Procedure Title: Informed Consent and Assent Processes

Associated Policy:	Human Research Protection Policy (OSA Policy 1.0)		
Responsible Unit:	Office of Scholarly Activity		
Created:	9/15/2017	**Executive Lead:**	Chief Research Officer
Effective:	9/15/2017	**Revision History:**	. 01-10/13/2017; .02-11/14/2018 .03 03/25/2019; .04 – 04/04/2019; 05-08/14/19; .06 – 07/21/2020; .07 – 10/27/2020; .08 – 3/27/2023; .09 – 11/14/2024
Approved by:	Institutional Review Board		
Procedure Number:	117.09		
Key Words:	Consent; Informed Consent; Assent; Children; Waiver; Altered; Legally Authorized Representative		
Purpose:	To meet the responsibilities for protecting human subjects as issued by the Office for Human Research Protections (OHRP) requirement for individuals involved in the conduct or review of human subjects research at institutions holding OHRP-approved Federal Wide Assurances (FWAs)		

Process:

This SOP serves to inform all agents, offices, departments, and affiliate sites of PNWU of the procedures to alter informed consent, waive informed consent, or to obtain informed consent from research participants, the legally authorized representatives (LAR) of adults unable to consent, or the parents or guardians of children.

These informed consent requirements are not intended to preempt any applicable federal, state, or local laws that require additional information to be disclosed for informed consent to be legally effective.

For additional procedures to obtain informed consent from participants or LARs who have limited English proficiency, are deaf, have low literacy, or are blind, please see SOP 116 (Communication Barriers in Informed Consent).

Background:

Informed consent is the process of documenting participants' voluntary agreement to take part in a study. This process involves three key features: (a) disclosing to the prospective participant information needed to make an informed decision; (b) facilitating the understanding of what has been disclosed; and (c) promoting the voluntariness of the decision about whether to participate in the research.

Informed consent is not merely a signature on the consent document, but an ongoing process throughout the study. Truly informed consent involves providing information to prospective research participants in a way that facilitates understanding and provides adequate opportunity to consider participation based on the information that has been provided.

Pacific Northwest University of Health Sciences (PNWU) provides standardized consent form templates. The Institutional Review Board (IRB) recommends the use of the templates to help ensure that the elements required by the regulations are included in the consent forms submitted for IRB review. Sample or draft consent documents may be developed by a sponsor or cooperative study group. However, the IRB-of-record is the final authority on the content of the consent documents that are presented to the prospective study participants.

Responsible Parties

The Institutional Review Board (IRB) is responsible for:

- Approving and requiring informed consent processes for human research
- Requiring that informed consent be obtained and documented in accordance with regulatory requirements unless the criteria for the waiver or alteration of such requirements has been satisfied and approved by the IRB.
- The IRB may require that information, in addition to that specifically mentioned in the regulations, be given to the participants when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of participants.
- Conducting continuing review of research at intervals appropriate to the degree of risk of the research

The Office of Scholarly Activity (OSA) is responsible for:

- Supporting investigators in helping determine consent processes best for the protection of research participants
- Monitoring compliance with this Standard Operating Procedure (SOP)
- Posting this SOP for the PNWU community
- Providing the necessary support to investigators and the IRB

The Investigator is responsible for:

- Training all research personnel in the informed consenting and assenting processes
- Communicating with IRB members and OSA staff in a timely fashion
- Seeking support from OSA and the IRB on proper informed consent processes
- Checking readability statistics (e.g., Flesch-Kincaid, Hemingway App) to ensure reading levels for consent forms are appropriate
- Posting a copy of an IRB approved consent form on a federal website (e.g., ClinicalTrials.gov) no later than 60 days after the last study visit for clinical trials conducted or supported by a federal department or agency.

