CHAPTER 5: VULNERABLE POPULATIONS

Studies proposing the involvement of vulnerable populations are reviewed to ensure that inclusion of these participants is justified and, if so, that adequate procedures are in place to minimize the risks related to physical harm, psychological harm and breach of privacy and confidentiality. The research must be relevant to the vulnerable population and not otherwise capable of being carried out with a non-vulnerable population. The IRB will fulfill the additional duties required by Federal Regulations outlined in Subparts B, C and D of 45 CFR 46 regardless of the source of funding for initial and continuing review by expedited or full board proceedings. For studies requiring full board review, a member or consultant who is knowledgeable about or experienced in working with vulnerable populations must review all material and be present (in person or via teleconference) at the meeting. The IRB Chair may use the IRB roster to identify such members and/or consultants to assign as reviewers. Consultants may participate in the discussion but may not vote. For studies requiring full board review, any decision made by a convened board will supersede the opinion of an individual reviewer. The minutes will reflect the determinations of the convened board regarding the required findings.

Vulnerable populations include those defined 45 CFR 46 Subparts B (Pregnant Women, Human Fetuses and Neonates), Subpart C (Prisoners), and Subpart D (Children), and those mentioned in 45 CFR 46.111(b): mentally disabled persons, or economically or educationally disadvantaged persons. The IRB also considers Heritage University students, employees, and HIV+ individuals to be vulnerable populations. The IRB may also require additional protections for any other group not specified in this policy but determined to be vulnerable by the IRB. Such additional protections may include, but are not limited to, the witnessing of the consent process, more frequent continuing review, or additional review by someone with a specific expertise.

I. Pregnant Women, Fetuses, or Neonates

Proposed studies involving pregnant women, fetuses or neonates may qualify for exempt or expedited review when no more than minimal risk is involved. The Chair or an IRB member will make the final determination. Studies requiring full board review will be reviewed and approved in accordance with the criteria of 45 CFR 46 Subparts A and B. The primary reviewers will be provided with the standard reviewer sheet that addresses Subpart A and information provided by the investigator that outlines the additional duties/findings required of the IRB under Subpart B. Unavailability of the father as related to consent issues is interpreted to mean that he is either deceased or that his whereabouts are not known and cannot be determined with a reasonable amount of effort. Note: The regulations specified in Subpart B apply when investigators engage in human participants research conducted or supported by any federal department or agency that has adopted the Federal Policy for the Protection of Human Subjects unless the research is otherwise exempt from the requirements of the Common Rule or a department covered by a separate assurance. In cases where clinical research is not supported by the federal government, as described above, the University will apply equivalent standards when 45 CFR 46.204 applies. However, this may not always be possible in social/behavioral research because such research (while the risk is not greater than minimal risk) may not directly benefit the pregnant woman and/or the fetus. In order to engage in
social/behavioral research involving pregnant women, the IRB determined that it will allow pregnant women to be enrolled in research involving interview, focus group, survey or similar procedures. These studies will be reviewed by the IRB following equivalent standards as set forth in the Common Rule.

Pregnant women or fetuses may be involved in research only if the IRB finds that:
   a) where scientifically appropriate, preclinical studies, including studies in pregnant animals, and clinical studies, including studies on pregnant women, have been conducted and provide data for assessing potential risks to pregnant woman and fetuses;
   b) the risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;
   c) any risk is the least possible for achieving the objective of the research;
   d) the woman's consent is obtained in accordance with the provisions of Subpart A if the research holds out 1) the prospect of direct benefit to the pregnant woman, 2) the prospect of a direct benefit to both the pregnant woman and the fetus, or 3) no prospect of direct benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means;
   e) if the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provision of Subpart A. The father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest;
   f) each individual providing consent under paragraph d or e of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
   g) for children who are pregnant, assent and permission are obtained in accord with the provisions of Subpart D – children involved as participants in research; (Subpart D is described under the section for children)
   h) no inducement, monetary or otherwise, will be offered to terminate a pregnancy;
   i) individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
   j) individuals engaged in the research will have no part in determining the viability of neonates.

Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:
   a) where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
   b) each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.
i. For neonates of uncertain viability, the legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence or temporary incapacity, the legally effective informed consent of the either parent's legally authorized representative is obtained in accordance with Subpart A, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

ii. For nonviable neonates, the legally effective informed consent of both parents of the neonate is obtained in accord with Subpart A. The provisions to request a waiver or alteration of consent described in Subpart A do not apply. If either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice. The consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice.

c) individuals engaged in the research will have no part in determining the viability of a neonate.

d) the following requirements have been met as applicable to neonates of uncertain viability.

i. until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research unless the IRB determines that 1) the research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and 2) any risk is the least possible for achieving that objective; or 1) the purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and 2) there will be no added risk to the neonate resulting from the research;

ii. the legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence or temporary incapacity, the legally effective informed consent of the either parent's legally authorized representative is obtained in accordance with Subpart A, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

Nonviable neonates: After delivery a nonviable neonate may not be included in research unless all of the following additional conditions are met:

a) vital functions of the neonate will not be artificially maintained;

b) the research will not terminate the heartbeat or respiration of the neonate;

c) there will be no added risk to the neonate resulting from the research;
d) the purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and

e) the legally effective informed consent of both parents of the neonate is obtained in accord with subpart A of this part. The provisions for a waiver or alteration of consent (46.116 c and d) do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice. The consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of the nonviable neonate will not suffice.

Viable neonates: A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of subparts A and D, Additional Protections for Children Involved as Participants in Research, describe in subsequent sections.

Research involving, after delivery, the placenta, the dead fetus, or fetal material may be conducted only if the IRB finds that:

a) research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable Federal, State or local laws and regulations regarding such activities.

b) if information associated with material described in paragraph a of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research participants and must be afforded the applicable protections of 45 CFR 46 its subparts as applicable.

Research involving pregnant women, fetuses or neonates that does not fit into one of the above categories may only be conducted if the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problems affecting the health or welfare of pregnant women, fetuses or neonates and after the Secretary has consulted with an expert panel and there has been opportunity for public review and comment. The required findings for such research are that the research does present the aforementioned opportunity, the research will be conducted in accord with sound ethical principles and informed consent will be obtained.

II. Prisoners
The full IRB board must initially review all studies involving prisoners. The membership of the board will be such that the majority of members have no association with the prisons involved and at least one member will be a prisoner, or a prisoner representative. Such membership constitutes compliance with 45 CFR Subpart C 46.304, Composition of Institutional Review Boards where prisoners are involved. A prisoner representative will be assigned as the primary reviewer. The primary reviewer will be provided with the standard reviewer sheets that address Subpart A and information provided by the
investigator that outlines the additional duties/findings required of the IRB under Subpart C.

Minimal risk as related to studies proposing to involve prisoners is defined as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental or psychological examination of healthy persons. In assessing the level of risk involved in a study, the IRB will not use risks that face prisoners in the prison setting as the standard for acceptable risk, and will only allow risks that are commensurate with those that would be accepted by non-prisoner volunteers. The IRB must find that the involvement of prisoners as participants is justified.

Requests for amendments to approved studies that are administrative in nature and/or that pose no change to the involvement of the prisoner or to the level of risk, for example corrections of typographical errors in consent documents or additional data elements in a file review study, may be approved through the expedited review process by the Chair or the prisoner representative. However, the Chair or the prisoner representative reserves the right to require full board review of any request for modification.

Continuing review of studies involving prisoners will require full board review unless no participants have been enrolled and no additional risks have been identified or the remaining activity is limited to data analysis in which case the PI may request expedited review under category 8(b) or (c). Per 46.305(a)(1), when reviewing proposals involving prisoners the IRB will ensure that the research is permissible under one of the categories of 46.306(a)(2) which are:

- study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the participants;
- study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the participants;
- research on conditions particularly affecting prisoners as a class (e.g., vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology medicine and ethics, and published notice in the Federal Register of his intent to approve such research; or
- research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology medicine and ethics, and published notice in the Federal Register of his intent to approve such research.
Per 46.305(a)(2-7), the IRB will also determine that the following additional criteria for approval have been satisfied:

- any possible advantages accruing to the prisoner through his or her participate in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
- the risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
- procedures for the selection of participants within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the PI provides to the Board justification in writing for following some other procedures, control participants must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
- the information is presented in a language which is understandable to the participant population; (note: use a 5th grade reading level as a benchmark)
- adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and
- where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoner's sentences, and for informing participants of this fact.

