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Policy 4.01

Topic: Full board review
Date of implementation: June 17, 2008
Revision date: October 21, 2009

The fully convened board reviews new applications and applications for continuing review that had been approved by the full board in the past, or had been approved by expedited review but changed such that expedited review would no longer be permitted. Applications that are reviewed by the full board have characteristics that place them in a higher category of risk or uncertainty. Examples include:

- the target participants are from an at-risk population such as the mentally impaired, or individuals engaged in illegal activity
- the research methods involve unusually invasive techniques such as certain types of blood drawing
- the area of research involves an unusually sensitive topic

The Human Protections Coordinator (Human Subjects Coordinator) decides which applications are reviewed by the fully convened Institutional Review Board (IRB).

The purpose for bringing an initial application to the full board is to ensure the thorough examination of the:

- research validity

These policies and related procedures are described here in compliance with the Code of Federal Regulations, Title 45, Part 46.103(b)(4) and 46.103(b)(5)
Institutional Review Board (IRB) – Types of Review

• methodology
• qualifications of the researchers
• data collection instruments
• all related procedures and documents

Being made of experts in a variety of academic fields, the board presents concerns that may not be raised in a review performed solely by the Human Protections Coordinator. Therefore, applications that include questionable or risky characteristics are reviewed and discussed by the fully convened board.

According to HHS regulations 45 CFR 46.111, the IRB shall determine that all of the following requirements are satisfied:

• risks to subjects are minimized by:
• using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk
• whenever appropriate, using procedures already being performed on the subjects for diagnostic or treatment purposes
• risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research).
• the IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility
• selection of subjects is equitable. In making this assessment, the IRB should take into account the purposes of the research and the setting in which the research will be conducted, and should be particularly cognizant of the special problems of research involving vulnerable populations, such as:
  • children
  • prisoners
  • pregnant women
  • mentally disabled persons
  • economically or educationally disadvantaged persons

These policies and related procedures are described here in compliance with the Code of Federal Regulations, Title 45, Part 46.103(b)(4) and 46.103(b)(5)
Institutional Review Board (IRB) – Types of Review

- informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116
- informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117
- when appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects
- when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data
- when some or all of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect the rights and welfare of these subjects

in cases where the IRB lacks sufficient information to make the determinations required for approval by HHS regulations 45 CFR 46.111 (stated above), and, if applicable, subparts B, C, and D of 45 CFR 46, the IRB will defer discussions for further review to a future IRB meeting, so that sufficient information can be gathered and distributed to the board

Policy 4.02

Topic: Full board review – procedures
Date of implementation: June 17, 2008
Revision date: October 12, 2009

Applications that are designated as requiring review by the full board are assigned a primary and secondary board member reviewer, selected by the Human Protections Coordinator. This selection is based on the areas of expertise of the board members. Primary and secondary reviewers are chosen according to whether or not they would have some knowledge, either directly or indirectly, about the topics or issues described in the IRB application.

At least one week prior to the next board meeting, the Human Protections Coordinator sends the IRB application and all supporting documents to all board members, making a specific request that the primary and secondary reviewers prepare their comments regarding the application for the upcoming board meeting. At this time, the Human

These policies and related procedures are described here in compliance with the Code of Federal Regulations, Title 45, Part 46.103(b)(4) and 46.103(b)(5)
Institutional Review Board (IRB) – Types of Review

Protections Coordinator contacts the Principle or Lead Investigators and Faculty Sponsor when applicable, to let them know that their application will be reviewed by the full board and that they are invited to attend the meeting for a question and answer session with the board.

At the board meeting, board members listen to the primary and secondary reviewers’ comments on the application, ask questions, and hold a general discussion. Then, if the investigator has agreed to attend, he or she is asked to enter the meeting for a question and answer period. Any board member or the Human Protections Coordinator can ask the investigator questions, and the researcher can ask questions to the board. When all questions have been asked and answered, the investigator leaves the meeting for the board to sum up their requests to the investigator.