Procedure:

General Requirements for Informed Consent

1. Investigators must obtain consent prior to entering a participant into a study and/or conducting any procedures required by the protocol, unless consent is waived by the IRB.
    a. Informed consent may only be obtained from participants who have the legal and mental capacity to give consent. For participants without that capacity, consent must be obtained from a legal guardian or LAR.

b. If someone other than the investigator conducts the interview and obtains consent from a participant, the investigator needs to formally delegate this responsibility and ensure they have received appropriate training to perform this activity. The person so delegated must be knowledgeable about the research to be conducted in order to accurately answer questions about the study.

2. An investigator shall seek informed consent only under circumstances that provide the prospective participant or the LAR sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.

3. The informed consent information must be presented in language that is understandable to the participant or LAR.
    a. To the extent possible, the language should be understandable by a person who is educated to an 8th grade level and non-technical terms should be used in the description of the research.
    b. Please see SOP 116 for (Communication Barriers in Informed Consent) for additional procedures to obtain informed consent from participants or LARs who have limited English proficiency, are deaf, have low literacy, or are blind.

4. The prospective participant or the LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

5. Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective participant or LAR in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

    Generally, the beginning of an informed consent should include a concise explanation of the following:
    - The fact that consent is being sought for research and that participation is voluntary,
    - The purposes of the research, the expected duration of the prospective participant's participation, and the procedures to be followed in the research,
    - The reasonably foreseeable risks or discomforts to the prospective participant,
    - The benefits to the prospective participant or to others that may reasonable be expected from the research, and
    - Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective participant.

6. Informed consent as a whole must present information in sufficient detail relating to the research and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective participant's or LAR's understanding of the reasons why one might or might not want to participate.

7. No informed consent may include exculpatory language through which the participant or the LAR is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the investigator, the sponsor, PNWU, or its agents from liability for negligence.

Elements of Informed Consent

<u>Basic Elements</u>

To be valid, the consent process must provide the following basic elements of information to potential participants in research subject to the revised Common Rule [see §46.116(b)]:

- A statement that the study involves research and an explanation of the purposes of the research,
- The expected duration of the participant's participation,
- A description of the procedures to be followed and identification of any procedures which are experimental,
- A description of any reasonably foreseeable risks or discomforts to the participant,
- A description of any benefits to the participant or to others which may reasonably be expected from the research,
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant,
- A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained,
    - **For FDA Regulated Studies:** The possibility that the Food and Drug Administration may inspect the records needs to be included in the statement regarding participant confidentiality.
- For research involving more than minimal risk, an explanation as to the availability of medical treatment in the case of research-related injury, including who will pay for the treatment and whether other financial compensation is available,
- An explanation of whom to contact on the research team for answers to pertinent questions about the research or to voice concerns or complaints about the research, and whom to contact in the event of a research-related injury to the participant.
- Contact information for the IRB to obtain answers to questions about the research, to voice concerns or complaints about the research, to obtain answers to questions about their rights as a research participant, in the event the research staff could not be reached, and in the event the participant wishes to talk to someone other than the research staff.
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.
- One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
    - Identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the participant or the legally authorized representative, if this might be a possibility, or
    - The participant's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used, or distributed for future research studies.

<u>Additional Elements</u>

The consent process must include the following additional elements of information when applicable [see §46.116(c)]:

- A statement that the treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant), which are currently unforeseeable,
    - Include when the research involves investigational test articles or other procedures in which the risk to participants is not well known.

- Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent,
- Any additional costs to the participant that may result from participation in the research,
- The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of their participation,
- A statement that significant new findings developed during the course of the research, which may relate to the participant's willingness to continue participation, will be provided to the participant,
    - Include when the research is long term and interim information is likely to be developed during the conduct of the research.
- The approximate number of participants involved in the study,
    - Include when the research involves more than minimal risk, or the IRB determines that the number of participants may affect a participant's decision to participate.
- A statement that the participant's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the participant will or will not share in this commercial profit,
- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to participants, and if so, under what conditions,
- For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Waiver or Alteration of Informed Consent

1. When reviewing research subject to the Common Rule, the PNWU IRB will evaluate requests for waivers or alterations of informed consent in accordance with the requirements and criteria specified in the revised rule and summarized below.

