



# INDIANA UNIVERSITY NORTHWEST

**HUMAN SUBJECTS COMMITTEE**

**Policy & Procedure Handbook**

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## **I. INFORMATION AND POLICIES**

Pursuant to federal law and University policy, all research involving human subjects, conducted by IUN investigators, must be reviewed and approved by the IU Northwest Human Subjects Committee (HSC). These policies and procedures are designed to provide an efficient avenue for the processing of applications. The smooth flow of applications is the only way to ensure that each research protocol is provided the level of review it deserves. Cooperation by faculty, students and staff with the Committee is essential if we are to comply with federal and University regulations. The Committee recognizes that the federal regulations and our interpretations of the regulations can be daunting to an investigator on first encounter. The Committee will provide whatever assistance it can to investigators or departments to explain our procedures and to secure compliance with a minimum of delay or disruption of research. We welcome suggestions for improvement of the information.

## **II. Definition of Terms**

### **A. Human Subject**

A human subject is a living individual, as well as human embryos, fetuses, and any human tissue or fluids, about whom an investigator (professional or student) conducting scientific research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information. Thus, the scope of "subject" is interpreted broadly. Even if you are "just interviewing" people, you are involving human subjects in your research.

The IU-Northwest Campus Committee for the Protection of Human Subjects, known as the Human Subjects Committee (HSC), is charged with safeguarding the rights and welfare of human subjects, and no research or related activity involving humans can be undertaken without HSC approval. Every research project involving human subjects in any way must be reviewed by the HSC, including, but not limited to, projects dealing with data already collected by someone else, and pilot studies. Even projects which qualify as exempt from the federal regulations must be submitted for review to the HSC prior to commencement. Consequently, every investigator should consider all ramifications of his/her research before determining that human subjects are not involved and that HSC approval is therefore not required.

### **B. Research**

Research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Not all data gathering or experimentation is necessarily research; it could be education or therapy. The difference is one of intent or primary goal. For example, if a physician finds a patient developing bad side effects from a drug, the physician may "experiment" using other drugs to see which works best with the fewest negative side effects. So long as the drugs being used are clinically approved (i.e., not themselves experimental), such activity would constitute therapy, not research. Yet, if this same physician decides to try these same drugs on a series of patients to see if the results are the same as they were with the original patient, then this activity is classified as research. Similarly, a teacher demonstrating how to make anthropometrics measurements is engaged in teaching rather than research as long as the activities are confined to a particular class or classes. The moment these activities occur outside the pedagogic context, they become research.

Research done outside of the United States is subject to the same considerations and review as work within the USA. The federal government feels very strongly on this point, particularly since some underdeveloped nations are of the opinion that some of their citizens have been used as guinea pigs in experiments which would not be permitted in the USA. The investigator also must abide by the laws and values of the country in which the research is to take place.

### **C. Non-Research**

Occasionally the Committee determines that an application involves activities that are not considered "research" under the definition because it is, for example, conducted for evaluation purposes for an entity (e.g., a government agency, commercial enterprise, workshop evaluation, or administrative review), but about which the investigator has no intention of publishing results or distributing outside the institutional setting, or the data are not used to evaluate or review a program in order to build a better program. It is therefore, not "designed to.....contribute to generalizable knowledge."

Another situation where this might occur is when the researcher has been hired by an outside agency as a consultant to conduct the research for the agency. The researcher would be required to write a report for the agency and turn all the data back to the agency. If the researcher is hired on his/her own time holds no rights in the work, and neither the researcher nor the University retains any rights to the data, HSC review and approval is not required.

The Committee is concerned, however, that investigators do not fully understand the implications of having their work classified as "non-research." Principally, results from such studies may not be published unless human subject's approval had been obtained prior to collecting the data. To do so is in violation of IU policy (because if the data and data analysis are to be published, the study was, in fact, research and required prior review and approval). Further, some scholarly journals will not publish studies involving human subjects without an assurance that human subject's committee approval was obtained.

Investigators requesting approval for what was once considered non-research that could have been reviewed prior to its commencement face the possibility that the Committee will disapprove their application. In this type of situation, the Committee will require the investigator to show he or she could not reasonably have foreseen having an interest in publishing the results of the "research." While the "existing data" exemption may be available for qualifying research, the Committee is reticent to approve such applications where it feels that the investigator has attempted to circumvent human subject's policies by collecting data as non-research and then applying to use them as existing data. It is therefore in the investigator's best interest to consider carefully the likelihood that he or she will want to use the data for research purposes in the future, and to err on the side of inclusion and seek human subject's approval prior to commencing the work.

### **D. Existing Data**

To qualify for this category the data, documents, or specimens must already be in existence before the researcher applies for approval to access it. If some, or all, of the data are going to be collected by the researcher or another party after the researcher applies for approval to access it, it is NOT existing data and does not qualify for this category.

### **E. Risk**

The HSC must decide what degree of risk (if any) is involved. Risk can be social or psychological as well as physical. For example, breach of confidentiality might result in a child being labeled the "stupidest" in an entire school, or a family could be upset by their neighbor's learning that they suffer from a particular disease. Even if confidentiality is not involved, psychological damage may occur. For instance, suppose a psychologist wants to induce stress on his subjects to measure resultant changes. To do so, he gives them insoluble problems and psychometric tests which he then announces reveal various mental and emotional deficiencies. This procedure places the subject at risk psychologically and, if not (and even if) given an adequate explanation after the experiment, he/she could remain disturbed for some time.

The HSC realizes that risks are an inevitable and accepted part of life, but the Committee's task is to ascertain whether the proposed research increases risks beyond this normal level. If so, the HSC must address two questions:

1. Could the research objective be attained through procedures bearing less risk? For example, could an aversive electric shock be given by batteries rather than by a transformer plugged into a 110 volt wall socket? Could anonymous numbers be used instead of names? Such risk-reducing options would be suggested to the investigator.
2. If the risk cannot be avoided, is the value of the research sufficient to justify the risk? This is the thorny "risk/benefit ratio" which poses a perpetual problem. While the regulations do not ordinarily require institutional review boards to concern themselves with the merit of the proposed research, when anything more than minimal risk is involved, the institutional review board must judge merit in order to evaluate the risk/benefit ratio. The benefit, if any, may be to the subject directly, to science, or to society in general.

## **III. Informed Consent**

In addition to concerning itself with risk, the HSC must consider the subject's consent to participate in the research project. An underlying ethical principle of the Federal regulations is that human subjects enter into research voluntarily and with adequate information. (See The Belmont Report on Ethical Principles and Guidelines for the Protection of Human Subjects of Research, 1979) Thus, consent must be informed and voluntarily given. A subject's consent is "informed" if he/she has a reasonable comprehension of that to which he/she is consenting. The investigator must use language appropriate to the subject's ability to comprehend. Generally, the consent form should be written at the 8th grade reading level. Nondisclosure of information to subjects must not be used simply to assure their participation in the research. It is desirable, but not mandatory, that the investigator, rather than an assistant, obtain the consent.

To ensure that subjects' consent is voluntary, the HSC considers whether any undue pressures will be brought to bear on potential subjects. Such pressure may be subtle as, for example, when a teacher asks his or her own students to become subjects of his or her

research. Excessive compensation or no payment for withdrawals is viewed by the HSC as pressure. See the Compensation Policy.

