UWEC Online Human Subject Protection Tutorial

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Introduction

Welcome to the University of Wisconsin-Eau Claire Human Subjects Protection Tutorial

Before your FIRST electronic submission of an IRB application, you must first complete this UW-Eau Claire online IRB tutorial. You will be required to page through all sections in order, then correctly answer the quiz questions at the end. Expect to invest approximately 1-2 hours to complete the tutorial. You may stop at any time, select "Save and Close for Later," and the tutorial will return to that section when next opened. When this tutorial is successfully completed, you will receive an email notification with a PDF of the certification. Then you will be able to begin the Initial IRB project application form.

Who should take human subjects training?

UW-Eau Claire requires that all individuals who contribute to the design of projects that involve human subjects or who work with human subjects complete this human subjects tutorial. This includes:

- All faculty and staff conducting research involving human subjects
- All personnel responsible for recruiting subjects, obtaining informed consent, conducting study procedures, and performing data analysis
- All investigators listed on a grant proposal
- All students conducting research involving human subjects
- Any new investigators or other research staff (including students) added during the course of a project

Many in the university community will have previously taken human subjects training through other systems. Because UW-Eau Claire has provisions unique to this campus, even investigators with prior training must complete this tutorial and have generated a certification of completion.

Collaborations

UW-Eau Claire encourages its researchers to collaborate with colleagues at other institutions. When UW-Eau Claire investigators collaborate on research with other colleagues outside of UW-Eau Claire, the research must meet the same high standards for protecting human subjects required of research headed by UW-Eau Claire personnel. The UW-Eau Claire IRB must approve all research projects of UW-Eau Claire investigators, including collaborative projects where investigators at another institution are involved. If this project has already been approved at another institution, attaching a copy of supporting documentation in the Initial IRB project application form will speed up the UW-Eau Claire approval process.

Additional information on the UW-Eau Claire IRB

The UW-Eau Claire IRB is responsible for reviewing research protocols and supervising the operations of the university's IRB program to protect human subjects. It establishes IRB policies and is responsible for communicating these policies to the university community. If at any time you have questions concerning the protection of human subjects, please contact UW-Eau Claire IRB Chair, Don Bredle, PhD, at 715-836-2373. The office of the UW-Eau Claire IRB Chair is located in the Office of Research and Sponsored Programs, Schofield 17.

This tutorial provides information on the rules and regulations governing research involving human subjects at UW-EC under the federal Common Rule (45 CFR 46) which will be referred to often and is available in its entirety athttp://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html as well as U.S. Food and Drug Administration (FDA) regulations (21 CFR 50, 56, 312, 600, and 812). The tutorial consists of four main modules, with examples, and a certification page. The examples illustrate the concepts introduced in the module.

Modules

- **Module 1: Introduction** will help you decide whether your research project will be subject to the rules and regulations governing the involvement of human subjects in research.
- **Module 2: Ethical, Historical, and Legal Background**, will explain why there is an extensive process for approving all research that involves human subjects.
- **Module 3: Basic Principles**, will describe the fundamental ethical principles that guide all decisions concerning the conduct of research with human subjects. It will also review issues relating to privacy and information security.
- **Module 4: Approval Process**, will describe the research approval process at UW-EC and the role of UW-EC's Institutional Review Board (IRB).

Acknowledgements

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Module 1: Introduction

To determine whether your project will be subject to IRB guidelines, you need to understand how UW-Eau Claire and the Federal Office for Human Research Protections (OHRP) define the terms research and human subjects.

What is research?

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities (45 CFR 46.102d). The primary outcome/goal of the

activity/study is to gain knowledge for the purpose of benefiting individuals other than those in the study.

Systematic Investigation:

A planned technique (e.g., survey, interview, observational study) for studying an area of interest (e.g. violence and the media), testing a hypothesis (e.g., exposure to violent media such as video games/music makes individuals more violent), answering specific questions, or developing some type of theory. For example, what are the key personality characteristics of persons that are prone to committing acts of violence following exposure to violent media?

Generalizable Knowledge:

In order to contribute to generalizable knowledge, the activity's conclusions are intended to be extended beyond the sample or internal program. The dissemination of findings to a scientific audience is a sufficient criterion for identifying generalizable knowledge.

Example: information is generalized from a sample (e.g., UW-Eau Claire's seniors' attitudes toward distant education for a math class) to a specific population (University of Wisconsin System) and the results are shared via internet, professional conferences, peer-reviewed journals, etc. Generalizable Knowledge includes one or more of the following:

- The data is geared for scholars, practitioners, and/or researchers within a specified field of study
- Results of the study are presented either by presentation and/or publication in order to illuminate some topic/issue within one's field of study
- Results from the study are applied to some population in addition to the sample
- The study's results can be replicated by others
- The study provides input into some field of study

Research can include:

- Pilot projects (e.g., a pilot project on a new technique for reducing drop-out rates for at risk students in the public schools). That is, a time-limited, experimental initiative.
- Exploratory studies (an inductive approach where theory is developed from gathered data)
- Independent student studies, theses, or dissertations (theses are in the library and abstracts are placed on the web/dissertation abstracts for public display)
- Some demonstration activities (e.g., initiatives, projects, and or policies that demonstrate good practice, generate ideas, and contribute to policy development)
- Some public benefit/service programs (e.g., procedures for obtaining benefits or services under those programs; possible changes in those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs
- Formal investigations
- Internet studies

Generally, research does NOT include:

- Classroom activities that teach research methodologies or simulate research activities
- Activities conducted to improve the quality of teaching in a particular classroom
- Activities required for quality assessment (QA) or quality improvement (QI)
- Institutional research studies that are not intended to be generalized beyond UW-Eau Claire
- Evaluation of speakers or other presentations conducted for the purposes of improving the presentation the next time

If you are not sure if the research you are proposing is covered by these rules and regulations, check with the IRB Chair, 715-836-2373.

What is a human subject?

A human subject is "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information" (45 CFR 46.102f). This definition includes pilot studies, feasibility studies and other preliminary research.

The definition continues:

"*Intervention* includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subjects environment that are performed for research purposes." (45 CFR 46.102(f))

"*Interaction* includes communication or interpersonal contact between investigator and subject." (45 CFR 46.102(f))

"*Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects" (45 CFR 46.102(f))

What is human subjects research?

Putting these definitions together, human subjects research covers a wide variety of activities, including studies of:

- Data from surveys/questionnaires, interviews, focus groups (only if focus group information is generalized outside the group to the general population) and observation
- School or correction records

- Employment information or records of earnings
- Bodily materials, such as cells, blood, urine, tissues, organs, hair, nail clippings, or DNA, when these are linked to specific individuals
- Analysis of existing data (e.g., medical records, school records)
- Cognitive and perceptual experiments
- Case Studies

While the scope of activities considered human subjects research under federal regulations is broad, not all human subjects research must undergo full review by an Institutional Review Board (IRB). Following procedures laid out in federal regulations, the UW-Eau Claire IRB grants exemptions and uses both expedited and full reviews to examine proposed human subjects research. All three kinds of review will be discussed in Module 4.

Examples:

This section contains examples of social, behavioral, and educational research, which apply the concepts introduced in Module 1.

Example 1.1

Professor Metzger conducts a telephone survey of middle school teachers in Dunn County to learn about television-watching habits.

Is this human subjects research?