2. Requirements for research in which information is withheld from participants during the consent process are outlined in SOP 139 (Research Involving Deception or Incomplete Disclosure).

3. FDA regulations do not provide for waivers of informed consent except in emergency situations (the PNWU IRB does not normally review FDA regulated emergency research).

4. The IRB's determination will be documented in the IRB record and communicated to the investigator.

<u>General Waiver or Alteration of Consent</u>

1. In order to approve a request from an investigator to waive the requirement for informed consent, or to omit or alter one or more basic or additional element of consent (an "Alteration"), under this provision, the PNWU IRB must determine and document that the below criteria are satisfied:
    - The research involves no more than minimal risk to the participants,
    - The research could not practicably be carried out without the requested waiver or alteration,
    - If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format,
    - The waiver or alteration will not adversely affect the rights and welfare of the participants, and
    - Whenever appropriate, the participants or LARs will be provided with additional pertinent information after participation.

    Investigators may be asked to provide justification, or additional information or documentation, to support that the above criteria are satisfied.

Waiver or Alteration of Consent in Research Involving Public Benefit and Service Programs

1. In order to approve a request from an investigator to waive the requirement for informed consent, or to omit or alter one or more basic or additional element of consent (an "Alteration"), under this provision the PNWU IRB must determine and document that the below criteria are satisfied.
    - The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is 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; or
        - Possible changes in methods or levels of payment for benefits or services under those programs; and
    - The research could not practicably be carried out without the waiver or alteration.

Restrictions

1. Waivers – If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

2. Alterations – An IRB may not approve a request to alter or omit any of the general requirements for informed consent. If a broad consent procedure is used, an IRB may not alter or omit any of the broad consent elements identified at §46.116(d).

Screening, Recruiting, or Determining Eligibility

The revised Common Rule removes the requirement for partial waivers of consent for the use of information or specimens for the purposes of screening, recruiting, or determining the eligibility of prospective participants for inclusion in the research.

1. Pursuant to the revised rule, the PNWU IRB may approve a research proposal in which an investigator will obtain information or biospecimens for these purposes without the informed consent of the prospective participant or the participant's LAR if either of the following conditions is met:
    - The investigator will obtain information through oral or written communication with the prospective participant or LAR, or
    - The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

2. When research is subject to the revised Common Rule, and the above conditions are met, investigators do not have to request waivers of consent for the purposes of screening, recruiting, or determining eligibility but do have to describe the activities in the application or protocol submitted to the IRB.

3. **The above does not negate the requirements of other rules, such as HIPAA, when applicable.** It also does not negate the requirement to obtain consent, or a waiver of consent, before involving a participant (including the use of their identifiable private information or biospecimens) in other research activities.

Documentation of Consent

1. Unless the requirement for documentation of consent is waived by the IRB, informed consent must be documented by the use of written informed consent document (ICD) approved by the IRB and signed (including in an electronic format) by the participant or the participant's LAR.

2. The ICD may be either of the following:
    a. A written consent document that embodies the basic and required additional elements of informed consent. The investigator shall give either the participant or the participant's LAR adequate opportunity to read the informed consent form before it is signed; or
    b. A short form written consent document stating that the elements of informed consent have been presented orally to the participant or the participant's LAR and that the key information required by §46.116(a)(5) was presented first to the participant before other information, if any, was provided.

       Please see SOP 116 (Communication Barriers in Informed Consent) for information on the appropriate use of the short form consent process.

3. A copy of the ICD must be given to the person signing the ICD.

4. When signed in an electronic format, to comply with Washington state regulatory requirements and FDA requirements, there must be a permanent record of the signed consent and the system must require attribution (e.g., multi-factor authentication that proves the person signing is the individual whose name appears on the form).