In order to obtain informed consent the investigator must provide a statement that includes the information listed on the Informed Consent Statement Checklist. A sample informed consent statement is included in the application forms to assist investigators in the preparation of the consent form. The sample reflects both requirements of the Federal regulations and customary language adopted by the HSC. Use of the sample will facilitate HSC review. Each subject must be given a copy of the signed consent form.

The consent statement (or information sheet) that is approved by the Committee will be stamped with two dates, the approval date and the expiration date. When the form has expired it must be submitted for re-approval by the Committee. Exempt level documents will be stamped for the time period of the study. Expedited and full committee documents will be stamped for the time period of the approval (no longer than one year). The stamped version must be used to make the copies for the subjects.

Who is to give consent? Any legally competent adult can give consent; but said adult cannot give valid consent if he/she is under the influence of alcohol or drugs, or if the consent is obtained under duress. This latter point is important in academic circumstances since students are often asked to volunteer as subjects. If possible, investigators should not use their current students. If current students must be used, it must be made clear to the subjects that the decision to participate will have no effect upon their grades.

Investigators should be aware that the HSC will not approve a study involving a researcher's current students even if no adequate alternative design is available, unless the HSC is satisfied that voluntary consent can be obtained. Guidelines with respect to the inclusion of the investigator's own students in research (including model consent forms) are available at Students as Subjects on the HSC web site.

The consent process for studies conducted in foreign countries, or with illiterate populations, may be altered so that consent may be given orally and documented on tape. Such tapes must be treated in the same manner as paper consent forms. Any other alteration to the consent process must be reviewed by the full committee.

### **A. Minors**

Minors require special consideration. Persons aged 18 and older may consent to participating in research and parental permission is not required. For subjects aged 17 and under, however, the consent of at least one parent or guardian is required. If a child is age 7 or older, the aims and general nature of the project must be described in language the child can comprehend, and the child's assent must be obtained. Children under age 7 need not be asked to assent; parental or guardian consent is sufficient. If biomedical research on infants is planned, the drugs or procedures must first have been tried on animals, adults, and older children. In certain cases where there is no risk and where it would be unreasonable to require parental permission, the HSC may waive the requirement. Research on minors which involves more than minimal risk will be approved only if it is

(i) of direct benefit to the subject or (ii) yields useful knowledge about a subject's problem or disorder. In the latter case, both parents must give consent. If a child is a ward of the state, the HSC must require that there be an advocate appointed to function as a guardian in the child's behalf.

### **B. Students in Indiana Public Schools**

The State of Indiana has placed certain restrictions on research conducted in the public schools. The restrictions apply to personal analyses, evaluations, programs, or surveys that:

1. Are not directly related to academic instruction; and
2. That reveal or attempt to affect the student's attitudes, habits, traits, opinions, beliefs, or feelings concerning:
  - political affiliations;
  - religious beliefs or practices;
  - mental or psychological conditions that may embarrass the student or the student's family;
  - sexual behavior or attitudes;
  - illegal, antisocial, self incriminating, or demeaning behavior;
  - critical appraisals of other individuals with whom the student has a close family relationship;
  - legally recognized privileged or confidential relationships, including a relationship with a lawyer, minister, or physician; or
  - income (except as required by law to determine eligibility for participation in a program or for receiving financial assistance under a program).

If the research falls into any of these categories, you must obtain:

1. The student's consent (if the student is an adult or an emancipated minor); or
2. The parent or guardian's written consent (if the student is an unemancipated minor), which form must accurately reflect the contents and nature of the personal analysis, evaluation, or survey prior to conducting the research.

State law also requires that the school corporation make available for inspection by parents or guardians any materials used in connection with research described above. Include in your application to the HSC a letter from the school corporation indicating that you have been given permission to do the research in the school.

### **C. Persons with Mental Disabilities**

Persons with mental disabilities also require special consideration. They may or may not be able to give consent depending upon the severity of their disabilities. If a person is capable of understanding the nature of the project, consent should be obtained from both the subject and a parent or guardian. In instances where the person is not competent to consent, parental or guardian consent alone is sufficient.

#### **D. Prisoners**

The use of prisoners as subjects is severely limited since such subjects' ability to voluntarily consent is limited by the "coercive nature of the environment."

Prisoner means any person involuntarily confined or detained in a penal institution. The term also includes persons detained in other facilities (e.g., group homes, work release centers) by statute or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, as well as persons detained pending arraignment, trial, or sentencing.

Funded research involving prisoners must be approved by both the local HSC and the funding department/agency head. The research must be limited to 'minimal risk' studies of criminal behavior and incarceration, penal institutions and prisoners as a social class; research on conditions affecting prisoners--including social and psychological problems--only if approved by the department/agency head after expert consultation; and therapeutic research, with control groups also requiring the department/agency head's approval.

Any researcher planning research involving prisoners is encouraged to review the current regulations for other requirements before submitting the Summary Safeguard Statement for review. These regulations are in Subpart C of 45 CFR 46, and are available from the HSC office, or on the web at the National Institute of Health (NIH) web site.

#### **E. Secondary Data Sources**

Secondary research is often a problem. Ordinarily, when a person uses data collected by someone else for another purpose, the consent of the subjects must be sought again. For example, if researcher A has interviewed a number of persons for project A, the interview cannot be released later to researcher B for project B. The subject who consented for his or her data to be used in project A might disapprove heartily of project B and would refuse to cooperate. The wording of the original consent form is critical. If a subject consented to allow his or her blood sample to be available to persons studying blood diseases, his or her sample could be shared with many researchers without additional consent. It is only when the secondary use is a distinctly separate research project that the need for a new consent arises. The original researchers who received consent can re-work the data without new consent provided it is for a related purpose.

If the original research has made the subjects truly anonymous or the data pooled in a form ensuring anonymity, then consent for secondary use generally is not required.

#### **F. Deception**

Deception should be employed only when there are no viable alternative procedures. Where deception is a necessary part of an experiment, the Committee will generally require that a preliminary consent be obtained, in which the investigator informs the subject that the experiment cannot be described fully in advance. After the experiment, the subject should be informed of the deception. We recognize that there are rare instances in which no consent can be obtained or debriefing done: e.g., if the researcher pretended to lie unconscious on a sidewalk and noted how many and what sorts of

persons stopped, attempted assistance, or simply hurried past; or where debriefing would cause more harm to the subject than the deception itself.

### **G. Web Based Studies**

The HSC understands that because of the two different methods (electronic versus paper), the processes of providing information to potential subjects and obtaining documentation of consent will not be the same. Nevertheless, the Committee wants to encourage subjects to read the consent documentation first, before being able to actually participate in the study.

When a study requires a Study Information Sheet, the following must be used in addition to the requirements for the Sheet itself:

1. Describe the process: "Here is an information sheet that describes the study. Please read it and if you want to participate, click the button at the bottom."
2. Then the subject works through (scrolls down) the entire Study Information Sheet, and at the bottom finds a button that they can click on to indicate that they are now ready to begin the study.
3. After clicking the button the subject will be taken via a link to the study task.

