

**Human Subjects Protections Program (HSPP) &  
Institutional Review Board (IRB)  
Standard Operating Procedures**

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SOP Number:	IRB 01	Revision Number:	01	Effective Date:	8/01/2018
Title:	Delegation of Authority				

## PURPOSE STATEMENT

Northwest Vista College is committed to the protection of the rights and welfare of human research participants recruited to participate in research conducted under its auspices. Northwest Vista College strives to adhere to the highest ethical standards in its protection of human research participants and seeks to further develop the methods and mechanisms for protecting human research participants rather than ensuring mere compliance with the federal regulations.

Northwest Vista College's Office of Institutional Research (IR) is tasked with the following goals in service of this mission:

- ❖ Create an atmosphere of respect for, and awareness of, the rights and welfare of human research participants at Northwest Vista College.
- ❖ Continue to inform established researchers about the application of the federal regulations and ethical principles to their particular area of research in an effort to keep researchers current with evolving standards.
- ❖ Educate students, faculty, and staff who conduct research about the ethical principles and federal regulations guiding research with humans.
- ❖ Administratively support and offer guidance to the Institutional Review Board (IRB) in the review of research activities.
- ❖ Facilitate compliance of researchers with the federal regulations and protection of research participants.
- ❖ Develop more efficient methods for processing applications, tracking and monitoring research activities, and assessing the overall effectiveness of Institutional Research.

## Institutional Research Role

Institutional Research's role is outlined as follows:

- ❖ Institutional Research - employs mechanisms to ensure the following responsibilities are met:
  - Ensure IR is provided budgetary and institutional support
  - Ensure the research review unit functions independently and free from coercion and undue influence
  - Make available to the research review unit legal counsel who is not conflicted by other organizational responsibilities
  - Make available to the research review unit more senior officials of the organization, when the IRB deems such access to be warranted.
  - Develop and provide educational programs for faculty, staff, and students
  - Ensures the independence of the IRB
  - Review and approve exempt research protocols
  - Support the IRB in all administrative capacities
- ❖ The Institutional Review Board (IRB) - The Institutional Review Board (IRB) for Northwest Vista College is responsible for the review and approval of all research involving human subjects conducted under its auspices. The IRB is charged with protecting the rights and welfare of human research subjects recruited to participate in research activities and to ensure compliance with applicable federal regulations. The board is responsible for reviewing all research projects involving human subjects that are conducted at institution facilities or property; is sponsored by the institution; is conducted by or under the direction of any employees or agents of the

institution in connection with their institutional responsibilities; or involves the use of the institution's non-public information to identify or contact human research subjects or prospective subjects.

## **DELEGATION OF AUTHORITY**

Authority is delegated to the Vice President of College Services to handle all matters regarding human subject research, in compliance with federal and state regulations and the ethical considerations set forth in The Belmont Report.

The Director of Institutional Research, Planning, and Effectiveness is delegated the authority to administer the day to day operations of the program. The IR Director is to document and disseminate comprehensive standard operating procedures detailing criteria for review and other procedures used in the review process.

The IR Director is to support the Institutional Review Board of Northwest Vista College. The Chair of said board is to have independent authority to institute and approve all procedures related to the review of research.

The IR Director will additionally support and assist the research community as needed. Support is to include outreach and education to faculty, staff, students and research subjects.

The IR Director serves as a non-voting member of the IRB. The IR Director cannot serve as IRB Chair.

SOP Number:	IRB 02	Revision Number:	01	Effective Date:	8/01/2018
Title:	Standard Operating Procedures – Creation and Maintenance				

## PURPOSE STATEMENT

Standard operating procedures (SOP) provide the framework for responsibilities and role of the Office of Institutional Research (IR). These SOP will fulfill the requirements for written procedures specified in 45 CFR 46.103.

This document applies to all SOPs for the review of human subject research at Northwest Vista College. It describes what SOPs are required and the process by which they are created, reviewed, revised, maintained and approved.

## SPECIFIC POLICIES

- A. Required SOP - At a minimum, the IR will create, distribute, maintain and follow SOP relating to the following areas:
- ❖ Organizational Administration
  - ❖ Program Administration
  - ❖ Review of Research
  - ❖ Documentation
  - ❖ Communication and Notifications
  - ❖ Investigator Responsibilities
- B. Review, Revision and Approval Standard Operating Procedures:  
Changes to regulations, federal guidelines, research practice or the policy and procedures of Northwest Vista College may require a new SOP or a revision to a previously issued SOP.
- SOPs will be reviewed by the Vice President of College Services and the Director of Institutional Research at least annually.

New SOPs or substantive revisions to existing SOPs will be approved by the IRB Chair prior to issuance.

Minor revisions related to formatting, grammar, style and appearance, and administrative actions may be approved by the Vice President for College Services without additional approval.

- C. Ratification of Existing SOPs - SOPs created, reviewed and approved according to the process described above, prior to the effective date of this document, will automatically be ratified as of the effective date of this document.
- D. SOP Dissemination and Training  
When a new or revised SOP is approved, it will be disseminated to appropriate individuals and departments.
- All SOPs are effective as of the stated effective date
  - All SOPs should be distributed to effected individuals within five calendar days of being approved.

Training will be provided to all members of the IRB on any new SOP.

Each new IRB member or employee must review all applicable SOPs prior to undertaking any responsibilities with the IRB.

E. Forms

Forms are used for the following purposes:

- To ensure that policies are integrated into the daily operations of research and review throughout Northwest Vista College.
- To enable the IR Director to manage review, tracking, and notification functions consistently.

SOP Number:	IRB 03	Revision Number:	01	Effective Date:	8/01/2018
Title:	Composition of the IRB				

## PURPOSE STATEMENT

This document specifies the criteria to be used in determining the composition of an IRB.

## FEDERAL REQUIREMENTS

- ❖ Per 45 CFR 46.107, Northwest Vista College will adhere to the following criteria regarding the composition of any IRB it creates or maintains:
  - Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.
  - The IRB shall be sufficiency qualified through the experience, expertise and diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.
  - The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall include persons knowledgeable in these areas.
  - Consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects if an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons.
  - Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection of an IRB member is made on the basis of gender.
  - No IRB may consist entirely of members of one profession.
  - Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
  - Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
  
- ❖ Alternate members may be used if they are formally appointed as alternate members.
  - The alternate member's qualifications shall be comparable to those of the primary member to be replaced.
  - When an alternate member replaces the primary member, the alternate member shall have received and reviewed the same material as the primary member.
  - The IRB roster shall identify the primary member(s) for whom each alternate member may substitute.
  - The IRB minutes shall document when an alternate member replaces a primary member.

## APPOINTMENT OF CHAIR AND VICE CHAIR

The Chairperson of the IRB will be appointed by the Institutional Official (Vice President of College Services). Ideally, the Chairperson of the IRB will be from the current membership of the IRB. Training will be provided to the Chairperson of the IRB. The IRB Chairperson can resign or be removed by the Institutional Official following written notification.

SOP Number:	IRB 04	Revision Number:	01	Effective Date:	8/01/2018
Title:	Appointment of IRB Members				

## **PURPOSE STATEMENT**

The Vice President for College Services (VPCS) delegates authority for management of the membership of the Institutional Review Board (IRB) and oversight of member nominations to the Director of Institutional Research.

The purpose of this document is to detail the process and by which IRB members are appointed.

## **APPOINTMENT AUTHORITY**

The VPCS has authority to appoint members to the IRB.

## **NOMINATION OF MEMBERS**

Nominations are submitted to the VPCS by the IR Director. The IR Director will seek candidates from individuals or departments. Self-nomination to the IR Director is acceptable. The IR Director may also actively solicit nominations from departments and the local community.

## **CANDIDATE REVIEW AND APPOINTMENT PROCESS**

Nominees will submit a CV or resume to the IR Director.

When an opening on the board is identified, all candidates nominated will be reviewed by the VPCS and IR Director.

- ❖ Special consideration will be given to candidates nominated by departments regularly having research reviewed by the board to ensure sufficient expertise in those areas.
- ❖ Special consideration will be given to faculty members who conduct research.
- ❖ Special consideration will be given to individuals with the ability to advocate for a vulnerable population.

## **TERM OF OFFICE**

Members will be appointed to serve on the IRB for a term of no more than five years. The Chair will be appointed to serve a term of no more than three years.

Reappointments may be recommended to the VPCS by the IR Director.

## **RESIGNATIONS AND REMOVALS**

A member may resign before the conclusion of his/her term. The vacancy will be filled as quickly as possible. Notification of resignation should be made, in writing, to the IR Director and IRB Chair.

The VPCS and Chair of the IRB have the authority to revoke the membership of an appointed IRB member. Revocation of membership will only occur when an IRB member fails to meet the responsibilities of IRB members. Revocation of membership will be made in writing.

## **COMPENSATION**

Participation by Northwest Vista College faculty or staff is considered a component of job responsibilities for service as established by the College.

## **MEMBERSHIP RECORDS**

A file will be retained on each IRB member. At a minimum, it will contain the following:

- ❖ Documentation of training
- ❖ CV or resume
- ❖ Conflict of Interest Statement
- ❖ Confidentiality Agreement

## **RESPONSIBILITY**

The IR Director is responsible for day-to-day management of the administrative activities of the IRB.

The IR Director is responsible for ensuring the IRB roster is updated with OHRP within thirty days of any changes being made to the membership of the IRB.

IRB Chairperson is responsible for management of the activities of the IRB members relevant to meeting conduct and review of research.

SOP Number:	IRB 05	Revision Number:	01	Effective Date:	8/01/2018
Title:	Responsibilities of IRB Members				

**PURPOSE STATEMENT**

Each Institutional Review Board (IRB) member’s primary duty is the protection of the rights and welfare of the individual human beings serving as the subjects of the research under review.

IRB members are expected to be versed in regulations governing human subjects’ protection, research ethics and the policies of Northwest Vista College pertinent to human subjects’ protection.

This policy indicates the responsibilities an IRB member must undertake in support of meeting their primary goal. Many of these responsibilities, particularly those related to the review of research, are described in greater detail within other standard operating procedures.

**TRAINING**

All IRB members are to complete the Collaborative Institutional Training Initiative (CITI) course and to review all SOPs prior to assuming full voting membership on the board. The IR Director will conduct IRB training requested by board members which will be scheduled at the convenience of the new members.

IRB members are encouraged to consider taking part in other training activities throughout the year. Optional training offerings may include national conference attendance, regional conference attendance, webinar offerings and topic specific training sponsored by other groups.

**SERVICE**

It is important that IRB members attend scheduled IRB meetings. Failure to attend can result in a loss of quorum and hinder the IRB’s ability to conduct business. The IR Director should be notified in advance if an IRB member is unable to attend.

IRBs are appointed as institutional committee members. IRB members serve Northwest Vista College as a whole, rather than a particular department. Member’s own interests or interests of their department do not supersede the duty to protect the rights and welfare of research subjects.

**REVIEWER RESPONSIBILITIES - CONVENED MEETING**

Each study referred to a convened meeting for review will be disseminated to each member. The responsibility of each IRB member is detailed below:

**Chair of the IRB**

The Chairperson presents an overview of the study to the board at convened IRB meetings including the goals of the study and the methods to be employed by the researcher in meeting the goals. Committee members then discuss the characteristics of the study based on federal criteria for review.

The chair guides discussion after members have spoken. The chair ensures the board has considered all elements required for approval prior to a vote.

The Chair ensures no conflict of interest exists before a vote is taken.

### **IRB Members**

IRB members have the floor immediately following the chair's overview to offer insight, other points to consider and/or a dissenting opinion.

### **ATTRIBUTE SPECIFIC DUTIES**

Everyone appointed to the IRB is encouraged to participate in all facets of the review discussion. Members should be aware of the additional responsibility based on membership attributes. The attributes and responsibilities are detailed as follows:

#### **Non-affiliated Member(s)**

Non-affiliated members are expected to provide input regarding their knowledge about the local community and be willing to discuss issues and research from that perspective.

#### **Non-scientific Members**

Non-scientific members are expected to provide input on areas germane to them: knowledge, expertise and experience, professional and otherwise. Members should advise the IRB if additional expertise in a non-scientific area is required to assess if the protocol adequately protects the rights and welfare of subjects.

#### **Scientific Members**

Scientific members are expected to contribute to the evaluation of a study on its scientific and statistical merits and standards of practice. Members should also be able to advise the IRB if additional expertise in a non-scientific area is required to assess if the study adequately protects the rights and welfare of subjects.

### **REVIEWER RESPONSIBILITIES - EXPEDITED REVIEW**

Expedited review responsibilities are delegated by the Chair to all members of the IRB. Each expedited protocol will be reviewed by two members of the board.

### **ALTERNATE MEMBERS**

Alternate IRB members may be appointed to the IRB. An alternate contributes to the quorum and functions as an IRB member if the regular member for whom they serve as alternate is unavailable. Appointed alternates will be listed on the IRB rosters submitted to Office for Human Research Protections (OHRP).

Alternate board member composition mirrors regular membership. It is necessary to ensure a committee is properly constituted, even when alternates are serving. The alternate should have expertise or experience similar to the regular member.

The IRB minutes must document when the alternate member serves in place of the regular member.

An alternate is appointed and trained in the same manner as a regular board member.

Alternate members are encouraged to attend IRB meetings and participate in other IRB activities even when the regular member is present; however, alternates do not contribute to the formation of a quorum or vote unless the member for whom they substitute is not available.

Alternates will receive the same materials provided to regular members. Depending upon the alternates' preferences, they may choose to receive materials only for the meetings they are called to serve on as a voting member, or they may choose to receive materials for every meeting regardless of whether the absence of their counterpart is anticipated.

Alternate members are expected to "vote their conscience" as opposed to representing the position of the regular member for whom they serve.

### **PROTECTION OF HUMAN SUBJECTS**

Any member of the IRB may terminate or suspend research if human subjects are being placed at risk or a study is being carried out in a manner inconsistent with approved procedures. The decision is not to be made lightly and if time permits, the Chair and IR Director should be consulted prior to taking this action.

SOP Number:	IRB 06	Revision Number:	01	Effective Date:	8/01/2018
Title:	Confidentiality of the Review Process				

**PURPOSE STATEMENT**

Confidentiality is to be maintained by Institutional Review Board (IRB) members and the Office of Institutional Research staff in handling information learned during the review process and IRB meetings.

**CONFIDENTIALITY GUIDELINES**

IRB members and IR staff will be privy to information of a sensitive, personal and confidential nature. The following standards of conduct and procedures will apply to maintain the confidentiality of information received and reviewed by the IRB:

- ❖ IRB members and IR staff will not discuss or divulge any information beyond what is required to fulfill the obligation to protect human subjects or to remain compliant with applicable laws.
- ❖ IR staff will notify IRB members in writing if they are required to participate in an audit. IRB members must answer all questions the auditor asks.

**CONFIDENTIALITY STATEMENT**

Each IRB member and all IR staff will sign a Confidentiality Statement. IRB members will sign a Confidentiality Statement at least once per term. Confidentiality Statements will be kept in each IRB or IR staff member's individual file.

SOP Number:	IRB 07	Revision Number:	01	Effective Date:	8/01/2018
Title:	IRB Member / Consultant Conflict of Interest				

## PURPOSE STATEMENT

It is imperative reviewers be free of all conflicts of interest to ensure adequate and equitable review of all proposed research. Both IRB members and consultants to the IRB are required to state any conflicts prior to conducting the review of a study.

The following outlines the specific processes the IRB has implemented to manage, reduce and/or eliminate actual or potential conflicts of interest.

## DEFINITION OF CONFLICT OF INTEREST

An IRB Member or Consultant is considered to have a conflicting interest if they or a member of their immediate family\* meet any of the following criteria:

- ❖ Is a member of the research team
- ❖ Has a financial interest in the research project
- ❖ Has received or will receive compensation with value that may be affected by the outcome of the study.
- ❖ Has a proprietary interest in the research, such as a patent, trademark, copyright or licensing agreement.
- ❖ Has received personal payment from the sponsor that exceeds \$5,000 in the past year.
- ❖ Is an executive or director of the agency or company sponsoring the research.
- ❖ Is the faculty advisor to a student seeking IRB approval.
- ❖ Has an interest that may conflict with the ability to objectively review a protocol.

*\*Immediate family is considered to be close relatives by birth or marriage including spouse, siblings, parents, children, in-laws, grandparents and any other financial dependents.*

## HOW TO REPORT

*Expedited Review* - The protocol should be returned to the IR Director with the conflict noted in lieu of review notes.

*During a Full Board Meeting*- A member or consultant must state before the review of the protocol with a COI that he/she has a conflict of interest with a protocol and the conflict will be formally noted in the minutes.

