III. The Institutional Review Board (IRB).....20
A.

**Mandatory Changes.** Policy and Procedure changes based on mandatory regulatory/statutory requirements do not require review or approval of the IRB, and will take effect on either the date specified by OHRP, or if no date is specified, as determined by the IRB Administrator.

**Emergency Changes.** The Institutional Official (UNE VPR), IRB Administrator, IRB chair or other official designated by the VPR may implement any emergency Policies and Procedures necessary to:

- Prevent harm to research subjects;
- Correct a latent policy issue; x

# II. Protection of Human Subjects

In 1974 the National Research Act established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This Commission in turn published The Belmont Report which articulated the ethical principles that guide human subjects research and served as the foundation for Title 45, Code of Federal Regulations, Part 46 (hereafter 45 CFR 46).

## A. Ethical Principles Governing Human Subjects Research

UNE is guided by the three ethical principles of research set forth in the Belmont Report. These principles are: respect for persons, beneficence, and justice.

### A.1. Respect for Persons

Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two

Respecting persons, in most hard cases, is often a matter of balancing competing claims urged by the principle of respect itself.

## A.2. Beneficence

Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such 4( i)3(sei)i2u

5. A description of any benefits to the subject or to others which may reasonably be expected from the research (if no foreseeable benefit exists, then a statement to that effect is appropriate);
6. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
7.

In addition, the subject must also be informed of any recent significant findings discovered during the course of the research study.

Use of Specimens for Future Research. If specimens are to be stored for use in future research, this information must be included in the informed consent process and the informed consent documentation. Further, it is the policy of the UNE IRB to require that a specific consent statement be included in consent forms that ask subjects to grant permission to store specimens for future research use. The purpose of the extra consent statement is to clearly indicate that the subject can participate in the current research study without agreeing to have specimens stored for future research. The only case where the separate consent line is not required is when the purpose of the current research study is to collect specimens for the purpose of storing them for future research or use.

## B.2. Documentation of Informed Consent

Informed consent must be documented by the use of a written consent form approved by the IRB. Consent forms serve as confirmation of the process of obtaining ihis inonsentd44211(t)-7(2)]TJ 0

## C.1. Minors (under 18 years of age)

In order to approve research involving children, the IRB must determine that the research meets one of the categories defined below:

1. Research not involving greater than minimal risk to the children (45 CFR 46.404).
    - The research presents no greater than minimal risk to the children; and
    - Adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in HHS regulations at 45 CFR 46.408.
2. Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child subjects involved in the research (45 CFR 46.405).
    - The risk is justified by the anticipated benefits to the subjects;
    - The relation of the anticipated benefit to the risk presented by the study is at least as favorable to the subjects as that provided by available alternative approaches; and
    - Adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in HHS regulations at 45 CFR 46.408.
3. Research involving greater than minimal risk and no prospect of direct benefit to the individual child subjects involved in the research, but likely to yield generalizable knowledge about the subject's disorder or condition (45 CFR 46.406) if:
    - The risk of the research represents a minor increase over minimal risk;
    - The intervention or procedure presents experiences to the child subjects 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 subject's disorder or condition which is of vital importance for the understanding or amelioration of the disorder or condition; and
    - Adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in HHS regulations at 45 CFR 46.408.
4. Research that the IRB believes does not meet the conditions of 45 CFR 46.404, 46.405, or 46.406, but finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children (45 CFR 46.407)

- Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in HHS regulations at 45 CFR.

The exemption at 46.101(b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research involving children, except for research involving research observation of public behavior when the investigator(s) do not participate in the activities being observed.

In all human subject research, the agreement of the subject to participate is an essential protection of the subject's rights and welfare. Minors, by definition, cannot give legal "consent". Therefore, a combination of "assent" (agreement) of the minor and "permission" (agreement) of the parent(s) or legal guardian(s) is generally deemed an adequate substitute. If either parent refuses permission or the minor subject refuses assent, the minor should not be enrolled in the research project.

Parental Consent: 'A parent' means a child's biological or adoptive parent. The UNE IRB requires the permission of both parents be given for research involving minors, unless:

- One parent cannot reasonably be found or contacted in a reasonable time period (typically 60 days);
- One parent is deceased;
- One parent has lost or surrendered all legal parental rights; or
- One parent has been granted by the court sole custody and all parental rights

There may be exceptions to this general policy that the IRB will determine on a case-by-case basis.