When a study requires documentation of consent, Informed Consent Statement, the following must be used in addition to the above:

1. The "agreement" button must contain a message, or there must be a separate statement right above the button, that indicates that clicking the button means the subject has read the statement, printed a copy for their files, and agrees to participate in the study and accepts that personal information will be electronically supplied to the researcher to document their participation (such as name, e-mail name, and date).
2. There must be a mechanism by which information is returned to the researcher that identifies the person who is participating. This documentation must be kept by the researcher for at least the standard three years beyond the end of the study.

The following apply to both information sheets and consent statements:

1. Subjects must be able to easily print a readable copy for their own records.
2. The document must carry the "approved" and "expires" dates as stamped on the paper copy that will be returned to the researcher. The researcher should replicate the text of the stamps on the electronic version of the information sheet or consent statement.
3. The HSC must be able to access the document on-line before approval will be given.

### **H. Foreign Studies**

In order to provide the institutional review boards (IRBs) on the Indiana University campuses with an efficient process for ensuring that the translation of IRB documents (i.e. consent/information sheets and/or recruitment materials) is accurate, the following procedures should be followed:

- 1) For the initial submission of the IRB application the principal investigator (PI) is to provide a copy of all documents in English.
- 2) After the IRB reviews the English version of the IRB application (including documents) and is satisfied with all revisions, they are to grant provisional approval, pending the submission of the translated documents and the signed "Translation Statement of Accuracy" form (see Exhibit C for form).
- 3) The "Translation Statement of Accuracy" form is to be signed by the PI. The PI is responsible for ensuring that the translation of all documents is accurate. In order to clearly communicate that this responsibility falls on the PI, the institutional review board is not to approve of the protocol without the PI signing the "Translation Statement of Accuracy" indicating that the translated version of the consent is complete and that it does not contain information that is not presented within the context of the English version of the consent.
- 4) After the office receives the translated documents and the signed "Translation Statement of Accuracy" form, the final approval can be granted.

#### **IV. Review Levels/Categories**

There has been some confusion over the categories of research reviewed by the Committee. We hope the following information will clarify the meaning of the categories and the implications for review under them. According to IU policy and its agreement with the federal government, all research involving human subjects conducted by persons associated with IU, regardless of where the research is done or what category of review it falls into must be submitted to the Committee for review.

Researchers not affiliated with IU, who wishes to come onto the IUN campus to conduct research, must either provide an approved application from an IRB at an institution with a Multiple Project Assurance, or submit a new application to the HSC. Either type of application must be sponsored by one or more full-time IUB faculty, librarian, salaried clinical rank, or research rank appointee. See the section Researcher Responsibility for a list of allowable sponsor ranks.

***All research involving human subjects falls into one of three categories.***

##### **A) Full Review**

All research is presumptively in this category unless it meets certain exceptions, as described below. The term "full review" refers to review before the full committee, which meets once a month. Investigators must fill out the pages for a "full" review. Signed informed consent is required from all subjects or their legal guardians. A sample Informed Consent Statement is included in the application packet to assist investigators. Multi-year studies in this category will receive full committee review throughout the life of the project. Continuing reviews will be required until the project's completion. Full review applications are reviewed monthly. Comments can be expected within a week of the meeting.

### **B) Expedited Review**

Some research may be reviewed by the chair of the Committee or by one or more experienced reviewers designated by the chairperson from among members of the HSC, if the research falls into certain categories defined by the federal government and if, in the discretion of the chair, review by the full Committee is not necessary. A list of the types of research that may qualify for expedited review is provided in the application packet. For clarification contact the Committee's office (980-6707). Investigators must fill out the pages for an "expedited" review. Signed informed consent is required from all subjects or their legal guardians. A sample Informed Consent Statements included in the application to assist investigators. Continuing reviews are required for projects at this level of review. Applications at this level are reviewed weekly. Comments can be expected shortly after the weekly review.

### **C) Exempt Review**

Under the federal regulations certain types of research are exempt from review, unless the institution chooses to review it. Under IU policy, ALL research involving human subjects must be reviewed and approved prior to commencement of the research, including research that falls into a federal "exempt" category. The categories of research which qualify as exempt are set forth in the Exempt Research Checklist. Investigators planning to conduct "exempt" research must fill out the Exempt Research Checklist and Research Statement and submit it to the HSC for approval by the chairperson prior to beginning any research. It is the Committee's practice to require signed parental informed consent when minors are involved, but, in most cases, not to require signed informed consent from adult subjects in exempt research projects. The HSC does, however, generally require that information about the research be given to subjects normally in written form in a "Study Information Sheet". A sample study information sheet is included in the application to assist investigators.

Research using existing data, documents, or specimens must have no identifiers attached in order to qualify for exempt level review under category 4. The researcher must describe the information provided in the data set and the number of subjects involved when the data was originally collected. Project start and end dates should be the time period the data set will be in use for the research project.

Continuing reviews are not required for "exempt" research, but investigators are required to notify the HSC of any changes to the project and when the project is completed. About one month after the indicated ending date, the HSC will send a notice to the investigator asking about the status of the project. The form should be completed and returned to the HSC for processing by the office staff. Applications involving research in this category are reviewed by the chair of the Committee on a weekly basis. Comments can be expected shortly after the weekly review.

## **V. Student Research**

Class assignments primarily intended for educational purposes (e.g., to demonstrate how research is conducted) are not subject to HSC review so long as such assignments do not

involve placing human subjects at more than minimal risk. However, HSC approval is required for any student class assignment research projects involving vulnerable populations (such as pregnant women, fetuses, prisoners, persons with mental disabilities, minors, or economically or educationally disadvantaged persons). Instructors are responsible for making the initial determination as to whether HSC review is required. Instructors and students are cautioned to consider the implications of not obtaining human subjects approval should they later decide that they wish to present the results in a public manner (e.g., at an academic conference, or through publication). Please refer to the section on Non-Research. Further information on student research is available under Student Research Policy.

When a student is working on a project that already has human subjects approval, and that student will use some of that data to fulfill a course or degree requirement, such as honor's thesis, first-year project, or master's degree, the original principal investigator must submit an amendment to the HSC requesting the student be added as a co-investigator on his/her project for the stated purpose. In all other situations student initiated research must be submitted as an independent project, NOT as an amendment to an already approved protocol. All student projects submitted to the IUN HSC must be sponsored by one or more full-time IUN faculty. See the section Researcher Responsibilities for the list of approved rank codes and titles. If the sponsor's appointments are at another campus, the review must take place on that campus.

#### **A. Student Research Policy**

As defined in CFR Title 45, Part 46 (Department of Health and Human Services policy for Protection of Human Research Subjects), "research" is a "systematic investigation designed to develop or contribute to generalizable knowledge," and 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." Since class work assignments are usually not intended to or likely to lead to generalizable results, the Human Subjects Committee (HSC) does not normally include these projects under its operational definition of research. Rather, they are viewed as practicum resources of teaching.

- A. Student projects which meet the following criteria, will **not** require review by the HSC.
  - 1. Projects that involve research practical (usually in the form of course related research projects and/or directed studies); and
  - 2. Projects that do not involve physically or psychologically invasive, intrusive, or stressful procedures; and
  - 3. Projects that, in the judgment of the instructor, do not have the potential for placing the subjects at more than minimal risk\* do not require review by the HSC.
  - 4. Projects that do **not** involve a vulnerable population (e.g. children, pregnant women, prisoners).
- B. Student research, including classroom and independent study projects, theses and dissertations, that may place the subjects at more than minimal risk **is subject** to

HSC review. In clinical courses, subjects will be considered to be at greater than minimal risk if the procedures used and/or the questions asked do not fall under what is construed as being ordinary practice. When the student researcher is also an AI/GA for the course from which the subjects will be recruited, the same concerns apply as are stated in the section titled *Students as Subjects*.