Yes. It is a systematic investigation with interaction between the investigator and the subjects.

Example 1.2

A business student interviews Roger Waters (former bassist, and singer/songwriter of Pink Floyd) about the songs he played on his recent solo concert tour.

Is this human subjects research?

Probably not. There is interaction, and the subject may be clearly identifiable, but the activity is not designed to yieldgeneralizable knowledge. The information only pertains to this musician.

Example 1.3

A staff researcher for the Rural Demography Project wants to combine two existing data sets to enhance her research. The combined data will identify individuals by county of residence, colleges or universities attended, and degree dates.

Is this human subjects research?

Yes. The combined information might well identify unique individuals. This means the research is a systematic investigation of identifiable private information.

Example 1.4

A student is studying qualitative research methods in a UW-Eau Claire course on sociology. As part of the course, the students conduct a small study. One student decides to study group interactions at the Student Center. Her data collection will consist of observational field notes and videotaping. She intends to use this data as part of a pilot study for a research paper.

Is this human subjects research?

Yes. As part of a research paper, the study contributes to generalizable knowledge.

Example 1.5

An education professor, Anna-Marie Rectoshnie, is collaborating on a research project with a colleague from Michigan. Professor Rectoshnie's colleague has already obtained approval from the University of Michigan's IRB.

Does the UW-Eau Claire researcher need to seek approval from a UW-Eau Claire IRB?

Yes. When UW-Eau Claire researchers collaborate on projects with human subjects, they must have the project reviewed by the UW-Eau Claire IRB, regardless of the location of the actual work with human subjects.

Example 1.6

A UW-Eau Claire student analyzes a group of politicians' communication styles via televised speeches.

Does the student need to seek approval from a UW-Eau Claire IRB?

No. This is not human subjects research. The data is derived from public speeches. There is no private identifiable information.

Example 1.7

A student in a history course studies the lives of early settlers (1800's) within Northern Wisconsin by analyzing letters, diaries, and other written communications.

Does the researcher need to seek approval from a UW-Eau Claire IRB?

No. This is not human subjects research since it does not involve living persons.

Example 1.8

A student will develop a research paper on the late renowned singer/songwriter Ronnie Van Zant from the Lynyrd Skynyrd Band.

Does the researcher need to seek approval from a UW-Eau Claire IRB?

No. This activity is not human subjects research because results of the activity are not intended to be generalized beyond Ronnie Van Zant.

Example 1.9

An undergraduate student develops a study to assess certain population trends in the U.S. using Census data.

Does the student researcher need to seek approval from a UW-Eau Claire IRB?

No. This is not human subjects research since no individually identifiable information is being used.

Example 1.10

A business student designed a study to assess client satisfaction of Vocational Rehabilitation services by analyzing data collected from the Wisconsin Department of Workforce Development.

Does the UW-Eau Claire researcher need to seek approval from a UW-Eau Claire IRB?

Yes. This is human subject research since it is a systematic investigation that is generalizable and interactions with living persons will be conducted. Furthermore, personal identifiers may be present.

Module 2: Ethical, historical, and legal background

Part 1: Ethics

The opportunity to conduct research using human subjects is a professional privilege. With that privilege comes responsibilities. The most basic of these responsibilities is to recognize that research has the potential to harm its subjects, directly or indirectly, and to strive to minimize that potential. Harm may be social, psychological, financial, or physical. In addition to the research subject, individuals discussed in a study, investigators, society, and UW-Eau Claire as an institution, may be subject to harm. Research can never be free from risk, but, as professionals, investigators and other key personnel involved in a study must be aware of risks and work to minimize them.

UW-Eau Claire's policies and procedures for working with human subjects are guided by the ethical principles set forth in The Belmont Report. Following Congressional directive, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research outlined basic ethical principles for guiding research with human subjects in 1979. These principles will be discussed at length in Module 3.

Part 2: History

During the 20th century, national and international researchers undertook a number of studies with human subjects that appalled their peers and society more broadly. In response to these projects and the controversy they generated, governments have established ethical standards for the involvement of humans as subjects in research. In the United States, the federal government has established an extensive process to ensure ethical treatment of human subjects. (45 CFR 46)

Milgram on obedience

In the 1960s, the social psychology research of Stanley Milgram brought public scrutiny to the issues of (1) informed consent in experiments using deception and (2) the potential for psychological harm in research.

Milgram recruited subjects through a newspaper advertisement to participate in a study of "memory and learning." The experiment lasted an hour, and subjects received payment for participation.

Three people participated in each experiment: a scientist, a "teacher" (the volunteer), and a "learner." Learners were asked to match word pairs. When the learner responded incorrectly, the scientist instructed the teacher/volunteer to administer an electric shock to the learner. As the experiment progressed, a control panel indicated the shocks increasing from 15 to 450 volts. Roughly one-third of the way through the experiment, the learner typically demanded that the experiment stop. Two-thirds of the way through, the learner typically became silent and nonresponsive.

Milgram found that 60% of his teachers/volunteers would follow the scientist's directions and administer the complete sequence of shocks. At the end of the experiment, Milgram disclosed to the teacher/volunteer that he was actually studying people's obedience to authority figures and that the learner had received no shocks. The learner was actually an actor pretending to be shocked. When Milgram published his findings in 1963, peer and public debate focused on the way deception undermined informed consent in this study. Further, the experiment came under criticism for placing volunteers in the extremely stressful position of believing they were administering severe punishment to other people.

Tuskegee Syphilis Study

This "Public Health Service Syphilis Study" was conducted in Tuskegee, Alabama. The subjects, approximately 400, mostly illiterate sharecroppers (African-American) were used to study the longitudinal impact of untreated syphilis. The subjects were told they had "bad blood" not syphilis, and that they could receive "free treatment". Even though penicillin (a cure for syphilis) was available by 1947, scientists did not make this information available. The point was to assess the stages of untreated syphilis. The study was leaked to the press in 1972 which then caused it to be disbanded. This experiment (The Tuskegee Syphilis Study) led to the establishment of the National Human Investigation Board, the Belmont Report, and the requirement for the establishment of Institutional Review Boards. This study emphasized a major breach in trust between patient and doctor.

Stanford Prison Experiment

This was a landmark study (1971) that addressed the issues of captivity (prison setting) and the impact of social roles on behavior. Zimbardo, a Stanford researcher, took a group of 24 young men and randomly assigned them to one of two groups, either the prisoners or guards. A mock jail was constructed in the basement of a Stanford building. Zimbardo was the superintendent. Guards were given wooden batons, mirrored sunglasses and military uniforms. Prisoners wore smocks (did not fit correctly and underwear were not allowed). Prisoners were referred to as a number, not name (sewn on prison uniform). They also had to wear tight pantyhose on their head to simulate a shaven head. A chain around the ankle was required to remind each prisoner of his imprisonment and oppression. Almost immediately, problems occurred. For example, guards set up a good cell and bad cell in hopes of pitting the prisoners against one another (groups would believe an informant was present). Guards did many acts of tormenting the prisoners. Physical punishment included long acts of a "forced exercise" regime. The prison became unsanitary and inhospitable. The bathroom was used as a privilege. Prisoners also cleaned the bathroom by hand. Prisoners in the "Bad Cell" were forced to sleep on concrete floors without clothes. Food was used as reinforcement and prisoners were forced into nudity and homosexual acts of humiliation. As the experiment continued, guards became more sadistic, especially at night when the cameras were off. Many of the guard gained truly sadistic characteristics and became upset when the experiment was discontinued. Of course, when the impact of this research was assessed, Zimbardo and his colleagues stopped the experiment.