Legal Guardians vs. Caregivers: 'Guardian' means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care. The permission of caregivers and/or service providers is not sufficient to conduct research with minors. Only parents and legal guardians have that authority and responsibility. School principals, teachers, clinic personnel, etc., do not have the authority to give "blanket" permission for their students/patients/clients to participate in research. They do have the authority to permit the research to be conducted in the facility under their auspices. (This permission should be made part of the study submission.) In classroom research, it must be made clear that the research is not part of the regular educational program and that the student's grades or standing will not be affected by participating or not participating.

the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

Wards: Children who are wards of the state or any other agency, institution, or entity can be included in research approved under 45 CFR 46.406 or 46.407 only if such research is: (1) Related to their status as wards; or (2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards. In such instances, the IRB is required to appoint an advocate for each ward (See 45 CFR 46.409 for more details).

## C.2. Subjects with a Diminished Capacity to Consent

Individuals in a wide variety of circumstances may have an impaired ability to make an informed decision. An impaired decision making capacity may not be limited to neurological, psychiatric, or substance abuse populations, nor should it be assumed that these populations automatically have diminished decision capabilities. Limited decision making capacity covers a broad spectrum, including a healthy person in shock or experiencing high stress, a severely mentally retarded individual since birth, or an individual in an acute psychotic state. Researchers must be sensitive to the fluctuating capacities of individuals and design the consent procedures accordingly.

Some research questions may only be answered in populations with an impaired decision making capacity. In these matters, investigators and members of the research team are responsible for protecting research participants.

Consent procedures must be proportional to the research risk. As impairment increases, so does risk and discomfort associated with the study and the safeguards should increase on a sliding scale. When a researcher is determining a participant's capacity for decision-making, a key factor is the participant's appreciation of how the risks, benefits and alternatives to participation apply to them personally. It is advisable that the consent processes actually include the researcher asking the participant; "Do you understand the risks and benefits of participation?" or "Do you have any questions about the study or process?" Options for additional safeguards include the use of an independent monitor, use of a legally authorized representative, use of assent and a legally authorized individual, use of an advance directive as local laws permit, or use of a waiting period.

In addition, researchers may need to write their informed consent forms (and assent forms, as appropriate) at a lower reading level in order to compensate for potential diminished capacity. For example, a mentally challenged individual who is their own legal guardian and has full control over their own activities of daily living (ADL's), may still only have a 4th Grade reading level.

## C.3. Pregnant Women, Human Fetuses, Neonates, and Products of Labor and Delivery

Pregnancy encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery. Definitions for delivery, fetus, dead fetus, neonate and nonviable neonate can be found in the glossary of this manual.

Pregnant women or fetuses may be involved in research if all of the following conditions are met:

- Where scientifically appropriate, preclinical studies, including on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;
- 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;
- Any risk is the least possible for achieving the objectives of the research;
- If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman not 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, her consent is obtained in accord with the informed consent provisions;
- 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 provisions except that 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;
- Each individual providing consent is fully informed regarding the reasonably forseeable impact of the research on the fetus or neonate;
- For children who are pregnant, assent and permission are obtained with the provisions for children in research.
- No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
- Individuals engaged in the research will have no part in any decisions as to the

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Furthermore, research in the latter two categories may proceed only after the Secretary of DHHS has consulted appropriate experts and published notice in the Federal Register of his/her intent to approve such research:

2. Conditions for Approval of Prisoner Research: All of the following conditions must be found to be in place by the IRB at a convened meeting.

   - Any possible advantages accruing to the prisoner through his or her participation in the research 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 subjects.
   - Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for the particular research study, unless the principal investigator provides to the IRB justification, in writing, for following some other procedure.
   - The information is presented in language that is understandable to the subject population.
   - 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.
   - If there is a need for follow-up examination or care of participants after 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.

## C.6. Students

Use of students as research subjects presents a special set of concerns, whether the students are at UNE or other educational institutions. This includes not only research studies that specifically recruit students, but also studies that are advertised on campus. Students may be below the age of consent, which in Maine is 18. Therefore, the special requirements for studies involving minors apply to such studies. One solution is to limit inclusion to individuals over the age of consent.