Consideration should be given to the research setting when assessing risk.

- C. Special populations including pregnant women, fetuses, prisoners, mentally disabled, economically or educationally disadvantaged or minors are considered vulnerable research subjects and, projects involving such subjects **are subject** to HSC review.

**The following procedures are to be followed for all student research projects:**

1. Instructors are responsible for screening individual research projects and making the initial determination as to whether the project may fall in the category of research as explained above, thus requiring HSC review.
2. If an instructor determines that a research project is assigned for the purpose of producing generalizable knowledge or that it may involve greater than minimal risk, the project must be submitted on the appropriate forms provided by the HSC for its review and approval prior to initiating the research. A copy of the application packet can be downloaded from this site in Microsoft Word format.
3. If there is any doubt as to whether the project should be reviewed by the HSC, the Human Subjects Committee is to be contacted for assistance at 980-6707. If the HSC believes that a particular project is subject to regular HSC review, the proposed project must receive HSC review.
4. In the event HSC review is not needed for a particular classroom research project, the student researcher and the instructor are not relieved of the obligation for ethical use of human subjects. Consequently, the researchers should adhere to ethical standards and use informed consent when appropriate.
5. If there is reasonable expectation on the part of the instructor and the student that the study will be funded (regardless of source) and/or published, HSC approval must be obtained.
6. In instances where a class of students will be conducting group or individual research projects as a part of the classroom instruction, and the instructor believes that, under our guidelines, HSC approval is required, the instructor shall present for Committee approval one form setting forth the parameters of the research being conducted by the students. The instructor should describe the types of research to be undertaken by the students, the nature of the subjects to be used, and the kinds of procedures to be used in the research projects. This means that individual forms are not to be filled out by each student researcher as long as the research falls within the parameters described in the "umbrella" form. Any research not within the described parameters would require separate approval.

When a student is working on a project that already has human subjects approval, and that student will use some of that data to fulfill a course or degree requirement, such as honor's thesis, first year project, or master's degree, the original principal investigator

must submit an amendment to the HSC requesting the student be added as a co-investigator on his/her project for the stated purpose. Any student working in the same capacity but who wishes to use the data for his/her dissertation must submit a separate application to the HSC describing the project and the data to be used. In all other situations student initiated research must be submitted as an independent project, **NOT** as an amendment to an already approved protocol. All student projects must be sponsored by one or more full-time IUN faculty, librarian, salaried clinical rank, or research rank appointee. See the section titled "Researcher Responsibility" for the list of allowable sponsor ranks. If the sponsor's appointments at another campus, the review must take place on that campus.

Sponsorship is more than simply a signature, and carries two responsibilities: (1) supervision of the student's research, and (2) assistance in preparing the student's application for Human Subjects Committee approval. While the Committee is able to offer assistance in how to complete the HSC application, it cannot take the place of the sponsor.

Please contact the office of the Human Subjects Committee at (219) 981-5646, if you have any questions about these procedures.

\*Minimal Risk, defined by HHS policy for the Protection of Human Research Subjects at 45 CFR 46.102i, means that "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

## **B. Students As Subjects**

Two issues arise frequently when researchers seek to use students in research projects: (1) Under what circumstances can class credit be given to student participants? and (2) Can a researcher use his/her own students as subjects? The HSC has developed policies with regard to both issues.

### **i. Credit**

The Committee has approved the giving of course credit or extra credit to students who participate in research as part of a course requirement only when alternative means of obtaining credit is made available to students who do not wish to volunteer as research subjects. The Committee carefully reviews these alternatives to make sure that students are not being coerced into becoming subjects. For example, the Committee is likely to view the choice of either volunteering for a 30 minute experiment involving filling out a questionnaire or writing a 5 page paper as coercive, since writing a 5-page paper involves considerably more time, effort, and stress.

The informed consent statement should make clear the consequences of withdrawing from a project prior to completion (e.g., will credit be given despite withdrawal?). As a general matter, the Committee favors giving credit even if the subject withdraws, unless

the student withdraws immediately or there is evidence of bad faith on the part of the student.

## **VI. USE OF RESEARCHER'S OWN STUDENTS**

### **A. Introduction**

These guidelines are designed to assist researchers who wish to use their own current students as subjects in research protocols. An underlying principle of the regulations governing use of human subjects in research is that the subject's participation is voluntary, based upon full and accurate information. The relationship of teacher and student is inherently one that raises the issue of "voluntariness." No matter how well intentioned the teacher is, students may feel compelled to participate, believing that failure to do so will negatively affect their grades and the attitude of the teacher (and perhaps other students) toward them. For this reason, the Committee has long taken the position that teachers should not use their own students as subjects in their research if it can be avoided. This general policy is in accord with that of other institutional review boards.

The Committee recognizes, however, that in some research situations, use of one's own students is integral to the research. This is particularly true of research into teaching methods, curricula and other areas related to the scholarship of teaching and learning. The following are two models of research design that have been approved by the Committee in the past for such circumstances which we believe strike a balance between the two interests.

### **B. Collection of Data by Third Party**

In situations where the activities to be undertaken by the students are not part of required class activities, and thus students may or may not choose to participate, the instructor/researcher should arrange to have the data collected by an independent third party, so that the instructor does not know who participated, and does not have access to the identifiable data or identity of participants for any purpose until grades have been assigned and entered.

For example, if the instructor wants to administer pre- and post- tests to determine the efficacy of a particular curriculum, the necessary consent form could be obtained, and administration of the tests conducted, by a colleague at times when the instructor was not present. (See Exhibit A for a model consent form).

### **C. Collection of Data by Instructor/Researcher**

In situations where the collection of data by a third party is not feasible, the Committee requires that the student's written consent to use of his or her own data, e.g., test results, papers written, homework, etc., be obtained after grades are entered. For example, use of a particular teaching method throughout the class might not be capable of being structured so that students could opt out. Typically, we ask the instructor/researcher to provide written information at the beginning of the course concerning the study, which makes clear that the students will have an opportunity, after the course is finished and grades entered, to agree or not to agree to the inclusion of their data in the instructor's study. By fashioning the student's participation in this manner, we do not place the

student in the position of having to either choose to participate or find an alternative course. Moreover, at the primary and secondary levels of education, election of alternative classes is not likely to be possible. (See ExhibitB-1 for model information sheet and ExhibitB-2 for model consent form).