When funding is from DHHS, the institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the Board under Subpart C have been fulfilled. The certification letter will be sent from the RCC or IRB on behalf of the IRB.

III. Epidemiologic Research Involving Prisoners

Effective June 20, 2003, the Secretary of the DHHS may also approve epidemiologic research involving prisoners as participants under a provision allowing for a waiver of the applicability of provisions 46.305(a)(1) and 46.306(a)(2) as set forth above. While prisoners may be included in such studies, they cannot be the only population included within the study. The epidemiologic research can present no more than minimal risk and no more than inconvenience to the prisoner-participants. To qualify for such a waiver the epidemiologic study must meet the following criteria:

- the sole purposes are to describe the prevalence or incidence of a disease by identifying all cases, or to study potential risk factor associations for a disease, and
- for DHHS supported research, the IRB, via the RCC or IRB, must include in the certification letter to OHRP that the additional criteria of 46.305(a)(207), as described above, have been satisfied.
that the research presents no more than minimal risk and no more than inconvenience to the prisoner-participants, and
prisoners are not a particular focus of the research

Studies for which the waiver may apply include epidemiological research related to chronic disease, injuries, and environmental health.

IV. Children

Research that involves children is subject to the additional requirements of Subpart D. Under DHHS and FDA regulations "children" are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

When research is conducted in Washington, persons who meet the above definition are all individuals under 18 years of age with the following exceptions:

1. Individuals between 16 and 18 years of age adjudicated as emancipated by a probate court
2. All individuals under 18 years of age, if the research procedures are limited to:
   a. HIV testing, counseling, and treatment
   b. Outpatient mental health services
   c. Testing or treatment for sexually transmitted diseases
   d. Treatment or rehabilitation for alcohol or drug dependence
   e. Abortion counseling and treatment
3. All individuals between 16 and 18 years of age, if the research procedures are limited to:
   a. Inpatient mental health services
4. All individuals between 17 and 18 years of age, if the research procedures are limited to donation of blood or any component thereof and to the withdrawal of blood in conjunction with any voluntary blood donation program.

Proposed studies involving children may qualify for exempt or expedited review if the study falls into one of the federally-approved categories defined in 45 CFR 46.101 or in the guidance published in the Federal Register for categories for which expedited review is acceptable. Exemption categories 1-5 do not apply to FDA regulated studies. Also the exemption noted at 45 CFR 46.101(b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research involving children unless the research involves the observation of public behavior and the investigator(s) do not participate in the activities being observed. The Chair will make the final determination regarding approval status and categories. Studies requiring full board or expedited review will be reviewed and approved in accordance with the regulatory criteria as summarized below. The primary reviewers will be provided with the standard reviewer worksheets that address Subpart A and information provided by the investigator within the protocol that outlines the additional duties/findings required of the IRB under Subpart D.
For research not involving greater than minimal risk, the IRB must find and document that adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

For research involving greater than minimal risk but presenting the prospect of direct benefit to the individual participants the IRB must find and document:

- the risk is justified by the anticipated benefit to the participants;
- the relation of the anticipated benefit to the risk is at least as favorable to the participant as that presented by available alternative approaches; and
- that adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

For research involving greater than minimal risk and no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant's disorder or condition the IRB must find and document:

- the risk represents a minor increase over minimal risk;
- the intervention or procedure presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
- the intervention or procedure is likely to yield generalizable knowledge about the participant's disorder or condition which is of vital importance for the understanding or amelioration of the participant's disorder or condition; and
- that adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

For research not otherwise approvable that presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children the IRB must find and document:

- the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children, and
- for studies funded by DHHS, the Secretary, after consultations with a panel of experts in pertinent disciplines and following opportunity for public review and comment, has determined either that the research in fact satisfies one of the set of conditions described above, or the following:
  - the research presents a reasonable opportunity to further the understanding, prevention or alleviation of a serious problem affecting the health or welfare of children;
  - the research will be conducted in accordance with sound ethical principles; and
  - adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

For studies regulated by the FDA, the Commissioner of Food and Drugs, after consultations with a panel of experts in pertinent disciplines and following opportunity for public review and comment, has determined either that the research in fact satisfies one of the set of conditions described above, or the following:
• the research presents a reasonable opportunity to further the understanding, prevention or alleviation of a serious problem affecting the health or welfare of children;
• the research will be conducted in accordance with sound ethical principles; and
• adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

The IRB must determine that adequate provisions are made for soliciting the assent of the children when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. The judgment may be made for all children to be involved in research under a particular protocol, or for each child. When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

Assent is not a necessary condition for proceeding with the research 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 IRB may also waive the assent requirement under provisions noted in 45 CFR 46.116 and/or 21 CFR 50.55(d)(1-4). Examples when assent might be waived include certain school-based behavioral studies or studies that meet the criteria under 45 CFR 46.101(b)(1).

In accordance with and to the extent that consent is required under regulation, the IRB shall determine that adequate provisions are in place for soliciting the permission of each child's parents or guardian. Under DHHS regulations, "guardian" means an individual who is authorized under applicable State or local law, to consent on behalf of a child to general medical care. Under FDA regulations "guardian" means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care when general medical care includes participation in research, or an individual who is authorized to consent on behalf of a child to participate in research.

When research is conducted in Washington, the persons who meet the definition of guardian are court-appointed guardians with the authority to consent to major medical, psychiatric or surgical treatment with specific authorization to consent to research. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research not involving greater than minimal risk or research involving greater than minimal risk but presenting the prospect of direct benefit to the individual participants. If the research is greater than minimal risk and offers no prospect of direct benefit to individual participants, but is likely to yield to generalizable knowledge about the participant's disorder or condition or is not otherwise approvable but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children 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.

In addition to the provisions for waiver of consent contained in DHHS regulations, if the IRB determines that a research protocol is designed for conditions or for a participant population for which parental or guardian permission is not a reasonable requirement to protect the participant (e.g., neglected or abused children) it may waive the consent requirements in 45 CFR 46 provided an appropriate mechanism for protecting the children who will participate as participants in the research is substituted, and provided further that the waiver is not inconsistent with Federal, state or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research participants, and their age, maturity status and condition. This is not applicable to FDA regulated studies. Permission by parents or guardians shall be documented in accordance with and to the extent required by regulations. FDA regulated studies do not qualify for the exception to the requirement to document consent noted at 46.117(c)(1).

Per regulations, children who are wards of the state or other agency, institution, or entity can be included in research involving greater than minimal risk and no prospect of direct benefit to the individual participants, but likely to yield generalizable knowledge about the participant's disorder or condition, or research that is not approvable under a defined regulatory category but that presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children only if the research is 1) related to their status as wards, 2) conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as participants are not wards. If the research is approved, the IRB will require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may be the advocate for more than one child. The individual acting as the advocate shall have the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except as the advocate or IRB member) with the research, the investigators, or the guardian organization.

V. Economically or Educationally Disadvantaged
Economically or educationally disadvantaged individuals may be particularly vulnerable to the risks of research. The IRB may require additional protections. For example, the IRB may require the use of a witness to the consent process or videotaping the consent process.

Educationally disadvantaged participants may not be able to fully understand the concepts presented by the research and the investigator must take extra precautions to ensure that the participants fully understand what is being asked of them. Similarly, economically disadvantaged participants may be easily persuaded to participate in research if the economic compensation is so great that it would result in the participant ignoring or disregarding the research risks because of the income offered by the study. In such cases investigators must be careful to set economic compensation at a
meaningful level that compensates the participant for her/his time, but it not so great that it unduly influences a participant's decision to enroll. It is also important in such cases that the risks to the participants be made clear to the participants.