An additional concern in studies that involve students is the possibility of undue influence. Recruitment of a subject by his or her advisor or faculty member holds the potential for undue influence. This also holds true whenever a student's participation will be made known to someone who holds power over that student's academic status or extra credit for course grading purposes.

Since participation in a research study must be completely voluntary, there must not be any loss of academic status if a student chooses not to participate. If academic benefits are offered as compensation for participation in a study, an equivalent alternative activity must be offered (with the same academic benefit offered) to students who choose not to participate. It is preferable, whenever possible, for the student’s decision to remain unknown to the advisor or faculty member.

The above issues must be addressed in all research studies involving students.

## D. Protected Health Information

The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (see http://www.hhs.gov/ocr/privacy/hipaa/understanding/index.html) governs dissemination of protected health information by covered entities.

'Protected health information' (PHI): Individually identifiable information about a person's health, whether it is transmitted by, or maintained in, electronic media or any other form or medium. PHI does not include individually identifiable health information in: (a) education records covered by the Family Educational Rights and Privacy Act (FERPA) or (b) employment records held by the University of New England in its role as employer.

'Covered entity' (CE): An entity to which HIPAA Privacy Regulations apply.

.The following parts of UNE qualify as a covered entity:

- University HealthCare (UHC)
- UHC Student Health Biddeford campus
- UHC OMM (Alfond)
- UHC Family Medicine (Saco)
- UHC OMM Saco
- UHC for Kids (Portland)
- UHC MatureCare

  - The UNE IRB does not review HIPAA applications for research activities conducted at sites other than UNE's CE. In those instances, the investigator should instead submit documentation of approval from the non-UNE CE and/or its IRB, as applicable.

- The investigator must complete HCCS/HIPAA training and submit evidence of completion along with the applications.
- The investigator must submit with the applications a letter from the senior administrator at each CE where they propose to obtain PHI. The UNE HIPPA Privacy Officer should be contacted to determine the appropriate senior administrator.
- The IRB Administrator forwards the HIPAA application to the HIPAA Privacy Officer, who will return it promptly with a written opinion as to compliance with federal and institutional requirements.
- The IRB will then review the HIPAA application along with the IRB application, following procedures set forth in this manual.

## D.1. Preparation for Research

Criteria:

- The use or disclosure of PHI is for the sole purpose of preparing a research protocol.
- No PHI will be removed from the CE.
- The PHI is necessary for the research purpose.

Investigators should submit a written request for approval to use PHI in preparation for research to the UNE HIPAA Privacy Officer.

## D.2. Deceased Subjects

Criteria:

- The use or disclosure of PHI is for the sole purpose of research concerning deceased subjects
- The PHI is necessary for the research purpose.

Investigators should submit a written request for approval to use PHI of deceased subjects to the UNE HIPAA Privacy Officer. The CE may request documentation of the death of such individuals.

## D.3. Limited Data Set with Data Use Agreement

Criteria:

- The data set that includes PHI excludes most individual identifiers
- Some individual identifiers are necessary for the research purpose, and therefore the data set fails to qualify as de-identified data (see D.6. below)

Investigators should submit a written request for approval to use PHI in a limited data set to the UNE HIPAA Privacy Officer. A data use agreement between the researcher and the CE providing the limited data set will be required.

**Research activity, including recruitment of subjects, may not begin without written approval from the IRB, and may not continue after IRB approval has ended.** If a researcher is found to be collecting data without IRB approval, the IRB will immediately suspend all research activity pending IRB review and approval, and may require the researcher to expunge the data.

## B.1. Submission Requirements

Every investigator who conducts an activity that *might be considered* research involving human subjects must submit an application or report to the IRB on each of the following occasions, described later in this section:

- Apply for Determination of "Not Research eith Human Subjects", Exemption, or Review and Approval before commencing activity;
- Apply for Renewal before approval expires;
- Apply for Approval of Protocol Amendment before changing an approved protocol;
- Report all Important Events (Significant Protocol Deviations, Unanticipated Problems, and Serious Adverse Events);
- Report the Conclusion of the research.