#### **D. Problem Practices**

1. Use of Extra Credit for Participation. Sometimes participation in the teacher's research is structured as an available extra credit assignment. Even when other means of obtaining extra credit are available, the Committee does not find this is sufficient to overcome the power disparity and the perception of students that participation in the instructor's research is advisable, even if not required.
2. Group activities. Group activities that are required as part of the course instruction pose a particularly difficult situation because the practicality of a student opting out is very limited. If the data is a group project or perhaps a videotape of the group interaction, each student's consent is necessary for the use of that data in the instructor's research. If one student does not consent, the data may be used only if the non-consenting student's data can be effectively excluded. In many cases this will not be possible. Thus, none of the data can be used.
3. Use of student grades and other assessments. In research where the instructor wants access to identifiable student academic records, signed consent forms are required even if the research activities conducted in the classroom are conducted by a third party and otherwise fall under an exempt category of research. For example, administration of a pre- and post-test by a third party will normally qualify as exempt research under either category 1 or 2 (see exempt list in Exhibit 2), requiring the provision of an information sheet, but not signed consent. If, however, part of the research also includes access to the individual, identifiable student's other grades etc., signed consent from each student is necessary.
4. Minors. Research involving minors (under 18 years of age) as subjects, (even 17 year old college students) in most instances requires a signed parental consent, as well as that of the student.

### **VII. Operations and Procedures of the Northwest Campus HSC**

#### **A. Review Schedule**

Exempt and expedited level projects and most amendments and continuing reviews are reviewed weekly by a co-chair of the HSC. Applications must be received by noon on Monday in order to be reviewed that week.

The Committee meets monthly to review those projects requiring full review, normally on the third Friday of each month. Applications must be received by 5:00 p.m. on the first Friday of the month, in order to be reviewed that month. There are some exceptions to these schedules and researchers are urged to contact the Human Subjects Committee at (219) 981-5646, for the current schedule. Investigators should allow sufficient time for review prior to the beginning date of the project. While projects are reviewed frequently, the entire process can take up to 4 weeks. The length of the process depends on how

quickly the researcher is able to respond to provisions. Projects that require full Committee review may take longer.

## **B. Commencement of Research**

Investigators are reminded that research may not begin (i.e., data may not be collected) until and unless they receive final written approval from the HSC. This includes any and all contacts with human subjects (or work with documents on, or from, human subjects) and any and all categories of research. This restriction applies not only to the initial application, but also to any amendments. Investigators may not institute changes to their research prior to receipt of written approval for the change. The regulations governing research involving human subjects and our Letter of Assurance with the federal government preclude the granting of retroactive approval.

Subjects should not be recruited in any manner before HSC approval is received. Any documents recruiting subjects must be submitted to the Committee with the application. This includes: fliers, e-mails, letters, newspaper and other media advertisements. Offers of compensation must not be in print larger than that used in the document generally. Nor can any other benefits be over-emphasized. Refer to the Recruitment Policy below. The Committee considers recruitment of subjects to be all procedures that take place from the first contact with a potential subject to the point when they enroll in a study or return a completed survey. This includes follow-up contacts, or "nudges", used as reminders to complete mail, e-mail, or telephone surveys.

## **C. Recruitment**

Following are policies regarding advertising that may be used, be it paper or oral, and the number of follow-up contacts that will be allowed. Any deviations to these policies must be submitted with justification for the need and are subject to review by the full committee.

### **i. Media Advertising:**

Direct advertising for research subjects, i.e., advertising that is intended to be seen or heard by prospective subjects to solicit their participation in a study, is not in and of itself, an objectionable practice. Direct advertising includes, but is not necessarily limited to: newspaper, radio, bulletin boards, posters, and flyers that are intended for prospective subjects. Also included are "dear doctor" letters when soliciting for study subjects. Not included are: (1) news stories and (2) publicity intended for other audiences, such as financial page advertisements directed toward prospective investors.

The HSC considers direct advertising for study subjects to be the start of the informed consent and subject selection process. Advertisements should be reviewed and approved by the HSC as part of the package for initial review. When the investigator decides at a later date to advertise for subjects, the advertising requires an amendment to the ongoing study. If such advertisements are easily compared to the approved consent document, the HSC chair, or other designated HSC member, may review and approve the advertising document by expedited procedures. If the HSC reviewer has doubts, or other complicating issues are involved, the advertising will be reviewed at a convened meeting

of the HSC.

The HSC reviews advertising to assure that it is not unduly coercive and does not promise a certainty of cure beyond what is outlined in the consent and the protocol. This is especially critical when a study may involve subjects who are likely to be vulnerable to undue influence.

When direct advertising is to be used, the HSC will review the information contained in the advertisement and the mode of its communication to determine that the procedure for recruiting subjects is not coercive and does not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol. The HSC will review the final copy of printed advertisements to evaluate the relative size of type used and other visual effects.

When advertisements are to be taped for broadcast, the HSC will review the final audio/video tape. The HSC may review and approve the wording of the advertisement prior to taping. The review of the final taped message prepared from HSC approved text may be accomplished through expedited procedures. The HSC cautions investigators to obtain HSC approval of message text prior to taping, in order to avoid having to re-tape because of a finding of inappropriate wording.

For clinical studies, no claims should be made, either explicitly or implicitly, that the drug, biologic or device is safe or effective for the purposes under investigation, or that the test article is known to be equivalent or superior to any other drug, biologic or device. Such representation would not only be misleading to subjects but would also be a violation of federal regulations concerning the promotion of investigational drugs.

Advertising for recruitment into investigational drug, biologic or device studies should not use terms such as "new treatment," "new medication" or "new drug" without explaining that the test article is investigational. A phrase such as "receive new treatments" leads study subjects to believe they will be receiving newly improved products of proven worth.

Advertisements should not promise "free medical treatment," when the intent is only to say subjects will not be charged for taking part in the investigation. Advertisements may state that subjects will be paid, but should not emphasize the payment or the amount to be paid by such means as larger or bold type.

Generally, any advertisement to recruit subjects should be limited to the information the prospective subjects need to determine their eligibility and interest. When appropriately worded, the following items may be included in advertisements. It should be noted, however, that the HSC does not require inclusion of all of the listed items.

1. the name and address of the investigator and/or research facility;
2. the condition under study and/or the purpose of the research;
3. in summary form, the criteria that will be used to determine eligibility for the study;

4. a brief list of participation benefits, if any (e.g., a no-cost health examination)
5. the time or other commitment required of the subjects; and
6. the location of the research and the person or office to contact for further information.

### **ii. Receptionist Scripts:**

Often, the first contact a prospective study subject makes is with a receptionist who follows a script to determine basic eligibility for the specific study. The HSC will assure the procedures followed adequately protect the rights and welfare of prospective subjects. In some cases, personal and sensitive information is gathered about the individual. The HSC should have assurance that the information will be appropriately handled. A simple statement such as "confidentiality will be maintained" does not adequately inform the HSC of the procedures that will be used.

Examples of issues that should be reviewed: What happens to personal information if the caller ends the interview or simply hangs up? Are the data gathered by a marketing company? If so, are names, etc. sold to others? Are names of non-eligible maintained in case they would qualify for another study? Are paper copies of records shredded or are readable copies put out as trash? The acceptability of the procedures would depend on the sensitivity of the data gathered, including personal, medical and financial information.

### **iii. Follow-ups :**

The Committee will generally allow 5 contacts with potential subjects in mail, e-mail, or telephone surveys.

1. Pre-contact postcard/letter
2. Information sheet and survey
3. Follow-up postcard/letter
4. Second mailing of survey
5. Telephone contact

After the telephone contact (actually speaking with a person, as opposed to leaving a message), any further contact would be with stipulations such as the caller verbally agrees to be re-contacted in a couple of weeks by a postcard reminder if the survey is not returned. The potential subject must explicitly agree to any further follow-up. For example, in the telephone contact, when the potential subject has agreed to have another survey sent, the researcher could ask: "Could we call you again in 2-3 weeks to remind you to return the survey?" or "Could we send you a card in 2-3weeks to remind you to return the survey?" Anytime a referral to amore appropriate potential subject is made, then the recruitment procedure can go back to item one and start over.

