk to the subjects;

- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- The research could not be practicably carried out without the waiver or alteration; and
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation in the study.

Depending on the nature of the research, it may be appropriate to offer an ‘opt out’ option whereby parents are provided a notification form about the research study which they may sign and return an included ‘opt out’ sheet to indicate that they do not want their child and/or their child’s data to be included in the study. Note that this type of “passive” consent process still involves waiving parental permission because it is not the equivalent of informed consent.

**Non-exempt Studies: Expedited and Full Board Review of Research Conducted in Educational Settings** If a research study will be conducted in a classroom setting and it does not qualify for exemption, in most cases, a parental consent form must be used to obtain signed parental permission, and when appropriate, signed assent from the students. A parental permission form must be used to obtain signed permission from at least one parent. The signature of both parents is typically required only for those studies determined to be of greater than minimal risk. Depending on the age of the students, a separate assent form written at an age-appropriate level can be used, or for older students, an added signature line on the parental permission form can be used. Assent must be obtained verbally if signed assent is waived by the IRB.

If the protocol does not qualify for exemption yet it poses minimal risk to participants, it may be eligible for expedited review. If the study poses greater than minimal risk to the participants, the protocol may be reviewed at a full board meeting. If a study poses greater than minimal risk to participants, the PI must ensure that the IRB-1 includes a careful consideration of those risks with a detailed plan for managing them.

**Suggestions for completing the IRB application for research in educational settings** When submitting an application for research in an educational setting, the following information should be included:

- If the researcher(s) is not directly involved in the implementation of the intervention, particular attention must be paid to the description of how the surrogate researchers will be trained in the conduct of human subjects research (obtaining consent, ensuring that those students whose parents do not want them to participate are excluded from the intervention, etc.) Describe who is responsible for distribution and collection of consent documents. Describe what plan is in place to monitor and manage data collection.
- Describe the plan for handling a student who wants to withdraw from the study after consent/assent has been obtained;

- Clearly describe the difference(s) between what would typically occur in class and what will occur related to the research (i.e., will all students be involved in the same activities or will there be individual students singled out within a classroom?);
- Coercion and undue influence is difficult to avoid in a classroom setting in which activities are determined and implemented by adults. Research designs should include strategies to reduce this risk. For instance, clear procedures should be in place for handling students who are not participating in the study in order to minimize interruption to the typical school day. Although students are generally obligated to participate in activity designed for the whole class, activities specifically implemented for the research need to be clearly explained and alternatives be provided for those choosing not to participate. Appropriate alternatives should be provided for those who opt out, and must be described in the protocol as well as the consent form.
- The risks and inconveniences should be assessed and clearly described in the protocol and consent. For instance, in studies involving examination of classroom management techniques, will individual students be singled out for use of specific techniques? If so, what risks does that present to that child and to the other students (e.g., possibility of increasing in disruptive behaviors)?
- Describe how privacy and confidentiality of all participants (i.e., student, teacher) will be maintained. For example, will study results be shared back with the school on an individual level or in aggregate? Will information about teacher performance be shared with school administration? What risks to participants are presented given how data will be both managed and shared?

## Resources and Links

For more information on FERPA, go to [www.ed.gov/policy/gen/guid/fpco/ferpa/index.html](http://www.ed.gov/policy/gen/guid/fpco/ferpa/index.html).

For more information on PPRA, go to [www.ed.gov/policy/gen/guid/fpco/ppra/index.html](http://www.ed.gov/policy/gen/guid/fpco/ppra/index.html).



## Office for Human Research Protections (OHRP)

March 2009

The Office for Human Research Protections (OHRP) protects the rights, welfare, and well-being of subjects involved in research conducted or supported by the Department of Health and Human Services (HHS) and helps ensure that such research is carried out in accordance with the regulations described at 45 CFR 46.

As noted in the UConn IRB Policy and Procedures, all research involving human participants conducted by the faculty, students, and staff of UConn, or research conducted using UConn facilities, is conducted in accordance with federal regulations, regardless of funding source. Because UConn is engaged in human subjects research that may be conducted or supported by an agency of the U.S. Department of Health and Human Services, UConn has an OHRP approved Federalwide Assurance (FWA). This FWA is our contract with OHRP whereby the University agrees to conduct all human subjects research in compliance with the HHS regulations. The UConn Storrs FWA number is 00007125.

If you go to the OHRP website you'll see that OHRP is comprised of five divisions – Compliance, Education, Policy and Oversight, Secretary's Advisory Committee, and International Research. The three most relevant divisions to researchers are the Compliance, Education and International Divisions.