Prisoners reacted in 3 ways to this situation: a) resisting the guards and situation, b) becoming model prisoners, or, lastly, c) breaking down and crying etc., In fact, one prisoner had a psychosomatic rash when he determined that his parole had been turned down. It was amazing what both the prisoners and guards did, that is their roles when placed in this environment. One prisoner went on a hunger strike because of the guards sadistic techniques. He then was placed in a small closet for 3 hours. Here he was forced to hold onto the sausage that he did not want to eat. The remaining prisoners saw him as a trouble maker. The guards said they could give up their blankets or the prisoner (on hunger strike) would remain in solitary confinement overnight. The prisoners kept their blankets. Zimbardo did return the prisoner to his cell early. In conclusion, the experiment illuminated the impressionability and obedience of individuals when a legitimizing ideology is present (e.g., social world of a prison) and institutional support. Here, cognitive dissonance theory and the power of authority were apparent based on the behaviors of both the prisoners and guards. Even Zimbardo became consumed in the experiment. For example, he and the guards attempted to move the experiment to an actual jail when they were notified that an escape plan was discovered. The local police said no. This experiment showed the power of the experiment and how individuals can be harmed (severely) by research. Human subject protection is imperative.

Part 3: Legal Requirements

The Federal Common Rule

The heart of U.S. federal policy on protecting human subjects in research comes from the Department of Health and Human Services (DHHS) and is codified as title 45, part 46 of the Code of Federal Regulations (45 CFR 46)[1].

In 1991, many federal agencies adopted Subpart A, the general provisions of 45 CFR 46, as the federal Common Rule. The Common Rule agencies are listed in the Code of Federal Regulations.

Other federal regulations and guidance

The Food and Drug Administration (FDA) has the authority to regulate a wide variety of research activity, regardless of who sponsors the research. The FDA's core policies are published as title 21, part 50 and part 56[2] of the Code of Federal Regulations. Subject-specific FDA regulations apply to research that involves:

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[1] Department of Health and Human Services. *Code of Federal Regulations, Title 45, Public Welfare. Part 46, Protection of Human Subjects.* 2005. Available from http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

[2] U.S. Food and Drug Administration. *Guidance for Institutional Review Boards and Clinical Investigators 1998 Update.* 1998. http://www.fda.gov/oc/ohrt/irbs/appendixc.html

- New pharmaceuticals (21 CFR Part 312)[3]
- Biological products (21 CFR Part 600)[4]
- Medical devices (21 CFR Part 812)[5]

Federal agencies may also impose requirements or provide guidance beyond the Common Rule. These agency-specific requirements apply only to research sponsored by the agency. For example, DHHS policy includes additional protections for fetuses, pregnant women, and neonates (newborns) (Subpart B, 45 CFR 46), prisoners (Subpart C), and children (Subpart D). The Office for Human Research Protections, in DHHS, also offers **guidance documents**[6] as a source of information about DHHS's interpretation of the requirements. Although this guidance is not regulation, the UW-Eau Claire IRB considers the guidance offered in these documents when establishing campus human subjects policy. Federal **HIPAA privacy rule**[7] creates additional requirements for medical research, but this tutorial does not address those issues. If you are doing research in the medical area, it may have HIPPA implications. Contact the IRB Chair or your medical supervisor.

Federal-Wide Assurance

Each institution that engages in federally sponsored human subjects research must provide the government with a written assurance. **UW-Eau Claire's Federal-Wide Assurance (FWA)**[8] guarantees that all UW-Eau Claire investigators, working on all human subjects projects, will comply with the terms of assurance for protection of human subjects for institutions within the United States.

The FWA places shared responsibility for protecting the rights of human subjects on research investigators and on UW-Eau Claire as an institution. Failure to comply with the FWA may constitute unethical behavior and violation of the law. Such violations can lead to loss of research privileges and federal aid, including Federal Financial Aid, for an individual, a laboratory, or the entire university. Leading research institutions have had their entire human subjects research activities suspended for extended periods because they were judged to be out of compliance with federal regulations.

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[3] U.S. Food and Drug Administration. *Part 312 - Investigational New Drug Application.* 1 April 2003. Available from http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=312

[4] U.S. Food and Drug Administration. *Part 600 – Biological Parts: General.* 1 April 2003. Available from http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=600

[5] U.S. Food and Drug Administration. *Part 182 - Investigational Devise Exemptions.* 1 April 2005. Available from http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=812

[6] U.S. Department of Health and Human Services. *Policy Guidance.* 15 October 2003. Available fromhttp://www.hhs.gov/ohrp/policy/index.html

[7] University of Wisconsin-Madison. *Health Insurance Portability and Accountability Act (HIPAA)*. 10 March 2003. Available fromhttp://www.wisc.edu/hipaa

[8] U.S. Department of Health and Human Services. *Federalwide Assurance (FWA) for the Protection ofHuman Subjects for Domestic (U.S.) Institutions*, by Janice Ferrar Walden. 29 April 2004.

Module 3: Basic Principles

Part 1: The Belmont Report

In 1979, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research established a set of basic ethical principles for guiding the involvement of human subjects in research in **The Belmont Report[9].** Congress set up this commission after the exposure of the Syphilis Study and other cases of grossly unethical treatment of human subjects in research. The commission set out three basic principles:

- Respect for persons
- Beneficence
- Justice

Respect for persons

The principle of respect for persons simultaneously requires that most people should be treated as autonomous individuals and that some people should be protected because of reduced autonomy. Treating someone as autonomous means recognizing that the person can and should freely make decisions and that these decisions must be respected. The concept implies that investigators must provide information to potential subjects of research so that they can truly make free decisions about participation. Our society recognizes autonomy for most adults, but it also recognizes that autonomy can be diminished in special circumstances. Most children have not yet matured into autonomy. Some physical disabilities as well as cognitive impairments (e.g., traumatic brain injury, cognitive disability, mental illness) can impair judgment and, as a result, autonomy. Prisoners, other institutionalized persons, and students can also have diminished autonomy. In these latter cases, circumstances make individuals particularly vulnerable to coercion by people with authority over them. When autonomy is diminished, investigators respect persons by acting to protect them.

Beneficence

The concept of beneficence holds that researchers should maximize the benefits of research and minimize any potential harm. Beneficence requires that researchers seek a balance between benefit and harm and between individuals and society. Most people would agree that research should not be undertaken if it has great potential to harm the individual subject and offers little or no potential benefit to either the individual or society. It is common practice to conduct research that poses minimal risk of harm to the subject and offers great potential benefit to society, even if the research offers no benefit to the subject. Cases in which research has a greater potential for harm are more difficult to evaluate. Should a competent individual take on risk to benefit society? Moreover, should a researcher ask an individual to do so?

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[9] U.S. Department of Health, Education and Welfare. *The Belmont Report* by The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. 18 April 1979.
Available from http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

Justice

The principle of justice holds that the risks of participating in research and the beneficial results of research should be distributed fairly across both the group to which research subjects belong and the larger society. One implication of the principle of justice is that medical research, as a whole, should ideally benefit all of society. For individual investigators, this raises questions about how scientifically rigorous information on population subgroups should be generated.