**A submission is considered complete only when it satisfies all four of these requirements:**

1. Each submission must utilize the appropriate form found at: http://www.une.edu/research/compliance
2. Each submission must answer all questions fully and in sufficient detail to allow IRB reviewers to make the determinations required under HHS regulations at 45 CFR 46.111.
3. Each submission must include all attachments requested in the form.
4. Each submission must be submitted in two formats, as follows:
   - **Electronically** to irb@une.edu. Word .doc or .pdf format is required.
   - A **hard copy**, with required signatures, to the IRB Administrator, Pickus Room 108, 11 Hills Beach Road, Biddeford, ME 04005

Applications that do not require review by the full IRB may be filed at any time, and are addressed on a rolling basis:

- *Application for Determination of "Not Research Involving Human Subjects"* (Section IV.A)
- *Application for Exemption* (Section IV.B).
- Applications that request and qualify for Expedited Review (Section IV.C.3). Those that do not qualify will be referred to the full IRB.

Applications requiring review by the full IRB. The IRB is scheduled in advance to meet once per month throughout the year. Because of necessary preparation time, the IRB will review only those complete applications that are received electronically no later than the **1st day of the month by 4:00 pm**, and in hard copy within 3 days thereafter. If the first of the month falls on a non-work day, submissions must be received by 4:00 pm on the previous work day. **There is no provision for exceptions.**

# IV. IRB Procedures

The investigator should submit an application for the category of review that s/he believes best matches the planned activity. The criteria for each category are explained below. Nevertheless, **only the IRB can determine the correct category of review.**

## A. Not Research with Human Subjects

### A.1. Criteria for "Not Research with Human Subjects"

In determining whether an activity constitutes research with human subjects, the IRB will apply the following definitions from 45 CFR 46.102:

'Research' means a systematic investigation - including research development, testing and evaluation - designed to develop or contribute to generalizable knowledge.

- Research may take place as part of a demonstration or service program.

- The level of risk has no bearing on whether or not a proposed activity constitutes "research".

- 'Generalizable knowledge' is information that has the potential to be expanded from the isolated circumstances in which it is acquired to any broader context. (Thus, a case study that illuminates the course of a single individual's experience generally will not be considered to be research, whereas a series of case studies intended to lead to improvements in the management of a particular condition generally will be considered research).

'Human Subject' means 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.

'Intervention' includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

'Interaction' includes communication or interpersonal contact between investigator and subject.

## A.2. Procedures for Determination of "Not Research with Human Subjects"

The investigator should send a "Request for Determination" letter to the IRB electronically to irb@une.edu describing the proposed activity and why it might or might not be considered research, taking care to address explicitly each of the criteria identified above. The IRB Chair, in consultation with the IRB Administrator, will make a preliminary determination and promptly convey its determination to the investigator, in writing.

- If the activity is determined not to be research with human subjects, the investigator will not be required to have any further interaction with the IRB, *provided*:
  - If there is a change in any material fact upon which the determination was based, the investigator is required to notify the IRB chair and renew the request.
  - If the activity entails collecting protected health information (PHI), the investigator is still required to submit a HIPAA application to the UNE HIPAA Privacy Officer (see Section II.D).
- If the activity is determined to be research with human subjects, the investigator must file the appropriate application for exemption or for review and approval.

## A.3. Student Research Projects

Student **research** involving **human subjects** is subject to the requirements of this policy, procedure and guidance document.

**'Research'** means a systematic investigation - including research development, testing and evaluation -

(1) Research conducted in established or commonly accepted educational settings, n-1ongle]TJ 0 d-1oesnokP[(nos)11( 9(o)u( )]TJ 0 ap-,)- ed4(ude]TJ 0 -1.141 TD [(i)3(nv)aco)-2(i(i)3(

4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative.
5. Informed consent will be appropriately documented.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
8. 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 vulnerable subjects.

## C.2. Content of the Application

In completing the Application for Initial Review and Approval, applicants are expected to address the following topics:

1.

## C.3. Expedited Review

Under Expedited Review procedures, detailed in under 45 CFR 46.110, the review and approval process rests with one or more experienced IRB members assigned by the IRB Chair to review the full submission. **'Expedited' does not mean that the review process takes less time.**

### *Criteria for Expedited Review*

Expedited Review will only be used for activities that:

A. Involve no more than minimal risk to the research subjects, **and**

> 'Minimal Risk' means 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 living or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102 (i)).