The [Compliance division](#) is essentially the auditing arm of OHRP. If it becomes necessary for the IRB to report unanticipated problems, serious or continuing noncompliance, protocol deviations, suspensions or terminations, the Compliance division reviews the report and the corrective actions. The Compliance division then determines what, if any, additional action needs to be taken to protect human research subjects. The Compliance division may also audit Research Compliance Services and the UConn IRB with regard to institutional compliance with 45 CFR 46. As indicated on the OHRP website, the division "evaluates all written substantive allegations or indications of noncompliance with the HHS regulations. If complaints or concerns arise regarding an institution's human subject protection practices, OHRP opens a formal evaluation and, if necessary, requires corrective action by the institution." Any findings of noncompliance are issued in the form of determination letters. OHRP maintains a list of determinations of institutional noncompliance. You can access the list here - <http://www.hhs.gov/ohrp/compliance/findings/index.html>. You will note that institutional noncompliance covers a wide range of IRB procedures involving: initial and continuing review, expedited review, informed consent, IRB membership, and IRB documentation.

The [Education division](#) is responsible for a number of initiatives including: (1) Responding to requests for clarification and guidance regarding ethical issues in biomedical and behavioral research involving human subjects and (2) Developing and conducting quality improvement activities to improve human research protection programs. The Education division developed the IRB Guidebook ([http://www.hhs.gov/ohrp/archive/irb/irb\\_guidebook.htm](http://www.hhs.gov/ohrp/archive/irb/irb_guidebook.htm)) as well as the Human Subjects Regulation

Decision Charts (<http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html>) which are helpful in determining whether or not the research activity requires IRB review and, if so, what level of review is required.

The [International Division](#) provides quality improvement consultation and research ethics training to domestic and foreign institutions involved in international biomedical and behavioral research. It maintains a compilation of human subjects protections laws, regulations and guidelines governing human subjects research around the world.

## Oral Histories; IRB Guidelines

In general, the IRB agrees that oral history interviews are not designed to contribute to generalizable knowledge and are therefore not subject to IRB review. However, at the present time, the Office for Human Research Protections has not issued formal guidance regarding oral history and the federal regulations. Therefore, at its meeting of January 18, 2005, the IRB determined that studies involving the use of oral histories would be reviewed by the IRB and that a determination would be made, on a case-by-case basis, as to whether the research meets the definition of research specified in the federal regulations. Until formal federal guidance is issued, the IRB would like to provide researchers with the following research scenarios <sup>1</sup> as examples of research that would or would not require IRB review.

### Scenario 1

Oral history activities, such as open ended interviews, that ONLY document a specific historical event or the experiences of individuals without an intent to draw conclusions or generalize findings would NOT constitute "research" as defined by HHS regulations 45 CFR part 46.

Example: An oral history video recording of interviews with holocaust survivors is created for viewing in the Holocaust Museum. The creation of the video tape does NOT intend to draw conclusions, inform policy, or generalize findings. The sole purpose is to create a historical record of specific personal events and experiences related to the Holocaust and provide a venue for Holocaust survivors to tell their stories.

### Scenario 2

Systematic investigations involving open ended interviews that are designed to develop or contribute to generalizable knowledge (e.g., designed to draw conclusions, inform policy, or generalize findings) WOULD constitute "research" as defined by HHS regulations at 45 CFR part 46.

Example: An open ended interview of Gulf War veterans to document their experiences and to draw conclusions about their experiences to help the VA evaluate VA health benefit policy for these veterans.

### Scenario 3

Oral historians and qualitative investigators may want to create archives for the purpose of providing a resource for others to do research. Since the intent of the archive is to create a repository of information for other investigators to conduct research as defined by 45 CFR part 46, the creation of such an archive WOULD constitute research under 45 CFR part 46.

Example: Open ended interviews are conducted with surviving Negro League Baseball players in order to create an archive for future research. The creation of such an archive would constitute research under 45 CFR part 46 since the intent is to collect data for future research.

Oral history research that does meet the definition of research is likely to qualify for review by the expedited mechanism (rather than meet the criteria for exemption because the interviews are generally

audio or videotaped). Therefore, such research must be submitted to the IRB using the IRB-1 protocol application. The IRB will determine whether a study involving oral history receives exempt, expedited or full board review as defined by the federal regulations.

Researchers are encouraged to contact the Research Compliance Services, or a member of the IRB, with questions pertaining to oral history research and IRB review prior to completing a protocol application.

<sup>1</sup> The scenarios were taken from a workshop presented by Tracy Arwood, Clemson University and Helen McGough, University of Washington held at the 2007 Social, Behavioral, Educational Research Conference. The scenarios were taken from a December 2003 e-mail exchange with Michael Carome, Associate Director Regulatory Affairs, OHRP and Lori Bross, Assistant to the Vice President for Research – Research Compliance, The Graduate School, Office of Research Compliance, Northern Illinois University, DeKalb, IL. For the full text of this exchange, read New York University's [Clarification on Oral History](#).