All possible follow-up procedures must be approved by the HSC first. Procedures requested outside of this policy will be evaluated on a case by case basis.

## **D. Compensation**

Payment to research subjects:

It is not uncommon for subjects to be paid for their participation in research. Payment to

research subjects for participation in studies is not considered a benefit, it is a recruitment incentive. Financial incentives are often used when health or other benefits to subjects are remote or non-existent. The amount and schedule of all payments should be presented to the HSC at the time of initial review. The HSC will review both the amount of payment and the proposed method and timing of disbursement to assure that neither are coercive or present undue influence.

Any credit for payment should accrue as the study progresses and not be contingent upon the subject completing the entire study. Unless it creates undue inconvenience or a coercive practice, payment to subjects who withdraw from the study may be made at the time they would have completed the study (or completed a phase of the study) had they not withdrawn. For example, in a study lasting only a few days, it is permissible to use a single payment date at the end of the study; even for subjects who have withdrawn before that date.

While the entire payment should not be contingent upon completion of the entire study; payment of a small proportion as an incentive for completion of the study is acceptable, providing that such incentive is not coercive. The HSC will determine that the amount paid as a bonus for completion is reasonable and not so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn. All information concerning payment, including the amount and schedule of payment(s), should be set forth in the informed consent document.

### **E. Submission Process**

ALL IUN investigators must submit an application detailing the involvement of human subjects in the research project. All documents must be typed or prepared legibly on a current edition of the forms as they appear on the web site <http://www.iun.edu/~hsc/> or they will be returned to the investigator. Some applications will require a sponsor. See the “Researcher Responsibility” section for details and requirements. If the sponsor is from another campus, the review must take place on that campus.

Requests for approval to use human subjects should be submitted to the IUN Human Subjects Committee, Tamarack Hall room F04, on the appropriate forms. The forms must be completed according to the instructions provided.

The application for approval from the HSC includes the required submission of a Summary Safeguard Statement in which the investigator sets forth answers to specific questions about his/her proposed research. Investigators may not submit a protocol or proposal in lieu of the Summary Safeguard Statement. The Committee will process only those applications that include a properly completed Summary Safeguard Statement; incomplete applications will be returned to the investigator. Applications must be submitted on versions of the forms that are no older than one year prior to the date of submission. A copy of the application packet can be downloaded from this site in Microsoft Word format.

In order for applications to be reviewed in a timely manner the Committee must be able to understand the purpose of the project, what the procedures are, and how human subjects are involved (i.e., what the subjects will be asked to do or will have done to them). Investigators are cautioned to avoid using discipline specific jargon, both in the description of the project and in the consent form. For projects being conducted where instruments and consent forms will be in a foreign language, two copies of the materials must be submitted; the foreign language version and an English translation. Investigators are urged to carefully follow the directions and to pay close attention to the quality of the consent statements and the clarity of the application in general.

Investigators submitting applications subject to full Committee review must provide the necessary number of photocopies for the Committee. Three (3) copies should be submitted initially, for all levels of review. Investigators will be contacted by the HSC as to the number needed when additional copies of their application are required for full review.

#### **F. Help with the Process**

Contact the office directly for assistance. Contact information is indicated on the cover of this booklet.

#### **G. Approval Process**

In its review of protocols, the Committee determines that the following requirements have been satisfied:

1. Risks to the subjects are minimized.
2. Risks to the 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.
3. Selection of subjects is equitable.
4. Informed consent meets the requirements of the federal regulations and provision is made to obtain an informed consent from each subject or the subject's legally authorized representative.
5. The research plan makes adequate provision to ensure the safety of subjects.
6. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
7. Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Studies are rarely disapproved by the Committee. However, many studies require additional information for adequate review. Occasionally, the Committee requests investigators to revise their procedures. Examples of common problems causing delays in the review and approval process are:

1. Failure to use a current application form.
2. Failure to complete the Documentation of Review and Approval page completely (dates, address, signatures, etc.).
3. Failure to complete each section of the Summary Safeguard Statement in a legible and comprehensible manner (making it impossible for the Committee to understand the research project and what subjects will be asked to do or have done to them).
4. Failure to provide additional materials as directed in the instructions.
5. Lack of acknowledgment of risk, although some element of risk is clearly present.
6. Lack of, or lack of an adequate, informed consent statement (containing all relevant information in language comprehensible to the prospective subject population).
7. Lack of screening of subjects to make certain they are not unduly at risk.
8. Need for the Committee to ascertain risk through consulting experts.
9. Unacceptable risk involved. (These are generally few in number and, typically, can be modified to meet concerns of the Committee.)

When approval is granted, the investigator will be sent a copy of the Documentation of Review and Approval with the Chairperson's signature and date. This page, along with a cover letter, will be sent to the address provided by the investigator.

#### **H. Committee Actions**

The review committee may take one of four actions in regard to proposed protocols and consent forms:

- a) **Final Approval** - The PI may commence the research only after receiving written approval indicated by a signed copy of the "Documentation of Review and Approval" with a cover letter outlining the additional responsibilities for conducting research at IUN.
- b) **Provisional Approval** - The PI must respond in writing to provisions requested by the board **and** receive final approval prior to initiating the research.
- c) **Tabled** - Deferred for reconsideration at a subsequent meeting after PI has responded to modifications requested by the board.
- d) **Denied** - The PI will be notified in writing of reasons for disapproval.

Upon completion of the review, the investigator will receive a written response from the IRB shortly after the meeting. Any questions raised by the committee must be responded to in writing within sixty (60) days (provisionally approved or tabled studies). No work may be initiated until written final approval is received from the IRB. In no circumstance may a study be approved retroactively.

#### **I. Amendments**

Investigators are required to report any proposed changes to their research study via a

Study Amendment Form (one copy). Investigators must report any changes whatsoever, regardless of the level of the original review and regardless of their assessment of the importance of the change. Reference the original title of the study, the principal investigator, and the protocol number. Any changes to the title or the investigator should be described in section 1. If the investigator's appointment does not carry an approved rank code, then both the investigator and the sponsor must sign the form. Amendments involving minor changes that pose no more than minimal risk to subjects will be reviewed on an expedited basis according to the weekly review schedule. Amendments involving more than minor changes or involving changes that pose more than minimal risk will be reviewed by the full Committee, at its next scheduled monthly meeting. Investigators are reminded that changes may not be implemented until final written approval is received from the Committee. A copy of this form can be downloaded from this site in Microsoft Word format.

### **J. Continuing Reviews**

Approval will be granted for up to one year. Studies (except exempt level) that continue for longer than the approval period must apply for an updated approval before the end of the approval period. The investigator will be notified by the chair of the Human Subjects Committee when it is time to apply for an updated approval. If the initial application indicates less than a one-year period, the investigator will receive a form to indicate whether the project has been completed or is continuing. Studies that initially received full Committee review will continue to receive full review for the duration of the project, unless the scope of the study changes such that it would qualify for a lower level of review. Studies that continue to recruit subjects beyond the initial approval period will need to submit consent forms/information sheets for reapproval and updated stamps. A copy of the continuing review form may be obtained from the HSC office in Academic Affairs. The instructions for downloading this form from the WWW are available at <http://www.iun.edu/~hsc/forms.shtml>.

