Procedure Title: Case Study, Single Subject Study, and Case Series of Human Subject Information

Associated Policy:	Human Research Protection Policy (OSA Policy 1.0)		
Responsible Unit:	Office of Scholarly Activity		
Created:	10/11/2018	**Executive Lead:**	Chief Research Officer
Effective:	10/11/2018; Reviewed 3/6/2023	**Revision History:**	.01 – 11/19/2018; .02 – 10/08/2019; .03 – 12/03/2021; .04 – 04/20/2022
Approved by:	Institutional Review Board		
Procedure Number:	SOP 133.04		
Key Words:	Case Study, Case Series, Case Report, Consent, Single-Subject Research Design, Single Subject Study		
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 regarding how the Institutional Review Board (IRB) at Pacific Northwest University of Health Sciences (PNWU) defines a human case study and/or case series.

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.

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 immune from pressure by 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 investigators in helping determine activities subject to human subject protection;
- Monitoring compliance with this SOP;
- Posting this SOP for the PNWU community;
- Providing the necessary support to investigators and the IRB;

The Investigator is responsible for:

- Asking the OSA if their activity is subject to human research protections;
- Communicating with IRB members and OSA staff in a timely fashion;

- Seeking support from OSA and the IRB on proper protocol development and submission

Definitions

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

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- Case Study
- Case Series
- Clinical Investigation
- Control
- Federal wide Assurance
- Generalizable Knowledge
- Health Insurance Portability and Accountability Act (HIPAA)
- Human Subject
- Investigator
- IRB
- Non-Research Activities
- Protected Health Information (PHI)
- Quality Improvement
- Research
- Single-Subject Design
- Systematic Investigation
- Test Article

Procedure:

1. Please review SOP 103 – Activities Subject to Human Research Protections

2. Case Study is defined as a single subject study with a clear intent to use data that would not ordinarily be collected in the course of daily life with intent to report and publish the case study.
    a. Single case study would not require IRB review.

3. Case Series. A group of subjects to use data that would not ordinarily be collected in the course of daily life. The intent is to report and publish the case series.
    a. Case studies or series less than five patients would not need IRB approval
    b. Case studies or series that include five or more patients must have IRB approval
    c. Single Subject Design (e.g. prospective case study)

4. A prospective (e.g. Single Subject Design) case study involves following an individual or a series of individuals over time and observing outcomes whereas a retrospective case study involves looking at historical information on the individual(s) to determine if there is a presence of risk factors that may have contributed to the outcome of interest. Case reports and case series are generally carried out by retrospective review of records and highlight a unique treatment, clinical case or outcome. As the collection and organization of information for such reports usually involves no data analysis or testing of a hypothesis, they do not constitute a systematic investigation.

5. Patient permission and consent for a case study/or part of a case series. Written consent for every patient mentioned/featured in a case report (one patient) or case series (four or less patients) is strongly recommended. The consent form used should be the consent form of the Institution where the patient was treated at the time of the treatment occurrence. If the Institution does not have a specific form, a template form found in the references below can be adjusted for the specific Institution and patient(s). If written consent cannot be obtained, documentation it is strongly recommended that supporting documentation be obtained from the Chair of the Department at the Institution OR a senior physician/attending physician such as a letter of support stating that despite exhaustive efforts, the patient and/or family could not be reached for proper consent.

6. Identifying information, including names, initials, or hospital numbers, should not be published in written descriptions, photographs, or pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian) gives written informed consent for publication. Informed consent for this purpose requires that an identifiable patient be shown the manuscript to be published. Authors should disclose to these patients whether any potential identifiable material might be available via the Internet as well as in print after publication. Patient consent should be written and archived with the authors. The authors must provide the journal with a written statement that attests that they have received and archived written patient consent. Nonessential identifying (HIPAA) details should be omitted. Informed consent should be obtained if there is any doubt that anonymity can be maintained. For example, masking the eye region in photographs of patients is inadequate protection of anonymity. If identifying characteristics are de-identified, authors should provide assurance, and editors should so note, that such changes do not distort scientific meaning.

7. The Difference between Case Study and Single-Subject Research Designs. The single-subject approach should not be confused with the case-study or case-history approach where a single individual is also studied exhaustively. The case-study approach is often an uncontrolled inquiry into history (retrospective) and it may yield interesting information. The single-subject approach is a method designed to study the behavior of an individual organism. In a clinical setting, these differences can be confusing, especially when health insurance companies are involved for reimbursement of standard of care practices and patients are being exposed to "research designs." Prior to any application of a single-subject investigation, please contact the OSA to discuss a risk/benefit assessment and a Medicare coverage analysis form.

8. Since journals often require proof of IRB administrative review, the "Determination of Activities Not Subject to Human Research Protections" form on IRB Manager should be completed to ensure the case studies are not human subject research (Note: You will need to attach a final copy of the case report to the Not Human Subjects Research Determination Form). If at the time of form completion, it is determined to not be an activity subject to human research protections, a letter from IRB administrator can be requested by the investigator. This letter can be uploaded to the journal of which the case studies are being submitted for consideration.

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 https://www.fda.gov/scienceresearch/specialtopics/runningclinicaltrials/guidancesinformationsheetsandnotices/ucm219488.htm
4. Medical student Research Journal. Sample Consent. http://msrj.chm.msu.edu/wp-content/uploads/2013/10/MSRJ-Case-Studies-Informed-Consent-10-3-13.pdf
5. JAMA Medical Network. Sample Consent. https://jamanetwork.com/DocumentLibrary/InstructionsForAuthors/PatientConsent.pdf
6. Chapter 14. Experimental Designs: Single-Subject Designs and Time-series Designs https://knowledgesociety.usal.es/sites/default/files/Single%20Subject%20and%20Time%20Series%20Designs.pdf

Revision History:

Version/ Effective Date	Author	Section Changed & Reason for Revision
.00 – 10/11/18	M. McCarroll	Original SOP
.01 – 11/19/2018	M. McCarroll	Removed old 6.2 section not relevant to SOP
.02 – 10/08/2019	C. Case	Put into new PNWU SOP Format
.03 – 12/03/2021	C. Case	Clarify last sentence in item 5 about patient consent and alternate documentation.
.04 – 4/20/2022	C. Case	Added note about requirement to attach a copy of the final case report to the Not Human Subjects Research Determination Form.
3.6.2023	C. Case	Reviewed to ensure that the content is still current. Changes were not made.

Appendices:
None