## ACTIONS TAKEN

*Expedited Review* - The protocol will be forwarded to another expedited reviewer if a conflict of interest is noted. The protocol will be placed on the agenda for the next available board meeting if another expedited reviewer is not available.

*During a Full Board Meeting* - The individual with a conflict will be asked to abstain from the voting on a protocol with which there is a conflict if a conflict. If the conflict stems from involvement with the protocol from a researcher or advisor role, the board may ask the member/consultant to answer questions or clarify points - as they may with any other advisor or researcher.

## **RECORDKEEPING**

*Expedited Review* – The conflict of interest notation will be maintained in the protocol file.

*During a Full Board Meeting* - The minutes will record all stated conflicts of interest as declared. If a conflict of interest is declared, the minutes document the member/consultant's abstention.

SOP Number:	IRB 08	Revision Number:	01	Effective Date:	8/01/2018
Title:	Definition of Human Subjects Research				

**PURPOSE STATEMENT**

Northwest Vista College has assured the federal regulatory agencies that the institution will review and approve all research involving human subjects, regardless of funding source, before it is initiated.

The purpose of this document is to define human subject research to describe projects that must be submitted to the IR Office for review.

Human Subject Research is defined in 45 CFR 46.102.

**FEDERAL DEFINITION OF RESEARCH**

Research is defined as a systematic investigation including research development, testing and evaluation designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research whether or not they are conducted or supported under a program considered research for other purposes.

**HUMAN SUBJECTS**

Human subjects are defined as living individuals about whom an investigator conducting research obtains data through intervention or interaction with the individuals or identifiable private information.

**SUBMISSION AND REVIEW**

Research involving human subjects must be submitted to the IR Director for administrative or IRB review prior to initiation.

Research in any of the following categories must be submitted for IRB approval:

- ❖ The research is conducted by or involves NVC faculty, staff or students
- ❖ The procedures are performed in college facilities.
- ❖ The procedures are performed with equipment belonging to the college.

SOP Number:	IRB 09	Revision Number:	01	Effective Date:	8/01/2018
Title:	Identifying and Assessing Risk				

## PURPOSE STATEMENT

The duty of the Institutional Review Board (IRB) is to protect the rights and welfare of human subjects. It is vital for the IRB to ensure any risks to subjects are minimized to protect those rights. The purpose of this document is to provide information regarding how the IRB is to identify and assess the level of risk proposed by investigators.

## RESPONSIBILITIES OF THE IRB

The IRB must be able to recognize the likelihood and magnitude of harms and benefits and understand the importance of the knowledge reasonably expected to result. Members must be cognizant of the range of harms and the range of benefits. The range of harms can include physical, social, economic, psychological and legal harm. Benefits can take the form of therapy, education, information, resources or empowerment. Both risks and benefits can be directed at participants or the community.

## CRITERIA FOR APPROVAL

Studies will not be approved by the IRB unless the following criteria are met:

- A. Risks to Subjects are minimized
  - ❖ Using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
  - ❖ Whenever appropriate, using procedures already being performed on the subjects for diagnostic or treatment purposes.
- B. Risks to subjects are reasonable in relation to any anticipated benefits to subjects and the importance of the knowledge that may reasonably be expected to result.
  - ❖ The IRB must consider only those risks and benefits that may result from the research when evaluating risks and benefits (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research).
  - ❖ The IRB must not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
- C. Additional safeguards must be included in the study to protect the rights and welfare of subjects likely to be vulnerable to coercion or undue influence (ex. children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons).

## ADDITIONAL CRITERIA NEEDED FOR APPROVAL

Applications must include detailed information allowing the IRB to conduct an analysis of the risks and potential benefits, such as:

- ❖ The purposes of the research.
- ❖ The scientific or scholarly rationale.
- ❖ The procedures to be performed.
- ❖ A description of the procedures being performed already for diagnostic or treatment purposes.

SOP Number:	IRB 10	Revision Number:	01	Effective Date:	8/01/2018
Title:	Privacy of Human Subjects				

## GENERAL POLICY

Research studies that intend to enroll human subjects as participants must ensure that adequate provisions are in place to protect the privacy interests of the participants.

Privacy can be defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. Privacy is a right that must be protected during and after involvement as research participants. It is the IRB's responsibility to systemically and rigorously evaluate privacy protections.

## SPECIFIC POLICIES

The following should be taken into consideration by the IRB when reviewing studies for approval:

- A. Privacy in the Gathering of Selection Criteria
 

The IRB must evaluate the means used to gather information used as selection criteria. The IRB must consider whether consent of the subjects should be required if the investigator uses existing records to identify people suitable for inclusion in the study. Considerations for consent of private information should include, but are not limited, to the following:

  - ❖ Sensitivity of the reviewed information
  - ❖ Vulnerability of the subject population
  - ❖ Investigator's purpose for gathering the information
  - ❖ Implied and/or specified Confidentiality agreements regarding the information on the Existing Records
  - ❖ Authorization necessary for the release of the Existing Records
  - ❖ Manner in which subjects will be approached upon selection.
- B. Privacy in the Nature of the Study
 

The subjective nature of privacy dictates that IRBs must base decisions on the members' sense of propriety and the particular circumstances involved in the study.
- C. Discretion
 

Efforts should be made by the investigator to provide discretion if the study involves a topic that could lead to social stigmatization or discrimination, or if involvement in the study could present legal concerns for the subjects. Considerations should be made regarding the location and manner of the procedures involved in the study to ensure that public knowledge of the subjects' involvement is limited.
- D. Observation
 

The IRB should make considerations for studies involving observation of subjects - especially if this observation will transpire without the subjects' consent:

  - ❖ Collection of private identifiable data
  - ❖ Potential risks of the disclosure of collected data
  - ❖ Likelihood that a reasonable person would be offended by the potentially intrusive nature of the observation
  - ❖ Justification for intrusions on privacy based on the potential gain

❖ Alternatives which are less intrusive

E. Intrusive Questioning

The investigator should have procedures in place to mitigate the intrusiveness of the questions if the topic of the study includes questions which would be considered personal or offensive in nature. Community and cultural standards should be considered when evaluating the likelihood that a subject will be offended by the topic of the study. Where appropriate, disclaimers will be given to inform subjects of potentially offensive topics or questions.

F. Third Party Participation

The privacy policy of the Third Party should be provided to the IRB in studies where it is necessary to use a third party to facilitate a procedure involved in the study. The IRB should consider whether a Third Party has a secure method to transmit and store personal information for studies involving internet data collection.

SOP Number:	IRB 11	Revision Number:	01	Effective Date:	8/01/2018
Title:	Confidentiality of Identifiable Information				

## GENERAL POLICY

Researchers must ensure that adequate provisions are in place to protect the confidentiality of human subjects' identifiable data during the study and after its conclusion.

Confidentiality refers to agreement between the researcher and the participant about how private information will be handled, managed, and disseminated.

IRB members should understand strategies involved in providing assurances of confidentiality to participants. Certain protocols may require the IRB to ensure that specific procedures are in place to prevent breaches of confidentiality.

## SPECIFIC POLICIES

### A. Confidentiality with Routine Protocols

- ❖ The IRB will evaluate the sensitivity of the information that will be recorded to determine what measures should be taken. Routine measures can be implemented by the researcher for studies not involving sensitive information. Measures include, but are not limited to:
  - Substituting codes for personal identifiers
  - Removing face sheets from survey instruments
  - Limiting access to identifiable data
  - Proper disposal of identifiable data that will not be retained
  - Storing research records securely.
- ❖ The researcher should make efforts to assure participants that personal information will be safeguarded even when a study involves a minimal amount of sensitive data collection.

### B. Confidentiality with Sensitive Protocols

Many protocols will gather information that would be considered "sensitive" and would potentially harm participants if the data became public knowledge. The researcher needs to be able to offer strong, truthful assurances of confidentiality and should have procedures in place to prevent a breach in studies involving sensitive information. The following list of sensitive information is not inclusive and other cultural factors should be considered, when necessary. Studies should be considered to be sensitive if they involve the collection of information relating to:

- ❖ Abortion
- ❖ AIDS/HIV
- ❖ Alcohol
- ❖ Body Composition
- ❖ Criminal Activity
- ❖ Psychological Well-being
- ❖ Financial Matters
- ❖ Sexual Activity
- ❖ Suicide
- ❖ Learning Disability
- ❖ Drugs

- ❖ Depression
- ❖ Medical issues that could lead to social stigmatization or discrimination

C. Waiver of Documentation of Consent

The investigator may choose not to record any personally identifiable data in research studies. The consent form will be the only recorded data that links the participant to the study in such cases. Federal guidelines allow IRBs to waive the requirement for a consent form if the study involves no more than a minimal risk, if breach of confidentiality is the principle risk and if the procedures would normally not require consent if they occurred outside a research environment.

The IRB requires the use of an Information Sheet in lieu of a signed consent form.

D. Certificates of Confidentiality

Protection of confidentiality may need to extend beyond prevention of accidental disclosure in studies involving sensitive data. The National Institutes of Health can approve Certificates of Confidentiality which will safeguard the research data from subpoenas from law enforcement.

- Alternate measures should be considered to safeguard sensitive data in the best possible manner if the study involves sensitive information and a Certificate of Confidentiality cannot be obtained.. The IRB should consider the approaches the researcher will take to keep records secure and decide if the need for confidentiality is met.

Legal advice may be necessary to protect the participant and/or the researcher.

E. Oversight of Repository Activities

Confidentiality also applies to the storage of biologic samples. The IRB is responsible for ensuring that biologic samples are stored in a manner maintaining confidentiality and researchers receive consent from participants whose biologic samples will be used for additional study.

SOP Number:	IRB 12	Revision Number:	01	Effective Date:	8/01/2018
Title:	Investigator Conflict of Interest				

## PURPOSE STATEMENT

It is imperative Investigators with conflicts of interest submit documentation of conflicts for review by the Institutional Review Board (IRB) to ensure adequate protection of research subjects.

The purpose of this documentation is to outline the specific processes the IRB will use to review conflicts of interest to protect human subjects. The requirements comply with Federal Regulations and are separate from other College Conflict of Interest standards.

## DEFINITION OF CONFLICT OF INTEREST

An Investigator is considered to have a conflicting interest if he or she or a member of his or her immediate family\* meets any of the following criteria:

- ❖ Has a financial interest in the research with value that cannot be readily determined.
- ❖ Has a financial interest in the research with value that exceeds \$5,000.
- ❖ Has received or will receive compensation with value that may be affected by the outcome of the study.
- ❖ Has a proprietary interest in the research, such as a patent, trademark, copyright or licensing agreement.
- ❖ Has received payment from the sponsor that exceeds \$5,000 in the past year.
- ❖ Is an executive or director of the agency or company sponsoring the research.

*\*Immediate family is considered to be close relatives by birth or marriage including spouse, siblings, parents, children, in-laws, grandparents and any other financial dependents.*

## REPORTING MECHANISM

Investigators are required to complete a Conflict of Interest Statement as part of the IRB protocol form stating whether a conflict of interest exists. The statement will be resubmitted annually with the Continuing Review Application.

## IRB REVIEW OF CONFLICT OF INTEREST

The IRB will verify financial conflicts of interests have been reported to the appropriate department and are in compliance with District Policy D.2.4 Nepotism, Conflicts of Interest and Procedure D.2.4.2 Conflicts of Interest. A copy of a management plan will be provided to the IRB, if applicable.

The IRB will determine the potential impact the Conflict of Interest may have on subjects and what course of action, if any, will be required of the investigator to mitigate potential harms. Examples of IRB requirements may include, but are not limited to the following:

- ❖ Disclosure of the Conflict of Interest in consent documentation
- ❖ Requiring procedures restricting or eliminating investigator's direct involvement with participants.
- ❖ Data monitoring

SOP Number:	IRB 13	Revision Number:	01	Effective Date:	8/01/2018
Title:	Study Design and Oversight				

## PURPOSE STATEMENT

Investigators have the responsibility to ensure the design and management of studies protect the rights and welfare of human subjects.

## SOUND STUDY DESIGN

Research studies must be designed in such a way that the research will likely develop or contribute to generalizable knowledge or allow conclusions to be drawn. Investigators should assess the proposal's ability to meet this objective before submitting it for review to the Office of Institutional Research Compliance and/or the Institutional Review Board (IRB).

Student investigators must obtain their advisor's signature on all applications submitted to the IR/IRB. Advisors are responsible for reviewing the study design and advising students on proper procedures.

## MINIMIZING RISKS

Using a sound study design and applying appropriate oversight will help prevent unnecessary risks. Investigators must be in compliance with 45 CFR 46.111(a) (1)-(2):

- ❖ Risks to subjects are minimized.
  - By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
  - Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- ❖ Risks to subjects, if any, are reasonable in relation to anticipated benefits, and the importance of the knowledge that may reasonably be expected to result.
  - Investigators should consider only those risks and benefits that may result from the research in evaluating risks and benefits (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research).
  - Investigators should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

## OVERSIGHT

Investigators must determine how the study will be managed once a study design has been created, especially if additional persons will be interacting with the subjects. Investigators will not be granted IRB approval unless the following items are addressed:

- ❖ Consent Protocol: Investigators must submit detailed description of how consent will be obtained from research participants.
- ❖ Guidance: Investigators must demonstrate to the IRB how research staff will be directed to be compliant with federal regulations and the IRB approved procedures.
- ❖ Reports to the IRB: Investigators must report any deviation of procedures from the IRB approved protocol. All unanticipated problems and serious adverse events must be reported to the IRB.

SOP Number:	IRB 14	Revision Number:	01	Effective Date:	8/01/2018
Title:	Risk Minimization				

## PURPOSE STATEMENT

All investigators engaged in research have a duty to protect the rights and welfare of human subjects. Any risks to subjects must be minimized to protect those rights. The purpose of this document is to provide information regarding how to minimize and/or eliminate risk.

## RESPONSIBILITY OF INVESTIGATORS

Investigators must be able to recognize the likelihood, magnitude and range of harms and benefits to subjects. The range of harms includes physical, social, economic, psychological and legal harm. Benefits can take the form of therapy, education, information, resources or empowerment. Both risks and benefits can be directed at participants or their community.

## MINIMIZING RISK

Apply the following guidelines to ensure minimal risks to participants:

- A. Risks to subjects are reasonable in relation to any anticipated benefits to subjects and the importance of the knowledge that may reasonably be expected as a result.
  - ❖ Investigators must consider only those risks and benefits possibly resulting from the research when evaluating risks and benefits (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research).
  - ❖ Investigators must not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among research risks falling within the purview of its responsibility.
- B. Study Design: Investigators must use a sound study design. Research studies must be designed in such a way that the research will likely develop or contribute to generalizable knowledge and/or allow conclusions to be drawn. Investigators should assess the proposal's ability to meet this objective before submitting it for review to the Office of Research Compliance (ORC) and/or the Institutional Review Board (IRB).
- C. Diagnostic Procedures: Investigators will continue procedures already being performed for diagnostic or treatment purposes if the procedures can help minimize risks.
- D. Conflict of Interest (COI): Anything that competes with the investigator or research staff's obligation to protect the rights and welfare of research participants is considered a COI. COIs will be reviewed by IR/IRB to determine the necessity of further action.
- E. Coercion: Subjects must not feel coerced or be heavily influenced to participate in research. Vulnerable populations are the most likely subjects to be coerced. Additional safeguards are required if vulnerable populations are used as subjects. The following are examples of vulnerable populations:
  - ❖ Children
  - ❖ Prisoners
  - ❖ Pregnant Women, Fetuses and Neonates

- ❖ Subordinate relationships, such as: Teacher/student, Employer/employee, Military officer/soldier, Doctor/patient

#### **ADDITIONAL CRITERIA NEEDED FOR APPROVAL**

Refer to 45 CFR 46. Applications must include information allowing the IRB to conduct an analysis of the risks and potential benefits, such as:

- ❖ The purposes of the research.
- ❖ The scientific or scholarly rationale.
- ❖ The procedures to be performed.
- ❖ A description of the procedures being performed already for diagnostic or treatment purposes.

SOP Number:	IRB 15	Revision Number:	01	Effective Date:	8/01/2018
Title:	Recruitment Procedures				

## PURPOSE STATEMENT

The following details the requirements for recruitment procedures of human subjects in research. Recruitment procedures must be submitted and approved by the Institutional Review Board (IRB) prior to implementation.