B. Involve only procedures listed in one or more of the following categories specified in 63 FR 60364-60367, November 9, 1998:

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not reqegor

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch 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.)

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

(8) Continuing review of research previously approved by the convened IRB as follows:

(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

(b) where no subjects have been enrolled and no additional risks have been identified; or

(c) where the remaining research activities are limited to data analysis.

(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply 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.

### *Procedures for Expedited Review*

If the researcher believes the research qualifies for Expedited Review, s/he should indicate on the application which category(ies) of expedited review may apply to the project. Nevertheless, **only the IRB can determine whether a proposed project qualifies for Expedited Review.**

The IRB Chair, in consultation with the IRB Administrator, will make a determination of whether an application qualifies for expedited review.

- If the IRB Chair determines that the application qualifies for expedited review, s/he will assign one or more IRB members to review it.
- If the IRB Chair - or the reviewer(s) - determine that the application does not meet the criteria for expedited review, or if the reviewer(s) fail to approve the protocol, it will be reviewed by the full board.

The IRB Chair will promptly convey its determination and any review findings to the investigator, in writing. The IRB Administrator will advise members of research protocols which have been approved under this procedure at monthly IRB meetings.

## C.4. Full Board Review

Unless an application is eligible for Expedited Review, it will undergo full board review at a duly convened meeting of the IRB at which a majority of the members are present, including

at least one member whose primary concerns are in nonscientific areas. Prior to the meeting each member receives the full submission.

The full board will discuss the application, and may take one of several actions including:

1. Approve the protocol as submitted;
2. Approve the protocol contingent upon changes;
3. Table the application until the next meeting to allow the applicant to address IRB concerns; or
4. Deny the application.

Additional actions that the IRB is authorized to take include:

5. Recommend the protocol be jointly reviewed by another committee that has the expertise or authority over a particular subject matter (e.g., the Institutional Biosafety Committee for research involving human blood samples, or by another IRB);
6. Require a primary investigator to apply for a Certificate of Confidentiality from the National Institutes of Health, to protect research data from legal demands (for more information see http://grants1.nih.gov/grants/policy/coc/).

## C.5. Notification

The IRB Chair will notify the Principal Investigator of the IRB's findings and actions in a letter which details the IRB's decision, sets forth any conditions of approval (clarification or modification), and/or invites resubmission after the protocol is revised.

Responses to the IRB's request for information or modification are expected within 60 days or the application will be withdrawn and a new one must be submitted. Timely responses will be revioc(i)3(c(onse)-ti)3(ioc(id(e)-3in(e)-3t02 Tc 0.002 Tw 3.92054 -i)3(ssi)-1(on a)11(f)7 )-2(r/0:9206tn5

a) authorization by the institution for the investigator to conduct the study at the institution;
b) assurance that the project has been reviewed by institution personnel with respect to appropriateness for its human subjects population;
c) if applicable, assurance that personnel from the institution who collect data have the appropriate expertise to carry out the research protocol as reviewed and approved by the UNE IRB; and
d) all research staff from the off-site institution listed on the UNE IRB application have completed the CITI human subjects training within the past 24 months.

3. **Multiple Sites with UNE Lead Investigator**. In research involving multiple sites where a UNE investigator is the lead investigator, the investigator provides additional information to the UNE IRB to ensure ongoing communication among the cooperating institutions and IRBs. The UNE investigator should submit the following information with the UNE IRB application:
    a) a contact name and contact information for each off-site institution;
    b) the FWA number for each off-site institution with an approved FWA;
    c) a plan for the management of information pertaining to the protection of human subjects, such as reporting protocol modifications and unanticipated problems, and reporting results, such as interim reports,

3. Cultural consultants may review consent documents, provide verification of translation, and provide guidance on the impact of the research on subjects and the impact of the culture on the research to be conducted.

## D. Ongoing Research

Whenever the IRB approves a protocol, it must establish the duration of the approval (and, consequently, the frequency of continuing review), which may not exceed one year. In addition, the IRB has the responsibility and the authority to monitor approved protocols, in order to verify from sources other than the investigators that no material changes have occurred since the previous IRB review.