Investigators of exempt level projects are required to notify the HSC when their project is completed. About one month after the indicated ending date, the HSC will send a notice to the investigator asking about the status of the project. The form should be completed and returned to the office for processing by the office staff. Studies that continue to recruit subjects beyond the initial approval period will need to submit consent forms/information sheets for reapproval and updated stamps.

If a study is terminated by the investigator, it may be reactivated within 60 days without having to submit a complete application to the HSC as a new study. If it is beyond the 60 days, or a significant number of changes have been made, a new application will be required.

### **K. Adverse Events**

Any adverse experience associated with a study must be reported to the HSC within 3 working days after the incident. The report should be in letter format which contains the following:

Study number and title to which the incident relates.

1. Description of the incident.
2. Principal investigator's assessment of the incident, outlining any changes and the significance/relevance to the study, e.g., changes in risk/benefit ratio.
3. Any changes that need to be made to the consent statement, plus the revised form.
4. Identification of the principal investigator and the principal investigator's signature.

#### **L. Record Keeping**

The Committee maintains the following files:

1. Federal regulations and communications, as well as University memoranda, and letters of assurance.
2. Minutes of the HSC meetings.
3. Original protocols and copies of memoranda sent to, and received from, investigators.
4. Protocols not yet reviewed.
5. Protocols from which approval has been withheld and for which suitable remedial action has not yet been taken.
6. Correspondence.

All protocols are kept for three years after completion of the research, and then are destroyed.

### **VIII. Researcher Responsibility**

#### **A. Sponsorship of Applications**

Some research involving human subjects must be sponsored by a responsible investigator. Investigators whose appointments carry the approved rank codes do not require sponsorship (primarily, tenured or tenure-track faculty, with or without administrative titles; tenure or tenure-track librarians; full-time salaried clinical rank appointees; and full-time research rank appointees). See the end of this section for a list of rank titles and their codes. All other investigators, including students, research associates, postdoctoral fellows, non-salaried clinical rank appointees, non-tenure track faculty and librarians, and part-time appointees must be sponsored by one or more full-time IUN faculty, librarian, salaried clinical rank or research rank appointee whose primary appointment carries one of the below-listed rank codes.

Sponsorship is more than simply a signature, and carries two responsibilities:

- (1) Supervision of the research, and
- (2) Assistance in preparing the application for Human Subjects Committee approval.

While the Committee is able to offer assistance in how to complete the HSC applications, it cannot take the place of the sponsor.

When a student is working on a project that already has human subjects approval, and that student will use some of that data to fulfill a course or degree requirement, such as honor's thesis, first-year project, or master's degree, the original principal investigator must submit an amendment to the HSC requesting the student to be added as a co-investigator on his/her project for the stated purpose. Any student working in the same capacity but who wishes to use the data for his/her dissertation must submit a separate application to the HSC describing the project and the data to be used. In all other situations student initiated research must be submitted as an independent project, NOT as an amendment to an already approved protocol. All student projects must be sponsored by one or more full-time IUN faculty, librarian, salaried clinical rank, or research rank appointee. If the sponsor's appointment is at another campus, the review must take place on that campus.

**Persons with the following ranks are approved to submit, or sponsor, an application to use human subjects in a research project.**

FT1 - Professor  
FT2 - Associate Professor  
FT3 - Assistant Professor  
EF1-3 - Emeritus Professor, Assoc. & Asst.  
FC1 - Clinical Professor  
FC2 - Clinical Associate Professor  
FC3 - Clinical Assistant Professor  
EC1-3 - Emeritus Clinical Prof., Assoc. & Asst.  
LT1 - Librarian  
LT2 - Associate Librarian  
LT3 - Assistant Librarian  
EL1-3 - Emeritus Librarian, Assoc. & Asst.  
RS1 - Senior Scholar/Scientist  
RS2 - Associate Scholar/Scientist  
RS3 - Assistant Scholar/Scientist  
AAA - President  
AAB - Vice President  
AAC - Associate Vice President  
AAD - Assistant Vice President  
AAE - Chancellor  
AAF - Vice Chancellor  
AAG - Associate Vice Chancellor  
AAH - Assistant Vice Chancellor  
AAI - Dean  
AAJ - Associate Dean  
AAK - Assistant Dean  
AAL - Chairperson  
AAM - Director  
HAI-HAM -Acting I-M

## **B. Follow-Up**

The Committee suggests that researchers be aware that materials can get lost in the mails. If an investigator has submitted an application but hasn't heard from the Committee within two weeks, the investigator should contact the Committee. If the investigator has provided an e-mail address, the Committee will use that means to convey any questions to the investigator. However, communication from a full Committee review will, in most cases, be by written letter sent via campus or U.S. mail, depending upon the address provided by the investigator. If no e-mail address is provided, a written memo will be sent to the address the investigator provides. For applications with a sponsor, the sponsor will be copied on all communication with the investigator.

The Committee allows approximately one month from the time it sends questions to the investigator before it will recontact the investigator as follow-up. If the Committee does not receive a response from the investigator by the end of 3 months, the application will be considered not approved/withdrawn.

## **C. File Maintenance**

It is important for investigators to **KEEP A COPY** of every document related to the research project which is submitted to the Committee. For audit purposes, these documents, and signed consent forms, must be kept for at least three (3) years after terminating the study. The HSC will **NOT** be responsible for duplicating any information submitted to the Committee.

## **IX. Noncompliance**

The HSC will NOT approve any project if the principal investigator has begun data collection prior to receiving HSC approval. This policy is needed to assure compliance with and carry out the purpose of the federal regulations: that is to protect human subjects involved in research.

In any instance in which HSC requirements are not being followed, the HSC shall inform (within five (5) working days) the principal investigator and also the Vice Chancellor for Academic Affairs, who will be asked to enforce the requirements. In the event that the principal investigator does not comply, the Vice Chancellor for Academic Affairs will terminate the research. Such action will be accompanied by a letter to the principal investigator, stating the reason for the action. If unanticipated problems involving risks to the subjects or others, noncompliance by the researcher, or termination by Vice Chancellor for Academic Affairs occur, these problems will be reported to the Indiana University Vice President for Research who will report them to the Secretary of the Department of Health and Human Services, or other appropriate federal agency, within seven (7) working days of the letter of termination to the principal investigator.

EXHIBIT A  
COLLECTION OF DATA BY THIRD PERSON  
SAMPLE CONSENT FORM  
Indiana University Northwest  
INFORMED CONSENT STATEMENT  
[Project Title] Study #\_\_\_\_\_

Dear [name of course] Students:

You are invited to participate in a research study which aims at improving the learning of [subject]. As you already know, the goal of [name of course or course number] is to [purpose of class]. Whereas the curriculum employed in this course has been successful in general during the last few years, we are always looking for ways to improve the course, and make it more in accordance with current trends in education. We are in the process of modifying the \_\_\_\_\_ class to introduce new teaching strategies. While making these changes, we would also like to measure their effectiveness by comparing data from students in classes that are now being modified with data from students in classes that have not yet been changed. In this way we can determine whether the changes are effective, and whether additional changes will also be necessary.

