Q. Does my project qualify as Research?

A. Research is defined as a systematic investigation designed to develop or contribute to generalizable knowledge.

In the clinical setting, it is important to make a distinction between research and practice. They are frequently carried out together. This is the case when a clinical research activity evaluates the safety and efficacy of a treatment.

Practice includes interventions that can reasonably be expected to enhance the well-being of a person through diagnosis or treatment. In contrast, research involves testing a hypothesis and drawing conclusions. Usually the research activity is described in a formal plan (protocol) that identifies the objectives and procedures to reach the objectives.

In addition to clinical research, other types of research include survey research, which involves interacting with individuals to gather information using questionnaires or interviews. Another involves the collection of data from identifiable private information sources, such as medical records, so that analysis of the data will yield conclusions. Yet another involves bench or laboratory research, e.g., the use of surgical and laboratory specimens that would otherwise be discarded.

Your project is most likely research if it contains any of the elements described above.

Q. Does my research require IRB approval?

A. All research projects involving human subjects require IRB review and approval. A human subject is any individual, living or deceased, about whom the investigator collects data through direct intervention or interaction, or from sources such as medical records, clinical databases, billing records and pathologic or diagnostic tissue specimens. Data from these sources is called identifiable private information. **IRB review and approval cannot be conducted retroactively.**

Q. What is the IRB’s authority?

A. The IRB has the authority under federal regulation and institutional policy to approve, require the modification of or disapprove research activities being conducted at or on behalf of PNWU.

It also has the authority to suspend or terminate research that was previously approved in which unforeseen harm to subjects occurs, or that is not being conducted as approved by the IRB. IRB decisions are final.
Q. May I recruit participants for my study before IRB approval?
A. No. Research subjects are not to be approached until the IRB has given final approval to the application.

Q. Do case reports require IRB approval?
A. The IRB is responsible for the review of research. Research is defined as a “systematic investigation...designed to develop or contribute to generalizable knowledge.” Most case reports do not meet this definition of research because there is no systematic investigation, i.e., no data analysis.

Therefore, most case reports do not require IRB review. However, it is important for investigators to recognize that the federal privacy rule HIPAA applies to case reports. Therefore, authors of case reports must be sure that all information conveyed in the report has been de-identified as required by HIPAA’s privacy regulations.

Investigator’s wishing to have the IRB make a determination of exemption from IRB oversight should complete the Case Study Review Checklist for Determinations of Exemption and submit the checklist and supporting documents to the IRB Administrator.

Q. How long does IRB review take?
A. We recommend that you allow 60 days for review. A well-prepared application will hasten the process. Many projects can be approved in less than 60 days if the application is complete and comprehensive.

When a new study is submitted it will be screened for completeness. If complete, the PI will be notified the application is complete and pre-review will begin. If the application is not complete, the PI will be notified of what items are needed to complete the application.

Q. What happens after I submit my IRB application?
A. The IRB Chair or his/her assigned representative(s) will determine if a study may be Exempt from IRB review, or if it qualifies for an Expedited Review. (See IRB Policies and Procedures for more information on these designations.) Assuming your study requires Full IRB Review, a meeting will be scheduled for the members of the IRB to examine, make comments, and finally vote to approve or disapprove your study.

In general, a minimum of two to three weeks is required to schedule a meeting of the IRB, so please plan your research activities accordingly and allow ample time for processing.

When your protocol has been approved, you will receive a letter from the IRB Chair (or his/her agent) signifying that you may begin your research. Occasionally, investigators will be given
“conditional approval” for a study, which means that before the research commences, certain
minor adjustments must be made to the protocol, consent or other supporting documents.
When a conditional approval is received, the study must be resubmitted to the IRB for final
approval after the requested changes have occurred.

Q. May I advertise to recruit participants for my study?
A. Any materials you plan to use to recruit research participants must be reviewed by the IRB
before you being contacting individuals. Advertising and recruitment materials must be
submitted with your IRB application and must be reviewed again when any changes or
revisions are made.

This includes advertisements that appear in the newspaper or on radio, television, or the
Internet. Flyers, letters of approach, emails and telephone scripts must also be approved.

Recruiting materials must not make promises to participants or overstate the benefits of the
study. Materials should provide basic information about the study, including the time involved;
the primary purpose of the research (e.g., testing an experimental drug), an overview of
procedures and testing, potential benefits to participants and compensation when applicable.

