Guide to the Policies and Procedures of the University of New Orleans Institutional Review Board

I. Federal, State and University Regulations Related to the IRB

The UNO Committee for the Protection of Human Subjects Research is designated as the Institutional Review Board (IRB). The IRB is guided by ethical principles established by the World Medical Association, and its adoption of the Declaration of Helsinki, the Belmont Report [Appendix 1] and by the Ethical Guidelines of Behavioral Research of the American Psychological Association. These principles are implemented in consonance with applicable university, state and federal laws and regulations. Review is required for all research and related activities involving human subjects conducted by investigators with an appointment (hereafter referred to as employee) at UNO, as established by federal law.

Information about the Office for Human Research Protections (formerly the Office for Protection from Research Risks -OPRR) and the rights of human subjects is available at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46. This link contains both regulations regarding OHRP authority (45 CFR 46; The Common Rule) and activities as well as the OHRP IRB Guidebook. The Guidebook can be downloaded and provides information regarding IRB activities and responsibilities.

Other important information related to human subjects protection including the Belmont Report can be found at the OHRP Website.

Approval of any submission to the IRB is contingent upon meeting all of the requirements of the Federal Code, 45 CFR 46. Submissions also must comply with all state and local requirements and laws.

Policies and procedures specific to research involving human subjects at the University of New Orleans and the UNO IRB are described in the following chapters. All of these regulatory documents must be understood and adhered to by all investigators.

If you require additional assistance, please contact the Chair of the IRB, Dr. Roberto Refinetti, rrefinet@uno.edu, (504) 280-7481.

II. Administration Responsibilities and Functions at the University of New Orleans

A. Administration of the IRB

The Administration of the University of New Orleans has delegated to the Committee for the Protection of Human Subjects in Research the full authority of the President's Office to function as the Institutional Review Board. The Institutional Review Board supervises and monitors adherence to the local, state, and federal regulations guiding research involving human subjects. The Vice-President for Research and Economic Development will exercise such functions that require official action. The day-to-day conduct of the committee will be the responsibility of the Chair or Vice Chair of the IRB.

The administration shall:

A. Provide necessary support services for the IRB.
B. Transmit to Department of Health and Human Services (DHHS) all actions on DHHS supported activities.
C. Make certain that all recommended actions are initiated pursuant to IRB decisions.
D. Present appropriate and ongoing educational opportunities for IRB staff, Board members, investigators and others about human subjects protection, related federal regulations, and IRB procedures and policies.
E. Make certain that the professional staff is informed as to the responsibilities of the institution for protection of human subjects.
F. Develop necessary arrangements with affiliated and other institutions for mutual assurance of protection of human subjects
G. Provide the liaison and channeling of appropriate information between staff, IRB, the administration, and governmental agencies.

The chair of the UNO IRB shall:

A. Screen all proposals to determine the need for IRB evaluation.
B. Maintain active files for all investigators submitting protocols to the IRB for approval.

B. Committee Disapproval

While IRB disapproval cannot be overruled by the University of New Orleans administration, approvals may be overruled. Project directors or principal investigators (PI) may appeal disapprovals or restrictions on approvals. If the PI wishes to further challenge any decisions made by the IRB, the PI may initiate

the process through the administrative official, the Vice-President for Research and Economic Development.

C. Research Funding

Funds for studies may be withheld at the discretion of the administration.

III.University of New Orleans Committee for the Protection of Human Subjects in Research: The IRB

A. IRB Authority

The Institutional Review Board (IRB) is responsible for reviewing all research projects involving the use of human subjects to determine that:

1) the risks to the subject are so outweighed by the sum of the benefits to the subject and the importance of the knowledge to be gained, as to warrant a decision to allow the subject to accept those risks,

2) the rights and welfare of the subject are adequately protected and

3) legally effective informed consent is obtained by adequate and appropriate methods.

As defined by federal regulations, IRB authority extends to any study using live human subjects, or data, or tissue collected from live humans.

The Board reviews all human research activities conducted only by employees of the University of New Orleans. Although the student or employee may work on a project, a faculty member must be listed as the principal investigator on the IRB application and must assume full responsibility of the project.

Any research that involves human subjects conducted by UNO faculty or employees regardless of the location of the study must be evaluated by the IRB. For example, if a faculty member or employee of UNO is named as a co-investigator on a federally funded grant, but the actually assessment of human subjects is being performed at a different university or setting, the UNO IRB must review and approve the study before the research may begin. Approval from other research sites must be submitted with the application. However, if a faculty member or employee of UNO is listed as a consultant, the UNO IRB does not need to approve the research project.

Approval by the UNO IRB for its employees rarely extends to individuals on the project who are not UNO employees. When a non-UNO employee seeks approval from the UNO IRB an unaffiliated investigator statement must be included with the application. A sample letter can be obtained from the IRB chair upon request.

Categories listed as exempt by the federal regulations also must be submitted for review and approval by the IRB.

The IRB has the authority to require progress reports from the investigators and may take any other action it deems appropriate to oversee the conduct of any study. While approval of an IRB application is given in the principal investigator's name, all investigators of the study have a responsibility to be sure that all IRB policies and procedures are adhered to during the conduct of the study.

The UNO IRB is unable to accept IRB review by other institutions in lieu of its own IRB review. Reciprocity of IRB review is not permitted by this university. However, for multisite projects, the UNO IRB may permit the submission of review materials formatted for review at a collaborating site. Please contact the IRB chair before submitting multisite projects for review.