## ETHICS OF RECRUITMENT

Investigators must adhere to The Belmont Report when conducting recruitment procedures. The main elements of The Belmont Report are as follows:

- A. Respect for Persons: Individuals should be treated as autonomous agents, and persons with diminished autonomy are entitled to protection.
  - ❖ An autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation.
  - ❖ To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions, unless they are clearly detrimental to others.
  - ❖ To show lack of respect for an autonomous agent is to repudiate that person's considered judgments, to deny their freedom to act on those considered judgments, or to withhold information necessary to make a considered judgment when there are no compelling reasons to do so.
  
- B. Beneficence: What benefits will come from the study? Investigators should ensure recruitment procedures
  - ❖ Do not harm and
  - ❖ Maximize possible benefits and minimize possible harms.
  
- C. Justice: Selection of research subjects needs to be scrutinized to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities or persons confined to institutions) are being systematically selected simply because of easy availability, compromised position or manipulability, rather than for reasons directly related to the problem being studied.
  - ❖ Compensation rates will be reviewed to ensure they are not coercive or manipulative.
    - Recruitment materials will be reviewed.
    - The rationale for targeting a particular vulnerable population must be provided. The review must determine if the rationale is sufficient and appropriate considering the principle of justice.

## DOCUMENTATION OF RECRUITMENT PROCEDURES

Investigators must submit all recruitment materials for review. Examples include flyers, emails, newspaper advertisements, and etcetera. Investigators must submit the script they plan to use if they plan to recruit participants in a verbal form, such as a telephone conversation or interview.

## CRITERIA FOR APPROVAL

The IRB will review the procedures and ensure procedures are ethical and protect the rights and welfare of possible participants. Investigators must include the following for approval:

- A. Investigators must explain the following to ensure the selection of participants is equitable and the policies and procedures are appropriate
  - ❖ The purposes of the research.
  - ❖ The setting in which the research will be conducted.
  - ❖ Whether prospective participants will be vulnerable to coercion or undue influence.
  - ❖ The selection (inclusion/exclusion) criteria.
  - ❖ Participant recruitment and enrollment procedures.
  - ❖ The amount, timing and influence of payments to participants.
  - ❖ The information contained in the recruitment material.
  - ❖ The mode of its communication.
  - ❖ The final copy of printed advertisements.
  
- B. Advertisements must at minimum contain
  - ❖ The name and address of the Investigator or research facility.
  - ❖ The purpose of the research or the condition under study.
  - ❖ A summary of the criteria used to determine eligibility for the study.
  - ❖ A brief list of participation benefits, if any.
  - ❖ The time or other commitment required of participants.
  - ❖ The location of the research.
  
- C. Advertisements cannot
  - ❖ State or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.
  - ❖ Include exculpatory language.
  - ❖ Emphasize the payment or the amount to be paid, by such means as larger or bold type.
  - ❖ Promise "free treatment" when the intent is only to say participants will not be charged for taking part in the investigation.
  
- D. Advertisements relating to FDA-regulated research cannot
  - ❖ Make claims, either explicitly or implicitly, about the drug, biologic or device under investigation that are inconsistent with FDA labeling.
  - ❖ Use terms, such as "new treatment," "new medication" or "new drug" without explaining that the test article is investigational.
  - ❖ Allow compensation for participation in a trial offered by a sponsor to include a coupon for a discount on the purchase price of the product once it has been approved for marketing.
  
- E. Payment requirements (if applicable)
  - ❖ The amount of payment and the proposed method and timing of disbursement is neither coercive nor presents undue influence.
    - Credit for payment accrues as the study progresses and is not contingent upon the participant completing the study.
    - Any amount paid as a bonus for completion is reasonable and not so large as to unduly influence participants to stay in the study when they would otherwise have withdrawn.

- ❖ All information concerning payment, including the amount and schedule of payments, is set forth in the consent document.
  - ❖ Policies and procedures describe acceptable and unacceptable payment arrangements among sponsors, organizations, Investigators and those referring research participants.
    - Policies and procedures on payment arrangements address the acceptability of payments in exchange for referrals of potential participants ("finder's fees").
    - Policies and procedures on payment arrangements address payments designed to accelerate recruitment that are tied to the rate or timing of enrollment ("bonus payments").
- F. Extra credit requirements (if applicable)
- ❖ The offer of extra credit for participation must be justified as neither coercive nor presenting undue influence.
    - Alternative exercise(s) for extra credit should be available for students who choose not to participate in the study.
    - Alternative extra credit should not be more difficult for students to complete than the requirements of participation in the study.
  - ❖ All information concerning extra credit must be set forth in the consent document.

## CONSENT

Recruitment methods, advertising materials and payment arrangements also represent a part of the consent process. Recruitment methods and advertisements are the beginning of the consent negotiations; payments for participation are provided to reimburse participants for time, effort or other expenses related to participation in the study.

Recruitment methods, advertisements, or payment arrangements that are misleading, inaccurate, exculpatory, coercive or unduly influential violate the regulatory requirements for consent. The IRB will review proposed recruitment processes and advertising materials to judge whether they fulfill the regulatory requirements for consent.

SOP Number:	IRB 16	Revision Number:	01	Effective Date:	8/01/2018
Title:	Informed Consent Process and Documentation				

## PURPOSE STATEMENT

The informed consent process is a key element in any proposed research study. The process is how "Respect for Persons" is achieved as described in the Belmont Report. Prospective subjects will be provided complete information regarding the procedures in which they are being asked to take part and will be given the opportunity to decide whether or not to participate.

Informed consent is a process, not merely a document subjects are asked to sign. Meaningful dialogue should occur between the person seeking consent and the potential subject. The dialogue should give the prospective subject accurate information in easily understood language. The script will offer potential subjects an opportunity to ask questions and it will stress the voluntary nature of participation. The informed consent process does not conclude once an informed consent document is signed. Study staff will be trained to recognize opportunities to reaffirm consent and be vigilant to identify any confusion or discomfort experienced by the subject.

The Institutional Review Board (IRB) requires a complete description of the consent process and the tools used during this process to review proposed research. Principal Investigators are responsible for ensuring the approved consent process is accurately and completely executed.

The following review requirements and procedures apply to all research submitted to the IRB with the following exceptions:

- Consent and documentation of consent may be waived by the IRB. See Waivers or Alterations to the Consent Process or Documentation Requirements for more information on waivers of consent and waivers to the documentation requirements.
- Exempt research consent requirements are more flexible.

Additional requirements will apply when research involves vulnerable populations.

The following specific requirements and review criteria related to the consent process and the requirements for documentation of consent. Requirements are based on the regulations set forth in 45 CFR 46.116 and 45 CFR 46.117.

## INFORMATION REQUIRED FOR REVIEW

IRB applications will include a thorough description of the informed consent process to aid in the determination that consent procedures are adequate and appropriate.

The description will include the following information:

- ❖ The name of the person(s) responsible for obtaining the participant's consent
- ❖ The person who will provide consent or permission. Whether consent be sought from:
  - ❖ Subject or Authorized representative.
    - How the authorized representative is determined and/or
    - The criteria for deferring to an authorized representative in lieu of the subject.
- ❖ Any waiting period between informing the prospective participant and obtaining consent.

- ❖ Steps taken to minimize the possibility of coercion or undue influence.
- ❖ A Consent Protocol outlining the consent process will be included with any study. The protocol should include the following:
  - Verbiage used by person(s) obtaining consent. The protocol should include verbal cues seeking confirmation of understanding of the protocol by prospective subjects.
    - Merely reading the consent materials to the prospective subject is not acceptable.
    - Script should be friendly, straight forward and conversational.
    - Script should include information regarding the research study presented in an easy to understand manner.
  - At what point in the process the consent form or information sheet will be distributed and the verbiage used in leading up to its presentation.
  - Amount of time allocated for the subject to review the consent documentation.
  - The identification of other points within the protocol where consent will be reaffirmed and how this may be achieved.
    - The IRB may require consent to be formally reaffirmed depending on the length and nature of the study. Lengthy studies involving children or the cognitively impaired are of particular concern.
- ❖ A full description and timeline of all anticipated interactions (Consent Protocol) shall be documented. The documentation will include a description of the means of communication and for obtaining consent.
- ❖ A copy of all consent documents or other written materials provided to the subject.

## **REQUIRED ELEMENTS OF CONSENT**

The required elements of informed consent are incorporated in the consent form template to help investigators include all the pertinent information. The elements are as follows:

### **A. Introduction/Purpose**

- ❖ A statement that the study involves research,
- ❖ An explanation of the purposes of the research,
- ❖ The expected duration of the subject's participation and
- ❖ A description of the procedures to be followed and identification of any procedures which are experimental.

### **B. Information regarding risks**

- ❖ A description of any reasonably foreseeable risks or discomforts to the subject.
- ❖ A description of any benefits to the subject or to others that may reasonably be expected from the research.
- ❖ An explanation for greater than minimal risk as to whether any compensation is provided and an explanation as to whether any medical treatments are available if injury occurs. The explanation should also describe what the medical treatments consist of or where further information may be obtained.

### **C. Alternatives: A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject.**

- D. Confidentiality: A statement describing the extent to which, if any, confidentiality of records identifying the subject will be maintained.
- E. Contact Information: An explanation of whom to contact
- ❖ For answers to pertinent questions about the research and research subjects' rights
  - ❖ For whom to contact in the event of a research-related injury to the subject
- F. Voluntary Nature: 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.
- G. Additional Elements to Consider: When appropriate, one or more of the following elements of information shall also be provided to each subject:
- ❖ A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus if the subject is or may become pregnant), which are currently unforeseeable.
  - ❖ Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
  - ❖ Any additional costs to the subject that may result from participation in the research.
  - ❖ The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
  - ❖ A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.
  - ❖ The approximate number of subjects involved in the study.
  - ❖ Any other information the IRB deems relevant to the safety and welfare of the subject(s).

## **REQUIREMENTS FOR DOCUMENTATION OF CONSENT**

A copy of the current, IRB-approved, consent form must be used when obtaining consent.

The IRB will require that informed consent is documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative in most circumstances. The IRB must specifically approve the use of a legally authorized representative as the signatory on the consent form.

The investigator should allow the subject or the legally authorized representative adequate opportunity to read the consent form before it is signed. A copy of the consent form must be given to the person signing the form.

- A. Each subject or his/her legally authorized representative must sign and date a copy of the consent form prior to subject's enrollment or participation in any phase of the study.
- B. The person signing the form should be given a blank copy of the consent document. A copy of the signed document will be provided if requested.

The informed consent process does not conclude once an informed consent document is signed. Study staff will be trained to recognize opportunities to reaffirm consent and be vigilant to identify any confusion or discomfort experienced by the subject.

## **ALTERNATIVE DOCUMENTATION OF CONSENT**

Oral Presentation Using Short Form –The following must be part of the consent process for the use of the short form alternative to be considered for approval:

- ❖ A "short form" written informed consent document stating that the elements of informed consent have been presented orally to the subject or the subject's legally authorized representative
- ❖ A written summary of the information presented orally.
- ❖ A witness to the oral presentation is required. The witness must sign both the "short form" written informed consent document and a copy of the written summary.
- ❖ The subject or the legally authorized representative must sign the "short form" written consent document.
- ❖ The person obtaining consent must sign a copy of the written summary of the information presented orally. The person obtaining consent may not be the witness to the consent.
- ❖ The short form should be written in a language the subject understands.
  - Applications containing foreign language consent documents must include an English translation for review.
  - The IRB, at its discretion, may require an official translation of the consent form.
  - The witness must be fluent in both English and the language in which the oral presentation is made.

## **RECORD RETENTION REQUIREMENTS FOR CONSENT DOCUMENTS**

Investigators shall maintain, in a designated location, all executed subject consent documents. Should an investigator depart from Northwest Vista College prior to the completion of an activity or less than the retention time specified, the investigator is responsible for initiating mutually satisfactory arrangements with his/her department and NVC administration as to the disposition of executed subject consents.

- ❖ Consent forms are to be available for inspection by the IR Director or authorized representatives.
- ❖ Consent forms must be maintained for three years following the completion of the study. Longer periods of time may be required by the sponsor or other governing rules, laws or policies.

SOP Number:	IRB 17	Revision Number:	01	Effective Date:	8/01/2018
Title:	Waivers or Alterations to the Consent Process or Documentation Process				

## PURPOSE STATEMENT

The requirements of consent and/or documentation of consent may be waived or altered under certain circumstances. The purpose of this document is to detail the circumstances in which waivers/alterations may occur. It is the responsibility of the Institutional Review Board (IRB) to make a determination as to whether or not the criteria for waiver or alteration have been met.

## CRITERIA FOR WAIVER/ALTERATION OF CONSENT REQUIREMENTS

The IRB must determine ALL FOUR of the following criteria are met to waive/alter consent requirements:

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

## CRITERIA FOR WAIVER OF SIGNED CONSENT

The IRB must determine ONE of the following criteria is met to waive the requirement for documentation of consent:

1. The only record linking the participant and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Participants will be asked individually whether they want documentation linking themselves to the research, and their wishes will govern; or
2. The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context. The investigator will provide participants with a written statement regarding the research in cases in which the documentation requirement is waived.

## WAIVER OF CONSENT FOR PLANNED EMERGENCY RESEARCH

Northwest Vista College does not currently conduct emergency planned research; therefore, a request for waiver of consent for planned emergency does not currently exist. Standard operating procedures regarding consent for planned emergency will be created if planned emergency research is proposed at Northwest Vista College. Waivers of consent for planned emergency research are typically used in clinical studies.

## DOCUMENTATION REQUIREMENTS

Waivers and alterations to consent and/or documentation of consent requirements must be documented by the IRB. Documentation will occur in the meeting minutes for studies reviewed by the convened IRB. Reviewers will document determinations in the expedited review comments for studies reviewed by expedited procedure.

SOP Number:	IRB 18	Revision Number:	01	Effective Date:	8/01/2018
Title:	Observation of Consent Process				

**PURPOSE STATEMENT**

The Institutional Review Board (IRB) has the right to observe the consent process of any study under its purview.

**AUTHORITY TO OBSERVE**

The IRB has the authority to observe the consent process any time concern arises that human subjects may not be appropriately protected or informed. Observation may be done by requesting documentation or attending a consent session. The IRB will include a report of the observation in the protocol file and provide the investigator with a copy.

The Investigator may or may not be notified of the observation in advance.

SOP Number:	IRB 19	Revision Number:	01	Effective Date:	8/01/2018
Title:	Amendment Requirements & Process				

## PURPOSE STATEMENT

Investigators have the responsibility to apply for an amendment in the event that procedures or protocol related materials change after receiving approval from the Institutional Review Board (IRB).

## REQUIREMENTS

All changes to approved studies must be reviewed and approved prior to implementation. Changes include and are not limited to edits to protocol procedures, recruitment materials, survey instruments, questionnaires, consent documents and so forth.

Investigators must submit an Amendment Application to thoroughly detail the proposed changes to initiate review of an amendment. Additional or altered materials must be submitted with the application.

## REVIEW PROCESS

**Amendments to Studies with an Exempt Status:** Amendments Applications submitted to seek approval for changes to exempt research should be submitted to the Director of Institutional Research for administrative review. The review will determine the impact the proposed change(s) will have on the overall study and whether or not the changes will prohibit the study from retaining exempt status. A letter of exemption will be granted for the study as amended if changes are compatible with the exempt status. Studies no longer eligible for exemption will be forwarded for review via expedited or full board review process.

**Amendments to Studies with an Expedited or Full Board Approval:** The IRB will review the study, as a whole, taking the proposed amendment into consideration against the regulatory criteria. The amendment will be approved if the board determines the criteria for approval are met.

Minor modifications - modifications not impacting the overall risk level of the study or increasing direct risk to subject may be reviewed by expedited review.

The amendment will be referred to the convened board for review if the risk level is increased or minimal risk threshold is breached for studies previously reviewed by expedited review.

## NON-COMPLIANCE

Failure to secure approval for an amendment prior to implementing a change is an act of serious non-compliance.

SOP Number:	IRB 20	Revision Number:	01	Effective Date:	8/01/2018
Title:	Continuing Review				

## PURPOSE

Continuing Review Applications are required for expedited and full board review protocols. A Continuing Review Application seeks authorization to continue a study at the end of the approval period according to previously approved parameters.

## PROCESS FOR CONTINUING REVIEWS

The investigator is responsible for submitting a Continuing Review Application to the IR Director at least 30 days prior to the end date of the protocol's approval period.

## APPROVAL PERIODS

Studies are approved for no more than one year. The approval end date is plus one year from the approval's start date if approved for a full year. The end date of the approval period is the last day the protocol is approved. Approval periods can be found on the approval letter in each protocol file.

The protocol is considered expired if a Continuing Review Application has not been approved by the end date of the approval period. Data collection and analysis must cease immediately if a protocol expires, as required by federal regulations. To continue the research, the PI must submit the protocol again for an initial review.