## Guidance for Recruitment and Advertising

March 2009

### General Recruitment

Advertisements and recruitment material are considered an extension of the informed consent and participant selection process. As such, recruitment of participants into a study may not begin prior to IRB approval. The IRB must approve all recruitment methods and material (flyers, letters, brochures, e-mail advertisements, radio announcements, etc.) prior to use. Materials must also be submitted for review and re-approval at the time of continuing review. The content of recruitment materials and the method for communicating it cannot create undue influence or contain misleading or exculpatory language.

The following are examples of common recruitment methods for human research studies. All recruitment methods must be described in the protocol application.

- Use advertisements, notices, and/or media to recruit subjects. Examples include flyers posted in public settings, newspaper ads, and radio and television advertisements.
- Direct recruitment of participants unknown to the researchers. Examples include random digit dialing, approaching people in public settings, snowball sampling, use of social networks, and Craigslist.
- Maintain a separate IRB-approved recruitment protocol to develop a database of potential participants (preparatory to research). The participants/patients provide consent ahead of time to be contacted for future research studies. Researchers contact patients about participation in IRB-approved studies in accordance with the signed consent.
- Provide colleagues with an IRB-approved Introduction letter describing the study. This letter would explain the purpose and procedures of the study and inform individuals how to contact the research team. Researchers are prohibited from having access to participant/patient names, addresses, or phone numbers; interested individuals must initiate contact.
- Send an IRB-approved letter to certain individuals asking for referrals of eligible participants interested in the study. The researchers may provide the referring individual with IRB-approved recruitment material for the study to give to potential participants. If interested, the participant contacts the researchers for additional information.
- Approach your own students or employees. This method raises ethical concerns because individuals may have difficulty saying no to an authority figure. For strategies to minimize undue influence, refer to the IRB policies and procedures regarding Review of Studies Involving Vulnerable Populations.

For studies that involve recruitment of patients from a medical practice or other treatment facility, it is not acceptable for investigators not affiliated with that practice or facility to directly recruit patients. The initial contact must be initiated by the physician or an employee of the practice or facility. Recruitment can take the form of a flyer posted in the waiting area or handed to potential participants by a physician or employee of the practice or facility. Due to HIPAA regulations, medical practices or treatment facilities may not give out telephone numbers or addresses of their patients.

If applicable to the study design, or required by a funding agency, the PI is responsible for tracking the ethnicity or race of participants who are recruited into studies. In such cases, investigators should ask participants to self-identify at the time of consent.

## Advertisements

Advertisements should contain information that provides enough detail to allow the prospective participant to determine his/her eligibility and interest. Visual effects that may create undue influence cannot be used, for example, placing the phrase "GET PAID \$100!!!" in all capital letters or an extra-large font while the rest of the ad is in lower case or a smaller font is not acceptable.

Generally, the elements of any advertisement to recruit participants should be limited to the following:

- the name of the PI and UConn Storrs department affiliation;
- an accurate description of the condition under study and/or the research purpose, e.g., "low fat vs. low carb diets for weight loss," or "acculturation of Cuban immigrants;"
- in summary form, the key eligibility criteria that will be used to admit (or exclude) participants into the study, e.g., acceptable age range or unacceptable physical limitations;
- a straightforward and truthful description of the benefits, if any, to the participant from participating in the study, e.g., "free health screening;"
- if applicable, a statement that compensation is available or a statement of how much compensation is available, e.g., "Participants may receive up to \$100;"
- the amount / length of time or other commitment required of the participants;
- the location of the research and contact information for obtaining additional information.

Advertisements must display the IRB validation stamp, unless an exception has been granted by the IRB. If it is not feasible to make copies of the validated version, it is acceptable to use the exact wording of the validation stamp: "UConn IRB, Approval On (date), Approved until (date), Approved by (initials)."

Recruitment information sent by email to listservs, Craigslist, etc. must include the following statement, "This research study was approved by the UConn IRB, Protocol # \_\_\_\_\_."

Advertisements cannot incorporate elements that:

- state or imply a certainty of favorable outcome or other benefit beyond what is in the informed consent form;
- Use catchy words like "free" or "exciting."
- For FDA regulated research studies (new drugs/devices) or studies on nutritional supplements:
  - make claims that the supplement, drug, device or biologic is safe or effective for the purpose under investigation or that the supplement, drug, device or biologic is known to be equivalent or superior to any other supplement drug, device or biologic;
  - use terms such as "new treatment," "new supplement" or "new medication" without identifying it as investigational.

Refer to the FDA's regulations concerning the promotion of investigational drugs (21 CFR 312.7(a)) and of investigational devices (21 CFR 812(7)) for additional information.