<u>Waiver of Documentation of Informed Consent</u>

1. For non-exempt research, the IRB may approve a request for a waiver of documentation of consent for some or all participants if it finds any of the following:
    - The only record linking the participant to the research would be the signed informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality.
        - Participants must be asked whether they want documentation linking them with the research, and their wishes must govern.
        - **This provision does not apply to FDA-regulated research.**
    - That 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, or
        - For example, non-sensitive surveys, questionnaires, and interviews generally do not require written consent when conducted by non-researchers.
    - The participants or LARs are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to participants and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

2. In cases in which the documentation requirement is waived, the IRB requires the investigator to provide in the application materials a written summary of the information to be communicated to the participant, and the IRB will consider whether to require the investigator to provide participants with a written statement regarding the research.

3. The IRB's determination will be documented in the IRB record and communicated to the investigator as described in the PNWU SOPs.

4. For research eligible for exemption, signed written consent is generally not required given:

a. The research is not FDA regulated and not subject to FERPA, HIPAA, or any other regulations that specifically require signed consent (or a documented IRB approval of a waiver),
b. The investigator provides a written summary of information that includes the minimal elements of informed consent, that participants must review prior to proceeding the research activities/survey/interview (e.g., "click-through" consent), and
c. Participants have the option/ability to print or receive a copy of the informed consent information (or are provided contact information for obtaining a copy).

Posting of Clinical Trial Consent Forms

1. The revised Common Rule includes a requirement for the posting of one IRB-approved consent form to a publicly available Federal website for each clinical trial conducted or supported by a Common Rule department or agency no later than 60 days after the last study visit by any participant.

2. This requirement may be satisfied by either the awardee or the Federal department or agency. If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal website (e.g., confidential commercial information), the department or agency may permit or require redactions to the information posted.

3. At this time, two publicly available federal websites that will satisfy the consent form posting requirement have been identified by OHRP: ClinicalTrials.gov and a docket folder on Regulations.gov (Docket ID: HHS-OPHS-2018-0021).

4. When PNWU is the prime awardee, the responsible party (e.g., investigators, sponsored programs staff) should consult with OSA regarding how to satisfy this requirement.

Consent of Adults with Impaired Decision-Making Capacity

1. When a prospective participant is deemed to lack capacity to consent to participate in research, investigators may obtain informed consent from the individual's surrogate or LAR.
    a. Under these circumstances, the prospective participant should still be informed about the research in a manner compatible with the participant's likely understanding and, if possible, be asked to assent to participate.
    b. Potential participants who express resistance or dissent (by word, gesture, or action) to either participation or use of surrogate consent, should be excluded from the study.
    c. A participant may initially assent but later resist participation at which point consent is to be considered withdrawn. Investigators are to immediately initiate procedures for the orderly termination of such participants' participation.

2. When inclusion of adults with impaired decision-making capacity is not anticipated and a plan for inclusion of such participants has not been reviewed and approved by the IRB, and an enrolled participant becomes unable to provide consent or impaired in decision-making capacity, the investigator is responsible for promptly notifying the IRB (as soon as possible but within 5 business days).
    a. The investigator should consider whether continuing participation is appropriate and, if so, present a plan for surrogate consent from a LAR and, if appropriate, a plan to periodically evaluate capacity and re-obtain consent if possible.

Parental Permission and Child Assent

<u>Parental Permission</u>

1. When the prospective population includes children aged 17 or younger, the IRB must determine that adequate provisions have been made for soliciting the permission of each child's parent or guardian.

2. Parents or guardians must be provided with the basic elements of consent and any additional elements the IRB deems necessary.

3. The IRB may find that the permission of one parent is sufficient for research to be conducted under the following categories of allowable research with children (see 45 CFR 46.404-407):
    a. Research not involving physical or emotional risk greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (i.e., minimal risk) (§46.404).
    b. Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subject (§46.405).