The study will be conducted within the context of your regularly scheduled class sessions. Your participation should require no additional out of class time. At the beginning of the semester you will be asked to take a short 12 item test on \_\_\_\_\_. Other data used in the study will come from the multiple choice portion of your final exam which will not be modified in any way for use in the research. An instructor other than your instructor will distribute and collect this consent form and the pretest, so that your instructor will not know if you have participated until after the course is finished and grades entered.

Confidentiality of participants will be protected by destroying all data once it has been analyzed. All identifiers will be removed and no reference will be made to individual students in oral or written reports which could link you to the study.

Your participation in this study is voluntary. If you decide not to participate, the scores obtained on your tests will be used for your course grade but will not be used for the study. There will be no penalty for not participating. If you decide to participate, you may withdraw from the study at any time. After completion of the study, I will be happy to discuss the results with you. Should you have any questions while the study is in progress, or should you decide any time to withdraw, please contact the person who is collecting this consent form \_\_\_\_\_ by email ( \_\_\_\_\_ iunhsc@iun.edu) or by calling \_\_\_\_\_. After the study is over and your grade had been posted I will be willing to answer any questions, or withdraw your data, if you wish.

If you are willing to participate in the study, please sign one of the two copies of this letter and return it to the \_\_\_\_\_. The second copy is for you to keep for reference. If you feel you have not been treated according to the descriptions in this form, or that

your rights as a participant have not been honored during the course of this project, you may contact the Human Subjects Committee, Indiana University Northwest, Tamarack Hall F04, 3400 Broadway, Gary IN 46408, 219 981-5646, or email at hsc@iun.edu. We appreciate your considering to participate in this research and thus enabling us to improve instruction in the \_\_\_\_\_ course.

Thank you.

[name of instructor/researcher]

**CONSENT**

I have read and understand the above described information and have received a copy of this form. I agree to take part in the study.

Subject's signature \_\_\_\_\_ Date \_\_\_\_\_

Consent form date XX-XX-XX

EXHIBIT B-1  
GIVEN TO STUDENTS AT BEGINNING OF COURSE  
SAMPLE INFORMATION SHEET  
Indiana University Northwest  
STUDY INFORMATION SHEET  
[Project Title] Study # \_\_\_\_\_

You are invited to participate in a research study. This study investigates \_\_\_\_\_ . It will be in conjunction with your course \_\_\_\_\_ which I will teach this \_\_\_\_\_ .

**INFORMATION**

The following activities are part of the normal curriculum of [name of course].  
[Describe activities, e.g. required writings, tests]

At the end of the course, after grades have been submitted, I will ask for your written consent to review your class activities for the study described above. I will also ask your consent to participate in an audio-taped interview regarding your experiences with this class. The interview will be no more than \_\_\_\_ hour(s) in length.

**BENEFITS**

The benefits are: \_\_\_\_\_.

**RISKS**

There are no foreseeable risks in participating in this study. No data will be analyzed until after grades are entered.

**CONFIDENTIALITY**

The information in the study records will be kept confidential. No reference will be made in oral or written reports that could link you to the study. Access to the tapes of your interviews will be limited to research investigators and paid transcribers. Typed transcripts of these tapes will be made and in those typed transcripts pseudonyms will be used for all names of persons. At the conclusion of the study (xx-xx-xx), these tapes will be \_\_\_\_\_.

**CONTACT**

If you have any questions about this study or its procedures, please contact \_\_\_\_\_.

If you feel you have not been treated according to the descriptions in this form, or that your rights as a participant have not been honored during the course of this project, you may contact the Human Subjects Committee, Indiana University Northwest, Tamarack Hall F04, 3400 Broadway, Gary IN 46408, 219 981-5646, or email at hsc@iun.edu.

**PARTICIPATION**

Your participation (allowing your class data to be used) in this study is voluntary .

Refusal to participate will involve no penalty. If you decide to participate, you may withdraw from the study at any time without penalty. If you withdraw from the study your data will be returned to you or destroyed.

Information Sheet date XX-XX-XX

EXHIBIT B-2

MAY BE SIGNED BEFORE THE END OF THE SEMESTER, COLLECTED BY A THIRD PARTY, AND GIVEN TO THE RESEARCHER AFTER GRADES ARE POSTED

SAMPLE CONSENT STATEMENT

Indiana University Northwest

INFORMED CONSENT STATEMENT

[Project Title] Study # \_\_\_\_\_

You are invited to participate in a research study. This study investigates \_\_\_\_\_ . The purpose of this study is to \_\_\_\_\_ .

INFORMATION

1. The following activities were part of the regular [name of course] curriculum of. [Describe activities, e.g. required writings, tests] If you volunteer for this study, the researchers will review your class activities as part of this study after grades have been turned in.
2. Your participation in this study requires no additional time with the exception of an audio-taped interview regarding your experiences with \_\_\_\_\_ lasting no more than \_\_\_\_\_ hour(s) in length.
3. In signing this consent statement, you agree to give permission for the researchers to use your materials and the audio-tapes for research purposes only. The transcribers will use pseudonyms to protect the identity of the participants. You may preview and make changes to the transcripts before they are analyzed.

BENEFITS

It is anticipated that you will benefit from your participation in the following ways:  
\_\_\_\_\_.

RISKS

There are no foreseeable risks or discomforts of any of the procedures to be used in this study.

CONFIDENTIALITY

There are numerous methods that will be used to preserve your confidentiality. All tapes will be stored in a locked metal cabinet in the primary researcher's office. The transcriber will preserve confidentiality by assigning a pseudonym to all participants. The analysis of the data will focus on group patterns that will be described in aggregate terms. Direct quotes will be used only for illustrative purposes. The tapes will be destroyed \_\_\_\_\_.

CONTACT

If you have any questions about this study or its procedures, you may contact the primary researcher, \_\_\_\_\_ at \_\_\_\_\_.

If you feel you have not been treated according to the descriptions in this form, or that your rights as a participant have not been honored during the course of this project, you may contact the Human Subjects Committee, Indiana University Northwest, Tamarack Hall F04, 3400 Broadway, Gary IN 46408, 219 981-5646, or email at [hsc@iun.edu](mailto:hsc@iun.edu).

#### PARTICIPATION

Your participation in this study is voluntary; you may decline to participate without penalty. If you decide to participate, you may withdraw from the study at any time without penalty and without loss of benefits to which you are otherwise entitled. If you withdraw from the study before data collection is completed your data will be returned to you or destroyed.

#### CONSENT

I have read this form and received a copy of it. I have had all my questions answered to my satisfaction. I agree to take part in this study.

Subject's signature \_\_\_\_\_ Date \_\_\_\_\_

Consent form date XX-XX-XX

EXHIBIT C

Translation Statement of Accuracy

I \_\_\_\_\_ *PI's name* \_\_\_\_\_ affirm that the translated documents (I.e. consent/information sheet and/or recruitment materials) for \_\_\_\_\_ *Title of study & Protocol number* \_\_\_\_\_ is a complete translation of the documents provided to the IRB in English, and such documents do not contain information that is not presented within the context of the English versions of the documents.

\_\_\_\_\_  
Principal Investigator's Signature

\_\_\_\_\_  
Date