### D.1. Criteria for Monitoring and Frequency of Review

The following conditions, but not limited to these, may form a basis for monitoring, or for establishing a shorter than one year approval period:

1. Protocols:
   - Novel or new interventions in a biomedical study;
   - Especially high risk protocols;
   - Involving especially high risk/vulnerable populations and/or groups highly susceptible to coercion;
   -

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When a determination has been made that monitoring will occur on a protocol investigators are notified in writing, of the monitoring process and the procedures the IRB Chair and/or IRB Administrator will employ in monitoring the identified protocol. The investigator will be notified of all relevant findings as a result of protocol monitoring. When appropriate the Sponsor will also be notified.

## D.3.

2. Withdrawal of subjects from the research since the last IRB review;
3. A summary of any unanticipated problems, and available information regarding adverse events;
4. A summary of any complaints about the research since the last IRB review;
5. Information regarding any amendments or modifi

Investigators may also be obligated under other policies, regulations or laws to report

- Any assigned Investigator(s);
- Any required or assigned specialists.

The committee will review the event report, the original IRB review forms, the original approval letter, renewals, and any IRB protocol monitoring notes for possible links of the event with the research procedure. The committee will discuss the protocol in light of the event, using the same criteria as for an Application for Initial Approval (see Section D2 above) to assure that the protocol continues to adequately protect research participants.

Depending on the nature and the seriousness of the event, the committee may, upon a majority vote, direct the IRB to take any of the following actions:

- Suspend or terminate the protocol. If suspension of the protocol or study procedures would result in harm to the enrolled research participants, the IRB chair or the designated investigator(s) will request that the Principal Investigator's department chair assign Principal Investigator's duties to another qualified person and submit an Application for Protocol Amendment, explaining this substitution and indicating temporary closure of the study. In this situation the official action will be the suspension of the investigator (45 CFR 46.109 (d)).
- Audit all protocols involving the Principal Investigator in question using procedures for monitoring enumerated in Section IV.D.2. s 11(t) Tf 36

# V. IRB Structure

Any IRB member may voluntarily resign their membership with advanced notice. As a matter of courtesy, it is requested that any member wishing to do so provide a written notice to the IRB Chair and to their Dept. Chair and Dean, at least 60 days prior to leaving. No justification is required.

An IRB member (including the IRB Chair) may be involuntarily terminated from the IRB for:

- Professional misconduct;
- Research misconduct, as defined under federal regulations;
- Breach of membership duties, e.g., attendance;
- Unethical or illegal activities related to their duties and obligations to the IRB; or
- A supermajority (75%) vote of all IRB voting members (minus the member in question).

The IRB Administrator will maintain an official roster of IRB membership, and update the official IRB roster of members with OHRP as is required under the terms of our Federalwide Assurance.

## A.3. Member Duties

All members, including the chair, have full voting rights and privileges.

All members are expected to:

1. Attend regularly scheduled meetings or notify the IRB Administrator in advance if unable to attend. Frequent absence may result in loss of membership status;
2. Serve as a reviewer for expedited protocols, and/or serve as primary reviewer for Full-Board reviews, upon request;
3. Sufficiently prepare for protocol reviews by reading all submitted application materials, and take an active part in the deliberation process when present for full board meetings;
4. Recuse oneself from voting or participating in IRB business when the member is the topic of business, including when the member is the PI or key personnel on an application under review;
5. Recuse oneself from voting or participating in IRB business when the member has a real or perceived conflict of interest concerning the matter at hand.

In addition, members must fulfill the following educational requirements:

6. Complete the CITI online IRB Members training module on Human Subjects Protection (

be reviewed, including all attachments, to every member of the IRB. Along with each application for renewal or amendment, and with other actions as needed, the Administrator will also re-send the original protocol, along with any subsequent amendment and/or approval.

Applications that are not expedited may be reviewed only at convened IRB meetings at which a majority of the members are present, including at least one member whose primary concerns are in nonscientific areas (a quorum). Should the quorum fail during a meeting (e.g., loss of a majority through recusal of members with conflicting interests or early departure, or absence of a nonscientist member), the IRB may take no further action or vote unless the quorum can be restored.

No IRB member may participate in reviewing an application in which the member has a conflicting interest, except to provide information requested by the IRB. IRB members are expected to absent themselves from the meeting room when the IRB reviews research in which they have a conflicting interest, except when the IRB requests that they be present in order to provide information.