At this point, the board votes on whether they would like to see the investigator’s response to the board’s requests and recommendations at a fully convened meeting, or if they would accept the Human Protections Coordinator’s assessment of how well the investigator responded to the board’s requests and recommendations. If the board votes to accept the Human Protections Coordinator’s assessment, the Human Protections Coordinator would follow that plan and report to the board on the investigator’s compliance at later meetings.

No more than three working days after the meeting in which the application is discussed, the Human Protections Coordinator contacts the PI, LI, and/or Faculty Sponsor to inform them of the status of the application and any changes or requests from the board. The investigator then has 90 days to respond back to the board via the Human Protections Coordinator.

The investigator’s response is reviewed by the Human Protections Coordinator for compliance with board’s requests and recommendations. If the investigator’s response is found to comply with the board’s requests and recommendations by the Human Protections Coordinator, the application is either:

- approved by the Human Protections Coordinator (if so voted in previous board meeting)
- discussed and voted on at the next board meeting for the board’s final approval

These policies and related procedures are described here in compliance with the Code of Federal Regulations, Title 45, Part 46.103(b)(4) and 46.103(b)(5)
Institutional Review Board (IRB) – Types of Review

Once the application is approved, the investigator receives a letter of approval sent by e-mail in PDF format by the Human Protections Coordinator. Only upon receipt of the approval letter from the IRB can the investigator begin the research.

Policy 4.03

Topic: Expedited review – policy
Date of implementation: June 17, 2008

Determination of IRB applications that may be reviewed under expedited review follows Title 45 of the Code of Federal Regulations, 46.110, as quoted below:

“Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.”

The Secretary, HHS, has established and published as a Notice in the Federal Register, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate, after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the Federal Register. A copy of the list is available from the Office for Human Research Protections, HHS, or any successor office.

An IRB may use the expedited review procedure to review either or both of the following:

- some or all of the research appearing on the list and found by the reviewers to involve no more than minimal risk
- minor changes in previously approved research during the period (of one year or less) for which approval is authorized

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in §46.108(b).

These policies and related procedures are described here in compliance with the Code of Federal Regulations, Title 45, Part 46.103(b)(4) and 46.103(b)(5)
Institutional Review Board (IRB) – Types of Review

Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

The department or agency head may restrict, suspend, terminate, or choose not to authorize an institution's or IRB's use of the expedited review procedure.

**Policy 4.03B**

Topic: Expedited review – categories
Date of implementation: October 21, 2009

Research involving no more that minimal risk and in which the only involvement of human subjects will be in one or more of the following categories (carried out through standard methods) may be reviewed by the IRB through the expedited review procedure authorized in 46.110 of 45CFR Part 46. Categories of expedited review include:

- clinical studies of drugs and medical devices only when either of these conditions are met:
- research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
- research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
- from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml. in an eight week period and collection may not occur more frequently than two times per week
- from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn

These policies and related procedures are described here in compliance with the Code of Federal Regulations, Title 45, Part 46.103(b)(4) and 46.103(b)(5)
Institutional Review Board (IRB) – Types of Review

may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week
• prospective collection of biological specimens for research purposes by noninvasive means, including:
  • hair and nail clippings in a non-disfiguring manner
  • deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction
  • permanent teeth if routine patient care indicates a need for extraction
  • excreta and external secretions (including sweat)
  • uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue
  • placenta removed at delivery
  • amniotic fluid obtained at the time of rupture of the membrane prior to or during labor
  • supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques
  • mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings
  • sputum collected after saline mist nebulization
  • collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples include:
    • physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject=s privacy
    • weighing or testing sensory acuity
    • magnetic resonance imaging
    • electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electoretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography

These policies and related procedures are described here in compliance with the Code of Federal Regulations, Title 45, Part 46.103(b)(4) and 46.103(b)(5)
Institutional Review Board (IRB) – Types of Review

• moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual
• research involving materials that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
• collection of data from voice, video, digital, or image recordings made for research purposes
• research on individual or group characteristics or behavior, including research on:
  • perception
  • cognition
  • motivation
  • identity
  • language
  • communication
  • cultural beliefs or practices
  • research employing:
    • survey
    • interview
    • oral history
    • focus group
    • program evaluation
    • human factors evaluation
    • quality assurance methodologies
• continuing review of research previously approved by the convened IRB as follows:
  • where the research is permanently closed to the enrollment of new subjects
  • all subjects have completed all research-related interventions
  • the research remains active only for long-term follow-up of subjects
  • where no subjects have been enrolled and no additional risks have been identified; or
  • where the remaining research activities are limited to data analysis

These policies and related procedures are described here in compliance with the Code of Federal Regulations, Title 45, Part 46.103(b)(4) and 46.103(b)(5)
Institutional Review Board (IRB) – Types of Review

continuing review of research, not conducted under an investigational new drug application or investigational device exemption but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified

Policy 4.04

Topic: Exempt review – policy
Date of implementation: June 17, 2008

Determination of IRB applications that may be reviewed under exempt review follows Title 45 of the Code of Federal Regulations, 46.101, as quoted below:

“Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

- research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
- research on regular and special education instructional strategies
- research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods
- research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
- information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects
- any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation
- research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt if:
- the human subjects are elected or appointed public officials or candidates for public office

These policies and related procedures are described here in compliance with the Code of Federal Regulations, Title 45, Part 46.103(b)(4) and 46.103(b)(5)
Institutional Review Board (IRB) – Types of Review

• federal statutes require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
• research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects
• research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
  • public benefit or service programs
  • procedures for obtaining benefits or services under those programs
  • possible changes in or alternatives to those programs or procedures
  • possible changes in methods or levels of payment for benefits or services under those programs

6. taste and food quality evaluation and consumer acceptance studies, if:
  • wholesome foods without additives are consumed
  • a food is consumed that contains a food ingredient at or below the level and for a use found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture
  • agricultural, chemical, or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture
  • department or agency heads retain final judgment as to whether a particular activity is covered by this policy
  • department or agency heads may require that specific research activities or classes of research activities conducted, supported, or otherwise subject to regulation by the department or agency but not otherwise covered by this policy, comply with some or all of the requirements of this policy
  • compliance with this policy requires compliance with pertinent federal laws or regulations which provide additional protections for human subjects

These policies and related procedures are described here in compliance with the Code of Federal Regulations, Title 45, Part 46.103(b)(4) and 46.103(b)(5)
Institutional Review Board (IRB) – Types of Review

• this policy does not affect any state or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.
• this policy does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.
• when research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the department or agency head, notices of these actions as they occur will be published in the Federal Register or will be otherwise published as provided in department or agency procedures.
• unless otherwise required by law, department or agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities or classes, or research activities otherwise covered by this policy. Except when otherwise required by statute or Executive Order, the department or agency head shall forward advance notices of these actions to the Office for Human Research Protections, Department of Health and Human Services (HHS), or any successor office, and shall also publish them in the FEDERAL REGISTER or in such other manner as provided in department or agency procedures.
• institutions with HHS-approved assurances on file will abide by provisions of Title 45 CFR part 46 subparts A-D. Some of the other departments and agencies have incorporated all provisions of Title 45 CFR part 46 into their policies and procedures as well. However, the exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, subpart C. The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, subpart D, except for research involving observations of public behavior when the investigators do not participate in the activities being observed.