To assure compliance with all policies and regulations, the IRB, following a thorough investigation, may take actions against any or all investigators listed on the study including but not limited to warning, reprimand, censure, or suspension and prohibition from conducting human subject research at UNO.

Any policies and procedures governing the IRB may be changed at a convened meeting. These changes require a vote by a majority of the Board members present based on a quorum.

The IRB, through the Vice-President for Research and Economic Development, interacts with all governmental agencies.

B. Responsibilities of the Board

The IRB is charged with the duty of making certain that all research activities involving human subjects conform to the following guidelines:

A. Research activity is based upon established and accepted procedures.
B. Research activity is conducted or supervised by a properly qualified individual.
C. Research planning includes a critical evaluation of the possibility of risk or harm (physical, physiological, sociological or others, including invasion of privacy) as the consequence of this research. The rights and welfare of the subject must be adequately protected, based on the above evaluation.
D. Research activity must have an objective that risks to the subject are so outweighed by the sum of the benefits to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept those risks.
E. Research activity can be initiated only after informed consent is obtained from the subject(s), documented by adequate and appropriate methods,

unless the IRB has granted a waiver of documentation or one or more elements of consent.

F. Any research activity that does not conform to all state and federal guidelines or IRB required procedures is subject to termination by the Board.

G. Research activity must have sufficient scientific merit in the field of research to allow subjects to participate.

H. Will receive all current training from the Office of Human Research Protection.

C. The Composition of the IRB and Quorum

The IRB is comprised of 7 voting members from diverse backgrounds in order to promote complete and adequate review of research and research related activities. IRB members representing a variety of professions and disciplines to assure appropriate expertise are available to evaluate applications. These members are appointed by the President of the University of New Orleans. The Board is comprised of both males and females and at least one member is an individual whose primary expertise is in a nonscientific area. At least one member is not an employee nor a part of the immediate family of a person affiliated with the institution.

A quorum of the Board is defined as a majority of the membership. The non-voting members do not count toward a quorum. No member may participate in the initial or continuing review of any project in which the member has a conflicting interest except to provide information requested by the Board. Members with conflicting interests will leave the meeting room during the deliberations and voting on said projects. Members must be present to vote. A majority of the membership present must vote in the affirmative for a motion to pass.

Information about the Board membership is available from the IRB Chair.

D. IRB Member Duties

The members are required to evaluate all applications assigned to them by the Chair. IRB members may be assigned applications requiring expedited or full-board review. Members may conduct an expedited review procedure as defined in federal regulations and exercise all of the authority of the IRB except disapproval.

During a full-board review meeting the IRB member assigned as primary reviewer for a protocol is expected to present an assessment of the project by explaining the rationale and design for the conduct of the study, highlighting

discussion items of importance and presenting suggested modifications to the consent form. All members are expected to contribute to a thorough discussion of all issues. The primary reviewer should present a motion for consideration.

Members also may be needed for their expertise to evaluate special concerns that may arise on any study.

Committees of the Board are utilized for special concerns (e.g. consideration of new policies, issues of non-compliance, special populations). The committee members are appointed by the Chair based on the required expertise for the issue at hand. Committee reports are presented for consideration by the fully convened Board.

No member of the IRB may participate in an initial or continuing review of any project in which the member has a conflict of interest; except to provide information to the IRB. Should a conflict of interest exist the member is responsible for notifying the IRB office one-week prior to review. A member with a conflict of interest must abstain from participation in deliberations and voting on that protocol.

The administration supports the members of the IRB through the following:

1) Liability coverage for all IRB members is provided for by the institution.
2) Reference materials are available in the IRB office for members or principal investigators to assist in the review and/or preparation of applications.

The IRB does invite individuals who are not members to serve as expert consultants for review of selected applications. These consultants serve in a non-voting, advisory only capacity.

E. The IRB Chair

The daily responsibility for the management and operation of the Board and the IRB Office is vested in the Chair. The Chair is selected and appointed by the President of the University of New Orleans. The President retains the sole authority to remove the Chair. The Board has designated two members to serve as Vice-Chairs. Each Vice-Chair has the full authority to act for the Chair in his/her absence.

1. Authority

a. Calls emergency sessions as needed.

b. May require study modifications which can include suspension of enrollment when risks/complications arise which significantly endanger the subjects until discussion by the full Board.

c. Requests files, reports, and additional data from principal investigators when the need arises.

d. May require principal investigator to appear before the IRB when questions arise about any study.

e. Votes as a member of the IRB.

f. May suspend studies when issues of non-compliance appear to place subjects at risk.

g. May approve responses to applications submitted to the Board which resulted in a vote of Approval with Changes. Consultation with another Board member(s) may be necessary.

h. May approve minor modifications to ongoing protocols with possible agreement by another Board member(s). These are modifications that do not significantly affect the risk to the subject.

i. May conduct an expedited review procedure as defined in federal regulations and exercise all of the authority of the IRB except disapproval.

j. Presides at all meetings.

k. Signs all official notifications from the Board.