VI. Heritage University Students

Studies that focus on Heritage University students as participants may raise concerns with issues of coercion, undue influence and privacy. While these studies may qualify for exempt or expedited review, the Chair, or authorized designee reserves the right to require full board review. The IRB may consult with students when considering approval of a study that involves them as participants.

Each application that involves students as participants must outline procedures to ensure that the students will not be subject to undue influence or coercion and to ensure that the student's privacy will be respected. While a PI may use his/her own students as participants, it is preferable for the PI to recruit students with whom he/she does not have a direct relationship. If it is not possible or practical to recruit from the general population of students due to the nature of the research (e.g., research on teaching methods or curriculum development) the study must be designed in such a way that any element of undue influence or coercion is minimized.

Suggestions to minimize elements of undue influence and coercion include anonymous data collection methods and the use of an independent third party to collect data or consent participants (a graduate teaching assistant in the class in which the student/participant is enrolled does not qualify as a third party for collecting the data on behalf of the instructor). In this way, the instructor does not know who did or did not participate. Another is to hold off seeking consent until after course grades have been determined. For example, if the research project involves evaluating the effectiveness of a new teaching method, once final grades are determined, consent from the student should be sought as to whether his/her individual information can be used in the research study. In this way, the element of coercion is minimized since grades would already have been determined. Students should also be recruited by a general announcement, central posting or announcement mechanism and should include a clearly written description of the project and a statement of the proposed student participation. In addition to being provided with the traditional information and consent forms, the student should also be provided with the name and contact information of a neutral third party to contact should they feel coerced at any time during the process. Note: The PI is required to submit the proposed study to the IRB prior to implementing the new teaching method that is the subject of the research and at that time may request the IRB's approval to delay the consent process. Also, the IRB suggests that when students are the targeted population, any payment for participation should be proportionate to the expense incurred with participation, for example parking expenses. Because students are often under financial constraints, larger payments may influence decisions to enroll.

As with all participants, participation must be voluntary and based on disclosure of complete and accurate information. Students should not be asked to participate in any study that will interfere with their curricular activities and obligations. A student's
decision to participate or not participate can not have any bearing on grades awarded by the instructor.

If extra credit is awarded for participation in a study, other comparable means of earning the same amount of extra credit must be available to those students who choose not to participate. Examples of other comparable means include: short papers, special projects, book reports, and brief quizzes on additional readings, research seminars, or completing a similar project. These projects should be comparable in terms of time, effort and educational benefit to participation as a research participant to ensure that students are not being pressured or coerced into becoming participants.

Whenever possible, researchers should avoid data collection during regular class meetings. When study participation consumes a significant portion of a class section, loss of instructional time for both participants and non-participants may be considered a loss of benefits. Also, when research participation is expected during the same session at which participation is invited, students may be unduly influenced to take part due to peer pressure, perceived stigmatization from non-participation, or a sense of having otherwise wasted time by attending that day's class.

Since there are special risks of confidentiality in the close environment of the university, special attention should be given to full disclosure of these risks in the consenting of a student to participate. The plan for handling research data should also be designed to minimize the risk that confidentiality will be breached. When instruments call for the disclosure of information which participants may view as personal or sensitive, data should be collected in a manner that minimizes the chance of one participant learning the response of another.

Students must be allowed to withdraw from the study at any time. The informed consent statement should make clear the consequences of withdrawing from a project prior to completion. In general, it is favorable to give credit if the participant withdraws, unless the student withdraws immediately or there is evidence of bad faith on the part of the student.

If the research is such that data are collected from 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.

Students have the right to full disclosure as soon as possible. Whenever possible a teaching opportunity in the form of an "educational debriefing" should be employed. Students should know something about the rationale for the study, the process of data collection, and intent of the researcher. In exceptional circumstances, the full or true purpose of the research may not be revealed to the participants until the completion of data collection. In such cases, students must not be subjected to undue stress or embarrassment and must have the right to full disclosure of the purpose of the study as soon as possible after the data have been collected. During the debrief students should be
told why the use of deception was necessary to carry out the research and be given an opportunity to decide whether the researcher(s) can use the data collected (refer to Informed Consent Requirements with Use of Deception in Research).