A protocol must be reviewed de novo every seven (7) years.

## MATERIALS FOR A CONTINUING REVIEW

Investigators must submit the following materials in addition to the Continuing Review Application:

- ❖ Consent/Assent Documentation: An unsigned copy of each approved consent/assent document the investigator intends to use during the new approval period.
- ❖ Amendments to externally funded projects applicable to the continuing review
- ❖ Adverse event form, if applicable

SOP Number:	IRB 21	Revision Number:	01	Effective Date:	8/01/2018
Title:	Unanticipated Problems and Serious Adverse Events				

## PURPOSE STATEMENT

The purpose of this document is to define and give examples of unanticipated problems or serious adverse events, as well as explain the process of how events are reported and resolved.

## DEFINITIONS

**Unanticipated Problems:** Problems where the specificity or severity of the adverse event is not consistent with the current expectation as outlined in the Investigator's brochure, consent form, protocol application or with other current risk information.

**Serious Adverse Events:** Problematic events affecting participants or Investigators, resulting in one or more of the following:

- ❖ Death,
- ❖ Life threatening status,
- ❖ Inpatient hospitalization or prolongation of existing hospitalization,
- ❖ Persistent or significant disability or incapacity,
- ❖ A congenital anomaly or birth defect,
- ❖ Causing cancer,
- ❖ An overdose or
- ❖ Any medical event which requires treatment to prevent one of the medical outcomes listed previously.

## REPORTING REQUIREMENTS OF INVESTIGATORS

Investigators or research staff must report unanticipated problems and serious adverse events to the Institutional Review Board (IRB) through the Office of Institutional Research within 24 hours of the event, regardless of whether the problem occurs during or after the study or after participant withdrawal or completion.

### A. Types of problems to report

- ❖ **Internal Adverse Events:** Adverse events pertaining to the administration side of the study.
  - Internal adverse events do not influence participants; only research staff. *Example: A lab technician sticks his finger with one of the used sharps.*
- ❖ **External Adverse Events:** Adverse events occurring outside the realm of the research staff, primarily to participants.
  - Any complaint of a participant that indicates an unanticipated risk which cannot be resolved by the research staff. *Example: A participant has an allergic reaction to an experimental medication given during testing. The participant must see her local physician to obtain an antihistamine to stop the reaction.*
- ❖ **Unapproved Protocol Changes to Protect Participants:** Any accidental or unintentional change to the IRB-approved protocol that involved risks or has the potential to recur.
  - Investigators may discover after starting procedures that participants are subject to risks. Although changing procedures without IRB approval puts Investigators in a state

of non-compliance, Investigators must conduct research in a way that protects the rights and welfare of human subjects.

- Investigators must then report the unapproved changes to the IRB as an unanticipated problem. *Example: After a focus group session for a study concerning bullying in middle schools, a participant wants to give more information, but is hesitant to do so in a large group setting. Although it has not been approved by the IRB, the Investigator meets with the participant individually to ensure the well-being of the participant.*

- ❖ Information Indicating Harm to Participants: Any publication in the literature or other finding that indicates an unexpected change to the risks or potential benefits of the research.

#### B. Content of the Report

- ❖ The nature of the event.
- ❖ The findings of the organization.
- ❖ Actions taken by the organization or IRB.
- ❖ Reasons for the organization's or IRB's actions.
- ❖ Plans for continued investigation or action.

### **RANGE OF POSSIBLE IRB ACTIONS**

The IRB will meet as soon as possible to discuss the unanticipated problem or serious adverse event. IRB members are given the same materials used in regularly scheduled IRB meetings for the protocol under review. IRB members will also receive a copy of the Adverse Event Report, and any documents pertaining to the occurrence, including communication from research staff, participants, the IRB and the IR Director about the event.

The IRB will decide what actions to take, if any, after an in depth review. Possible actions include, but are not limited to the following:

- A. Suspend or terminate research.
- B. Notify current and/or past research participants.
- C. Modify research protocol and/or consent.
- D. Monitor some or all aspects of the research.
- E. Request more information: The IRB may require more information from Investigators or participants if members feel they do not have adequate information of the seriousness or impact of the event.
- F. Refer to other organizational entities: The IRB may contact other organizational entities if they need expertise or counsel not available within the body of the IRB. The following are possible organizational entities:
  - ❖ Legal counsel
  - ❖ Risk Management
  - ❖ Institutional Official
- G. Contact Federal Departments: Federal departments who have regulatory oversight due to funding, conduct or an assurance of compliance for a research study must be contacted.
  - ❖ Office of Human Research Protections (OHRP), when research is covered by DHHS regulations.
  - ❖ Food and Drug Administration (FDA), when the research is FDA-regulated.
  - ❖ Other federal agencies when the research is overseen by those agencies, and they require reporting separate from that to OHRP.

- ❖ The IRB does not need to report to federal agencies already made aware of the event through other mechanisms, such as reporting by the Investigator, sponsor or another organization.

### **NON-COMPLIANCE: SERIOUS AND CONTINUOUS DEVIATIONS**

Non-compliance refers to any non-compliance with the regulations or the requirements or determinations of the IRB. Non-compliance can be relatively minor, such as reporting an event to the IRB in 31 days when policies and procedures require reporting in 30 days, or it can be serious, such as non-compliance that adversely affects the rights and welfare of participants.

All issues of non-compliance will be acknowledged and noted in the protocol file. Noncompliance can be a one-time event or a continuing problem. Non-compliance will be brought to the IRB for review if it is a continuing problem. The IRB will require an amendment be submitted to the protocol if the issue is not problematic in nature but will most likely recur in protocol procedures.

The IRB will review all issues of non-compliance will be reviewed by the IRB and the Institutional Official. Reports will be filed as appropriate with OHRP, funding agencies, participants, administrators, etc. Investigators may be consulted during the reporting process and will be notified of a report within 15 days of the filing date.

SOP Number:	IRB 22	Revision Number:	01	Effective Date:	8/01/2018
Title:	Protocol Deviations and Non-Compliance				

## PURPOSE STATEMENT

The purpose of this document is to differentiate the definitions of protocol deviations and issues of non-compliance from adverse events. The document also informs Investigators about how to report deviations and non-compliance to the Institutional Review Board (IRB) through the IR Director

## PROTOCOL DEVIATIONS

A protocol deviation is any change, divergence, or departure from the study design or procedures of a research protocol that is under the Investigator's control and that has not been approved by the IRB. An adverse event affects the subjects' rights, safety or well-being and/or the completeness, accuracy and reliability of the study data.

## NON-COMPLIANCE

Non-compliance refers to any failure to comply with the federal regulations or the requirements or determinations of the IRB approval. Non-compliance can be relatively minor, such as reporting an issue to the IRB in 31 days when policies and procedures require reporting in 30 days, or it can be serious, such as non-compliance that adversely affects the rights and welfare of participants, such as conducting a study without IRB approval or not following approved consent procedures.

## REPORTING TO IR Director

Investigators may discover after starting procedures that participants are subject to risks. Investigators must conduct research in a way that protects the rights and welfare of human subjects even though changing procedures without IRB approval puts Investigators in a state of non-compliance.

The Investigator is responsible for submitting a report to the IR Director, including the following, upon discovery of a protocol deviation or issue of non-compliance:

- ❖ The nature of the deviation or non-compliance.
- ❖ Actions taken by the Investigator.
- ❖ Reasons for the Investigator's actions.
- ❖ Plans for continued investigation or action.

Protocol deviations and issues of non-compliance can be a one-time event or a continuing problem. The IRB will review all issues of non-compliance will be reviewed by the IRB and the Institutional Official. Reports will be filed as appropriate with OHRP, funding agencies, participants, administrators, etc. Investigators may be consulted during the development of reports and will be notified of a report within 15 days of the filing date.

All protocol deviations and issues of non-compliance will be acknowledged and noted in the protocol file.

SOP Number:	IRB 23	Revision Number:	01	Effective Date:	8/01/2018
Title:	Completion Reports				

## **PURPOSE STATEMENT**

Investigators have the responsibility to submit a Completion Report once an approved study is concluded. Full, expedited and exempt reviewed protocols require a Completion Report.

## **COMPLETION REPORTS**

Investigators must notify the Institutional Review Board of the conclusion of research studies by submitting a signed Completion Report to the Office of Institutional Research. A Completion Report is required for all protocols, including exemptions. The protocol file will be handled according to the records management policy once a Completion Report is received and processed.

SOP Number:	IRB 24	Revision Number:	01	Effective Date:	8/01/2018
Title:	Conducting International Research				

## PURPOSE STATEMENT

The Institutional Review Board (IRB) and Office of Institutional Research (IR) will take special consideration with research conducted internationally to ensure adequate protection of research subjects. The IRB will consider the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards. These must not be contradictory to the ethical principles set forth in the Declaration of Helsinki, the Belmont Report or the federal regulations as written at 45 CFR 46.

The purpose of this document is to define the requirements for investigators conducting human subject research in an international setting. Specific guidelines the IRB will use to review studies conducted in an international setting are outlined as well. The requirements are in addition to those of an IRB protocol review.

The Office of Institutional Research set forth these specific requirements to ensure that subjects are not exposed to more risk or harm from protocol procedures due to cultural aspects or customs different from those in the United States.

## LETTER OF CULTURAL EVALUATION

Investigators must obtain a letter of cultural evaluation from an expert on the local culture of the location where the research is to be conducted. The expert may be a current resident of the culture or may live outside the culture, but has exceptional knowledge of the culture's customs, public policies, history and so forth. The expert cannot also be a part of the research team in most cases.

While there are no specific requirements for the letter of cultural evaluation, the focus of it should identify any risk, harm or offense introduced by the consent process or other aspects of the investigator's protocol procedures. Guidelines for Cultural Evaluation are available to help investigators better explain the purpose and desired content of the letter to the expert. The Guidelines for Cultural Evaluation information sheet is available on the Institutional Review Board (IRB) website.

The letter must be provided in English and signed by the expert providing the evaluation. It must be submitted to the Director of Institutional Research with all other study materials.

## IRB CULTURAL EXPERIENCE & EXPERTISE

Board members with experience or expertise in the culture of the research setting will act as a source of knowledge for studies requiring full board review. Additional consultants or advisors may be invited to the meeting to give additional counsel.

The Institutional Research Director and IRB will use a cultural evaluation from an expert on the culture of the research setting to help assess the level of risk to participants. The letter will specifically assist in answering the following questions:

- ❖ Subject Recruitment
  - Is the method of recruitment culturally appropriate?
  - Is the setting of recruitment procedures culturally appropriate?
  - Are recruitment instruments, such as a flyer or email socially acceptable?
  - If offering compensation, is the amount/form of payment coercive to participants?
  
- ❖ Consent
  - Is the language and tone used in the consent form/information sheet understandable to the participants?
  - Will the format of consent process intimidate or confuse participants?
  - Does the setting of the consent process allow for adequate privacy?
  
- ❖ Risk
  - Are additional safeguards required to protect the rights and welfare of subjects?
  - Could altering some of the procedures lower the risks to participants from a cultural perspective? If so, please explain.

## **TRANSLATED MATERIALS**

Materials to be given to participants must be written in a language understandable to the participants including consent documents, surveys, recruitment e-mails and so forth. All materials to be given to participants must be submitted to the ORC both in English and the native language of the participants (if the native language is not English).

## **SPECIAL CONSENT CONSIDERATIONS**

Consent documents and processes must be understandable to the subjects to meet the requirements of 45 CFR 46.116 and 45 CFR 46.117. Understandability not only includes being written/spoken in the participants' fluent language but also in a manner that does not intimidate or offend participants.

It may be appropriate for the IRB to waive some or all requirements for documentation of consent in some instances. Research proposals requesting a waiver or alteration should include explanations of cultural norms or conditions that justify the waiver (i.e. societies where no written language is used, societies where signatures represent the surrender of spirit or soul to the researcher and so forth).

While the IR Director/IRB cannot impose standards for written documentation on other cultures, it will not compromise standards for ethical conduct of research or for a meaningful consent process. Special attention will be given to local customs and to local cultural and religious norms in drafting written consent documents or proposing alternative consent formats.

SOP Number:	IRB 25	Revision Number:	01	Effective Date:	8/01/2018
Title:	Investigator Concerns				

**PURPOSE STATEMENT**

The Institutional Review Board (IRB) is tasked with protecting the rights and well-being of human subjects involved in research. The IRB strives to accomplish its task in a collaborative manner with investigators and study personnel.

The IRB's review decision is sovereign. No member of Northwest Vista College's Administration or Faculty can approve human subject research without IRB approval or override a decision made by the IRB regarding the conduct of research.

This authority is derived from federal law. Specific details may be found in 45 CFR 46.109, 45 CFR 46.112 and 45 CFR 46.113.

The purpose of this document is to outline the process to be used by investigators to appeal a review decision made by the IRB or to report concerns with the review process.

**CONCERNS WITH THE REVIEW OF RESEARCH**

Issues regarding the review of a particular study or protocol will be arbitrated by the Institutional Official, IRB Chair or designee.

Broad issues relating to the review of research should be addressed with the Institutional Official.

The IRB will re-consider a decision at the request of the investigator.

Study Disapproval: A new application for review must be submitted prior to the protocol being reconsidered if a study has been disapproved by the IRB. The IRB will review any additional information provided by the investigator at the time of reconsideration. Written clarifications, assessments of the study provided by experts in the field of study or any other information the investigator feels would impact the IRB's decision can be included.

Conditional Approval: Concern with a condition of approval may be appealed in writing to the IRB via email or letter to the IRB Chair or IR Director. The board will consider the appeal and any additional materials at its next regularly scheduled meeting.

The IRB will reverse its decision and approve the study if the materials submitted support the criteria for approval.

**ADMINISTRATIVE CONCERNS**

Administrative concerns typically are those regarding processing time, application processes or interactions with IR staff. Concerns of this nature are most appropriately addressed with the IR Director or the Institutional Official (IO).

## **IRB INDEPENDENCE**

The IRB is an independent body as stipulated by Federal law. Its protocol review decisions may not be overturned by any member of administration. It is also unethical and inappropriate for any member of administration to exert pressure on the IRB to obtain a particular review outcome.

SOP Number:	IRB 26	Revision Number:	01	Effective Date:	8/01/2018
Title:	Review Process				

## PURPOSE STATEMENT

Any Northwest Vista College faculty, staff, or student who proposes to engage any research activity involving the use of human subjects must submit an IRB protocol application to the Office of Institutional Research.

## Review Process

- A. The IR Director will review the application packet upon receipt to ensure compliance with the following criteria. Principle Investigators (PIs) will be notified of any incomplete or missing items.
- All application materials are only accepted electronically. Digital signatures should be utilized on the protocol application.
  - ❖ Applications must be signed by the following individuals:
    - PI and all Co-Investigators
    - Student applications must be signed by the student PI and a faculty advisor.
  - ❖ IRB protocol applications will be reviewed to ensure the following items are also included:
    - Completed IRB Form (current format available on the IRB website)
    - Consent Documentation as applicable: informed consent form, assent form, translated informed consent form, translated assent form, etc.
    - Recruitment Materials as applicable: flyers, letters, phone scripts, emails, etc.
    - Permission from site of study, as applicable
    - Any other documents referenced in this application as applicable (survey instrument, interview questions, debriefing form, payment schedule, etc.)
  - ❖ Continuing Review Applications will be reviewed to ensure the following items are also included:
    - Clean copy of any previously approved consent forms. *If study is closed to the enrollment of new subjects or is only analyzing data, inclusion of this form is not required.*
  - ❖ Copy of grant proposal must be included for any funded study.
    - Review of study will not continue until the proposal is received.
- B. Protocol applications will be routed for review.
- ❖ *Exempt Applications* will be routed to the IR Director for review.
    - Protocol applications containing sufficient information to determine exempt status will be granted an exemption.
    - The PI will be sent a request for modification, revision or clarification if information is insufficient to declare the exemption.
  - ❖ *Expedited Applications* will be routed for Expedited Review by the IR Director to two members of the IRB.
    - The PI will be sent a request for modification, revision or clarification if information is insufficient to approve the protocol.

