Procedure Title: Research Involving Deception or Incomplete Disclosure

Associated Policy:	Human Research Protection Policy (OSA Policy 1.0)		
Responsible Unit:	Office of Scholarly Activity		
Created:	4/28/2020	**Executive Lead:**	Chief Research Officer
Effective:	05/14/2020	**Revision History:**	.00 – 4/28/2020; .01 – 3/22/2023
Approved by:	Institutional Review Board		
Procedure Number:	139.01		
Key Words:	Deception, Disclosure, Incomplete Disclosure, Omission		
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 Standard Operating Procedure (SOP) serves to inform all agents, offices, departments, and affiliate sites of PNWU regarding research that involves deception or incomplete disclosure of research activities to participants.

This SOP must be used as a guide in parallel with OSA Policy 1.0. SOPs are not intended to supersede existing institutional policies, and local, state, and federal laws and regulations.

General Information
Respect for persons is one of the fundamental ethical standards that governs human subjects research. This standard requires that subjects enter research voluntarily and that adequate information be given to allow the participant to make an informed decision.

Deception (intentionally providing false or misleading information) or incomplete disclosure (withholding information about some aspect of the study) may interfere with a participant's ability to make an informed decision (informed consent). Research that fails to meet the principle of respect for persons by providing incomplete information during consent generally would not be approved. However, under some circumstances an investigator may be approved to conduct a study that includes deception or the withholding of certain information to study participants to avoid study bias. Studies must still meet the criteria in the regulations for 45 CFR 46.111 (risks to subjects are minimized by using procedures consistent with sound research design, and risks to subjects are reasonable in relation to the anticipated benefits).

The Institutional Review Board may require that the study team provide additional safeguards to protect the rights and welfare of the study participants when studies involve deception or incomplete disclosure.

Responsible Parties
The Institutional Review Board (IRB) is responsible for:

- Protecting the rights and welfare of human research participants.
- Impartiality when conducting reviews of human subject research.
- Remaining free from any possible influence or pressure from the institution's administration, the investigators whose protocols are brought before it, or other professional and nonprofessional sources.

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

- Supporting the investigator in the development of appropriate research protocols that involve deception and/or incomplete disclosure.
- Monitoring compliance with this SOP.
- Posting this SOP for the PNWU community.

The Investigator is responsible for:

- Providing the IRB with a clear and complete description of the deception to be used in the research, including methods for reducing or managing the risks to study subjects.
- Adhering to methods to reduce and manage the risks to study subjects participating in studies that include deception and/or incomplete disclosure.
- Carrying out additional safeguards, if any, required by the IRB.
- Debriefing research subjects when completing their participation in the research.

Definitions

Please reference the Glossary for complete definitions of the following terms and additional terms not listed.

- Deception
- Disclosure
- Federal wide Assurance
- Generalizable Knowledge
- Incomplete Disclosure
- Informed Consent
- Omission

Investigator Procedures:

1. The IRB Application must include:
    a. a clear and complete description of the deception or incomplete disclosure;
    b. justification for the use of deception or incomplete disclosure (e.g., why it is necessary or how it relates to the study aims and design);
    c. indication of whether or not the deception might increase the risk to subjects;
    d. indication of whether or not the deception may affect the willingness of subjects to participate in the research;
    e. a detailed description of how and when research participants will be debriefed. In most cases it is expected that each subject will be debriefed at the end of their participation unless standard briefing procedures would jeopardize study results (note: any debriefing form or script must be submitted with the IRB application);
    f. if an exception to the requirement for debriefing is requested, the study must be reviewed by the full Institutional Review Board.

2. Informed Consent for research with deception or incomplete disclosure may require a waiver or alteration of one or more basic elements of consent. To qualify for a waiver of one or more elements of consent, the research:
    a. must involve no more than minimal risk;

b. must not adversely affect the rights and welfare of the research subjects;
c. could not be practicably carried out without the waiver or alteration (whether or not the research uses identifiable information or biospecimens);
d. must, when using legally authorized representatives for consent, provide the legally authorized representative additional pertinent information about the study after participation.

3. Informed Consent Procedures:
    a. must provide subjects with enough information about the risks, required effort, and procedures of the study so they can make an informed decision as to whether or not to participate in the research.
    b. for exempt category 3 research (benign behavioral interventions) deception is only allowed when the subject authorizes the deception through a prospective agreement which informs the subject that they will be misled regarding the nature or purposes of the research.
    c. must assess the subject's understanding of their role, time required, and any anticipated risks.
    d. must document that subjects voluntarily agree to participate (unless waived); and
    e. must not use deception to entice or lure subjects to participate.

4. Debriefing procedures:
    a. The investigator is responsible for ensuring that study participants leave the research setting with an accurate understanding of the deception and/or incomplete disclosure as well as why it was necessary for the study.
    b. The investigator is responsible for ensuring that study participants have an opportunity to ask questions, have their questions answered, and have an opportunity to withdraw from the study or withdraw their study data (if identifiable).
        i. In most instances, it is expected that this will occur when an individual subject completes his or her participation in the study.
    c. Delayed debriefing at the completion of the study may be permitted when standard debriefing procedures would compromise study results. Strategies for delayed debriefing may include:
        i. giving the subjects a URL address where they can get debriefing information after a particular date;
        ii. sending a letter/email to participants (if collecting appropriate demographics such as name, address, or email address); or
        iii. having participants address an envelope to themselves before leaving the study.

5. FDA Regulated Studies and Placebos:
    a. Studies subject to FDA regulations cannot include deception/incomplete disclosure because waivers of consent can be granted only under limited conditions. An example of a situation where a waiver of consent would be granted in FDA Regulated research would be the emergency use of an experimental drug or device to preserve the life of the subject. [21 CFR 50.23]
    b. Placebo use during the course of a clinical trial (e.g., a control arm of a randomized clinical trial) is not considered to be deception or incomplete disclosure as long as subjects are fully informed that they may receive a placebo in the course of the study.

IRB Procedures:

1. The IRB will review research involving deception and/or incomplete disclosure while examining the risks and benefits of deception methods and/or incomplete disclosure.

2. The IRB will consider whether or not the deception and/or incomplete disclosure is scientifically justified.
3. The IRB will review the informed consent form and process and make determinations as to whether or not basic elements of consent may be waived under the regulations.
4. The IRB will consider whether there is a reasonable expectation that subjects would still consent to participate in the study after the investigator informs them of the study methods that include the deception and/or incomplete disclosure.
5. The IRB will ensure that the study is reviewed at a level appropriate to the risks of the deception and/or incomplete disclosure.
6. The IRB chair or member of the committee completing IRB review has the discretion to require a study to undergo full board review (e.g., studies designed to invoke feelings of rejection, negative response, stress, anger, or aggression).
7. IRB revision decisions will be communicated to the principal investigator in writing.

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. The Belmont Report. https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html
4. U.S. Department of Health & Human Services, Office of Human Research Protections website: https://www.hhs.gov/ohrp/
5. U.S. Food and Drug Administration Protection of Human Subjects, 21 CFR 50, Subpart B. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.23
6. PNWU SOP 124 – Review and Approval of Studies

Revision History:

Version/ Effective Date	Author	Section Changed & Reason for Revision
.00 / 05-14-2020	C. Case	Original SOP
.01 / 3-22-2023	C. Case	Clarified the last sentence in the general information section to state when the study involved deception or incomplete disclosure; removed L: Drive in the footer of the document as all SOPs are now stored in the electronic IRB management system; corrected punctuation; added a link in the references section to PNWU SOP 124 – Review and Approval of Studies

Appendices:
None