Research conducted by graduate students in a class in which the researcher teaches, assists in the class, or does any grading will be subject to the same restraints described above.

**VII. Heritage University Employees**
Studies that focus on Heritage University employees as participants may raise concerns of coercion, undue influence and privacy. While these studies may qualify for exempt or expedited review, the Chair or authorized designee reserves the right to require full board review. The IRB may consult with employees when considering approval of a study that involves them as participants.

Within each application that involves employees as participants, the PI must outline procedures to ensure that the employees will not be subject to undue influence or coercion and to ensure that the employee's privacy will be respected. While a PI/supervisor may use his/her own direct report employees as participants, the preference of the IRB is that the PI recruit employees with whom the PI does not have a direct relationship. For example, if the research study is an analysis of the performance evaluation process, the PI may recruit employees from the general population of the institution as opposed to employees from the PI's department. If colleagues or subordinates will be recruited the PI must provide a rationale for their recruitment other than for convenience sake.

Additional suggestions to minimize concerns of coercion, undue influence and privacy include the general recruitment of participants through IRB approved advertisements, collection of data in an anonymous method, the use of an independent third party to recruit, consent and/or collect data. The IRB will also closely review how study data is reported back to management.

The employee's participation must be voluntary and based on disclosure of complete and accurate information. Employees should not be asked to participate in any study that will interfere with their job obligations. An employee's decision to participate or not participate can not have any bearing on the employee's performance evaluation. The IRB will follow these same policies and procedures when it reviews research studies that seek to enroll non-Heritage University employees in research.

**VIII. Decisionally Impaired**
Individuals considered to be decisionally impaired may include those with psychiatric, cognitive or developmental disorders, substance abuse problems or individuals in chronic pain. Studies involving decisionally impaired participants may qualify for exempt or expedited review. However, the Chair or designee reserves the right to require full board review. Individuals who are decisionally impaired may still be capable of providing consent. If evidence is present that they are incapable of providing informed consent, for
example, due to the incapacity to understand, an individual who is legally authorized to consent for them must sign and date the consent document. The IRB will make a determination as to whether the target participant population is capable of providing consent or whether a legally authorized representative must provide consent. The IRB may also require additional protections such as a witness to the consent process or requiring the PI to determine on an individual basis whether an individual is capable of providing consent, e.g., the IRB may require that the PI ask the participant to articulate in his/her own words the purpose of the study, the risks involved with the study, the benefits of the study and may request that those responses be documented. If the participant cannot answer such questions, consent from a legally authorized representative must be obtained.

When reviewing protocols that focus on decisionally impaired participants as the target population, the IRB must find that they are an appropriate participant population for the study, that the research question focuses on an issue unique to this population, that the level of risk is appropriate to the study and that, unless a waiver or alteration of consent has been approved, the provisions for obtaining informed consent from a legally authorized representative and the assent of the participant are adequate.

The IRB will use the additional protections set forth in Subpart D 46.404 (Research not involving greater than minimal risk), 46.405 (Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual participants), 46.406 (Research involving greater than minimal risk and no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant's disorder or condition) or 46.407 (Research not otherwise approvable via 404, 405 or 406 which presents an opportunity to understand, prevent or alleviate a serious problem affecting the health or welfare of the individuals) as guiding standards for the review process. Legally authorized representative will be substituted for reference to parent or guardian made in subpart D. Research involving decisionally impaired adults that would fall under category 407 will not require a Secretarial consult but the IRB may call upon consultants with additional expertise.

The provisions for obtaining the assent of an individual with impaired decision making ability are based on those set forth in subpart D. The IRB shall determine that adequate provisions are made for soliciting the assent of the decisionally impaired individual, when in the judgment of the IRB the individuals are capable of providing assent. In determining whether the individuals are capable of assenting, the IRB shall take into account the maturity and psychological state of the individual involved. This judgment may be made for all individuals to be involved in research under a particular protocol, or for each individual, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the individuals 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 individual and is available only in the context of the research, the assent of the individual is not a necessary condition for proceeding with the research. Even where the IRB determines that the participants 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(d)(1-4). For FDA regulated studies, assent may be waived in accordance with 50.55(d)(1-4).