## **Recruitment/Advertising Tips and Suggestions**

- Understand the target population. What media does the population read or view? Where do they go for information?
- Make concerted efforts to recruit participants from minority and under-represented groups. Describe those efforts in the protocol application.
- Spend the time to make the recruitment flyers easy to read and understand. Advertisements must be written using lay language, at an 8th grade reading level (similar to the level used popular magazines and newspapers) that is appropriate for the participant population. You should select a font style and size that is easy to read such as Times Roman , Arial, or Garamond.

A sample, recruitment flyer template is available with the IRB Templates on the website.

Source material for this policy guidance was provided by the University of California – Irvine IRB. The UConn IRB gratefully acknowledges this support.

## Guidance for Research Studies Involving UConn Student Athletes

*April 2009*

Student athletes, like all students at UConn, are considered to be a vulnerable population because of concerns with issues of coercion, undue influence and privacy. However, their involvement in research studies raises special concerns regarding recruitment and compensation for research studies since they are subject to NCAA rules and regulations that are related to their scholarships and participation in athletics (scholarship, and drug testing).

### Recruitment

Any member of the coaching staff, faculty or graduate student researchers (particularly those assigned to an athletic team) are encouraged to contact the IRB office prior to submission of the protocol for advice to minimize the potential for undue influence or coercion. You may be advised to consider using anonymous data collection methods or an independent third party to consent participants or collect data.

If student athletes are specifically recruited for a research study because of their status as athletes, the researchers must obtain approval from the Athletics Compliance Office before the IRB will grant approval of the study. The Athletics Compliance Office must provide written documentation to the IRB indicating that they understand the research and agree that it will not jeopardize the student-athlete's NCAA eligibility.

### Confidentiality

If results of the research will be shared with the coach or any member of the coaching staff, sports medicine or athletic training staff or any staff person in the Director of Athletics office, the nature of the data being shared must be fully explained in the protocol application. In addition, the student athletes must be informed of this in the consent form.

### Compensation to Student Athletes

According to the NCAA Compliance Office and the Big East Compliance Office, student athletes may be paid for their participation in research studies provided that the student athletes are being recruited from the general student body because they are students at UConn and NOT because they are student-athletes. If a research study targets individuals who are athletic and, as an example, a soccer or field hockey player wants to participate in the study, they may be able to participate and get paid. However, student athletes MAY NOT be recruited for a study AND be provided with payment for participation JUST BECAUSE of their student-athletes status.



## Review of Study Design and Science by the IRB

### The Basis for the IRB's Obligation of Scientific Review

The IRB has an ethical obligation to review the design or other aspects of a study that may affect the scientific quality of the protocol. The following sections from internationally recognized ethical guides state that ethical research requires that:

- 1) the study is designed to minimize the risks to subjects and
- 2) the potential risks of the research are justified by the potential benefits.

### The Ethical Codes

#### Nuremberg Code (1949)

Several sections including the following address the question.

Point 3. "The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment."

#### Declaration of Helsinki (2000)

Several sections including the following address the question.

Section 11. "Medical Research involving human subjects must conform to generally accepted scientific principles and be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and when appropriate, animal experimentation."

Section 18. "Medical research involving human subjects should only be conducted if the importance of the objective outweighs the inherent risks and burdens to the subject. This is especially important when the human subjects are healthy volunteers."

Section 29. "The benefits, risks, burdens, and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic or therapeutic methods. This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic or therapeutic method exists."

#### Federal Research Regulations

DHHS and corresponding FDA Sections (21 CFR 56.111).

45 CFR 46.111 Criteria for IRB approval of research.

In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

- 1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- 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 should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not 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.

## Guidelines

Robert J. Amdur in Ch. 5-2 "Evaluating Study Design and Quality" in IRB Management and Function by Elizabeth A. Bankert and Robert J. Amdur notes the references above and offers the following guidelines to IRBs when evaluating a study's scientific design and benefit from the perspective of risk to participants.

The IRB should use independent judgment and common sense. For example if the design of a student research project for a course is flawed but creates no effective risk to subjects, there is no ethical basis for the IRB to require revisions for approval. There are only educational reasons to suggest changes.

The IRB should NOT approve a study without requiring revisions if:

- revising the design will decrease the risks to participants in a meaningful way without a major compromise to the persuasiveness of the study results; OR
- the study design is "so flawed that the value of the study results will be almost zero." In this case, even though the risks may be low if the potential benefit is zero, the overall risk/benefit ratio would be unacceptable; OR
- the study involves a meaningful risk and asks a question that was already answered in earlier research or "not important" to the field of scientific inquiry.

## Policies and Procedures

See the IRB Policies and Procedures document on the OVPR website for sections on the UConn IRB, Submission to the IRB, and Scientific Review.

## **Wording Tips & Substitutions**

Download the PRISM Toolkit Word List from the IRB section of the OVPR website.

Download the full PRISM Readability Toolkit from the IRB section of the OVPR website.