This principle also raises questions about whether the subjects of research, or those like them, must be potential beneficiaries of the results of research. History offers examples of practices that many now deem unjust. For example, in the 19th and early 20th centuries, physicians typically conducted research on poor patients in hospitals, but wealthy patients, whom physicians saw in private practice, had better access to beneficial treatments developed through research.

The Belmont Report concludes that:

Whenever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of research.

Part 2: Private information and information security

In addition to providing protection to the human subjects of research, investigators have ethical and legal obligations, under the federal Common Rule, to protect the privacy of their subjects. Investigators should also communicate clearly to their subjects how they will use and protect private information.

Privacy refers to the control of information about an individual by that individual. The right to control information about one's self is an aspect of autonomy. Further, a legal right to privacy exists in the U.S. based on common law principles. A research subject surrenders a certain level of privacy to researchers by sharing information for a research project. Subjects may relinquish control of the extent, timing, and circumstances of sharing themselves, or information about themselves, with others.

A research subject maintains a certain level of control over the disclosure of information by understanding and agreeing to the ways an investigator will use and provide protection for information gathered through research, as set out in the consent process. In biomedical or behavioral research, the subject often reveals private information to a researcher in exchange for an assurance that the information will be used only for the described research purpose and will not be disclosed outside the study, except to meet regulatory requirements (e.g. requests to the sponsor and FDA). In contrast, in anthropological and historical research, subjects sometimes wish to be identified in any resulting publication or other dissemination of research results.

Investigators should clearly understand what kinds of information may identify individual research subjects or may be sensitive. Unless investigators make specific provisions, UW-Eau Claire's IRB expects investigators to keep research data confidential. Investigators intending to identify research subjects in publications and presentations should indicate this in their research protocols and in their communications with research subjects.

Internet research with human subjects

Data pertaining to human subjects collected through the internet (i.e., listservs, web surveys, electronic bulletin boards, chat rooms, and emails) are subject to review by UW-Eau Claire's IRB and should follow the same guidelines as other types of research. When using either a listserv or chat room, permission must be granted by the listserv owner or chat room manager (e.g., no pretending to be a chat room member). In addition, be sure that the level of security is compatible with the risk (e.g., encryption and secure socket layer—SSL, or S-HTTP) such as when social security numbers, attitudes toward specific groups, or medical information is collected. Here, technical separation of identifiers (personal information can be stored separately from data in an encrypted format) and data and certified digital signatures may be used. Keep in mind that internet data in transit is vulnerable. It is imperative that the risk be aligned with the security level of the researcher's system. For on-line surveys, the combined cover letter/consent document should parallel a regular consent form. For example, "By clicking the 'yes' button, you understand what is expected of you and agree to take part in this research project." Follow UW-Eau Claire's IRB guidelines when developing your online research protocol. Please ensure that your project addresses potential risks (e.g., stress, physical harm, financial harm) and protect your subjects as you would for other types of research (e.g., voluntariness, informed consent, confidentiality, right to withdraw).

Anonymity and confidentiality

Many investigators use the terms anonymity or confidentiality to refer to the protection of the privacy of human subjects.

Anonymity means that no one, not even the investigator, has any information that can be used to connect information in a data set with a particular individual. Anonymity is a very high standard of information security. For example, many questionnaires will not contain identifiers such as phone numbers, name, or social security numbers/student ID numbers. For true anonymity, there is no way to connect the subject with her/his responses.

Confidentiality is an agreement between the investigator and subject that individuals will not be identified in public dissemination of research results. In this case, the investigator does maintain records that link data to individuals, but he or she must take great care to restrict the circulation of those records. Here, the researcher will inform the participant of how the data will be secured (locked file) and when it will be disposed (tapes will be erased following the experiment or questionnaires will be shredded following data input, etc.) Electronic documents must be maintained with a high level of security.

Sensitive information

Maintaining confidentiality of sensitive information is particularly important. Release of sensitive information may harm research subjects. For example, a data set could contain information that would make subjects criminally or civilly liable. Alternatively, it could contain information that would damage a subjects reputation (e.g., substance abuse patterns, attitudes, sexual and orientation), employability (e.g., political affiliation, religious beliefs, and health), financial standing (e.g., bank account information), or insurability (e.g., health related issues).

Examples of sensitive research activities include the following:

- Collecting information on psychological well-being of subjects
- Collecting information on subjects' sexual attitudes, preferences, or practices
- Collecting data on substance abuse or other illegal behaviors
- Collecting genetic information
- Collecting data on subjects who may be involved in litigation related to exposures under study (e.g. breast implants or occupational exposures)

Direct identifiers

One way to distinguish between information that is truly anonymous and information that is simply being kept confidential is to determine if the data set contains direct or indirect identifiers. Information in a data set with either direct or indirect identifiers is not anonymous. Direct identifiers include:

- Names
- Addresses
- Telephone and fax numbers
- Email addresses, IP addresses, and URLs
- Student ID numbers
- Social Security numbers
- Medical record numbers
- Account numbers, such as those associated with bank accounts or health plans
- License or certificate numbers, including driver's license numbers
- License plate numbers and other vehicle identifiers
- Fingerprints, voiceprints, or full-face photographic images

Indirect identifiers

Indirect identifiers can be combined with publicly available information to identify individuals. The significance of indirect identifiers depends on the nature of the research subjects. For example, in a study of residents of the state of Wisconsin, the information that someone graduated from one of the UW system schools probably would not be a unique identifier. However, in a study of small business leaders in Menomonie, Wisconsin, the same information might well apply to only one individual. In general, if any single variable in a data set applies to fewer than five subjects, it is considered a potential indirect identifier. Examples of indirect identifiers include:

- Detailed geographical information, such as state, county, or census tract of residence
- Organizations to which subjects belong
- Educational institutions from which subjects graduated
- Exact occupations
- Places where subjects grew up
- Many dates, including birth dates, hospital admission dates, high school or college graduation dates, etc.
- Detailed income information
- Offices or posts held by subjects

Careful data collection can minimize indirect identifiers in a data set. For example, asking research subjects to identify their ages by range, such as 20-29, 30-39, etc., rather than asking for birth dates or specific ages may eliminate variables applying to fewer than five subjects.

Certificates of Confidentiality

The National Institutes of Health (NIH) issues Certificates of Confidentiality[10] to protect from forced disclosure identifiable private information collected in important research projects. These certificates allow an investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. NIH can issue certificates for any federal or nonfederal research. Other federal agencies may also provide similar services. More info is available at: http://grants.nih.gov/grants/policy/coc/faqs.htm

Health Insurance Portability and Accountability Act (HIPAA)

A newer federal law, HIPAA, protects the privacy and security of written, spoken, and electronic protected health information (PHI). All UW-Eau Claire employees, students, and volunteers who handle PHI must learn about this law and the detailed regulations issued under it. Further information is provided at the national HIPAA web site www.hhs.gov/hipaa/ and https://privacyruleandresearch.nih.gov/pr_02.asp.

Examples:

This section contains examples of social, behavioral, and educational research, which apply the concepts introduced in Module 3.

Example 3.1

One requirement of Rehabilitation 230-Psychosocial Aspects of Disabilities is student participation in a study on learning practices that the professor is preparing for publication.

[10] National Institutes of Health. Office of Extramural Research. Certificates of Confidentiality Kiosk. 21 May 2004. Available from http://grants1.nih.gov/grants/policy/coc/index.htm

Does this study violate the principle of autonomy?