- ❖ The study will be placed on the first available agenda for review by the convened IRB if the protocol is not eligible for approval via the expedited process. The reviewer will ensure all necessary information is included in the application prior to placing the protocol on the agenda. The PI may be required to submit additional materials/information before the reviewer authorizes placing the study on the IRB agenda.
  - ❖ *Amendment Applications* will be routed based on the status of the original protocol.
    - Amendments to exempt protocols will reviewed by the IR Director.
      - The amendment application will also be considered exempt if the amendment application does not contain information contradicting the exempt status of the protocol.
      - The PI will be sent a request for modification, revision or clarification if information is insufficient to declare the exemption.
      - The application will be routed for Expedited or Full Review if the amendment is not eligible for exemption.
    - Amendments to Expedited or Full Board protocols will be routed to the IRB Chair or the designee of the Chair and one additional IRB member.
      - Amendment applications containing sufficient information to determine eligibility for expedited approval will be approved.
      - The PI will be sent a request for modification, revision or clarification if information is insufficient to declare the exemption.
      - The study will be placed on the first available agenda for review by the convened IRB if the amendment is not eligible for approval via Expedited process.
  - ❖ *Continuing Review Applications* will be routed for Expedited Review.
    - Continuing Reviews are eligible for review via expedited procedures if the original application was reviewed via expedited procedures.
      - The IR Director will schedule the application for full review at the next available convened meeting if amendments to the study or new information indicate the risk level has increased.
      - Any application for Continuing Review may be referred to the convened board for review at the discretion of any expedited reviewer.
    - Protocol applications containing sufficient information to determine eligibility for expedited approval are approved via expedited review.
    - The PI will be sent a request for modification, revision or clarification if information is insufficient to declare the exemption.
    - Studies previously approved by the convened board will be placed on the next available agenda
      - The continuing review does not have to go before the convened IRB for Continuing Review and may be reviewed by expedited procedure if one of the following criteria are met:
        - (i) the research is permanently closed to the enrollment of new subjects,
        - (ii) no subjects have been enrolled and no additional risks have been identified,
        - (iii) remaining research activities are limited to data analysis,
        - (iv) 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.
- C. Results of Review will be communicated to the PI.
- ❖ The PI will be sent a request for modification, revision or clarification if information is insufficient for approval.

- Investigators have 30 days to respond to the request. Failure to respond will result in the application being administratively withdrawn from consideration. The PI will be notified of the administrative withdrawal.
  - ❖ The PI will be sent an exemption letter if a study or amendment is determined to be exempt.
  - ❖ The PI will be sent an approval letter if study is approved by Expedited or Full Board review.
- D. The PI's responses to reviewer inquiries will be reviewed and processed accordingly, if applicable.
  - ❖ Upon receipt, response will be added to application file.
  - ❖ The entire file, including response, will be reviewed by IR Director for follow-up review.
  - ❖ The IR Director may process exempt/approval notification upon receipt if a response is made to provide administrative items.
- E. Full Board Review
  - ❖ Each protocol reviewed by the convened IRB will be disseminated to all members of the board.
  - ❖ Actions taken by the convened IRB require the affirmative vote of a majority of the members present.
- F. Administrative Considerations for Review
  - ❖ Processing time - The times are estimates and delays due to unforeseen complications or necessary revisions may extend the stated time periods.
  - ❖ Confidentiality of the Review Process - Applications and all related materials submitted to the IR Director will be handled confidentially. Information related to the study will be released only to the PI, Co-Investigator(s), Faculty Advisor(s) and IRB members. Exceptions to this policy are as follows:
    - The PI may authorize access for other individuals by notifying the IR Director in writing.
    - Approval letters may be released to funding administrators.
    - Information will be released as required by law.

SOP Number:	IRB 27	Revision Number:	01	Effective Date:	8/01/2018
Title:	Initial IRB Protocol Review Process & Required Materials				

## PURPOSE STATEMENT

All applications submitted to the Institutional Review Board (IRB) and the Office of Institutional Research undergo an administrative review to increase efficiency and to better ensure compliance with both federal and institutional policies.

The purpose of this document is to define an administrative review and detail the responsibilities and scope of authority of an administrative reviewer.

## DEFINITION OF ADMINISTRATIVE REVIEW

The IR Director has the following two forms of administrative review:

- ❖ Pre-Review of Expedited and Full Board Research: Each expedited or full board submission will be pre-reviewed to ensure appropriate documents are present before the submission is routed for official review.
- ❖ Review of Exempt Research: Some research projects involving human subjects are exempt from the federal regulations but must still be submitted to the IR Director for administrative review.

Administrative reviews as defined above will be carried out by the Office of Institutional Research staff. IRB members may also conduct an administrative review.

## MATERIALS FOR INITIAL REVIEW

- ❖ IRB Protocol Form: Investigators will be required to submit an IRB Protocol Form for review. Only the current version of the form published on the IRB website will be accepted.
- ❖ Consent Documentation: Specific requirements for consent documentation vary widely based on the type of research being done.
  - Investigators can submit a Request Waiver- Consent or Documentation of Consent if the research meets all the criteria of 45 CFR 46.116 or one of the criteria of 45 CFR 46.117.
  - Special considerations are given to exempt research.
- ❖ Study Materials: Investigators must submit all final materials planned for use with participants. Typical study materials are listed below.
  - Recruitment materials such as e-mails, flyers, advertisements, etc.
  - Scripts.
  - Observation guides.
  - Surveys/questionnaires.
  - Other pertinent documents
- ❖ Grant Proposal: Investigators must submit the grant proposal or funding from the funding source if the research study is funded.

## RESPONSIBILITIES OF ADMINISTRATIVE REVIEWERS

- ❖ Pre-Review of Expedited and Full Board Research: At minimum, IR staff will ensure the following items are complete before routing them for official review:
  - The information submitted is presented on the current version of the IRB protocol form.
  - Each investigator has completed currently required human subject research training.

- The appropriate persons have signed the protocol.
  - The appropriate consent documents are submitted.
  - Any tool or form mentioned within the application is included with the submission.
  - The grant proposal or contract is submitted, if the study is funded.
- ❖ Review of Exempt Research: IR staff members conduct a pre-review as detailed above for exempt research. However, the review goes beyond the elements of a pre-review to consider the actual content and purpose of the submitted research.
- IR staff will determine if the study qualifies for an exemption as defined by the federal regulations, and if so, designates which exempt category is appropriate. The submission will be routed to an appropriate expedited reviewer if it does not qualify for an exemption.
  - IR staff will ensure the principles listed in the Belmont Report are reflected in the study's intended procedures.

The Office of Research Compliance will maintain procedures for administrative reviews.

### **SCOPE OF AUTHORITY**

The IR staff (or designated IRB member) may review exempt research.

IR staff may request any outstanding items required to complete a submission packet and hold the incomplete submission until all items are submitted. Since a complete submission is required for review, if requested administrative items are not received within 45 days of the request being made, IR staff will administratively withdraw the application. The investigator will be required to resubmit the application in its entirety if he or she wishes to initiate the project.

IR staff members do not have the authority to disapprove any study. Disapproval can only be decided by the convened IRB.

SOP Number:	IRB 28	Revision Number:	01	Effective Date:	8/01/2018
Title:	Exempt Research				

## PURPOSE STATEMENT

Some research projects involving human subjects are exempt from the federal regulations regarding the review of human subject research. The criteria for exemption is found at 45 CFR 46.101(b). IR staff will use the criteria in making an exempt determination.

All human subject research must be submitted to the Office of Institutional Research for review. Office of Institutional Research staff will review applications for exemption to make a determination if the study meets one of the exemption criteria. The study will be referred for Expedited or Full Board Review if it does not meet the criteria.

## CRITERIA FOR EXEMPTION

- A. Research activities in which the only involvement of human subjects will be in one or more of the following categories may be exempt:
- ❖ Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
    - Research on regular and special education instructional strategies.
    - Research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.
  - ❖ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
    - Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
    - Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
  - ❖ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt, if:
    - The human subjects are elected or appointed public officials or candidates for public office; or
    - Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
  - ❖ Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the Investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

- ❖ Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:
  - Public benefit or service programs.
  - Procedures for obtaining benefits or services under those programs.
  - Possible changes in or alternatives to those programs or procedures.
  - Possible changes in methods or levels of payment for benefits or services under those programs.
  - The research or demonstration project must be conducted pursuant to specific federal statutory authority.
  - There must be no statutory requirement that the project be reviewed by an IRB.
  - The project must not involve significant physical invasions or intrusions upon the privacy of participants.
  - The exemption should have authorization of concurrence by the funding agency.
  
- ❖ Taste and food quality evaluation and consumer acceptance studies:
  - If wholesome foods without additives are consumed.
  - If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

B. Exempt research will pose little, if any, risk to the subject.

## **EXCEPTIONS**

- ❖ Research with the following characteristics will not be granted exempt status even if it meets one or more of the above criteria:
  - Research involving any designated vulnerable population
  - Research involving a faculty member's students does not qualify for exempt review and is subject to expedited or full review

Research involving the following and similar sensitive subject matters which can potentially cause discomfort and stress to the participant does not qualify for exempt review and is subject to expedited or full review: Abortion, AIDS/HIV, Alcohol, Body Composition, Criminal Activity, Psychological Well-being, Financial Matters, Sexual Activity, Suicide, Learning Disability, Drugs, Depression, Medical issues which could lead to social stigmatization or discrimination.

Office of Institutional Research staff may submit a protocol application or expedited review if circumstances warrant the expedited review (ex. previous issues of non-compliance).

SOP Number:	IRB 29	Revision Number:	01	Effective Date:	8/01/2018
Title:	Ethical Considerations and Exempt Research				

## PURPOSE STATEMENT

The Office of Institutional Research staff makes determinations of exemption and will conduct an evaluation of the exempt study procedures to ensure ethical principles listed in Belmont Report are reflected. Participants involved in exempt research are to be provided additional protections to ensure their safety and privacy when appropriate.

This document highlights considerations to be made during exempt review to support the Belmont principles.

Exempt research studies, as defined by 45 CFR 46.101, are not bound by the consent requirements set forth in 45 CFR 46.116 and 45 CFR 46.117. It is generally expected that some form of consent will be sought to honor the principle of Respect for Persons.

Investigators are strongly encouraged to take advantage of the flexibility afforded them in the consent process when doing exempt research. The research experience can be less intimidating to subjects and respect for persons can be maintained by using alternative measures for obtaining consent.

All consent processes submitted for review under the exempt categories will be evaluated to determine appropriateness. Modifications may be required by IR staff or Institutional Review Board (IRB) members prior to exemptions being granted.

Templates are available to assist investigators and reviewers in determining how to best achieve consent in exempt research.

## CONSIDERATIONS FOR CONSENT IN EXEMPT STUDIES

- ❖ Each study's process and materials will be evaluated on an individual basis.
- ❖ When appropriate, the consent process must accomplish the following:
  - Prospective subjects should be informed of the research purpose and procedure(s).
  - The voluntary nature of participation must be communicated.
- ❖ Process and materials will be evaluated for simplicity, understandability and directness.

## CONSENT GUIDELINES

The following guidelines are given on a category by category basis and indicate typical expectations for consent when conducting research within the constraints of a particular exemption category:

*Exemption Category 1* - Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

- ❖ Obtaining consent from participants in the educational settings is appropriate when conducting research under this exemption in most cases.
- ❖ Permission will be required from the educational institution where the research is conducted.

*Exemption Category 2* - Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

- ❖ Survey or test cover sheet simply explaining the research purpose and the voluntary nature of participation.
  - This page must contain the link to any web-based surveys.
- ❖ Verbal scripts may be used to introduce surveys, tests or interviews and seek participants
- ❖ Brief information sheet detailing purpose(s) of interview and the voluntary nature of participation
- ❖ Observation of public behavior does not require consent

*Exemption Category 3* - Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research project and thereafter.

- ❖ Surveyor test cover sheet simply explaining the research purpose and the voluntary nature of participation.
  - This page must contain the link to any web-based surveys.
- ❖ Verbal script may be used to introduce surveys, tests or interviews and seek participants
- ❖ Brief information sheet detailing purpose of interview and the voluntary nature of participation
- ❖ Observation of public behavior does not require consent

*Exemption Category 4* - Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

- ❖ Consent is not required when conducting research under this exemption in most cases.
- ❖ Permission will be required from the source providing the data for the study, if the data is not publicly available.
- ❖ HIPAA may require the use of an authorization agreement when conducting research involving medical records. *Note: Research protocols involving medical records will require at minimum an expedited review.*

*Exemption Category 5* - Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

- ❖ Consent is not required when conducting research under this exemption in most cases.
- ❖ Notification that data is being collected for an evaluation of the program may be required.

*Examples of programs typically eligible for exemption under this category include welfare, Medicaid, unemployment and Social Security.*

*Exemption Category 6* - Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety Inspection Service of the U.S. Department of Agriculture.

❖ Brief information sheet detailing purpose, procedures and the voluntary nature of participation

## **BELMONT PRINCIPLES**

*Respect for Persons* - Respect for persons incorporates at least two ethical convictions: first, individuals should be treated as autonomous agents, and second, persons with diminished autonomy are entitled to protection. An autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation.

To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. To show lack of respect for an autonomous agent is to repudiate that person's considered judgments, to deny an individual the freedom to act on those considered judgments, or to withhold information necessary to make a considered judgment, when there are no compelling reasons to do so.

*Beneficence* - Two general rules have been formulated as complementary expressions of beneficent actions: (1) do not harm and (2) maximize possible benefits and minimize possible harms. Researchers and reviewers should ensure that all studies involving the use of human subjects honor this principle.

❖ Exempt studies will incur little, if any, risk to the subject.

❖ The following types of studies do not qualify for exempt reviews and are subject to expedited or full reviews:

- Studies involving a faculty member's current students
- Data studies involving medical records
- Studies supported by external funding
- Studies involving the following and similar sensitive subject matters which can potentially cause discomfort and stress to the participant: Abortion, AIDS/HIV, Alcohol, Body Composition, Criminal Activity, Psychological Well-being, Financial Matters, Sexual Activity, Suicide, Learning Disability, Drugs, Depression, and Medical issues that could lead to social stigmatization or discrimination.

*Justice* - Who ought to receive the benefits of research and bear its burdens? Selection of research subjects needs to be scrutinized to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied.

❖ Recruitment procedures should not be coercive or manipulative.

- Compensation rates will be reviewed to determine if they are coercive or manipulative.
- Recruitment materials will be reviewed.

❖ The rationale for targeting or excluding a particular sex, race, religious or ethnic group is targeted or excluded must be provided. The review must determine if the rationale is sufficient and appropriate considering the principle of justice.

SOP Number:	IRB 30	Revision Number:	01	Effective Date:	8/01/2018
Title:	Expedited Review Criteria				

## PURPOSE STATEMENT

An expedited review is conducted and will receive approval from one or more members of the IRB.

Research must meet the following criteria and the following policies and procedures must be adhered to for research to be eligible for review via expedited procedures.

## SPECIFIC POLICIES

- A. Research activities must present no more than minimal risk to human subjects. Minimal risk is defined as "... the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests .... "
- B. Research Categories: Research may only involve procedures listed in one or more of the specific categories listed below: *NOTE: Categories one (1) through seven (7) pertain to both initial and continuing IRB review.*
- 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 required. (Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
    - b. Research on medical devices for which
      - an investigational device exemption application (21 CFR Part 812) is not required; or
      - the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
  - 2) Collection of blood samples by finger stick, heel stick, ear stick; or venipuncture as follows:
    - a. From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
    - b. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
  - 3) Prospective collection of biological specimens for research purposes by noninvasive means. Examples:
    - a. Hair and nail clippings in a non-disfiguring manner
    - b. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction
    - c. Permanent teeth if routine patient care indicates a need for extraction
    - d. Excreta and external secretions (including sweat)

- e. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue
  - f. Placenta removed at delivery
  - g. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor
  - h. Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques
  - i. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings
  - j. Sputum collected after saline mist nebulization.
- 4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. Examples of interactions approvable under tills category include the following:
- a. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy.
  - b. Measuring weight or testing sensory acuity.
  - c. Magnetic resonance imaging.
  - d. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography.
  - e. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

*NOTE: Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.*

- 5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non research purposes. This includes materials collected for 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 non-exempt research.*

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

*NOTE: Risk level of study must be determined to be minimal by expedited reviewer for these collection methods to be approved. Mitigating controls to protect confidentiality will be required in most cases to meet minimal risk standard.*

- 7) Research on individual or group characteristics or behavior. This includes, but is 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 non-exempt research.*

- 8) Continuing review of research previously approved by the convened IRB may be Expedited if one of the following conditions applies:
  - a. The research is permanently closed to the enrollment of new subjects
  - b. All subjects have completed all research-related interventions
  - c. The research remains active only for long-term follow-up of subjects
  - d. Where no subjects have been enrolled and no additional risks have been identified
  - e. 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.

C. Exceptions and items to consider not noted above.

- 1) The activities listed should not be deemed to be of minimal risk simply because they are included on the list of eligible research. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when specific circumstances of the proposed research involve no more than minimal risk to human subjects.
- 2) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability; be damaging to the subjects' financial standing, employability, insurability, or reputation; or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- 3) The expedited review procedure may not be used for classified research involving human subjects.

D. Authority of the IRB Chair for Expedited Review Procedure

The IRB Chair (or designated reviewer) may exercise all of the authorities of the IRB, except that he/she may not disapprove the research. A research protocol may be disapproved only after review by the full IRB. All regular members shall be informed of actions taken by the IRB at the next convened meeting when the expedited review procedure is used.

E. Documentation

The IRB Chair or designee will document his/her determination of risk if the study qualifies for expedited review

The determination and any resulting discussion will be recorded in the file.

F. Following are additional items that may be reviewed by expedited review:

- Conditional approval of subjects to minor revisions, clarifications: Revisions to consent documents and other documentation or clarifications submitted as a result of full IRB review and as a condition to final approval may be reviewed by the authorized Chair or Expedited reviewer. The Chair or Expedited reviewer may issue final approval provided the revisions, documentation or clarifications do not indicate or result in a change to the study or change in the risk/benefit ratio.

- Amendments: Minor changes that do not affect the rights and welfare of study subjects, or do not involve increased risk or significant changes in study procedures, or addition of new procedures, may be reviewed and approved by the chair and/or designee.

G. Responsibility

- IR staff is responsible for identifying submissions that may qualify for expedited review.
- IRB members are responsible for conducting expedited reviews.

SOP Number:	IRB 31	Revision Number:	01	Effective Date:	8/01/2018
Title:	Expedited and Full Review of Proposed Research				

## PURPOSE STATEMENT

All research studies intending to enroll human subjects as participants must meet certain criteria before study related procedures can be initiated. The criteria are based on the principles of justice, beneficence and autonomy as discussed in The Belmont Report and are specified below. Certain other criteria unique to Northwest Vista College may apply and must be met as well. The Institutional Review Board (IRB) is the review body with the authority to determine whether all criteria have been met.

## MINIMUM CRITERIA FOR APPROVAL OF RESEARCH

The IRB must find the following to approve a research project:

1. Risks to subjects are minimized. Procedures consistent with sound research design, which do not unnecessarily expose subjects to risk, are to be utilized. Whenever appropriate, procedures already being performed on the subjects for diagnostic or treatment purposes should be used.
2. Risks to subjects are reasonable in relation to anticipated benefits to subjects, and the importance of the knowledge that may be expected to result. The IRB will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy).
3. Selection of subjects is equitable. The IRB must take into account the purposes of the research and the setting in which the research will be conducted. IRB members must be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, handicapped, mentally disabled persons, or economically or educationally disadvantaged persons.
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. The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects, when appropriate.
7. Adequate provisions are used to protect the privacy of subjects and to maintain the confidentiality of data, when appropriate.
8. Additional safeguards included in the study will be reviewed to ensure adequate protection of the rights and welfare of these subjects when some or all of the subjects are likely to be vulnerable to coercion or undue influence or for subjects found at international sites.

Vulnerable subjects receiving extra protections from the IRB include, but are not limited to, the following:

- Children
  - Prisoners
  - Students and other subordinate persons
  - Pregnant Women
  - Handicapped or mentally disabled persons
  - Economically disadvantaged persons
  - Educationally disadvantaged person
9. Studies are reviewed annually or at shorter periods either appropriate to the degree of risk research subjects are exposed to due to their participation in the study or deemed administratively necessary.

SOP Number:	IRB 32	Revision Number:	01	Effective Date:	8/01/2018
Title:	Full Board Meeting – Agenda and Material Distribution				

## PURPOSE STATEMENT

Studies in which the risk to participants is greater than minimal risk or in which the IRB exercises its discretion to decline review via expedited review will be reviewed at a convened full board meeting.

All IRB members (including alternate members) need to review materials in enough depth to discuss the study when present at the convened meeting.

## AGENDA

- ❖ Training Items: Notify IRB members of training requirements or provide training of specific topics relevant to the meeting.
- ❖ Meeting Minutes: View minutes from the prior meeting and note any changes or additions.
- ❖ Other Business: Miscellaneous business items.
- ❖ Full Board Review: Discuss studies under review classified as one of the following:
  - Initial Review
  - Continuing Review
  - Amendments
  - Adverse Events
  - Incidents of Non-compliance

## MATERIALS PROVIDED FOR IRB REVIEW

- ❖ Board Materials: The week prior to an IRB meeting, members will receive an all materials needed to consider approval for the studies under review. Materials include the following:
  - Agenda for the meeting.
  - Meeting minutes from the last meeting.
  - Studies under review

SOP Number:	IRB 33	Revision Number:	01	Effective Date:	8/01/2018
Title:	Full Board Categories of Action				

## PURPOSE STATEMENT

The IRB will make a decision as to whether or not a study is approved upon completing its review of research.

The IRB may take action as a convened body or through the expedited review process. Only the convened IRB may disapprove research.

## SPECIFIC POLICY

The four primary determinations made as a result of the convened IRB's review of research are:

- A. Approval: The protocol and accompanying documents are approved as submitted. Approval will commence the day the study is approved by an action of the convened IRB or by the Chair/designee in the case of expedited review.

Approvals may be granted for up to one year from meeting/approval date. The IRB may require continuing review to occur more often depending upon their assessment of risk to subjects.

- B. Conditional Approval: Minor modification of, or addition to, a protocol or accompanying document(s) is required. Terms of approval will be clearly stipulated and determined by vote.
- The Investigator will be informed by email of the required changes and requested information and must provide the IRB with the changes or information.
  - The IRB Chair or his/her designee has the authority to review the information requested via expedited review unless the IRB requires the material or information be reviewed by the full IRB. Approval will be issued as of the date the requested information or materials are approved. The expiration date of IRB approval will be based on the anniversary date of the initial IRB review. Subjects must not be recruited into the study until final approval has been issued.
- C. Tabled: Significant questions are raised by the protocol requiring its reconsideration or substantive changes are required. The PI's responses and/or revisions are forwarded to the committee providing the initial review for review at the next convened IRB meeting.
- D. Disapproval: The protocol fails to meet one or more criteria used by the IRB for approval of research. Disapproval cannot be given through the expedited review mechanism and will only be given by majority vote at a convened meeting of the IRB.

## OTHER ACTIONS MAY BE AUTHORIZED BY THE CHAIR/DESIGNEE

Examples include and are not limited to the following:

- ❖ Referred for Expedited Review - Convened IRB reviewed risk level of proposed study and determined it to be minimal risk. Data collection methods are permissible under expedited procedures. Board refers study to expedited review process.
- ❖ Tabled - Board does not review the protocol. The study is placed on the next available board agenda.

SOP Number:	IRB 34	Revision Number:	01	Effective Date:	8/01/2018
Title:	Research Involving Children				

## PURPOSE STATEMENT

The purpose of this document is to detail the requirements for Institutional Review Board (IRB) approval of research involving children as human subjects. Children are considered to be a vulnerable population, and therefore must be treated with special consideration.

## DEFINITIONS

The following definitions are referenced in 45 CFR 46.402:

- A. Children: Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.
  - The state of Texas defines children as persons less than 18 years old.
  - The IRB will seek legal counsel regarding special review considerations if a child outside of the state of Texas participates as a human subject.
- B. Assent: A child's affirmative agreement to participate in research. Mere failure to object should not be construed as assent.
- C. Permission: Agreement of parent(s) or guardian to the participation of their child or ward in research.
- D. Parent: A child's biological or adoptive parent.
- E. Guardian: An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

## CRITERIA FOR APPROVAL

The IRB should approve research only if it finds the following criteria from 45 CFR 46, Subpart D:

- A. Risk level must be determined and categorized as follows:
  - ❖ Research not involving greater than minimal risk. Most of the research involving children conducted at Northwest Vista College falls into this category. The following are examples of research not involving greater than minimal risk:
    - Educational Tests
    - Survey Procedures
    - Interview Procedures
    - Curriculum Evaluation
    - Observation of Public Behavior
  - ❖ Research involving greater than minimal risk but presenting the prospect of direct benefits to the individual subjects.
    - The risk is justified by the anticipated benefit to the subjects;
    - The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

- Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in 45 CFR 46.408.
- ❖ Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder of condition. *It is unlikely that Northwest Vista College will be involved of this type of research; however, specific guidelines will be created if this type of research is proposed.*
- ❖ Research not otherwise approvable which presents an opportunity to understand, prevent or alleviate a serious problem affecting the health or welfare of children. *It is unlikely that Northwest Vista College will be involved of this type of research; however, specific guidelines will be created if this type of research is proposed.*

## B. Consent Requirements

- ❖ Requirements for permission by parents or guardians and for assent by children.
  - Only one parent or guardian is required to give permission if the research study involves minimal risk or more than minimal risk but presents the prospect of direct benefits to the individual subjects.
  - Both parents are required to give permission if research involves greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder of condition. Research not otherwise approvable but presenting an opportunity to understand, prevent or alleviate a serious problem affecting the health or welfare of children also falls under this requirement.
  - Parental/guardian permission may be waived if the IRB determines it is not a reasonable requirement and if a waiver is allowable by federal, state, or local law. A waiver will be granted for the following: (i) situations of child abuse or neglect; when one or both parents are deceased, unknown, incompetent or not reasonably available.
  - The IRB must substitute an appropriate mechanism to protect the children acting as subjects if parental/guardian permission is waived. Substitute will be determined depending on the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.
- ❖ Assent: The IRB must account for ages, maturity and psychological state of the children involved to determine if they are capable of assenting. The IRB can determine if assent standards apply to every child involved in the protocol or if assent should be individually based for all the children involved in the protocol.
  - Assent is not necessary if IRB determines that the child does not have the ability to understand what he or she is asked.

## DOCUMENTATION OF CONSENT

Investigators must submit consent documentation for IRB review in addition to the IRB Protocol Application. Consent for research involving children is a twofold process. Consent from two different groups, children and their parents, is required. Templates can be found at the IRB website.

- A. Assent: All children must give assent before research procedures begin. The IRB should look for age appropriate questions investigators will ask children to obtain assent. These questions include the following:
- What will constitute assent denied?
  - What will constitute assent given?
  - How can the child withdraw assent?
  - How will you introduce yourself?
  - How will you engage the child?
  - How will you invite the child?
  - How will you tell the child about the research activity?
- B. Parental Permission: Investigators must provide a Parent Permission Form informing parents of the procedures, risk, privacy, possible benefits, etc. of the research study if parent or guardian permission is required. Investigators cannot begin research procedures until Parent Permission Forms are signed and returned.
- C. Waiver of Consent: A Waiver of Consent must be submitted if parent permission is unavailable or unnecessary.

## **WARDS**

- A. Children who are wards of the state or any other agency, entity or institution can only act as research subjects if research is
- Related to their status as wards; or
  - Conducted in schools, camps, hospitals, institutions or similar settings in which the majority of children involved as subjects are not wards.
- B. Advocates
- An advocate must be appointed for wards acting as subjects, as well as any other individual acting on behalf of the child as guardian or in loco parentis.
  - One individual may serve as advocate for more than one child.
  - The advocate shall be an individual who has the background and experience, as well as agrees to act in the best interests of the child for the duration of the child's participation in the research.
  - The advocate cannot be associated in any way with the research, the investigator(s) or the guardian organization.

SOP Number:	IRB 35	Revision Number:	01	Effective Date:	8/01/2018
Title:	Research Involving Prisoners				

## GENERAL POLICY

Prisoners may be under constraints because of their incarceration which could affect the ability to make a truly voluntary and un-coerced decision whether or not to participate as subjects in research.

Additional safeguards are necessary for the protection of prisoners involved in research as subjects. The requirements are in addition to those stipulated in other SOPs related to the review of research.

## SPECIFIC POLICIES

### A. Institutional Review Board (IRB) Membership

- A majority of the IRB members shall have no association with the prison(s) involved.
- At least one IRB member shall be a prisoner representative with appropriate background and experience to serve in that capacity.

### B. Additional Review Criteria

The IRB shall approve research only if it finds the following:

1. The research under review represents one of the following categories of research:
  - ❖ Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects
  - ❖ Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects
  - ❖ Research on conditions particularly affecting prisoners as a class
    - For example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere
    - Research on social and psychological problems such as alcoholism, drug addiction and sexual assaults
  - ❖ Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject
2. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers.
3. 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 that particular research project, unless the principal investigator provides justification in writing for following some other procedures.
4. The information is presented in a language which is understandable to the subject population.

5. Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and that each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole.
  6. Adequate provision must be made if the Board finds there may be a need for follow-up examination or care of participants after the end of their participation. Provisions must be made for examination or care, taking into account the varying lengths of individual prisoners' sentences, and the requirement for informing participants of this fact.
- C. When a study does not intend to conduct research involving prisoners, but a participant becomes incarcerated while enrolled in a study, precautions must be taken to protect the participant.
- ❖ The participant will be withdrawn from the study.
  - ❖ The IRB will consider alternatives to withdrawal and will work with the Investigator to determine the best course of action for protection of the participant if withdrawal from the study will adversely impact the participant.
    - The Investigator will notify the IRB of the participant's incarcerated status immediately.
    - The IRB's prisoner representative will assist in determining the best course of action.

SOP Number:	IRB 36	Revision Number:	01	Effective Date:	8/01/2018
Title:	Research Involving Pregnant Women, Fetuses, or Neonates				

## PURPOSE STATEMENT

The purpose of this document is to detail the requirements for Institutional Review Board (IRB) approval of research involving pregnant women, fetuses or neonates as human subjects. Pregnant women, fetuses and neonates are considered to be a vulnerable population, and therefore must be treated with special consideration.

## DEFINITIONS

The following definitions are found as stated in 45 CFR 46.202:

- ❖ Dead Fetus: A fetus not exhibiting heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles or pulsation of the umbilical cord.
- ❖ Delivery: Complete separation of the fetus from the woman by expulsion, extraction or any other means.
- ❖ Fetus: The product of conception, from implantation until delivery.
- ❖ Neonate: Newborn.
- ❖ Nonviable Neonate: A neonate after delivery that is not viable even though he or she is living.
- ❖ Viable: Refers to a neonate's likelihood of survival post-delivery, given the benefit of available medical therapy, to the point of independently maintaining heartbeat and respiration. The Secretary may, taking into account medical advances, publish guidelines in the federal register to assist in determining whether a neonate is viable for purposes of this subpart. A viable neonate may be included in research only to the extent permitted and in accordance with the requirements of 45 CFR 46 subparts A and D.
- ❖ Pregnancy: Refers to the period of time from implantation until delivery. A woman is assumed to be pregnant if she exhibits any of the pertinent signs of pregnancy, specifically missed menstrual cycles, until the results of a pregnancy test are negative or until delivery.

## CRITERIA FOR APPROVAL

Research involving pregnant women, fetuses or neonates qualifies for Exemptions at 45 CFR 46.101 (b) (1) through (6). The provisions of 45 CFR 46.101 (c) through (i) also apply. The study will automatically be sent to full board for review if it does not qualify for an exemption. The following criteria from 45 CFR 46 Subpart B must be met.

## PREGNANT WOMEN OR FETUSES

- ❖ Where scientifically appropriate, preclinical studies (including studies 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 risk, 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;

- ❖ The pregnant woman's consent is obtained in accord with the informed consent provisions of subpart A if the research holds out the prospect of direct benefit to her and/or to the fetus. Consent is also obtained when no prospect of benefit for the pregnant woman or 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;
- ❖ The consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A if the research holds out the prospect of direct benefit solely to the fetus. The father's consent is not necessary if he is incapable to consent because of unavailability, incompetence or temporary incapacity, or if the pregnancy resulted from rape or incest, as stated in 45 CFR 46.204(e);
- ❖ Each individual providing consent is fully informed regarding the reasonably foreseeable impact to the fetus or neonate from the research;
- ❖ Assent and permission are obtained in accord with the provisions of subpart D for children who are pregnant;
- ❖ No incentives, monetary or otherwise, will be offered to terminate a pregnancy;
- ❖ Individuals involved in the research will have no part in any decisions relating to the timing, method or procedures used to terminate a pregnancy; and
- ❖ Individuals involved in the research will have no part in determining the viability of a neonate.

#### **45 CFR 46.205 RESEARCH INVOLVING NEONATES**

Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:

- ❖ Preclinical and clinical studies have been conducted, where scientifically appropriate, and provide data for assessing potential risks to neonates.
- ❖ Each individual providing consent as describe in subpart B (b)(2) or (c)(5) is fully informed regarding the reasonably foreseeable impact to the neonate from the research.
- ❖ Individuals involved in the research will have no part in determining the viability of a neonate.
- ❖ The following requirements of paragraph E or F of this section have been met as applicable.
- ❖ Neonates of uncertain viability: A neonate may not be involved in research until it has been ascertained whether or not a neonate is viable, unless the following additional conditions have been met as determined by the IRB:
  - The research has allowed the opportunity for increased attempts for the survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or
  - The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means. There will also be no added risk to the neonate resulting from the research; and
  - The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of provisions listed in 45 CFR 46.204(e).
- ❖ Nonviable neonates: A nonviable neonate may not be involved in research after delivery unless all of the following additional conditions are met
  - Vital functions of the neonate will not be artificially maintained;
  - The research will not terminate the heartbeat or respiration of the neonate;
  - There will be no added risk to the neonate resulting from the research;
  - The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
  - The legally effective informed consent of both parents of the neonate is obtained in accord with subpart A, except that the waiver and alteration provisions of 45 CFR 46.116(c) and (d)

do not apply. If either parent is unable to consent because of the provisions listed in 45 CFR 46.204(e), the consent of one parent of a nonviable neonate will suffice; however, the consent of a legally authorized representative of either or both of the parents of a nonviable neonate is not an equal substitute.

- ❖ Viable neonates: A neonate determined to be viable after delivery may be included in research only to the extent permitted by and in accord with the requirements of subparts A and D.

#### **45 CFR 46.206 RESEARCH INVOLVING, AFTER DELIVERY, PLACENTA, THE DEAD FETUS OR FECAL MATERIAL POST-DELIVERY**

- ❖ Research involving post-delivery placenta; the dead fetus (or cells, tissue, or organs excised from a dead fetus) or macerated fetal material shall be conducted only in accord with any applicable federal, state, or local laws and regulations regarding such activities.
- ❖ If information associated with material described in the above paragraph of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects, and all pertinent subparts of this part are applicable.

#### **45 CFR 46.207 EXCEPTIONS**

If research is not approvable by the Federal Regulations contained in this document but presents an opportunity to understand, prevent or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses or neonates, it may be approved by special standards. The Secretary will conduct or fund research that the IRB does not believe meets the requirements of 45 CFR 46.204 or 46.205 only if:

- ❖ The IRB finds the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates; and
- ❖ The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in the federal register, has determined either:
  - The research does satisfy the conditions of 45 CFR 46.204, as applicable; or
  - The following: (i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates; (ii) The research will be conducted in accord with sound ethical principles; and (iii) Informed consent will be obtained in accord with the informed consent provisions of subpart A and other applicable subparts.

SOP Number:	IRB 37	Revision Number:	01	Effective Date:	8/01/2018
Title:	Research Involving Other Vulnerable Populations				

## PURPOSE STATEMENT

The purpose of this document is to detail the requirements for Institutional Review Board (IRB) approval of research involving vulnerable populations other than children, prisoners, pregnant women, fetuses and neonates. Vulnerable populations must be given special consideration.

## DEFINITIONS

- ❖ Vulnerable population: persons who cannot act as autonomous agents because of various handicaps or specific circumstances.
- ❖ Autonomous person: an individual capable of deliberation about personal goals and of acting under the direction of such deliberation. Persons with diminished autonomy used as human subjects are entitled to additional protection as outlined by the Belmont Report.

## EXAMPLES OF VULNERABLE POPULATIONS

- ❖ Handicapped persons: Persons with mental or physical handicaps may be considered a vulnerable population, depending upon the study design.
- ❖ Subordinate Individuals: Subordinate relationships can be unduly influenced by their superior. The following are examples of such relationships:
  - Teacher/student
  - Employer/employee
  - Military officer/soldier
  - Doctor/patient
- ❖ Persons with mental health conditions

## SPECIAL CONSIDERATIONS

The IRB must consider risks to participants when reviewing proposed research. Special considerations for vulnerable populations include the following:

- ❖ To what risks, unique to their status, will participants be exposed?
- ❖ What protections will be made to mitigate risks?
  - Example: In research involving a student/teacher relationship, the IRB may require the study instruments to be administered by someone other than the teacher.
- ❖ Are subjects capable of providing consent?
  - If the IRB determines that a legal representative is appropriate, such as when the subject is an adult with a cognitive disability, the IRB will work together with its legal advisor to determine who is most appropriate according to Federal Regulations and state law to provide legally effective consent on behalf of the subject.

The IRB will partner with investigators to identify mutually acceptable solutions.

SOP Number:	IRB 38	Revision Number:	01	Effective Date:	8/01/2018
Title:	Concealment or Deception in Research				

## PURPOSE STATEMENT

Many professional organizations, such as the American Psychological Association, consider concealment or deception undesirable except in the rarest of cases. Strong justification must be provided for procedures calling for either concealment or deception, and participants must be fully informed of the concealment or deception at the conclusion of the activities. Participants will have an opportunity to withdraw consent after the concealment or deception is disclosed.

## DEFINITIONS & RELEVANT REGULATION

"*Concealment*" is involved when the researcher intentionally does not initially reveal all the details of the protocol to the participant (not the whole truth).

"*Deception*" is involved when participants are intentionally told something untrue (not the truth).

*American Psychological Association Ethical Principles of Psychologists and Code of Conduct*

### 8.07 Deception in Research

(a) Psychologists do not conduct a study involving deception unless they have determined that the use of deceptive techniques is justified by the study's significant prospective scientific, educational, or applied value and that effective nondeceptive alternative procedures are not feasible.

(b) Psychologists do not deceive prospective participants about research that is reasonably expected to cause physical pain or severe emotional distress.

(c) Psychologists explain any deception that is an integral feature of the design and conduct of an experiment to participants as early as is feasible, preferably at the conclusion of their participation, but no later than at the conclusion of the data collection, and permit participants to withdraw their data. (See also Standard 8.08, Debriefing.)

## SPECIFIC POLICIES

The use of concealment or deception must be clearly described, reasonable, justified, and assessed for risks and protections in the IRB protocol application.

Concealment or Deception are only allowed in human subject studies when the IRB determines researcher(s) engaging in research protocols involving concealment or deception have taken all reasonable steps to ensure the following conditions are met:

1. The participant is honestly and fully informed about participation requirements before they participate in the study. Every precaution should be taken to minimize potential psychological discomfort for participants. The traditional Consent Form is used for this documentation.
2. Debriefing: The participant is fully informed about the concealment or deception, the exact nature of the concealment or deception, and the reason for the concealment or deception as soon as possible after the concealment or deception. At that time, the participant is presented with a second consent form that fully explains the concealment or deception and its purpose. It also provides the participant the opportunity to not have their data used. For example, after full disclosure, the participant could be provided with 2 choices:

\_\_\_ You may not use the data collected from me. Please destroy all data collected from me immediately.

\_\_\_ I give permission to have my data used in this research project.

3. Studies involving vulnerable populations (i.e. minors, prisoners, individuals with disabilities, etc.) and the use of concealment or deception are exceptional circumstances and will be scrutinized carefully. Risks must be minimal and will be evaluated for reasonableness.
4. The study design does not involve immoral behaviors/actions.

SOP Number:	IRB 39	Revision Number:	01	Effective Date:	8/01/2018
Title:	Continuing Review of Research				

## PURPOSE STATEMENT

Investigators are expected to conform to the highest ethical standards of research conduct and to maintain communication with the IRB when needed.

IRB approval may be withdrawn at any time warranted as determined by the IRB. The regulations authorize the IRB to establish procedures for the concurrent monitoring of research activities involving human subjects. Periodic review of research activities is necessary to determine whether approval should be continued. All non-exempt research involving human subjects must be reviewed no less than once per year.

## SPECIFIC POLICIES

- ❖ All non-exempt research is required to be reviewed at least annually by the IRB. Investigators are required to submit a Continuing Review application to initiate this process.
  - Submissions should be sent to the Office of Institutional Research for routing at least thirty days prior to the expiration of the current approval period.
  - The IRB should take any changes in institutional policy or regulation into consideration when conducting a Continuing Review and ensure all current criteria are met.
- ❖ IRB approval for the conduct of a study may be withdrawn at any time if the risks to the subjects are determined to be unreasonably high. Examples include more than an expected number of adverse events, unexpected serious adverse events, or evidence that the Investigator is not conducting the investigation in compliance with IRB or Institutional guidelines. Such findings may result in more frequent review of the study to determine if approval should be withdrawn or enrollment stopped until corrective measures can be taken or the research study terminated.
- ❖ Other activities or events may initiate further IRB review within an approval period. Activities or events include, but are not be limited to the following:
  - Site Visits and Third Parry Verification
  - Review of Serious Adverse Events and Unanticipated Problems
  - Amendments
  - Review of Significant New Findings
  - Reports from Employees, Staff and Faculty
  - Noncompliance

## SITE VISITS AND THIRD PARRY VERIFICATION

The IRB or Office of Institutional Research has the authority to observe, or have a third parry observe, the informed consent process of research it has approved, and to verify the study is being conducted as required by the IRB and within the institutional policies and procedures and site-specific procedures. The IR staff or IRB members may perform site visits or use another parry, either affiliated or not with the institution, to verify information in the study application, or in any interim or continuing review submissions.

- ❖ The criteria for selecting Investigators to be visited may include, but is not limited to:
  - Investigators who conduct studies that involve a potential high risk to subjects,
  - Studies that involve vulnerable populations,
  - Investigators who conduct studies that involve large numbers of subjects, and
  - Investigators selected at the discretion of the IRB.
- ❖ Other means of verification include questionnaires sent to investigative staff to verify information submitted by the Investigator. Sponsors may be asked to submit copies of monitoring reports, or may be requested to complete a questionnaire regarding the protocol and/or the investigative site.
- ❖ Investigators may be asked to submit copies of signed informed consent forms or other documents to ensure compliance with IRB requirements. The IRB may conduct interviews with screened and/or enrolled subjects as deemed necessary.

## **SERIOUS ADVERSE EVENTS AND UNANTICIPATED PROBLEMS**

Subject safety is of the greatest importance for both the individual subject and the goals of the research study. Principal investigators are required by regulation and Northwest Vista College policy to promptly report any adverse event, regardless of the severity. The event will be reported to the IRB Chair, Institutional Official and OHRP as appropriate. Adverse events must also be reported to the federal sponsor, if applicable.

*Receipt:* An adverse event is defined as any potential for harm or any unanticipated problem(s) involving risks to subjects or others. Such reports should be submitted to IR within 24 hours. Other documents, such as those provided by study sponsors, should be attached. The report should summarize the event(s) and be signed by the PI. A summary of the event should be sent via electronic mail if the event occurred at Northwest Vista College and when the Office of Institutional Research is not normally open.

## **AMENDMENTS**

Changes in approved research, during the period for which approval has already been given, may not be initiated without prior IRB review (full or expedited review, as appropriate) and approval. Changes may only be initiated without prior approval when necessary to eliminate apparent immediate hazards to human subjects.

*Requests:* Requests to modify or amend an IRB approved protocol, consent form, or any other document related to an IRB approved protocol must be made in writing by the principal investigator (PI) using an Amendment Application. The Chair/designee will determine if the revision meets the criteria for minimal risk upon receipt of the protocol change. The change must be reviewed and approved by the IRB if it represents more than a minimal risk to subjects. Minor changes, involving no more than minimal risk to the subject, will be reviewed by the expedited review procedure.

*Review:* The chair (or designee) and another IRB member will review the request and approve, request clarifications, or refer the request to the full board for review, if the requested changes are more than minor. A request that should be forwarded for full board review would be one in which a change in methods, activities or procedures would increase risks to subjects or decrease the potential for benefit. The amendment may be reviewed by the IR staff if the amendment is to an exempt study and the amendment does not negate the study's exempt status.

*Reporting:* All requests for modifications reviewed by expedited procedures will be reported to the IRB.

- ❖ **Filing and Retention:** Amendment requests and any correspondence generated by the IRB in response to the request must be filed with the original file and retained for three years beyond the life of the protocol.

## **SIGNIFICANT NEW FINDINGS**

The IRB should review adverse event reports, current literature, and other sources as it may find useful during the course of a study to ascertain the status of the study and assess whether or not the risk/benefit balance is still acceptable. The IRB will determine whether or not new information needs to be conveyed to subjects, or if a segment of the population may be bearing an undue burden of research risk or being denied access to promising therapy.

## **REPORTS FROM EMPLOYEES, STAFF AND FACULTY**

It is the responsibility of the IR staff and IRB members to act on information or reports received from any source reporting a study conducted at any facility under the jurisdiction of the IRB that could adversely affect the rights and welfare of research subjects.

## **NON-COMPLIANCE**

All credible reports of inappropriate involvement of human subjects in research and other instances of non-compliance must be investigated. The results of the investigation will be reported to the appropriate Northwest Vista College official(s). Regulatory authorities or Sponsors may also be notified. Such reports of non-compliance may come from any source including IRB members, Investigators, subjects, institutional personnel, the media, anonymous sources, the public, etc.

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB policies, is not in compliance with federal regulations, or has been associated with unexpected serious harm to subjects. All such suspension and or terminations will be reported to the OHRP and FDA as appropriate.

Any study conducted without IRB approval is considered an instance of serious non-compliance and will be reported as such to OHRP, Northwest Vista College officials(s), regulatory authorities, sponsors and any additional appropriate individual(s)/organization(s).

Instances of continued non-compliance will also be reported as such to OHRP, NVC officials(s), regulatory authorities, sponsors and any additional appropriate individual(s)/organization(s).

SOP Number:	IRB 40	Revision Number:	01	Effective Date:	8/01/2018
Title:	Suspension or Termination of Previously Approved Research				

## PURPOSE STATEMENT

The purpose of this document is to explain the process to be used by the Institutional Review Board (IRB) for suspension or termination of research. This only applies to research previously approved by the IRB.

## PROCESS OF SUSPENSION OR TERMINATION

The Institutional Official (IO) and any member of the IRB have authority to immediately suspend approval of research not conducted in accordance with Federal Regulations, and/or IRB requirements or that has been associated with unexpected serious harm to subjects. The authority is derived from federal law. Specific details may be found in 45 CFR 46.109, 45 CFR 46.112 and 45 CFR 46.113.

Research not in compliance can be suspended by any of the aforementioned persons upon first discovery of possible harm to human subjects. Suspension will be immediately communicated in the most expeditious manner possible. The Investigator(s), the IRB Chair, IO and Institutional Research and Funding Administrator will be notified via email or telephone call at the first opportunity after suspension.

All suspensions will be reviewed at the next convened IRB meeting to determine the best course of future action. An emergency meeting will be called within 72 hours of the suspension in cases requiring immediate review by the convened IRB. Termination of approval shall be decided by a majority vote at the first available meeting of the convened IRB.

## REPORTS OF SUSPENSION OR TERMINATION

A written statement of the reasons for suspension or termination will be sent to the Investigator, appropriate institutional official(s) and the department or agency head of the Investigator after the vote.

All protocols suspended or terminated by the IRB must be reported to the Office for Human Research Protections (OHRP). Any other affiliated agency that governs the research must also be contacted. The FDA must be contacted with a report if the research is United States Food and Drug Administration (FDA) regulated.

The IRB must determine whether it is appropriate to inform the research participants of the suspension or termination. Participants will be encouraged to submit reports of any adverse events. Actions must be taken to protect the rights and welfare of participants already enrolled, such as providing medical care outside of the research study, transfer participants to another Investigator or continue research under independent monitoring, and so forth.

## RECONSIDERATION

The IRB will reconsider a decision at the written request of the Investigator. The IRB will review any additional information provided by the Investigator at the time of reconsideration. Additional

information may include written clarifications, assessments of the study provided by experts in the field of study or any other information the Investigator feels would impact the IRB's decision.

A new application must be submitted in addition to the written appeal and other supporting documents if a study has been disapproved by the IRB and the Investigator requests reconsideration. The IRB will reverse its decision and approve the study if the materials submitted support the criteria for approval.

SOP Number:	IRB 41	Revision Number:	01	Effective Date:	8/01/2018
Title:	Sponsored Research				

## **PURPOSE STATEMENT**

The following guidelines were created to ensure agreements between researchers and sponsors do not compromise the review authority of the Institutional Review Board (IRB).

The purpose of this document is to explain the IRB's additional requirements for sponsored research and the expected timeline for review.

## **REVIEW OF SPONSORED RESEARCH**

The grant proposal or contract supporting the research will be reviewed in conjunction with the application when the IRB reviews sponsored research to ensure all activities supported by the sponsor are adequately addressed in the submitted IRB protocol. All sponsored research IRB protocols will be reviewed through an expedited or full review.