The IRB may impose additional protections. For example, the IRB may require the use of a witness to the consent process or videotaping the consent process. The IRB may also require that the investigator consider the following issues and address each issue as appropriate:

The investigator should explain how he/she plans to determine competency to consent. Observed deficits in cognitive or mental status testing may indicate need to evaluate participant's decision making in more detail. Cognitive functions related to competency are attention, abstraction, judgment, reasoning, memory, learning, comprehension, language expression, mood and affect. In addition, severe decisional impairment to the extent that institutionalization (nursing home, hospitalization) is probable or actual for the potential participant should be considered a criterion in the determination of competency to consent. Components of the research consent capacity should be evaluated and documented during the consent process. The investigator should address how he/she will separate the roles of clinician and clinical investigator, if applicable.

It should be recognized that decision-making capacity may fluctuate, requiring ongoing assessment during the course of the research. The consent process should be ongoing and periodic reconsent may be needed. The investigator should describe his/her process for reconsent or reassent or reassessment of willingness to continue participation. As impairment increases, along with risks and discomforts, safeguards should increase according to a sliding scale, i.e., protections should be proportional to the severity of capacity impairment, or to the magnitude of experimental risk, or both.

**IX. HIV-Infected Individuals**

HIV-infected individuals will be considered a vulnerable population because of the risks of social stigma, employability and insurability facing them if their HIV status were revealed. The University will comply with federal and state guidelines, including those concerning notification of seropositivity, counseling, and safeguarding confidentiality where research activities directly or indirectly involve the study of human immunodeficiency virus (HIV).

All research with HIV-infected individuals is reviewed by the full IRB to ensure that the participants' rights and privacy are thoroughly safeguarded. At such a review the IRB may determine that a particular research study is sufficiently low in risk so as to allow continuing review to be conducted on an expedited basis. Research about HIV/AIDS that does not include HIV-infected individuals may be considered exempt or expeditable. In addition, the IRB will consider the guidelines set forth from OHRP with regards to AIDS/HIV Related Research (OHRP: Institutional Review Board Guidelines, Chapter 5, Section F). When necessary the IRB may call upon consultants with additional expertise in this area.
X. Members of the Armed Forces
Studies that focus on military personnel may also raise concerns of coercion, privacy and, in particular, undue influence. While these studies may qualify for exempt or expedited review, the Chair or authorized designee reserves the right to require full board review. The IRB may consult with military personnel when considering approval of a study that involves them as subjects.

Within each application that involves military personnel as participants, the PI must outline procedures to ensure that personnel will not be subject to undue influence or coercion and to ensure that the employee's privacy will be respected. The IRB suggests that PIs review the Department of Defense (DoD) directive 3216.2 (Reissued March 25, 2002). While this directive concerns clinical research studies, it describes additional protections for certain categories of research that go beyond those outlined in 32 CFR 219 (the DoD implementation of the "Common Rule" Federal Policy) and are relevant for social and behavioral research. The directive includes the following requirements (see section 4.3) to minimize concerns of coercion, undue influence and privacy as they apply to more than minimal risk studies. The requirements include ensuring that unit officers and noncommissioned officers (NCOs) shall not influence the decisions of their subordinates to participate or not to participate as research participants. Unit officers and senior NCOs in the chain of command shall not be present at the time of research subject solicitation and consent during any research recruitment sessions in which members of units under their command are afforded the opportunity to participate as research subjects. When applicable, officers and NCOs so excluded shall be afforded the opportunity to participate as research subjects in a separate recruitment session. During recruitment briefings to a unit where a percentage of the unit is being recruited to participate as a group, an ombudsman not connected in any way with the proposed research or the unit shall be present to monitor that the voluntary nature of individual participants is adequately stressed and that the information provided about the research is adequate and accurate. These requirements should also be taken into consideration for studies not supported by the DoD. The IRB will also closely review how study data is reported back to officers.