Yes. While a professor may request consent from students to use class materials in research, students always have the right to withhold that consent. A person must always have the right to decide not to be in a study.

Example 3.2

Some participants in a study of adults with recently divorced parents develop "serious" psychological reactions to the study questions that the researcher did not expect. The researcher stops the research for further evaluation.

Is this a case of following the principle of beneficence?

Yes. In assessing the beneficence of a research project, investigators and the IRB consider the balance between benefits and the risks. In this case, the investigator appropriately decides to reassess the project. The revelation of unexpected risks (the psychological reactions) may change the balance between benefits and risks.

Example 3.3

A graduate student is developing a study to test the effects of a new learning technique on average individuals. A few of these individuals may not be able to adapt to the new learning style.

Is this an ethical question of beneficence?

Yes. Both beneficence and justice are important issues to address in study design. Beneficence requires assessing both risks and benefits to participants and to society. The UW-Eau Claire IRB might allow this project by reasoning that the failure of some of the subjects to realize a possible benefit of the study is not objectionable when (1) the study presents no or very low risk to the subjects and (2) the study will produce information valuable for society.

Example 3.4

Individuals from upper socioeconomic brackets are selected to be in a study solely because they have better access to transportation that will get them to the study location.

Will this design create a subject pool in accord with the principle of justice as laid out in The Belmont Report?

Probably not. These participants are being selected solely because of their availability based on their higher economic status. This is an arbitrary way of establishing a group of research subjects. The principle of justice suggests that investigators should carefully consider how to construct a group of subjects. Ideally, subjects should have the potential to benefit from research or should belong to a group with such potential.

Example 3.5

Professor Burroughs proposes to survey landowners in several northern states, collecting names and addresses. He will keep these in a secure location and put a code number on each subjects response form. The consent form states Professor Burroughs will not disclose the subjects' names and addresses in publications or presentations of the research.

Is this research confidential?

Yes. This project is confidential but not anonymous. Names and addresses are direct identifiers. The agreement with the subjects to not circulate such identifiers makes this study confidential. Separating direct identifiers from other data is a method of protecting the confidentiality of the research subjects. However, any study in which direct identifiers are collected and kept is not anonymous.

Example 3.6

Professor Jahnke in the Business Department proposes to interview all willing employees at a small local business. Employee names will not be recorded. However, the gender and title of each employee will be recorded.

Is this study anonymous?

Probably not. In a small company, the indirect identifiers of gender, title, and department may identify unique individuals.

Example 3.7

Consider further the case of interviewing employees at a small business. There has been a great deal of employee unrest in the past six months, and, although management objects, several employees are attempting to unionize the staff. The interview Professor Davis wants to conduct asks many questions about the work situation, employee views of supervisors, and unions.

Does this study create potential risk for the subjects?

Yes. A qualitative write-up of this material could reveal an individual employee's feelings about his boss or unions. This information could put the employee's job in jeopardy.

Module 4: Approval process

Part 1: Roles and Responsibilities of an Institutional Review Board

The federal Common Rule specifies an institutional structure be in place for the protection of human subjects in research. Each organization must establish one or more IRBs to review and approve research involving human subjects. At UW-Eau Claire, a single IRB committee reviews all research, including that initiated by faculty, staff, and students.

The IRB has one paramount responsibility: To protect the rights and welfare of human research subjects. The IRB will take into account national and, when appropriate, international ethical standards of research on a protocol-by-protocol basis. At UW-Eau Claire, the IRB is a peer-review body. The IRB chair and most members are UW-Eau Claire faculty or staff. The IRB also has at least one community member; someone not affiliated with the university.

The IRB is charged with reviewing:

- Research protocols before any work is started
- Ongoing research (except exempt projects) at least once per year
- All changes to research protocols before implementation (except when implementation is necessary to eliminate immediate hazards to subjects)
- Reports of unanticipated events (e.g., unplanned mental anguish from subjects)
- Protocol violations (e.g., researcher deviates significantly from an IRB approved methodology)

The IRB has the authority to suspend or terminate research that is not being conducted in accordance with the IRB decisions, conditions, and requirements or that has been associated with unexpected serious harm to subjects.

The campus IRB and its staff provide faculty, staff, and students with expert advice on protecting human research subjects. They can provide guidance on:

- Applicability of the federal regulations to a research project
- Research protocols
- Risks and benefits of research
- Privacy, anonymity, and confidentiality
- Informed consent
- Consent forms
- Recruitment of subjects
- Certifications and assurances
- The continuing review process
- Protocol changes

- Project closure
- Record maintenance
- Security of data
- E-surveys
- Student research
- Class projects

Part 2: Submitting a protocol

In general, protocols submitted for IRB approval will include description and discussion of:

- Proposed research activity, including surveys or experimental procedures
- Potential risks to human subjects
- Anticipated benefits to subjects and society
- Subject selection, recruitment procedures, and anticipated number of subjects
- Proposed consent process
- Additional safeguards for working with potentially vulnerable subjects

Exempt research--- 45CFR 46.101(b)(1)

The federal Common Rule identifies categories of research eligible for exemption from IRB review. Although these categories involve research with human subjects, the research exposes subjects to very little to no psychological, social, or physical risks. (Minimal risk is a risk of harm to the subject that is no greater than the risk encountered in normal, day-to-day activities or during routine physical or psychological examinations.)

According to federal regulations, the IRB, not the investigator, determines whether the research is exempt from further review and regulation. At UW-Eau Claire, investigators must submit protocols for potentially exempt research. The IRB then reviews and determines whether it meets the criteria for exempt status.

If requesting an exemption, you will be asked to identify which category you think your research falls into:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular or special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management method.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement), survey procedures, interview procedures, or observation of public behavior, unless: (i) information obtained is recorded in a manner that human subjects can be

identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

3. Research not covered in #2 above, if the subjects are elected or appointed public officials or candidates for office.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in a manner thatsubjects cannot be identified, directly or through identifiers linked to the subjects.
5. Research by federal departments or agencies to assess public benefit or service programs
6. Research on taste, food quality evaluation, and consumer acceptance.

Exempt research--- 45CFR 46.101(b)(1)

EXAMPLES of research that is typically exempted:

- Study of normal educational practices
- Study of educational tests
- Anonymous surveys
- Interviews that do not collect sensitive information
- Observation of public behavior
- Analysis of existing data, documents, or records
- Analysis of anonymous residual specimens
- Assessment or analysis of federal programs
- Food taste and consumer preference tests

Note: The exemption from review for surveys, interviews, and observations of public behavior typically does not apply to research with protected populations (e.g., children).

Expedited review

Federal rules allow for expedited review of some research that involves only slight to moderate risk and that falls within the categories listed below. At UW-Eau Claire, an expedited review is completed by 2 reviewers rather than a full committee meeting.

According to federal regulations, the IRB, not the investigator, determines whether the research fits the expedited category. Since the submission process for the researcher is the same, the UW-Eau Claire IRB no longer asks the researcher to request an expedited review.