Q. May I pay study participants?
A. Whether or not individuals or families are paid for participating in research can depend on a
number of factors, including availability of funds and the extent of effort on the part of study
participants.

The IRB's primary consideration in looking at remuneration plans involves the effect that
coercion or undue influence could have on a prospective participant's ability to make an
informed, voluntary choice about taking part in the research. This is especially important when
the study involves vulnerable populations.

This is especially important when participation may include significant discomfort or the
assumption of risk, and when involving children in a study. In some instances researchers
choose to offer non-monetary incentives, like gift certificates for toys or meals at a fast-food
restaurant. If expenses for travel, lodging or meals are incurred the IRB may recommend that
participants be reimbursed for such expenses.

If compensation or the use of incentives is to be part of your study, specific information must
be included in the IRB application. Provide detailed information about payment, including
amount of payment, terms of payment, in the protocol and informed consent document.

Procedures for payment or distribution of incentives must be established before the first
participant is recruited.
Q. What if there are changes to my study after I receive IRB approval?
A. You are required to obtain IRB approval before implementing any changes to an approved study. This is called a Protocol Amendment.

The only exception to this requirement is when an immediate change is made to eliminate a risk or hazard to a subject. In such a case the change must be submitted to the IRB as soon as possible for review.

Minor changes to a study not involving greater than minimal risk usually undergo an expedited review by a subcommittee of the IRB. Major changes to a study require full IRB review.

Q. What if adverse event, unanticipated adverse events or unanticipated problems occur in my study?
A. Under federal regulations, the IRB is responsible for receiving and reviewing information about adverse events or unanticipated problems experienced by research participants. In general, there are two types of adverse events: expected and unexpected. An unanticipated problem may include deviations from the protocol, breaches of confidentiality, inappropriate access to PHI, or stolen or lost data.

Adverse event or unanticipated problems involving subject injury, study team injury, breaches of confidentiality, inappropriate access to PHI, or stolen or lost data must be report to the IRB Chair within 24 hours of discovery.

Unexpected adverse events are those that are not expected to occur, are more serious than anticipated when they do occur or occur more frequently than reasonably anticipated. Unexpected adverse events must be report to the IRB within 3 working days of discovery.

Expected adverse events must be described in the consent form that participants read and sign. Expected adverse events must be reported to the IRB within 10 working days of discovery. If the frequency or the severity of expected events is greater than anticipated, these events should be reported to the IRB as unexpected.

Minor protocol deviations must be reported within 10 working days of discovery.

For more information about the specifics of reporting adverse events, please view the PNWU IRB Event Reporting Form.
Q. My project uses only medical records to collect data. Will I need IRB approval?
A. Yes. The use of medical records, clinical databases (paper, electronic or any form) for research purposes requires IRB review in accordance with the federal regulations for the protection of human research subjects, Washington state law pertaining to health care records and the federal privacy rule known as HIPAA.

Generally, if you will be gathering information from sources that already exist (retrospective review) and need to collect identifiers like patient names and medical record numbers so the data can be linked to individuals, your project qualifies for expedited review.

Additional information regarding the use of private or protected health information for research can be found in HIPAA Regulations at 45 CFR 164

Q. What if my research involves other sites besides PNWU, many with their own IRB?
A. If the project is conducted by an employee of PNWU; includes PNWU students, families or staff as research participants; or involves PNWU assets or facilities, PNWU IRB review is required.

Q. What is a cooperative agreement?
A. A cooperative agreement is an agreement reached between PNWU and another research institution to delineate the responsibilities of each institution with regard to IRB activities.

Q. What is the link between the grant proposal and the IRB application for funded projects?
A. The funding agency expects the IRB to review and approve the use of human subjects as described in the funding proposal. Before funds are awarded, the agency requires certification of approval from the IRB.

If the funding agency requires IRB approval before the funding proposal will be reviewed by the agency, then an IRB application must be submitted and pending approval in the IRB office before the funding proposal is mailed to the funding agency.

Q. What is minimal risk?
A. The federal regulations define minimal risk as follows: The probability and magnitude of harm or discomfort anticipated by participating 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.

Procedures that may involve a small degree of risk for a healthy person may involve a higher risk to a person with an illness or a condition.