These policies and related procedures are described here in compliance with the Code of Federal Regulations, Title 45, Part 46.103(b)(4) and 46.103(b)(5)
Institutional Review Board (IRB) – Types of Review

Policy 4.05

Topic: Exempt and expedited review – procedures  
Date of implementation: June 17, 2008  
Revision date: October 21, 2009

The Human Protections Coordinator reviews all applications to determine the level of review (exempt, expedited, or full board). Research determined to involve no more than minimal risk to participants are reviewed using an exempt or expedited review procedure. Applications designated as qualifying for exempt or expedited review are reviewed and approved by the Human Protections Coordinator, who is a member of the board designated by the Northern Arizona University IRB Chair to review and approve studies qualifying for expedited review and has written permission from the IRB Chair. If no such permission is granted, applications are reviewed and approved by the IRB Chair or designate.

Exempt and expedited review categories are limited to initial or continuing review of research that falls under the categories listed in Policy 4.03B (expedited categories) and Policy 4.04 (exempt categories) per 45CFR46.101 and 110. The Human Protections Coordinator reviews exempt and expedited applications using a checklist form. If the application does not require additional information or documents, revisions, or changes, the Human Protections Coordinator approves the application (if permitted to approve by the IRB Chair) and sends a letter of approval to the investigator, along with any stamped approved informed consent forms in PDF format, if included.

The Human Protections Coordinator contacts investigators whose applications require additional information or documents, revisions, or changes by email, and waits to hear a response from the investigator, who has 90 days to respond (see policy 3.05, Applications Not Yet Approved). The investigator’s response is reviewed by the Human Protections Coordinator for compliance with the requests and recommendations. If the investigator’s response is found to comply with the requests and recommendations, the application is approved by the Human Protections (if permitted to approve by the IRB Chair). Once the application is approved, the investigator receives a letter of approval sent by email in PDF format by the Human Protections Coordinator. Only upon receipt of the approval letter from the IRB can the investigator begin the research.

These policies and related procedures are described here in compliance with the Code of Federal Regulations, Title 45, Part 46.103(b)(4) and 46.103(b)(5)
Institutional Review Board (IRB) – Types of Review

Applications approved under expedited review are approved for no more than 365 days. An approval of less than 365 days is based on factors such as extent of risk to participants, inclusion of special populations, or some other factor that would warrant more frequent IRB review. Applications approved under exempt review are approved indefinitely. In either case, investigators must submit an Amendment to Research form (available on the IRB website) to report any changes in their research plan, at which point the type of review could be reassigned.

Policy 4.06

Topic: Continuing review of research
Date of implementation: June 17, 2008
Revision date: October 21, 2009

Full board and expedited human subjects approval must be renewed no less frequently than once a year. To continue human subjects’ protection for approved studies, researchers file an Application for Continuing Review with the IRB before the expiration of their IRB approval. The Application for Continuing Review is available on the IRB website and can be submitted electronically to the IRB.

The IRB will send a letter to investigators reminding them to file an application for Continuing Review 30 days or more prior to the expiration of their approval. If an investigator continues to engage in the research by, for example, enrolling participants, collecting data, or analyzing data, he or she will need to file an Application for Continuing Review. If the IRB office does not hear a response within 30 days of the date of the letter, the study will be assumed to be completed and the IRB will close that study. If the researcher decides to re-activate the study after it has been closed, it will be treated as a new study and a new IRB application will need to be submitted.

The Application for Continuing Review consists of:

- questions regarding the current stage of the research
- any changes in participant population or procedures
- any complications
- adverse reactions
- unforeseen events

These policies and related procedures are described here in compliance with the Code of Federal Regulations, Title 45, Part 46.103(b)(4) and 46.103(b)(5)
Institutional Review Board (IRB) – Types of Review

If the study was originally approved under full board review, then the continuation must be reviewed by the fully convened board at the next scheduled meeting. In cases of expedited review, the investigators’ responses are reviewed by the Human Protections Coordinator, who is a member of the board designated by the Northern Arizona University IRB Chair to review and approve studies qualifying for expedited review.