The service member's participation must be voluntary and based on disclosure of complete and accurate information. Military personnel should not be asked to participate in any study that will interfere with their responsibilities. A service member's decision to participate or not participate can not have any bearing on the service member's performance evaluation.

XI. Non-English Speaking Individuals
The involvement of non-English speaking individuals in research studies raise concerns with issues of informed consent as well as their inclusion and exclusion in research. While these studies may qualify for exempt or expedited review, the Chair or authorized designee reserves the right to require full board review.

Investigators must be aware that individual participants, and sometimes significant portions of the potential participant population, may not speak English. Investigators
must plan for populations that are likely to be recruited into the research and incorporate translations into the study design to allow for appropriate recruitment and enrollment. When applicable, the PI must outline in the protocol application procedures to recruit non-English speaking participants as well as procedures to translate study material and consent documents. The protocol must also describe procedures for ensuring that informed consent is presented to participants in a language understandable to them. Procedural requirements for the informed consent process for these participants can be found in the informed consent section of the policies (see Consent for Participants Not Fluent in English).

Non-English speaking participants, who meet enrollment criteria, may not be excluded because they cannot understand or read English. Non-English speaking participants may not be excluded from research that may have direct potential benefits. If non-English speaking participants will be specifically excluded from research, the PI must provide an ethical and scientific explanation for doing so.

XII. Indigenous Populations

Indigenous knowledge, traditional resources, and properties are central to the maintenance of identity for indigenous peoples. Traditional resources include plants, animals, and other material objects that may have sacred, ceremonial, heritage, or aesthetic qualities. Property for indigenous peoples has intangible, spiritual manifestations. The term Traditional Resource Rights (TRR) is used to define the many 'bundles of rights' that can be used for protection, compensation, and conservation of resources and properties of indigenous peoples. TRR includes basic human rights, the right to self-determination, collective rights, land and territorial rights, intellectual property rights, rights to protection of cultural property, folklore and cultural heritage, the recognition of cultural landscapes, and recognition of customary law and practice. Every indigenous community has its own customs and laws covering privacy, respect, permission, and compensation for its people during research, exploitation or non-indigenous uses of traditional resources or properties.

Heritage University recognizes and respects TRR of indigenous peoples and undertakes to inform faculty, staff, and students that these must be considered before any activity is undertaken involving TRR. University personnel working with indigenous peoples are expected to adhere to Section III.A. of the Code of Ethics of the American Anthropological Association. If requested by Heritage University, the principal or lead investigator must be prepared to certify that advance permission has been obtained from appropriate individuals or groups of the indigenous peoples to be studied and that the research procedures comply with all applicable tribal, state, and federal laws.

Among American Indian/Alaska Native (AI/AN) nations, groups have rights in addition to those held by individuals. Among those rights are protection of traditional ways of thinking and connecting to the land, the plants, the animals, and the rocks of the places where indigenous people live. Indigenous people have the right to protect their knowledge, their language, their traditional resources, their ceremonies, their songs, and
their traditional properties. As sovereign nations, they have the right to regulate what happens on their lands.

It is the intent of this IRB to be responsive to the concerns and needs of the Yakama Nation. If a researcher intends to conduct research about tribal culture, traditions, language, physical or emotional health, or about the current practices on a tribal reservation, it is the responsibility of the researcher to contact the indigenous nation, find out what their protocol for approving research is, follow that protocol, and obtain permission for the study to proceed. The IRB will ascertain if that process has been followed.

A research proposal for American Indian/Alaska Native people should pay particularly careful attention to confidentiality. Indigenous communities may be small and tightly-knit making confidentiality both more important and more difficult to maintain than in other studies. Protocols should describe precautions for safeguarding the confidentiality of participants. Further, because indigenous people are fewer in number than other populations, they are more easily identifiable. The research protocol should describe how identifiers will be coded or removed.

Some indigenous communities remember being humiliated by research or deceived by it. If deception is necessary, then the research proposal should explain the need for it and describe why the benefit to the community outweighs the risk of damage because of humiliation or deception.

An IRB-1 proposal for American Indian/Alaska Native people should be conducted with the purpose of supporting the interests and visions of the research participants as they define them.