All meetings will be conducted in closed door sessions, unless non-IRB personnel are invited to attend.

## B.1. Minutes of IRB Meetings

At every IRB meeting the IRB Administrator, or other designated individual, will record minutes of the meeting. All minutes will include, at a minimum:

1. Members in attendance and absent;
2. For every decision or action taken:
    - Full statement of any motion made;
    - Deliberations;
    - Decision;
    - Number of members voting, and the number of votes for, against, and abstaining;
    - Reasons for votes against the motion.
3. Deliberations, actions, and votes for each application reviewed, including but not limited to:
    - Four findings required under 45 CFR 46.116(d) whenever the IRB approves a consent procedure that alters some or all of the required elements of informed consent or when waiving the requirement to obtain informed consent – and the protocol-specific information justifying each finding;
    - Specific findings required when approving research involving pregnant women, human fetuses or neonates (45 CFR 46.204-207), prisoners (45 CFR 46.305-306), or children (45 CFR 46.404-407)
    - Determinations of approval period (review interval) and level of risk for each protocol approved - in particular when risk is a basis for requiring review more often than annually;
4. Summary of any formal UNE Policy changes, changes in Federal regulations or guidance, about which the Full IRB Board needs to be informed;
5. Summary of discussions held during the meeting;

The IRB Administrator will supply copies of the meeting minutes to all IRB members, and the UNE IO, in advance of the subsequent meeting. In addition, the IRB Administrator will append a summary of activity during the intervening interval, including, but not limited to;

- Expedited Reviews (new applications, continuing reviews, minor protocol revisions);
- Ongoing Research Reports;
- Reports of Important Events (protocol deviation, unanticipated problem, or serious adverse event)

Minutes will be presented to the IRB at each meeting for approval, and will be kept on file for a minimum of three years.

# C. Administration

## C.1. IRB Administrator

The IRB Administrator is UNE's primary institutional agent who exercises operational responsibility, on a day-to-day basis, for UNE's IRB program. The IRB Administrator's duties and responsibilities include, but are not limited to:

- Review human subjects research protocols in order to ensure that regulatory compliance requirements are met and appropriate ethical conduct standards are upheld;
- Provide technical assistance to the IRB, and update the IRB on current changes in federal policies and guidance;
- Provide assistance in drafting and administering UNE's policies and procedures governing the ethical conduct of human subjects research and associated activities;
- Provide professional, technical, and educational assistance to members of the UNE community on all aspects of the ethical conduct of human subjects research and associated activities; and
- Perform initial detection and inquiry into possible important events and make preliminary recommendations.

Under the direction of the IRB Chair, the IRB Administrator may:

- Review Applications for Exemption, Expedited Review, Continuing Review, Amendment;
- Assign reviewers to applications;
- Sign approval letters;
- Approve minor protocol changes;

# VI. Glossary

**Adverse research event**: An unfavorable occurrence in a human subject that causes physical or psychological harm or injury that is temporarily associated with the subject's participation in the research. An adverse event is considered **serious** if it: (a) is fatal or life threatening; (b) results in significant or persistent disability; (c) requires or prolongs hospitalization; (d) results in a congenital anomaly/birth defect; or (e) may jeopardize the subject's health and may require medical or surgical intervention, based on appropriate medical judgment.

**Assent**: A Child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

**Certificate of confidentiality**: A discretionary document procured from the National Institutes of Health which helps researchers protect the privacy of human research participants enrolled in biomedical, behavioral, clinical and other forms of sensitive research. Certificates protect against compulsory legal demands, such as court orders and subpoenas, for identifying information or identifying characteristics of a research participant. Further information is available at http://grants1.nih.gov/grants/policy/coc/.

- Fabrication is making up data or results and recording or reporting them.
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**Unanticipated problem**: Any event that is (a) not expected given the nature of the research procedures, and the subject population being studied, (b) related or possibly related to participation in the research, and (c) places subjects or others at greater risk or harm/discomfort related to the research than was previously known or recognized. An event which was previously unforeseeable based on the information provided to the IRB.

**Undue influence**: Inappropriate remuneration or any other form of compulsion offered to an