Protocols incorporating the following kinds of research may be reviewed through an expedited procedure, though the IRB chair/members may determine that full committee review is needed:

- Collection of data by noninvasive and routine clinical practices
- Analysis of existing voice, video, digital, or image recordings
- Study of behavior
- Surveys
- Interviews
- Oral history
- Focus groups

In addition, the following stipulations apply:

- No use of deception
- No study of minor children, prisoners, pregnant women, impaired adults
- No study of illegal activities like drug use
- No study of private activities like sexual behavior

Timelines

UW-Eau Claire IRB works to protect human subjects. Since no protective intervention can be taken after research has occurred, the IRB DOES NOT grant retroactive approval of research protocols. The penalties for conducting research on human subjects without IRB approval can be serious. Many professional journals in the medical and behavioral sciences will not publish articles unless the author can demonstrate that the research was conducted with IRB approval. Federal agencies, such as the National Institutes of Health or the National Science Foundation, can stop funding to all research on the UW-Eau Claire campus if we were found to be sufficiently negligent in how we ensure the protection of human subjects in research.

The goal of the UW-Eau Claire IRB is to respond to submitted protocols as quickly as possible. This is generally within one week to determine the category of review: exempt, expedited, or full board review. Then the review process will average an additional week for exempt, 2-3 weeks for expedited, and in the case of a full-board review, one month or more is typical. The primary investigator may be asked to attend the IRB meeting if the committee has questions which are best answered via a discussion.

Part 3: Informed consent

Informed consent is the process of: 1) communicating to a prospective subject, in easy to understand language (usually sixth- to eighth-grade reading level), the details he or she needs to know about a research project in order to make a reasoned decision whether or not to participate, and then 2) obtaining, without coercion, the prospective subjects agreement to participate (See Cover Letter and Informed Consent under What to Submit on the IRB website, http://www.uwec.edu/orsp/irb).

The following eight elements of consent are widely accepted as required in the consent process:

1. An *explanation that the study involves research,* including goals, procedures, expected length of participation, and any procedures which may be experimental.
2. A *description of any reasonably foreseeable risks or discomforts* for the subjects.
3. A d*escription of any benefits* to the subject or to others which may reasonably be expected.
4. If relevant, a disclosure of *any appropriate alternative procedures* or courses of treatment.
5. A statement describing *how private information (e.g. anonymous, confidential)* and *information security* (e.g. electronic security) will be managed.
6. For research involving more than minimal risk, a statement as to whether any compensation or medical treatments are available if injury occurs, and where further information may be obtained. (Minimal risk is a risk of harm to the subject that is no greater than the risk encountered in normal, day-to-day activities or during routine physical or psychological examinations)
7. Contact information for questions about the research procedures (the primary investigator) or human subjects' rights or treatment (the IRB Chair). If the project involves student research, the name and contact information of the student's advisor must also be included.
8. A statement that research participation is voluntary and that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled. Also, the subject may withdraw from participation at any time without penalty or loss of benefits. If the subject is a patient or client receiving psychological, counseling, or other treatment services, there should be a statement that withdrawal from the study will not jeopardize or otherwise affect any treatment or services the subject is currently receiving or may receive in the future. Subjects also should be told whether their data will be destroyed should they withdraw from the study. If a survey instrument or interview questions are used and some questions deal with sensitive issues, the subjects should be told they may refuse to answer individual questions.

Informed Consent- Additional Elements, if appropriate

A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subjects consent. Any additional costs to the subject that may result from participation in the research. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject. A statement that significant new findings developed during the course of the research, which may relate to the subjects willingness to continue participation, will be provided to the subject. The approximate number of subjects involved in the study.

Documentation of Informed Consent Checklist 45CFR46.117

Except as provided in this section, informed consent shall be documented by the use of a written consent form approved by the IRB, and signed by the subject or the subjects legally authorized representative. A copy shall be given to the person signing the form.

WRITTEN Consent:

1. A **written consent** document that embodies the elements of informed consent required by federal regulations. This form may be read to the subject or the subjects legally authorized representative, but in any event, the investigator should give either the subject or the representative adequate opportunity to read it before it is signed.

ORAL Consent

2. A **short form written consent** document, stating that the elements of informed consent have been presented **orally** to the subject or the subjects legally authorized representative. When this method is used, there shall be a **witness** to the oral presentation. Also, the IRB shall approve a **written summary** of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

WAIVER of requirement for signed form

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects, if it finds either:

1. That the only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality; or, That the research presents **no more than minimal risk** of harm to subjects, and involves no procedures for which written consent is normally required outside of the research context. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written description of the research (Cover Letter).

IRB Latitude to Approve a Consent Procedure that Alters or Waives some or all of the Elements of Consent

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent, provided the IRB finds and documents that:

1. The research or demonstration project is to be conducted by, or subject to the approval of, state or local government officials, and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and
2. The research could not practicably be carried out without the waiver or alteration.
3. The research involves no more than minimal risk to the subjects;
4. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
5. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Protected populations

When some or all of the research subjects are children, prisoners, students, persons with disabilities, or others who are likely to be vulnerable to coercion or undue influence, the project should include additional safeguards to protect the rights and welfare of these subjects. In addition, the federal Common Rule requires special protection for fetuses, newborn babies, and pregnant women.

Protected populations: Children

Children (legally defined as anyone under the age of 18) cannot give informed consent. Instead, a respectful consent process includes obtaining both assent from the child and permission from one or both of the child's parents or guardians. Assent is an affirmative agreement by the child to participate in research and not merely a lack of objection. In addition, the federal Common Rule limits the kinds of research in which children may participate. Research on children is allowed if:

- Only minimal risks are involved; or
- Any risks greater than minimal are balanced by the potential of direct benefits to the children or produce general knowledge about the subjects' disorder or condition.

Investigators should review Subpart D of the federal rules 45 CFR 46 http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html before proposing research involving children.

Protected populations: Students

Being a research subject may be a valuable part of the education of students. At the same time, students depend on faculty and staff for grades and many other things. Because of these dynamics, students may feel unable to decline participation in research. Further, research may reveal to an investigator, who is also the research subjects' instructor, private and sensitive information that would not normally be divulged.

Special Requirements - 45 CFR 46 Subpart D - Additional DHHS Protection for Children Involved as Subjects in Research

The IRB shall determine that adequate provisions are made for soliciting the assent of children, when in the judgment of the IRB the children are capable of providing assent. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted, or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children, and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances, in which consent may be waived in accord with §46.116 of Subpart A.

Parents

The IRB may find that the permission of **one** parent is sufficient for research to be conducted under §46.404 or §46.405. Where research is covered by §46.406 and §46.407, and permission is to be obtained from parents, **both parents must give their permission**, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. If the IRB determines that a research protocol is designed for conditions or for a subject population, for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, state or local law.

Written consent, oral consent, and waivers

Often, informed consent is embodied in a consent form that sets forth the information called for by the elements of consent discussed previously. If an investigation uses written consent, each potential subject receives an explanation of the process and the written form and signs the form before becoming a research subject.

UW-Eau Claire's IRB requires that consent processes explicitly disclose any image or audio recording of subjects. There should be a statement about how the recordings will be used and how long they will be kept. This statement should identify who will see or hear recordings and specify where they will be used, such as in classrooms or at professional meetings. In some cases, it is impossible or undesirable to obtain written consent. Field research conducted in another culture, especially one with little or no local experience with scientific research, may be one such case. If a written consent process will significantly hinder research or increase potential risk to subjects, researchers may substitute an oral consent process, with IRB permission.

UW-Eau Claire's IRB may also waive some of the eight elements of consent or the requirement for a consent procedure, in accordance with federal regulations found in **45 CFR 46.116**[2]. Complete waivers of consent are generally considered only when an investigation poses no or only minimal risk (e.g., types of research similar to those that fall into the exempt and expedited categories).

Waivers of Parental Permission:

According to the Common Rule, there are four criteria for waivers of both informed consent and parental permission. It must be demonstrated that the following points have been addressed:

1. No more than "minimal risks" are expected to impact the subjects of the study.
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects.
3. Subjects shall be debriefed following the study.

4. The research could not be carried out without the waiver. The researcher must explain why the waiver is necessary. Investigators' time, money, and convenience are not valid justifications. Even when a waiver has been granted, the IRB may expect researchers to inform the parents of the major components of the study.

Deception (Definition)

Withholding full information about the nature of the experiment or misleading the participants is referred to as deception. Examples of this include not saying the true purpose of the study, the role of the researcher, or which conditions are experimental. This may be necessary when, once a participant realizes the purpose of the research, they would likely act in a way that would bias the results. If the subject is unaware of the researcher's true intent, then they should not be biased. Of course, informed consent and autonomy are of the utmost importance with deception studies.

Only studies that pose minimal risk may utilize deception. If deception can be avoided, it is advised to do so. In addition, the researcher must justify their use of deception from both an ethical and scientific standpoint. Furthermore, the participants should be fully debriefed (provided an accurate picture of the deception in a manner understandable to the participant) following the study. Participants have the right to ask further questions during the debriefing and have their data removed from the study (Adapted from the University of Las Vegas).

Some research can only be conducted without the full knowledge of the research subjects. Take the following study as an example.

Subjects are told language ability is being studied and asked to construct grammatically correct sentences using a set of words. One group is given words commonly associated with old age. Another group is given words without any such connotations. As the subjects leave the study room, the researcher measures the time each takes to walk down the hall. Those in the first group take significantly longer. Before the subjects leave the building, the investigator stops them and explains the full experiment. Adapted from: Harvard University, "Human Subject Protection."

One IRB found deception acceptable in this study because the research could not be conducted with the subjects' knowledge and it poses little or no risk to the subjects. Explaining the goal of measuring walking speed would make subjects conscious of the way they walk and might well change it. This measurement consists of observation of commonplace behavior.

UW-Eau Claire's IRB will review closely any research involving deception. The investigator should demonstrate that:

- Deception is necessary to conduct the study;
- The subjects will be debriefed after the experiment is completed;
- The subjects will not be exposed to more than minimal risk; and

- The withheld information is not likely to change people's decisions to participate in the study.

Part 4: Continuing review

All investigators should continually assess research protocols to ensure that human subjects are adequately protected from research risks. If, in the process of conducting research, an investigator discovers that the experience for human subjects differs significantly from that described in the protocol, the investigator should take appropriate action. Modest variation might lead to revision of the consent procedure. Serious reactions might necessitate suspension of research until procedures can be modified to better protect the human subjects.

The investigator is responsible for ensuring that any changes to a protocol are submitted to the IRB for review before the changes are incorporated into research. Only those procedures specifically approved by the IRB may be initiated, unless the change is needed immediately to eliminate hazards to subjects.

New information that would significantly change the assessment of the potential risk to subjects must also be brought to the IRB's attention in a timely way.

Adverse events that are serious, unexpected, and possibly related to the study--as well as any deaths, regardless of whether they are related to the study—are of major concern. The IRB can provide information on the specific requirements for reporting adverse events. For all non-exempt research, investigators submit an annual progress report (Continuation/Termination/Change Form). **If the project continues for more than five years, investigators must submit a complete application every fifth year**, just as if the project were new. This procedure insures that long-term projects are thoroughly reviewed on a periodic basis.

Certification Page

As part of the effort to guarantee that all research on campus provides protection to human subjects, UW-Eau Claire keeps records of all personnel, including students, who have completed human subjects training. The Certification Page is the mechanism for keeping these records. All researchers must certify completion of this tutorial before submitting a protocol to the UW-Eau Claire IRB for review. You may also need to demonstrate to a funding agency, an instructor, or others that you have completed this training. Once this certification has been completed, you will receive **a copy of this certificate that should be kept with your records.**

Examples:

Example 4.1

Professor Scott Steben is running behind in submitting his protocol to the IRB for review. He cuts and pastes the abstract of the project from his grant proposal to use as the description of the project in his consent form.

Will Professor Steben have an acceptable description of his project in the consent form?

Probably not. Because the grant abstract was written for Professor Steben's academic peers, its language is probably too technical. A consent form must explain the goals of the project in terms that the prospective participants can understand. Meeting this standard requires translating medical and scientific terms into lay language. UW-Eau Claire's

IRB generally expects consent forms to be written at a sixth- to eighth-grade reading level.

Example 4.2

An IRB approves a protocol, consent procedure, and written consent form in English. A number of the potential subjects for the study turn out to be native speakers of Spanish, and many do not read English. The investigator decides that he can speak enough Spanish to give the prospective subjects a rough oral translation of the consent form.

Is this an appropriate way to obtain informed consent?

No. Investigators should seek consent in language that the potential subjects understand. Satisfying this requirement can entail providing consent documents or procedures in languages other than English, as well as translating scientific English into lay language. Further, the prospective subjects deserve better than a "rough translation." The UW-Eau Claire IRB will review both original versions and all translations of consent documents.

Example 4.3

Professor Edwards has a graduate student who wants to analyze a data set from a previous study. The data set came from telephone surveys conducted two years ago. The data has not been publicly available. The data set contains demographic information and answers to questions. All identifying information on individual subjects has been stripped from the data set. Some of the questions concern a referendum that generated heated debate in the community.

Should this student apply for an exemption?

Yes. This research is work on an existing data set, which is anonymous because the identifiers were removed. As such, an IRB may grant it an exemption. The level of controversy is irrelevant because the data is anonymous.

Example 4.4

Professor Metzger proposes to conduct interviews at the Student Center. No names or other identifiers will be recorded. Subjects will be randomly stopped at the Student Center and asked

if they would take five minutes to answer some questions about current events. Professor Metzger will then proceed to ask a series of questions about events that have been reported in the news, for example, "What is your opinion of the governor's proposed budget bill?" and "Would you be in favor of increased taxes to alleviate the current state budget crisis?"

Does this project qualify for an exemption?

Probably so. This protocol would likely be exempt because the content of the interviews would not create potential risk for the subjects, even if their responses were known outside the research. The anonymity of this study further ensures the lack of risk to subjects.

Example 4.5

Consider again the earlier example of conducting interviews in a small business. To review, Professor Newtson proposes to interview all willing employees at a small local business. Over management objections, several employees are attempting to unionize the staff. Professor Newtson proposes to ask employees many questions about their views of the work situation, supervisors, and unions. Employee names will not be recorded. However, the gender, title, and department of each employee will be recorded.

Should Professor Newtson apply for an exemption?

No. This interview-based study is not anonymous, and it does create potential risk for the subjects. It will not qualify for exemption. However, it might be considered under expedited review by the IRB.

Example 4.6

Professor Thorn in Human Development and Family Studies is studying the prevalence of illegal drug use and drug dealing on college campuses. She recruits subjects by posting announcements in the student center. Subjects agree to participate in a half-hour interview. Professor Thorn does not intend to record direct or indirect identifiers in her interview notes. She proposes to use an oral consent procedure to further guarantee the anonymity of her subjects.

Would oral consent be appropriate for this study?

Probably so. Inadvertent release of information concerning illegal drug activity, especially drug dealing, would create potential risk of legal action for research subjects. In this case, the IRB would encourage Professor Thornton to use an oral, rather than a written, consent procedure because a written consent form would be the only recorded information identifying study participants and thus exposing them to potential risk.

Example 4.7

A Sociology professor wants to write an article for publication on support for political change in the former Soviet Union. She plans to interview randomly selected adults in several locations in one or more former Soviet states. She suspects that she will have difficulty recruiting a set of interviewees if subjects must sign a consent form.

Would an oral consent procedure be appropriate for this study?

Yes. This individual could probably obtain IRB approval for an oral consent procedure. Given the history of political repression in these areas, individuals may not be willing to participate in research if a record of their identities is kept. An oral consent process provides an alternative for protecting the rights of human subjects while making valuable research possible. Even though written consent may be waived, an IRB might require that the investigator give a written information sheet to the subjects, including information on who to contact if they have questions or concerns.

Example 4.8

Professor Jin wants to study prejudice and racial discrimination. He proposes to send three assistants into department stores in Chicago. The assistants will be dressed similarly. In some cases, they will wear business clothes and, in others, jeans and a T-shirt. One assistant will be Caucasian, one African-American, and one Hispanic. The assistants will enter the stores at different times and approach the clerk to ask for assistance. Professor Jin requests a waiver of consent because the reactions of the subjects would not be spontaneous if he were required to obtain consent. He indicates no intent to debrief subjects.

Should the IRB waive both informed consent and debriefing for Dr. Jin?

An IRB may waive consent if it finds: (1) the risk to subjects is minimal; (2) the research could not practicably be carried out without waiving consent; and (3) if possible, subjects will be provided with pertinent information after participation. The risk created by this experiment is minimal. The researcher will simply observe behavior in a normal situation. It seems clear that the research could not be carried out if Professor Jin were required to obtain consent. It is not possible to tell subjects that you are studying prejudice and then expect to find out how they really respond to customers of different ethnic or racial backgrounds. Debriefing, in this case, might heighten risk to subjects. If the subjects did act in a prejudiced manner toward the assistants, debriefing might draw attention to their actions and possibly put them at risk of discipline or dismissal by their employers. An IRB could decide to waive debriefing, reasoning that such as waiver would further minimize risks to subjects.

Example 4.9

Dr. Keller wants to study clients' mental health counseling records to prepare an article on relationships between age and type of diagnosis.

Is this human subjects research?

Yes. The investigator is obtaining identifiable private information from the subjects' clinical records. It is a systematic investigation, and, for publication, she will create generalizable knowledge. This also, potentially, is covered under the HIPPA regulations. Check with the IRB in cases like this.

Example 4.10

A pair of UW-Eau Claire students needed to conduct a small research project for their Research Foundations class. For their project, they had two ideas: one was to interview students about their travel destinations over spring break; the other idea was to interview students about their drinking behavior over spring break. Since this is a class project, they wonder if they need to worry about IRB approval.

Is IRB approval required?

Some form of Human Subjects Protection approval is required. At UW-Eau Claire, we have a policy of Course Approval that many instructors utilize for their research classes. After being granted Course Approval, the instructor assumes the role of a mini-IRB, educating the students on the main issues of research ethics, and approving those projects that would fall in the 'exempt' or 'expedited' categories (as the two ideas above probably would). Any projects that would ordinarily fall under the category of full board review must be submitted to the UW-Eau Claire IRB.

Example 4.11

A student is working for a company to complete her internship requirement for her Bachelor's degree. As part of the internship, the company asks her to conduct research on ergonomic evaluations of work stations within the company. Since the student is on internship and is working for the company full-time, does this student need IRB approval?

Is IRB approval required?

Possibly, as she is getting University credit for the internship, IRB approval would be needed if the results will be generalized beyond quality control within the company.

Example 4.12

Two UW-Eau Claire nursing students wanted to find out if there was any link between a nurse's weight and their perception of overweight patients. A small clinic in Hudson was used as the data gathering site. They were to gather information on the weight of each nurse at the facility, take the information from the patient's charts on their weight, then have the nurse complete a survey about attitudes and perceptions of different patients. They were then going to look for a correlation between each nurse's weight and her/his view (positive or negative) toward overweight patients. Are there any issues in this instance for protecting human subjects?

Is IRB approval required?

Yes, what if there was only one overweight nurse that had negative feelings toward overweight patients? That one nurse could easily be identified by the clinic and then subjected to negative comments from other staff, disciplinary actions, or even termination. The researchers need to ensure there was a sufficient sample size of nurses within all weight categories in order for each subject to remain totally anonymous.

Example 4.13

Students from UW-Eau Claire wanted to administer a questionnaire to grade-school children asking them to detail how they felt about the 9/11 disaster. The researchers had the appropriate protocol for getting permission from the children's parents, and making sure the students were aware the project was voluntary as well as only answering questions they felt comfortable with. The questionnaire was to be administered by the students while the teacher was absent from the classroom. Following this, the researchers would gather the questionnaires, and the teacher would return and continue on with their day's teaching schedule. The proper IRB steps were followed, yet this case was sent back to the researchers because of concern for the protection of human subjects. Why was the proposal returned?

Why did the IRB return the proposal?

The students failed to recognize the emotional impact the questionnaire (which brought up images of the death and destruction based on a violent terrorist attack) might have on the young grade-school children. How would the researchers know whether one of these children had a relative that died in this disaster? There was no support or counseling offered to those children after they were done completing the instrument, therefore, the IRB required some methodology that would assist the children in dealing with any emotional feelings the questionnaire brought up.

Example 4.14

As a Master's thesis, a student wanted to assess the relationship between eating patterns and issues of control among adolescent females (ages 12-17). In a classroom setting, the researcher

proposed administering a questionnaire that was used to screen for eating disorders (asking questions about eating behaviors, attitudes, weight, and body image) and another that assesses perceptions of control over personal behaviors and behavior of others. In addition to eating-related questions were items that asked about alcohol consumption, sexual behaviors, and emotional concerns, among other things. The initial informed consent submitted to the IRB contained the phrase “there are no risks associated with this study”. The researcher submitted the protocol requesting expedited review. The IRB reviewer made several recommendations and referred the proposal for a full-board review. What are some of the issues pertaining to protection of human subjects and how might they be best addressed?

Major issues pertaining to this protocol?

First of all, the study involves minors, a “special population” under federal guidelines, which requires heightened consideration of human subjects protection. The researchers need a plan to obtain informed consent form both the students and their parents. Given the sensitive nature of the questionnaire items, the IRB also requested that more attention be paid to potential risk factors, in particular confidentiality as well as a plan for responding to students who might feel distressed in any way and wish to talk to a counselor. To help ensure confidentiality (as the researchers wanted to assure anonymity to participants), the researchers needed to strike the “name” line from one of the questionnaires, and have participants place the questionnaires in a blank envelope before turning them in (as the study was being completed in a classroom setting). To address potential distress that might be triggered, the researchers secured the availability of a school counselor during and after the time questionnaires were being completed, and added a statement to the informed consent form about potential emotional risks and the availability of the counselor. After these modifications were made, the IRB approved the protocol.