2. Responsibilities

a. Schedules meetings.

b. Sets the agenda for monthly or called emergency meetings.

c. Provides for the distribution of the meeting agenda and materials to be considered at the meeting.

d. Provides for the taking of minutes, duplication of minutes, and distribution of minutes to IRB members in a timely fashion.

e. Distributes literature to IRB members regarding the concerns of the IRB.

f. Keeps an updated file on all studies submitted to the IRB.

g. Maintains a file of curriculum vitae and training certifications for all members of the Board.

h. Communicates all decisions of the Board and the Chair to the PI.

IV. Operating Procedures of the IRB

The functions of the IRB include conducting initial and continuing review of all human research activities conducted at UNO. The IRB also evaluates all amendments, revisions, changes, advertisement for subjects, adverse events and special situations affecting research proposals and brought to the attention of the Board, the Chair or

Vice-Chair, or any member. For all of these actions, the communication to the IRB office must be signed by the principal investigator or initiated through the principal investigators official UNO e-mail account.

A. Conducting Review of New Applications

Preparation instructions for submitting applications are contained in the Application Instructions. New applications are accepted throughout the month. However, the DEADLINE for submission of any new application that requires full Board review is the last working day of the month to be eligible for the next month's meeting.

Upon receipt of a new application the IRB office date stamps and assesses the application for completeness. Complete applications are assigned a tracking number. Applications that do not contain the appropriate physical or electronic signatures (i.e., all investigators CC'ed on an e-mail submission) will be returned to the PI. The PI will be contacted for additional information and/or incomplete data. Incomplete applications received before the deadline will not be eligible for review until the next review cycle. Consequently, please make certain that the application and all required material are complete before submission. Principal investigators are recommended to contact the IRB Chair prior to submission to discuss concerns.

All new applications are evaluated by the Chair or designee to determine if they are eligible for expedited review according to 45 CFR 46.110. Applications for exemption are evaluated by the Chair or designee to determine if they are eligible for consideration under 45 CFR 46.101b.

Each application requiring full Board review is distributed to all Board members and is assigned a primary reviewer by the Chair. The application is reviewed at the next scheduled meeting. The Board evaluates each proposal with a full discussion on the merits of the full protocol. These include but are not limited to scientific merit, risks/benefit ratio to subjects, expertise of the investigator, etc. Particular emphasis is placed on the risks to subjects that may be encountered as a result of enrollment in the protocol. These risks may include but are not limited to medical, psychological, financial and social risks. To properly prepare the protocol for the review, the investigator must consult the Instruction Guide to Completing the Application Form.

During the meeting, the primary reviewer presents a summary and recommendation based on the review of the full protocol, application, consent forms, investigator's brochure and related federal grant application. These materials are available to all members prior to and during the meeting. Members discuss the application and the Chair calls for a vote. The vote is recorded.

The IRB Chair notifies each investigator in written memo form regarding the decision of the Board. The memo will outline any necessary actions and upon receipt of that memo the PI makes the required corrections, modifications, or resubmits a new application. If a response is not received within the time noted on the letter, the recommendation is rescinded and a new application package must be submitted for consideration by the Board at a future meeting.

A copy of the signed approval form with the IRB approval number will be sent to the PI once all necessary documentation has been received and approved. All correspondence regarding the project to the IRB must contain the UNO IRB form number.

B. Types of Recommendations from the Board:

Approval: No further changes needed

Approval with pending changes: Moderate revisions are necessary. The modifications in the study provided in response to Board concerns will be reviewed by the Chair or Vice Chair to assess that changes have been incorporated. The Chair may seek assistance of any member of the Board for this process. In most cases these "approval with changes" will not have to be re-assessed by the full Board. However, if the Chair or any other Board member is not satisfied with the quality of the response it will be re-assessed by the full Board at an officially convened meeting.

Rejected: Extensive revisions needed or scientific or ethical problems posed by the study are of grave concern to the Board. Modifications must be re-submitted for Full Board Review. In order to be assessed at the next meeting, changes will have to be in the IRB office by the last working day of the month. The time frame for return of the response may be short if the investigator wishes to be re-evaluated at the next scheduled meeting. The investigator should be prepared to attend the meeting to discuss his/her application if so requested by the Board.

C. Approval timeframe

The period of approval is determined by the Board based on the merit of the study and the level of risk to the subject. The duration of the approval period is tracked through a computer database. The period of approval is included on the approval form and will not exceed one year. If the determination that a period of less than one year is required, the IRB may set any time period as the appropriate interval and may change that interval at any time.

The IRB may require progress reports from the principal investigator. The IRB has the authority to suspend, terminate or require changes at any time. If the Board requires any restrictions in the protocol this information is included in the written documentation. The investigator signs both copies of the assurance

document mentioned above, keeping one and returning the other to the IRB office. The original of the signed assurance is kept in the protocol file for that project.

D. Changes to an Approved Protocol

The IRB cannot consider changes in investigator, sites, amendments, revisions, addendums, investigator brochures, advertisements for subjects, etc. without a memo from the PI that details the impact of those items on the consent form and the conduct of the study. The investigator must submit a memo requesting approval for all modifications. The memo must describe the addition, deletion, or revision with an assessment of the expected impact on the conduct of the study and the consent form. Examples of such changes are the site, increases in the number of subjects, addition of measures, amendments from the sponsor, changes requested by hospitals, etc. A copy of the new consent form with all changes "highlighted" must be submitted and a "non-highlighted" copy of the revised consent form must be submitted when modifications require changes to the consent form(s).

The Chair and/or the Vice-Chair review the proposed change to determine if the change is appropriate for expedited approval as defined by federal regulations. Changes not meeting the criteria will be reviewed only at an officially convened full Board meeting. In this case, the amendment is assigned to a primary reviewer who evaluates the amendment and presents a summary to the Board. Each Board member receives a description of the amendment prior to the meeting.

The Principal Investigator and the Faculty Supervisor, if applicable, must notify the Board of any changes to a study initially classified as exempt. At that time, the Chair will re-evaluate the exempt status of the study.

Upon final approval, the IRB office will forward to the PI notification of modification approval.

All changes in protocol must be approved by the IRB. To insure that investigators do request modifications, the Board will monitor all submitted documents for any suggestion of changes. If any changes are noted, following a thorough investigation, appropriate administrative action will be taken which may include but are not limited to: contacting the investigator, co-investigators, administrative de-activation of the study, warning, reprimand, censure, or suspension or prohibition of the principal investigator’s, co-investigator’s, and/or faculty supervisor’s right to conduct human subjects research at UNO. An additional method of insuring that protocol modifications are requested prior to initiation will

be a follow-up of any reports of such incidences from subjects, board members, other investigators, etc.

The IRB may require additional reports at any time during any investigation and may review the project in order to determine whether the rights and welfare of the subjects are appropriately protected or whether the risk/benefit ratio of the study has changed. When necessary the IRB conducts selected evaluation of investigator records to assure compliance with all federal and state regulations.

E. Continuing Review

IRB review of approved protocols is on-going. Approval is granted for a set period of time that is determined by the Board. This period of approval is granted for a period up to one year depending upon the nature of the study and the degree of risk to the subject. The purpose of the IRB continuing review is to ensure that: 1) the risk/benefit of the research remains acceptable, 2) the informed consent process and documents are still appropriate, and 3) the enrollment of subjects has been appropriate. The IRB may require information from outside sources to verify that no material changes have occurred since the previous IRB review.

The application for continuation (see Forms) is forwarded to the principal investigator two months prior to the expiration of the currently approved period. This form must be returned prior to the deadline listed on the form. This continuation application must be completed in its entirety and accompanied by the most recently approved consent form. Incomplete or late re-approval applications may result in suspension of all activities for that protocol. Investigators cannot enroll new subjects, continue participation of currently enrolled subjects (unless medically indicated for safety), or continue data collection during any period not approved by the IRB. If the investigator does not receive a signed and approved continuation of study form from the IRB before the study's expiration date, the study is administratively de-activated. Investigators must refrain from enrolling any subjects until formal notice of continuation is received. The investigator is ultimately responsible for assuring that an application for continuation and all renewal materials are supplied to the Board in a timely manner. All materials must be received in the IRB offices at the end of the month prior to the expiration date to assure review at the next meeting.

All applications for continuation of an on-going protocol are date stamped as received in the IRB office. Applications are matched to study folders and the packet is provided to the Chair for consideration. Applications that are complete and require full board review for continuation are placed on the agenda for the full Board meeting.

All continuing review applications are evaluated by the Chair or designee to determine if they are eligible for expedited review and expedited re-approval. The continuation period will start the day the Chair approves it but in no case will that period be longer than one year. Under most circumstances protocols that originally were expedited or exempted would receive expedited approval by the Chair. If changes are requested in the continuation application form, the application must be re-evaluated to determine if the study remains eligible for expedited approval. If not eligible for expedited review or if the status has changed, the application is forwarded to the full Board for review.

Studies which are considered exempt at initial review do not require continuing re-approval. Investigators however must notify the IRB of any changes to the protocol so that an evaluation may be made to determine if the study remains exempt from IRB review.

If a study must receive full Board consideration for re-approval, the Chair will assign a primary reviewer for the evaluation of the continuation of this protocol in the same manner used for new applications. The continuation application and the current consent form are sent to each Board member prior to the scheduled meeting. During the full Board meeting, the primary reviewer presents a summary and recommendation based on the review of the full protocol file kept in the IRB office. This material is available to all members prior to and during the meeting. Members discuss the project and the Chair calls for a vote. The vote is recorded and notification of the Board's decision is made to the principal investigator following the meeting.

The continuation form indicates the new approval period. That approval period starts the day of the meeting (if approved) or the day that changes required by the Board are finalized and approved by the Chair. The IRB computer file record is updated to indicate the start day of the new period. In some cases, the application will be returned to the full Board for review. The period of approval in all cases will be for no more than one year. In some cases, the approval period will be less than one year.

The principal investigator receives a document indicating the new approval period. Any restrictions or additional requirements imposed by the Board are communicated to the principal investigator in writing.

F. Adverse Event Reporting

The IRB must assess all serious adverse events (SAE) associated with any research conducted by UNO faculty, students, and employees. The UNO IRB must report any confirmed SAE to the Office of Human Research Protection and the funding agency. Please refer to the UNO SAE guidelines for reporting serious adverse events.

A serious adverse event (SAE) is defined by the Code of Federal Regulations as events which meet any of the following criteria:

- Results in death
- Is life threatening
- Requires inpatient hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability/incapacity
- Is a congenital anomaly/birth defect

In addition, an event that does not meet these criteria should be reported as an SAE if, in the medical judgment of the treating physician and/or investigator, it may jeopardize the participant or require intervention to prevent one of these outcomes.

All SAEs must be reported promptly. The reporting procedure is as follows:

All SAEs that are:

a) probably related to the study,
b) related to the study, or
c) unexpectedly related and not disclosed in the consent form

must be added to the risk section of a revised consent form. A highlighted copy of the revised consent form must be included with the event report. If an adverse event occurrence is more severe or more frequent than described in the consent form the principal investigator must provide a written explanation of the impact on the study.

For serious adverse events occurring to subjects enrolled by UNO investigators special reporting requirements apply.

1. All SAEs that occur with subjects enrolled by UNO investigators must be reported in writing within 5 working days. Fatal local events must be reported within 48 hours.

2. All SAEs that are probably related or related, unexpected and not disclosed in the consent form must be added to the risk section of a revised consent form. A highlighted copy of the revised consent form must be included with the event report.

3. If adverse events whose occurrence is more severe or frequent than described in the consent form are experienced, the principal investigator must provide a written explanation of the impact on the study.

All events reported are evaluated by the Chair to determine if immediate action is required. If immediate action is needed, the Chair may suspend enrollment until the SAE can be evaluated by the full Board. This may require an emergency meeting of the Board.

All serious, unexpected, and probably related or related events whose frequency or severity is greater than originally expected will be discussed at a full Board meeting. The Chair assigns the SAE to a primary reviewer who presents a summary to the Board. Each Board member receives a short description of the SAE prior to the full Board meeting. The Board will determine whether the study may continue without change, if modifications are required in the protocol or if suspension of the study is required. If the Board votes to suspend UNO participation in a protocol all appropriate parties including institutional officials, the study sponsor, and OHRP (if applicable) will be notified.

G. Non-compliance by Investigators

Any reports of serious or continuing non-compliance by investigators will be investigated by the IRB. These investigations may involve review of patient records, review of study files, requests for additional information, interviews with the investigator(s), or any other required methods. The results of the investigation will be communicated to the investigator in writing.

Any documented instance of continuing or serious non-compliance of the requirements or determinations of the IRB or federal policy or regulations may result in suspension or termination of IRB approval of an open study and/or sanctions against any or all investigators listed on the study. These sanctions may include but are not limited to warning, reprimand, censure, or suspension or prohibition to conduct further human subject research at UNO. Principal investigators are ultimately responsible for the work being conducted by their students and/or employees.

Investigators will be notified in writing of the results of the Board's decision. In addition, for federal policy, any serious or continuing non-compliance with DHHS human subject regulations or the determinations of the IRB will be promptly reported to the sponsor, institutional officials, and OHRP.

H. Schedule of Meetings

The IRB meets monthly 9 times during the year (during the months of: August, September, October, November, December, February, March, April, and June). The deadline for applications to the IRB is the last working day of the month prior to the next meeting with no exceptions. The IRB meets

The IRB office prepares an agenda and an official notification of the time and place of the meeting under the direction of the Chair. The agenda, previous month's minutes, new applications, continuing review applications, adverse event packets, and significant amendments to on-going protocols as needed for review are distributed in advance of the meeting to all members of the Board.

I. IRB Records

The written procedures and guidelines of the IRB are maintained in this Guidebook. The IRB maintains a separate permanent file for each pending and approved protocol. Written and electronic documentation of activities between the investigator and the IRB are maintained in separate written and electronic files. All correspondence regardless of the source including all correspondence between the investigator and the IRB is maintained in the permanent protocol file. These documents create a complete record of a protocol and its activity. Note that all correspondence between the investigator and the OHRP must be copied to the IRB and will be maintained in the IRB protocol files.

V. ITEMS OF SPECIAL INTEREST

A. Assessment of Risks to Subjects

No subject in a scientific investigation can be exposed to unreasonable risks to health or well-being. An individual is at risk if exposed to the possibility of any harm (e.g. physical, psychological, sociological, or legal). Determination of risk is a matter of the application of common sense and sound professional judgment. The UNO IRB is the final authority at this institution.

A. "No risk" refers to investigations in which the subject is not placed in jeopardy of any kind. Examples are use of educational tests, observation of public behavior or interview procedures, each under certain conditions. This type of investigation may qualify for exempted verification by the IRB.

B. "Minimal risk" means that the risks of harm anticipated in the proposed research are not greater, considering the probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Examples are voice recordings made for research purposes, moderate exercise by healthy volunteers, venipuncture under certain conditions, or collection of urine specimens. Some "minimal risk" protocols may qualify as involving "vulnerable populations."

C. Psychological injury might involve subjection of subjects to deceit or withholding of information, public exposure, humiliation, invasion of privacy, or coercion. Social injury can occur if there is risk of loss of personal reputation or professional status, defamation of character, personal degradation in the eyes of others, or revelation of information related to sensitive social issues.

All projects involving greater than minimal risk must be reviewed at a full Board meeting of the IRB.

B. Subject Entry Site Approval

Since most institutions have committees which assess the impact of the proposed research at their facility. The principal investigator is responsible for assuring that approval has been obtained from the appropriate officials of the sites listed on the application form.

C. Waiver of Informed Consent

Federal regulations in 45 CFR 46.116(d) provide for the waiver of informed consent when the following conditions are met:

1) the research involves no more than minimal risk to the subjects;
2) the waiver or alteration will not adversely affect the rights and welfare of the subjects;
3) the research could not practicably be carried out without the waiver or alteration; and
4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

D. Subject Population

The Principal Investigator is responsible for describing:

1) the sources of potential subjects,
2) the characteristics of the subject population (i.e., anticipated sample size, age, sex, ethnic background, and state of health),
3) the criteria for inclusion and exclusion in the study,
4) the rationale for the use of special classes of subjects, such as fetuses, pregnant women, children, institutionalized individuals (mentally disabled, prisoners, or others) especially those whose ability to give voluntary informed consent may be in question, and
5) the involvement of disproportionate numbers of racial or ethnic minorities, the aged, or persons of low socioeconomic status should be presented.

Vulnerable Populations are those whose ability to give voluntary informed consent may be in question. Examples of vulnerable populations are children, pregnant women, fetuses, terminally ill patients, prisoners, institutionalized persons (mentally ill), wards, and individuals who might be under psychological pressure to volunteer. If vulnerable populations are to be used, investigators must deal thoroughly with the potential for risk. The definition of minimal risk is different for vulnerable populations and for non-vulnerable populations. Consultation with the IRB Office on this issue is strongly urged if vulnerable populations are being asked to participate as research subjects. Federal regulations require additional IRB considerations if vulnerable populations of subjects are used.

Under most circumstances, employees/students at UNO may not participate in projects where the investigators, in their roles of faculty members or supervisors, are involved in grading the academic or clinical performance or otherwise evaluating the subjects. Research involving students/employees as subjects is reviewed on a case-by-case basis. The single most important factor in considering exceptions to the above rule is the complete absence of either coercion or the perception of coercion by the students/employees who are asked to participate. Other factors affecting this decision of exception include: having a mechanism to assure anonymity; having a method to assure that no penalties can be imposed on students/employees who refuse to participate, etc. Approval of projects utilizing students/employees that do not fit in either the exempted or expedited categories is unusual. The request to include UNO students or employees must be included in the application project summary.

E. Subject Payment

Compensation to subjects must never constitute an undue influence or coercion to participate and should be limited to nominal payment for time and inconvenience of participation. Any payment(s) made must be pro rated, based on the time actually spent in the study, regardless of whether or not the subject completes the study.

Subject payment procedures cannot violate anonymity if a study is using anonymous participation. For example, if participants are requested to complete measures without revealing their identity, asking participants to complete tax forms with identifying information violates anonymity. Anonymous studies do not need to give names and identifying information to an accounting office for payment.

F. Advertisements for Subjects

If notices are posted or other advertising used for recruitment of volunteers to participate in the research, the specific advertisement and methods of recruitment must be approved by the IRB prior to use. Any type of advertising for research subjects that is intended to be seen or heard by prospective subjects is considered to part of the informed consent and subject selection process. Since this may be the initial contact by the investigator with the subject, the IRB must ensure that the information is not misleading to subjects. This is especially important when a study may involve subjects who are likely to be vulnerable to undue influence, for example financially impaired subjects.

When advertising is to be used, the IRB must review both the information contained in the advertisement and the mode of its communication. This is to determine that the procedure for recruiting subjects is not coercive and that the recruitment material does not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.

Advertisements should not promise "free treatment", when the intent is only to say subjects will not be charged for taking part in the investigation.

If an investigator decides to begin advertising for subjects after the study has received IRB approval, the advertising is considered as an amendment to the ongoing study and must be reviewed by the IRB. When such advertisements are easily compared to the consent, the IRB will review and approve the advertisement using expedited procedures. When the comparison is not obvious or other complicating issues are involved, the advertisement will be reviewed at a convened meeting.

Generally, advertisements should be limited to the information the prospective subjects need to determine their eligibility and interest. The following items must be addressed to qualify the advertisement for review:

1) The name of the investigator, the name and phone number of the contact person for the study and the name of the institution (e.g. UNO).
2) The purpose of the research (e.g. the general goal of the project)
3) The eligibility criteria (which may be in summary form, or listed as bullets or points)
4) The time frame required for participation.
5) A short list of benefits. [Payments to subjects for participation are not benefits.]

G. Educational Materials for Subjects

Education materials related to the consent process or to be used as part of the study, e.g. videos, brochures, etc. must be reviewed and approved by the IRB before use. These items must be submitted with the application if used as part of the consent process.

H. Confidentiality of Data

When the research involves collection of data which might be harmful to subjects if disclosed to third parties in an individually identifiable form, the investigator and faculty supervisor, if applicable, must be attentive to the adequacy of provisions to protect the confidentiality of data. The investigator must limit the collection of personal information to that essential for the research. Depending upon the degree of sensitivity of the data, the methods for protecting the confidentiality of data may include coding or removal of identifiers as soon as possible, limitation of access to data to the investigator and authorized staff, the use of locked file cabinets, and plans for the ultimate disposition of data. The investigator should be aware of the extensive vulnerability of research data to subpoena, particularly in studies that collect data which would put subjects in legal jeopardy if disclosed.

The subject's name should be recorded only when necessary and they must be informed that their identity can be protected only to the extent allowed by law.

I. Record Keeping by Investigators

Copies of all signed consent forms must be kept by the principal investigator. These consent forms must be made accessible for review by the IRB. Files of all signed consent forms from research must be retained for a period of 3 years after the date on which the investigational study (not merely an investigator's portion of a study) is terminated, completed or discontinued.

J. Educational Policies and Resources

1. Investigator

All UNO investigators engaging in research using human subjects must familiarize themselves with all IRB policies and procedures and related federal regulations. Investigators should maintain an on-going relationship with the IRB office staff to gain assistance in the preparation of applications and to gain assistance in following all IRB policies and procedures during the conduct of their studies. This process helps assure that both investigators and the UNO remain in compliance with all state and federal regulations regarding research involving human subjects. All employees involved in human subjects research must take advantage of the educational opportunities listed below.

All investigators if applicable, must take the Protecting Human Research Participants on-line certification course at:
http://phrp.nihtraining.com/users/login.php

All investigators and

2. IRB Board Members

Members of the IRB have the important responsibility of protecting the many individuals of our community that volunteer to participate in the UNO's human subjects research programs. Board members are expected to familiarize themselves completely with this Guidebook and the IRB process just described for investigators. New members are asked to attend a number of scheduled IRB meetings to observe and to contribute to the discussion at the meeting before being assigned primary reviewer responsibility. New members should interact with the IRB Chair about the requirements of and assistance with reviews.

At each IRB meeting an Educational Component is included where issues of current interest related to human subject protection are discussed.

VI. Notification of Termination of the Study

Termination of a research protocol must be reported in writing by the principal investigator and faculty supervisor, if applicable, to the IRB. The report must provide the number of subjects enrolled, the number withdrawn and any results that are known at the time of closure.

VII. The IRB Application

Research involving the use of human subjects first must be approved by the IRB prior to implementation. In addition to protocols requiring full board approval, certain categories of research may qualify for expedited or exempt review. Expedited or exempt review only requires review and approval by the IRB Chair (or another member designated by the Chair).

All incomplete or inadequate IRB application packets will be returned to the principal investigator without review. As a result, the applications which are returned will experience an additional delay of one month over and above the current schedule.

The IRB revised application consists of: the face page, the project description, data collection, funding information, risks to participants, informed consent, data use, and investigator assurances. Please complete all sections of the application in order to reduce delays due to incomplete protocols.

For questions regarding the completion of the application, please contact Dr. Roberto Refinetti (rrefinet@uno.edu, unoirb@uno.edu).

Submitting Protocols. Please submit an electronic copy of your protocol, excluding signatures, to Dr. Roberto Refinetti (rrefinet@uno.edu) and directly to the UNO IRB (unoirb@uno.edu). Emails that contain the electronic copy of your protocol should also cc all co-investigators so that they can also access the approval form that'll be sent electronically to the original email that was sent.

Meeting schedule. Meetings are scheduled monthly and a list of meetings can be obtained from the Chair.

A. Application Form: Face Page

All sections of the form must be completed prior to submission to the IRB Office. Instructions for completing each section follow.

1. Protocol title

The protocol title is the official title of the project. This is the title used on grant proposals or theses or dissertation projects. The protocol title also is the title that must appear on the signature page of the protocol.

2. Alternate title

At times the title used to communicate to participants or participating organizations is different from the official title. This title reflects the title used in communications with participants or participating agencies. If you do not have an alternative title, leave this section blank.

3. Principal Investigator

The name, campus address, department, phone number, preferred e-mail address, and university affiliation of the Principal Investigator must be complete. For PI's who primarily use an off campus address, please put the off campus address in the campus address box.

Note: Graduate students are not eligible to serve as PI. The PI of a thesis or dissertation must be the student's faculty advisor.

4. Co-Investigator(s)

Please complete all contact information regarding each co-investigator on the project. All identified co-investigators must complete the on-line Human Subjects certification course and submit a copy of that certification.

If a project has more than two co-investigators, please submit an additional copy of the face page and include only the protocol title on the second copy of the face page

B. Project Description

Provide a **brief** description of the **background, purpose, and design** of your research. Avoid using technical terms and jargon. Be sure to list all of the means you will use to collect data (e.g., instruments, measures, tests, questionnaires, surveys, interview schedules, focus group questions, or observational procedures). Provide a short description of the tests, instruments, or measures and **attach copies of all instruments, questionnaires, and procedures** for review.

This section has no page limit. In general the background and purpose sections should not exceed 2 single spaced pages. The length of the study design and measurement sections will vary based on the complexity of the study.

Note: Federal regulations require that the IRB chair has complete, accurate, and up-to-date copies of all measures and procedures for each active research study.

C. Data Collection

1. Sample size

Provide the total number of participants that you plan to include/enroll in your study.

2. Age range of participants

Please include the range of expected ages of all participants in your study. If your study involves parents and children, then include the expected age of the youngest child and the oldest parent.

3. Recruiting from special populations

Check the box of each category of participants you plan to recruit. The list is not exhaustive and your participants may not fall into any of the listed categories.

If you check any of the boxes, federal regulations require that you describe how you will provide special protections to these identified participants. See a description of special considerations in Subparts B, C, and D at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46.

4. Type of data collected

Check the boxes for the types of data you will collect. If no box is checked go on to question 5. If you check at least one box, please describe how the media will be used and destroyed.

For instance, if you audiotape conversations with participants, you must describe what you will do with those audiotapes (e.g., hire a transcriptionist to transcribe the audiotapes, protect the participant's identity with a pseudonym, destroy the audiotapes, and analyze the data).

5. Deception

If your study involves no deception, mark no and go to question 6. If your study involves deception of any kind, please check the yes box and describe the type of deception you will use, why the deception is necessary, and provide a copy of the debriefing script.

6. Recruitment procedures

Describe how you will recruit participants and inform them about their role in the study. Please attach copies of advertisements, flyers, website postings, recruitment letters, oral or written scripts, or other materials used for this purpose.

D. Funding Source

1. Receipt of funding

Please indicate whether you have received any source of **funding** for the proposed research (e.g., federal, state, private, corporate, or religious organization support).

2. Review status

Indicate whether or not the protocol is currently under review or under consideration for funding

3. Explanation of funding

If you have received funding or your project is currently under review, please indicate any source(s) of funding for the proposed research (e.g., NIH, NSF, departmental funds, private foundations or corporations).

4. Potential conflicts of interests

Indicate whether the funding source(s) have any potential for financial or professional benefit from the outcome of this study and explain those benefits.

E. Risks to participants

1. Actual and potential risk

Review each statement and decide whether or not the statement reflects either an actual or potential risk. If the statement does reflect an actual or potential risk, check the box. If the statement does not reflect an actual or potential risk, leave the box blank. Checking box does not mean a study will not be approved, it simply means that you must describe the risk and how you will minimize the risk to the participant. Failure to reveal real risks may result in disciplinary action.

F. Informed consent

1. Definition of Informed Consent

Informed consent is an individual's voluntary agreement to become a subject of research after having been informed of the purpose of the

study, the procedures that are used, and potential risks or benefits to reasonably be expected. Additional information which must be given to the subject includes: expected duration of subject's participation, selection of subjects, alternative treatment procedures available, extent of record confidentiality, and all financial issues.

The investigator should offer any questions and, further, be satisfied that the subject, or his legally authorized representative, understands the procedure or treatment the subject is to undergo. To this end, the explanation must be in the language the subject best understands. While complete understanding is neither practical nor possible, an extra burden placed on the investigator is to serve the best interests of the subject. A legally effective consent form is to be read to or by the subject and must be signed by the subject or his/her legally authorized representative. Consent Forms in languages other than English are sometimes required. These must be submitted for IRB review and must be accompanied by certification (e.g. legal notary) that the form is an accurate translation of the English version.

Consent procedures for research involving children must be carried out in accordance with applicable federal regulations, and special provisions should be followed in obtaining parental permission and the child's assent. The investigator is responsible for following these regulations.

In giving consent, the subject should show the ability to exercise free power of choice without intervention of any element of constraint or coercion. The agreement should include no exculpatory language through which the subject is made to waive, or appear to waive, any legal rights, or to release the investigator and institution from liability for negligence. The investigator must honor a request by any subject to withdraw consent and to discontinue participation in the investigation and do so without prejudice. If significant findings develop during the course of the research which may relate to the subject's willingness to continue participation, that information must be provided to the subject.

Investigators are responsible for retaining signed consent forms in their personal research files. In addition, the principal investigator should permanently keep copies of the signed consent forms in the subject's hospital/clinic chart as a matter of record. Because consent form documents are an agreement between two parties, the subject must be given a copy to keep. Instructions for completion of consent forms are attached to the IRB application form. The principal investigator must tailor each point individually to the specific study.

2. Procedural Consent Requirements

In Section V, item 11 describe the procedures you will use to obtain and document informed consent and/or assent. Attach copies of the consent forms that you will use. The UNO Human Subjects website has additional information on sample forms and letters for obtaining informed consent. In the case of secondary data, please attach original informed consent or describe below why it has not been included.

Consent forms must include the following items:

☐ The name, campus address, and campus phone number of the principal investigator and alternative contact persons if applicable (e.g., graduate research assistants). In order to protect the privacy of investigators, investigators are not allowed to give participants their home addresses or home telephone numbers.

☐ An explanation of the purpose(s) of the research

☐ The expected duration of the subject's participation

☐ A description of the procedures to be followed

☐ Identification of any procedures which are experimental

☐ A description of any reasonably foreseeable risks or discomforts to the subject

☐ A description of any benefits to the subject or to others which may reasonably be expected from the research

☐ A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject

☐ A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained

☐ For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained

☐ The statement: "**Please contact Dr. Ann O'Hanlon (504-280-3990) at the University of New Orleans for answers to questions about this research, your rights as a human subject, and your concerns regarding a research-related injury.**"

☐ A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled.

☐ A statement regarding the amount of financial compensation to be given for the time spent participating in the research project, if applicable.

☐ All physical consent forms requiring a signature must be on University of New Orleans letterhead.

Sample consent forms can be found on the Human Subjects website. Assent forms should contain as many of these items as possible, written in a language suitable for the subject population.

3. Requests for Consent Waivers

In rare instances, investigators may request a consent waiver. See http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.117 for a summary of the federal code documenting criteria under which written consent may be waived.

G. Data Use

1. Data use

Check the boxes corresponding to each way in which the data collected will be used.

2. Data protection

Describe all steps you will take to ensure the confidentiality of participants and the data. Be thorough! Describe how you will safeguard the data, including how you will protect identifying information. Indicate where and how you will store the data, how long you will retain it, when and how you will destroy the data. Describe procedures for each type of data collected (e.g., questionnaires, audiotaped transcripts, videotape).

H. Signature Page/ Principal Investigator's Assurance

All principal investigators must read and sign the assurance document. In addition, this assurance must be signed by the department chair. Protocols will not be processed without these signatures.

I. Application checklist

A checklist is provided to assist with the application process. Please do not submit this checklist with your protocol.