4. Consent from both parents is required for research to be conducted under the following categories of allowable research:
    a. 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 or condition (§46.405).
    b. Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (§46.406).

5. The IRB's determination of whether consent must be obtained from one or both parents will be documented in the consent checklist when a protocol receives expedited review and in meeting minutes when reviewed by the convened committee

6. For research not subject to FDA regulations, the IRB may waive the requirement for obtaining consent from a parent or legal guardian if:
    a. The research meets the provisions for a waiver of consent as previously outlined, or
    b. If the IRB determines that the research protocol is designed for conditions or a participant population for which parental or guardian permission is not a reasonable requirement to protect the participants (e.g., neglected or abused children) provided:
        i. The waiver is not inconsistent with federal, state, or local law, and
        ii. An appropriate mechanism for protecting the children who will participate in the research is substituted. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities, the risk and anticipated benefit to the research participants, and their age, maturity, status, and condition.

7. Parental Permission may not be waived for research subject to FDA regulations.

<u>Child Assent</u>

When children are involved in research, the federal regulations require Investigators to have the child's agreement to take part in the study. This is known as assent. In the case of children, the PNWU IRB defines assent as the willingness to participate in research by persons who are by definition too young to give informed consent but who are old enough to understand the proposed research in general terms, its expected risks and possible benefits, and the activities expected of them as participants.

1. The IRB should consider the nature of the proposed research activity, and the ages, maturity, and psychological state of the children involved when reviewing the proposed assent procedure and the form and content of the information conveyed to the prospective participants.

2. The assent procedure should reflect a reasonable effort to enable the child to understand, to the degree they are capable of, what their participation in research would involve
    a. For adolescents whose capacity to understand resembles that of adults, the assent procedure should likewise include information similar to what would be provided for informed consent by adults or for parental permission.
    b. For children whose age and maturity level limits their ability to fully comprehend the nature of the research activity but who are still capable of being consulted about participation in research, it may be appropriate to focus on conveying an accurate picture of what the actual experience of participation in research is likely to be (e.g., what the experience will be, how long it will take, whether it might involve any pain or discomfort).

3. Because “assent” means a child’s affirmative agreement to participate in research, the child must actively show their willingness to participate in the research, rather than just complying with directions to participate and not resisting in any way.
    a. Researchers should try to draft a form that is age appropriate and study specific, considering the typical child's experience and level of understanding, and composing a document that treats the child respectfully and conveys the essential information about the study. The assent form should:
        i. tell why the research is being conducted,
        ii. describe what will happen and for how long or how often,
        iii. say it's up to the child to participate and that it's okay to say no,
        iv. explain if it will hurt and if so for how long and how often,
        v. say what the child's other choices are,
        vi. describe any good things that might happen,
        vii. say whether there is any compensation for participating, and
        viii. say that the child should ask questions if they have any.
    b. For younger children, the document should be limited to one page if possible. Illustrations might be helpful, and larger type makes a form easier for young children to read. Studies involving older children or adolescents should include more information and may use more complex language.
    c. If the child is not old enough or cannot document their agreement in writing, the child should verbally indicate their willingness to participate.

4. At times there may be inconsistency between parent permission and child assent. Usually a "no" from the child overrides a "yes" from a parent, but a child typically cannot decide to be in research over the objections of a parent. Obviously, there are individual exceptions to these guidelines (such as when the use of an experimental treatment for a life-threatening disease is being considered).

5. The IRB may waive the requirements for assent or documentation thereof when the criteria described at 45 CFR 46.404-407 or 21 CFR 50.51-54 are met.