Sponsored research may be reviewed in stages. If work to be conducted in year three, for example, is contingent upon data collected and analyzed in year one, the IRB can review and approve the work proposed for year one. Year three may be reviewed at a later date, but it must be reviewed prior to implementing the year three body of work with human subjects.

## **RELEASE OF FUNDS BY ADMINISTRATOR/FUNDING AGENCY**

It is not a requirement that the IRB review all proposals prior to funding being released.

Northwest Vista College requires, in compliance with federal law, that all protocols be reviewed and approved prior to the start of any human subject research. The IRB will work with Investigators on a case by case basis to provide necessary documentation should a funding agency require a "pre review".

## **PROTECTION OF HUMAN SUBJECTS**

At no time will any sponsor pre-empt or over-ride any decision made by the IRB. Contracts with sponsors will not have any language contradicting the IRB's authority in the protection of human subjects.

SOP Number:	IRB 42	Revision Number:	01	Effective Date:	8/01/2018
Title:	Use of Consultants				

**PURPOSE STATEMENT**

Ad hoc consultants may be requested if at any time the IRB Chair, an IRB member or Office of Institutional Research staff determine they do not have the necessary scholarly or scientific expertise for sound review.

Consultants are independent of the IRB and are selected according to scholarly and scientific expertise. This document describes the role of the consultant and the process for acquiring a consultant.

**CONSULTANT'S ROLE**

Consultants may be called upon to judge the scientific soundness of a research protocol, make a fair and accurate determination of the risk-benefit ratio, review the cultural appropriateness of the informed consent process and offer additional and unique expert advice.

Consultants are required to either attend meetings to present comments (in person or via phone/video conference) or to provide comments to the IRB in a written report. A summary of the findings will be described in the minutes if consultants attend a meeting. A copy of the report will become part of the protocol file and will be distributed to the IRB with the protocol if consultants provide a written report.

Consultants cannot make any review determinations and may not vote with the IRB. Consultants may only provide counsel.

**CONFLICTS OF INTEREST**

Consultants must disclose and document any conflicts of interest prior to counsel. Consultants with conflicts of interest will be replaced and will not be used.

**PROCESS FOR ACQUIRING OUTSIDE CONSULTANT**

The process for acquiring outside consultation will be coordinated by IR staff. The person requesting the use of a consultant may suggest an appropriate consultant or identify the subject matter needing outside review. IR staff will consult with the appropriate department head or dean to identify potential consultants if no consultants are recommended. An expert may be sought from other institutions or the private sector if Northwest Vista College resources are not sufficient.

The IRB may appoint standing consultants to provide expert counsel.

SOP Number:	IRB 43	Revision Number:	01	Effective Date:	8/01/2018
Title:	Securing Legal Counsel				

**PURPOSE STATEMENT**

Various state, local and federal laws impact the conduct of research. The IRB may require the services of an attorney to assist with the identification, interpretation and application of relevant laws. This document details how the IRB will access legal counsel.

**LEGAL COUNSEL**

The Alamo Colleges District Office of Legal Services is available to assist the Office of Vice President of College Services with legal issues. The appointed attorney will serve as a legal advisor to the IRB. He or she may attend all IRB meetings and participate in protocol related discussion.

The legal advisor will not serve as a member of the IRB and does not have a vote in IRB actions.

The legal advisor will facilitate securing necessary expertise or resources from the Alamo College District Legal Services if the board requires more specialized counsel than the legal advisor is able to provide.

SOP Number:	IRB 44	Revision Number:	01	Effective Date:	8/01/2018
Title:	Cooperative Research & Deferral of Review to Other Institutions				

## PURPOSE STATEMENT

The Office of Institutional Research and Institutional Official (IO) shall have special responsibilities in the review and approval of protocols involving cooperative activities.

Cooperative activities are those in which Northwest Vista College faculty, staff or students obtain access to human subjects through one or more cooperating institutions or when Investigators from cooperating institutions obtain access to human subjects at Northwest Vista College.

This document outlines the responsibility in reviewing cooperative research and deferring review to other institutions.

## IRB REVIEW RESPONSIBILITIES IN COOPERATIVE RESEARCH

Faculty members, staff or other employees or students from Northwest Vista College may obtain direct access to subjects at a cooperating institution. When the cooperative institution has an approved general assurance on file with Department of Health and Human Services (DHHS), or has a DHHS approved special assurance for the activity, the IRB from each of the cooperating institutions shall conduct an independent review of the cooperative activity.

The cooperative activity shall not be initiated if either the IRB of a cooperating institution or the Northwest Vista College IRB finds reason not to approve the cooperative activity. The Northwest Vista College IRB, at its discretion, may concur with, reject or further restrict the recommendations from the cooperating institution.

The cooperating institution will be required to provide permission for the cooperative activity if the cooperating institution does not have a DHHS approved Federal Wide Assurance (FWA).

An Investigator from a cooperating institution with a DHHS approved FWA desiring direct access to any subject at Northwest Vista College must obtain joint review of the protocol. Any restrictions imposed by the Northwest Vista College IRB are binding on the outside Investigator.

## DEFERRAL OF REVIEW TO OTHER INSTITUTIONS

Northwest Vista College may elect to defer review responsibility institutions to facilitate research while adequately protecting the subjects. The purpose of this document is to outline the procedures the circumstances in which deferral may be granted.

Northwest Vista College will consider deferral review institutions in the following circumstances:

- ❖ Data analysis of identifiable data is the only activity undertaken by Northwest Vista College Investigator.
- ❖ If the other IRB has more direct responsibility, whether geographically or institutionally, for the subjects under study.
- ❖ Northwest Vista College is subcontracting a portion of a study to another entity.

- ❖ Another entity has more direct responsibility for the actions of the researcher than Northwest Vista College.
- ❖ Other requests will be considered on a case by case basis.

### **PROCESS FOR DEFERRAL**

The following must be met for Northwest Vista College to defer to another Institution's IRB:

- ❖ The institution to which the deferral is proposed must have a current Federal wide Assurance (FWA) on file with the Office of Human Protections
- ❖ An Authorization Agreement (AA) must be executed by both Northwest Vista College and the institution conducting the review.
- ❖ Northwest Vista College retains the right to revoke a deferral, at any time, to conduct its own review.
- ❖ The Office of Institutional Research is responsible for managing all Authorization Agreements.

### **OTHER ENTITIES' DEFERRAL TO NORTHWEST VISTA COLLEGE**

It may be prudent for Northwest Vista College to serve as the IRB of record for a protocol and for NVC to allow other entities to depend upon it for review of a study.

The following criteria must be met for another IRB to defer to Northwest Vista College:

- ❖ The deferring institution must have a current FWA on file with OHRP.
- ❖ An AA must be executed by both Northwest Vista College and the deferring institution.
- ❖ Northwest Vista College retains the right to revoke a deferral at any time and require the deferring institution to conduct its own review.

SOP Number:	IRB 45	Revision Number:	01	Effective Date:	8/01/2018
Title:	Participant Concerns				

## PURPOSE STATEMENT

The purpose of this document is to provide information regarding the process to be followed in response to any participant concerns.

The Office of Institutional Research and Institutional Review Board (IRB) will be readily available and responsive to the concerns of research participants and potential participants.

## INTAKE AND PROCESSING OF CONCERNS

Participants may communicate concerns in whatever manner is most comfortable.

Contact with the IRB will be made through the IR office. Contact information for IR will be made available in the following locations:

- ❖ The IRB website
- ❖ Consent forms and information sheets
  - Investigators are required to list IR Director contact information in consent forms and information sheets.
  - Northwest Vista College IRB may permit the use of the contact information of a collaborating institution's IRB in lieu of the Northwest Vista College IR/IRB contact information in collaborative research projects.
- ❖ Recruitment materials, as appropriate

Concerns administrative in nature will be addressed at the IR office level. Examples of these types of concerns include those relating to delay of compensation, scheduling of identifying study personnel. Resolution will be sought by working collaboratively with the principal investigator (PI) and participant. Any issues not resolved by this method will be referred to the IRB Chair for guidance.

The IRB Chair and the PI will be notified by email or telephone upon receipt of any concerns involving the health, safety and/or well-being of subject(s). The concerns will be investigated and resolved in a timely manner, and adjustments will be made to the study protocol if necessary.

Actions taken to resolve a participant's concern involving the health, safety and/or well-being of a participant will be communicated to the full board at its next convened meeting.

Actions taken as a result of a participant concern will be communicated to the participant to the level possible and appropriate.

## DOCUMENTATION

Participant concerns and resolutions will be acknowledged and resolved (if necessary) by the IRB Chair or IR staff and then documented in the protocol file. Any concern referred to the convened IRB for review or comment will be documented in the minutes. The concern will be documented and reported accordingly if the concern reveals a serious unanticipated problem or adverse event.

SOP Number:	IRB 46	Revision Number:	01	Effective Date:	8/01/2018
Title:	Meeting Minutes				

## PURPOSE STATEMENT

The purpose of this document is to detail the information to be recorded in the minutes of Institutional Review Board (IRB) meetings and to specify the manner by which the minutes will be reviewed, authorized and retained. Northwest Vista College accepts and upholds the requirements of meeting minutes provided in 45 CFR 46.115(2).

## CONTENT OF MINUTES

Minutes will be taken at all convened meetings of the IRB. The minutes will be recorded in writing, in sufficient detail, to show the following:

- ❖ Administrative items, such as those listed on the agenda.
- ❖ Meeting attendance, including members who recuse themselves because of conflict of interests (COI) or other reasons.
- ❖ Summary of the discussion of each study, including required changes or disapproving research.
  - The minutes will state if the study was determined to be minimal risk and can be routed through expedited review.
- ❖ Actions taken by the IRB.
- ❖ The vote taken on actions, including number of members voting for, against, and abstaining.
- ❖ Any provisions of the determined decision.

## REVIEW AND AUTHORIZATION

Minutes from previous meeting(s) will be distributed to members following convened IRB meetings for review and approval. Any corrections requested by the IRB will be documented and appropriate updates made for presentation at the next meeting.

## RETENTION

Meeting minutes are to be retained for a minimum of three years after the conclusion of the longest running study documented in the minutes.

SOP Number:	IRB 47	Revision Number:	01	Effective Date:	8/01/2018
Title:	Training, Outreach and Education				

**PURPOSE STATEMENT**

The protection of research participants is the responsibility of many individuals at Northwest Vista College, including Institutional Review Board (IRB) members and chairs, Office of Institutional Research staff, investigators, research staff and the Institutional Official. Individuals need to understand and be able to apply several areas of knowledge to protect human research participants. Areas of knowledge include ethical principles, professional standards, organizational policies and procedures, federal regulations and other applicable laws.

The depth of knowledge and skill required depends on each individual's specific task and role. IRB chairs or reviewers designated to use the expedited procedure of review should have more knowledge and skill than a new IRB member. IRB members need skills specific to the types of research they review, such as clinical trials, psychological research, or international research. Investigators need different skills depending on the nature of their research or the expertise of their support staff.

This document provides the foundation for a comprehensive training, outreach and education program housed within the Office of Institutional Research.

**RESPONSIBILITIES**

Office of Institutional Research staff is responsible for developing, communicating, implementing and maintaining training programs.

The budgetary needs are the responsibility of the VPCS. The Office of Institutional Research is responsible for communicating budget requests and modifications to the VPCS in a timely manner.

The VPCS/IO is responsible for ensuring adequate resources are made available to ensure implementation and maintenance of adequate support for the IRB.

**COMMUNICATION OF TRAINING**

Changes to required training for investigators and study personnel will be communicated a minimum of thirty days prior to implementation.

Institutional Research will track training, outreach and education activities.

SOP Number:	IRB 48	Revision Number:	01	Effective Date:	8/01/2018
Title:	Reports to IRB				

**PURPOSE STATEMENT**

This document details the reports to be disseminated to the Institutional Review Board (IRB) and the method by which they will be disseminated.

**REPORTS AND REPORT DISTRIBUTION**

The Director of Institutional Research will provide the following reports to the IRB:

*Report of All Studies Approved via the Expedited Review Process* - The report will be generated biannually. The report will be e-mailed to all board members. Members will be given opportunity to ask for additional information and discuss the report at the next scheduled meeting.

*Report(s) of all Serious Unanticipated Problems and Adverse Events* – IRB chair(s) will be notified immediately. The issue and actions taken by the chair(s) or designee will be reported at the next convened meeting.

*Report(s) of Serious or Continuing Non-Compliance* - IRB chair(s) will be notified immediately. The issue and actions taken by the chair or designee will be reported at the next convened meeting.

SOP Number:	IRB 49	Revision Number:	01	Effective Date:	8/01/2018
Title:	Annual Resource Review				

**PURPOSE STATEMENT**

An annual review of personnel and budget allocations is to occur to ensure adequate resources are available to conduct the business of the research compliance and the Institutional Review Board (IRB).

This document details the review process and the responsibilities of the Director of Institutional Research.

**ANNUAL RESOURCE REVIEW**

The IR Director is responsible for reviewing personnel and budget allocations on an annual basis. The review is to occur in conjunction with Northwest Vista College’s annual budget review process.

The IRB has the option to identify any outstanding needs of the program and report these to the IO. Budget requests will be communicated through the standard process as set by the VPCS.

SOP Number:	IRB 50	Revision Number:	01	Effective Date:	8/01/2018
Title:	Protocol File				

## PURPOSE STATEMENT

The purpose of this document is to detail the records to be included in and the organization of protocol files for the Office of Institutional Research.

## OFFICIAL RECORDS

All files will be maintained digitally in a secure location to protect the confidentiality of the files.

## FILE CONTENT

The following items must be maintained in the official protocol file, as applicable:

- 1) Protocol Related Communication: Communication between the investigator and IR staff and/or the Institutional Review Board (IRB) will be kept in the protocol file. Communication includes approval and exemption letters, requests for revisions and follow-up communication.
- 2) Administrative Items
- 3) Applications
  - IRB Protocol Application
  - Continuing Review Application(s)
  - Amendment Application(s)
- 4) Instruments/Interventions
- 5) Recruitment Materials
- 6) Grant Proposals or Contract
- 7) Consent Documentation
- 8) Reports
  - Reports of serious unanticipated problems
  - Reports of protocol deviations
  - Reports of issues of non-compliance
  - Reports of adverse events
  - Reports of participant concerns
  - Completion Report
  - Review Documentation
  - Minutes from full board review
  - Approval letters from IRBs at other institutions and/or approval to utilize data from other institutions

SOP Number:	IRB 51	Revision Number:	01	Effective Date:	8/01/2018
Title:	Protocol Level Communication				

## PURPOSE STATEMENT

The purpose of this document is to detail protocol level communication between the Office of Institutional Research and investigators.

## COMMUNICATION OF REVIEW STATUS

The IR office provides all official communication via e-mail unless otherwise stated below. Submissions receive at least one of the following types of notifications after the initial review:

*Revisions:* The investigator will be sent an e-mail outlining the missing information or documents.

*Exemptions:* Once an exemption has been declared by the reviewer, an e-mail with an attached exemption letter will be sent to the investigator.

*Approvals:* An e-mail with an attached approval letter will be sent to the investigator once a protocol has been approved by the reviewer.

*Full Board Review:* Investigators will receive an e-mail notifying them of the full board review if the reviewer determines a full board review is required. Full board approvals will be delivered through the same process as described above. An e-mail will be sent by the IR Director, listing the revisions required for approval if the IRB determines the study to be conditionally approved or deferred. An e-mail will be sent by the IR Director explaining the board's decision and suggested next course of action if the IRB tables or disapproves a study.

*Withdrawals, Terminations and Expirations:* An e-mail will be sent to the investigator notifying him/her if a study expires or is withdrawn or terminated. The investigator's faculty advisor and funding administrator will also be copied on the e-mail, if applicable.

## QUESTIONS/INQUIRIES

Anyone with an IRB or human subject related question or concern can contact the IR office via telephone, e-mail or one-on-one consultation.

SOP Number:	IRB 52	Revision Number:	01	Effective Date:	8/01/2018
Title:	Records Retention				

**PURPOSE STATEMENT**

The purpose of this document is to detail the records retention requirement for Office of Institutional Research records and materials.

**RECORD RETENTION REQUIREMENTS**

IR study files must contain a complete history of all Institutional Review Board (IRB) related activities respective to review and approval of research. Records include initial reviews, continuing reviews, amendments, incidents of non-compliance and adverse event reports. All records from a proposed study, regardless of whether the study is approved, must be maintained according to these requirements.

All active study files are to be maintained within the Office of Institutional Research. Files may be destroyed according to the Alamo Colleges District’s records retention policy after at least three years of records retention. The IR office will maintain a log of all files destroyed.