If no problems are reported and the research seems to be going along as planned, the project is approved for another period of up to 365 days from date of approval expiration. If problems that seem to incur a greater risk to participants than previously believed are reported, the investigators are referred to the policy on adverse events. This may result in several outcomes ranging from a revision of procedures to the discontinuation of the research.

Once the application is approved, the investigators receive a letter of approval sent by e-mail in PDF format by the Human Protections Coordinator. In many cases, applications are approved for an additional 365 days. An approval of less than 365 days is determined based on factors such as extent of risk to participants, inclusion of special populations, or some other factor that would warrant more frequent IRB review.

Policy 4.07

Topic: Reciprocal agreement with University of Arizona and Arizona State University
Date of implementation: April 14, 2008

Read more

Research projects that are collaborative among researchers from Northern Arizona University, the University of Arizona, and/or Arizona State University are subject to the signed Authorization Agreement of April, 2008. Projects that have been reviewed by the Arizona State University or University of Arizona IRBs are not required to be reviewed separately by the Northern Arizona University IRB. However, the Northern Arizona University IRB must be informed of any such approved projects. Investigators must submit hard copies of their original IRB applications and the approval letter from the University of Arizona or Arizona State University IRB to the Northern Arizona University IRB office.

These policies and related procedures are described here in compliance with the Code of Federal Regulations, Title 45, Part 46.103(b)(4) and 46.103(b)(5)
Institutional Review Board (IRB) – Types of Review

Pursuant to this agreement, IRB review shall be assigned to the home institution of the Principal Investigator.

• **University of Arizona or Arizona State University IRB review:** When University of Arizona or Arizona State University is the designated IRB of record, then the Northern Arizona University IRB will not review the project. Northern Arizona University may rely on the review, approval, and continuing oversight by the University of Arizona and Arizona State University’s IRB of those protocols approved by University of Arizona and Arizona State University pursuant to the terms of this agreement. University of Arizona and Arizona State University represent that such review, approval, and continuing oversight performed by their IRBs will satisfy the requirements of the HHS regulations for the protection of human subjects at 45 C.F.R. Part 46, 21 C.F.R. 50, 56 and 812 as well as the requirements of the assurance, and that their review of projects shall be conducted in accordance with all applicable federal and state laws.

• **Northern Arizona University IRB review:** When Northern Arizona University is the designated IRB of record, then the University of Arizona and Arizona State University IRB will not review the project. The University of Arizona and Arizona State University may rely on the review, approval, and continuing oversight by the Northern Arizona University IRB of those Protocols approved by Northern Arizona University pursuant to the terms of this Agreement. Northern Arizona University represents that such review, approval, and continuing oversight performed by the Northern Arizona University IRB will satisfy the requirements for the HHS regulations for the protection of human subjects at 45 C.F.R. Part 46, 21 C.F.R. 50, 56 and 812 as well as requirements of the Northern Arizona University assurance, and that its review of Projects shall be conducted in accordance with all applicable Federal and State laws.

• **Co-principal Investigators from two or more institutions:** If there are co-principal investigators from more than one institution on a project, the investigators shall present the project to their respective institution’s IRBs with a cover letter requesting that one IRB become the reviewing IRB. IRB chairs, their co-chairs, or designees shall jointly determine which IRB will become the reviewing IRB.

The IRB Chair, Co-Chair or designee from the non-reviewing institution will be responsible for consulting as necessary with the designated reviewing IRB and will be

These policies and related procedures are described here in compliance with the Code of Federal Regulations, Title 45, Part 46.103(b)(4) and 46.103(b)(5)
Institutional Review Board (IRB) – Types of Review

responsible for performing the local review for context as required by federal regulation.

No principal investigator, no co-investigator, or other individual with a conflict of interest on a project shall participate in the University of Arizona, Arizona State University, or Northern Arizona University IRB review of, continuing review of, or other IRB deliberations concerning a project for which they are involved.

These policies and related procedures are described here in compliance with the Code of Federal Regulations, Title 45, Part 46.103(b)(4) and 46.103(b)(5).