References:

1. Food and Drug Administration (FDA) Federal Regulations (21 CFR 50, 54, 56, 312, 314, 600, 601, 812 and 814) http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm

2. Department of Health and Human Services (DHHS) Regulations (45 CFR 46 Subparts A, B, C, and D) http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
3. International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073122.pdf)
4. Agency for Healthcare leadership and Quality (AHRQ). Be Cautious About Using Readability Formulas. Accessed November 14, 2018. Available at: https://www.ahrq.gov/professionals/quality-patient-safety/talkingquality/resources/writing/tip6.html
5. Electronic Signatures in Global and National Commerce Act (ESIGN Act) https://www.govinfo.gov/app/details/PLAW-106publ229
6. Uniform Electronic Transactions Act (UETA) https://www.uniformlaws.org/committees/community-home?CommunityKey=2c04b76c-2b7d-4399-977e-d5876ba7e034
7. Washington State Bill 6028-S (Adoption of the UETA effective June 11, 2020) http://lawfilesext.leg.wa.gov/biennium/2019-20/Pdf/Bills/Session%20Laws/Senate/6028-S.SL.pdf#page=1
8. PNWU SOP 116 Communication Barriers in Informed Consent
9. PNWU SOP 139 Research Involving Deception or Incomplete Disclosure

Revision History:

Version/ Effective Date	Author	Section Changed & Reason for Revision
.00 – 9/15/2017	M. McCarroll	Initial SOP
.02 - 10/13/2017	M. McCarroll	Section 6.14.1 Added bullet with assent information for children
.03 – 11/14/2018	M. McCarroll	Added references on readability stats and accepted programs
.04 – 04/04/2019	M. McCarroll	Put into new format and revisions per the Revised Common Rule
.05 – 08/14/2019	C. Case	Spelling error correction and formatting correction only.
.06 – 07/21/2020	C. Case	Item 13 removed repeat sentence in second bulleted item. Added references to the Uniform Electronic Transaction Act (UETA); the Electronic Signatures in Global and National Commerce Act (ESIGN), and Washington State Bill 6028SL (adopting the UETA).
.07 – 10/27/2020	C. Case	Added Legally Authorized Representative to the key words section at the top of page 1 General Information Section added to page 1 which includes a statement about the use of consent form templates provided by PNWU. Added the following note to item 5 regarding the key information section "Note: In relatively simple studies with minimal risk or benefits, where the consent form is four pages or less, it may be acceptable to leave out the key information section."

.08 – 4/4/2023	C. Case	Removed reference to the L Drive in the footer of the SOP as all SOPs are now available in the electronic IRB management system; cleaned up punctuation; added a statement of equivalent protections for exempt research participants to the general information section; added the posting of a consent form for clinical trials conducted by or sponsor by a federal department or agency to the PI list of responsibilities; revised #2 to clarify that consent is required for exempt and non-exempt research; revised #9 & 10 and moved restrictions for Waiver or Alteration of Consent to a new number (now 11) as the information was repetitive and also added a note that the PNWU IRB has not adopted broad consent; #15 revised to include all of the rationale from 45 cfr 117 for waiver of documentation of consent (not just the added item from the revised common rule); #19 revised to clarify what publicly accessible data; Added language in the appendices for "Sample documentation of participant comprehension of informed consent; Added the Informed Consent and Assent Process Diagram to the appendices; Inserted the web link to the Translation Certification Form.
.09 – 11/14/2024	J. Simmons	Major revisions to layout and scope of content. Minor changes to institution-specific requirements. Content related to communication barriers in consent has been transferred to a new SOP (116) and has thus been replaced with a reference here. Expanded explanations of requirements for parental permission and child assent – will eventually move to separate vulnerable subjects SOP. Clarified WA requirements for electronic documentation of consent. Removed requirement for signed informed consent for most exempt research – exceptions (such as for FDA regulated studies) are outlined. Clarified requirements for consent forms in FDA and HHS regulated clinical trials to be uploaded ClinicalTrials.gov. Added guidance for some of the Additional Elements of consent on when they should be included. Added section headers for clarity. Added background and purposes statements where applicable. Added references to the CFR when applicable. Grammar and language edits to improve clarity and comprehension.

Appendices: