Procedure Title: Advertising, Recruiting & Enrolling for Human Subject Research

Associated Policy:	Advertising and Promotional Items		
Responsible Unit:	Office of Scholarly Activity & Marketing and Communications		
Created:	6/7/17	**Executive Lead:**	Chief Research Officer
Effective:	6/7/17	**Revision History:**	.00-6/7/17; .01-7/6/19; .02-6/26/19; .03 – 3/7/2023; .04 – 06/26/2023; .05 – 8-26-2024
Approved by:	Institutional Review Board		
Procedure Number:	107.05		
Key Words:	Recruitment; Human Subjects; Advertising for a 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 the process for advertising, recruiting, and enrolling for research studies while fulfilling ethical responsibilities for protecting the rights and welfare of human research participants.

Responsible Parties

The Institutional Review Board (IRB) is responsible for:

- Reviewing the reading, cultural, length, font, type, etc. levels of the various advertising and recruiting materials to ensure appropriateness of human subject protections.
- Evaluating undue influence in advertising, recruiting, and enrolling human subjects.

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

- Monitoring compliance with this SOP.
- Posting this SOP for the PNWU community.
- Communicating with the Office of Marketing/Communications to ensure brand management.

The Office of Marketing/Communications is responsible for:

- Reviewing advertising and recruitment materials for public view (e.g. PNWU brand management).

- Providing brand templates to OSA and investigators to use for advertising and recruiting human subjects.
- Supporting studies wishing to use any media outlet such as radio, television, newspaper, etc. or social media outlet such as Facebook, Twitter, Instagram, Vimeo, etc. to advertise and/or recruit human subjects.

The Investigator is responsible for:

- Using the templates provided by Communications and Marketing.
- Detailing in the submitted protocol how participants will be recruited, and the specific recruitment materials to be used.
- Getting IRB approval of the recruitment materials and methods prior to starting recruitment.
- Screening, reviewing, verifying, and documenting all potential participants for inclusion/exclusion criteria as applicable.
- Documenting that all participants have a signed informed consent (as applicable) prior to study procedures being performed.
- Maintaining accurate and complete records of screened and enrolled study participants.
- Monitoring and recording the progress of study advertisement, recruitment, and enrollment.

Definitions

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

- Conflict of Interest
- Conflict of Commitment
- Conflict of Conscience
- Conflict Management Plan
- Federal Wide Assurance
- Financial Conflict of Interest
- Human Subject
- Immediate Family Member
- Investigator
- Legally Authorized Representative
- Remuneration
- Significant Conflict of Interest
- Standard Operating Procedure

Procedure:

1. Recruitment strategies - Participants can be recruited from a variety of sources including but not limited to: clinician referrals, clinic or internet postings, social media, newspaper/television/radio advertisements, word of mouth from support groups, health fairs, or from local hospitals and clinics. Clinicians can be notified about research studies by letter or by word of mouth.
2. Many researchers maintain a database of patients or former research participants from which they identify potential participants for new research. If potential participants are identified through the researcher's database, researchers must obtain IRB approval to access currently stored data sets from a previous study. Also, there may be the need for additional informed consent and/or HIPAA/FERPA authorization in some cases prior to

accessing this database in order to ethically and confidentially contact potential participants even with previously obtained and consented data/samples.

3. Researchers who get referrals from clinician colleagues may not contact these referrals directly. The colleagues of the researcher may inform their patients of the research activity and encourage their patients to contact the study team per the IRB approved advertisement and recruitments methods.
4. Researchers may identify potential participants for research from hospital medical records or institutional records by getting an approved waiver of authorization from the IRB, **unless** the conditions for preparatory to research are met.
    a. Under the preparatory to research provision, a covered entity may permit a researcher who works for that covered entity to use protected health information (PHI) for purposes preparatory to research. A covered entity may also permit, as a disclosure of PHI, a researcher who is not a workforce member of that covered entity to review PHI (within that covered entity) for purposes preparatory to research. Within a hybrid entity, the situation is similar. A covered entity that is a hybrid entity may permit a researcher within its health care component to use, without an individual's authorization, PHI for activities preparatory to research. A covered entity may also permit a researcher who is outside the hybrid entity's health care component to review PHI within that health care component without an individual's authorization for purposes preparatory to research. The following criteria must be met:
        i. Use or disclosure is sought solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research;
        ii. No PHI is to be removed from the covered entity by the researcher in the course of the review; **and**
        iii. The PHI for which use or access is sought is necessary for the research purposes.
5. It is strictly forbidden for research staff to accept financial or other incentives from funders/sponsors based on numbers of participants recruiting or enrolled.
6. Recruitment Materials - The IRB protocol needs to be approved prior to any advertising or recruiting activities. All advertising and recruiting materials (including any text that would accompany an approved recruitment flyer) and modes of recruitment must be submitted with the protocol and approved by the IRB prior to use. These include but are not limited to announcements, advertisements, flyers, phone scripts for screening, oral scripts for consenting participants, newspaper ads, videos, radio and television announcements, bulletin board tear-offs, internet postings, emails, and posters.
7. In sponsored/funded research, the sponsor may request to approve all advertising and recruiting materials.
8. Advertisements - Advertising materials should include all of the following elements:
    - A statement that the study involves research.
    - A brief description of the disorder that the study is investigating.
    - Eligibility criteria (in summary form).
    - A truthful description of potential benefits, if any, to the subject from study participation (incentives are not a benefit).
    - The name of the institution and principal investigator conducting the study.
    - The name and phone number of a person to be contacted for further information.
9. Advertisements must not include:
    - Any misleading claim or language that appears to promise that the research will treat the medical condition or that the study medication is safe or effective. (Includes examples of study results.)
    - Claims that the research will improve the subject's medical condition.

- Expressed or implied statement that the research is FDA-approved.
- Use of the term "new" (e.g., new research medication, new treatment, or new drug without explaining that the test article is investigational.
- Any promise of free treatment or cure.
- Use catchy words such as free or exciting.
- Any expressed or implied statement that the research is PNWU IRB Approved.

10. General Recruiting and Initial Enrollment Procedures - Recruitment rates should be regularly evaluated during the recruitment period, with reassessment of the strategy when recruitment targets are not being met.
11. The study team should keep records of recruitment and inform the Principal Investigator(s). When applicable, every person who is considered a potential candidate for the study should be entered in the Screening and Enrollment Log (based on study inclusion and exclusion criteria). Note whether individuals have enrolled in the study and, if not, document the reason.
12. Not English Proficient (NEP) or Limited English Proficient (LEP) Subjects - When a study is anticipated to recruit and enroll LEP or NEP subjects, the investigator must identify in the submitted protocol the target population(s), the language(s), and must specify who will provide the translation/interpretation services, and their qualifications. The protocol should include:
    a. The advertising, recruitment, and enrollment materials must be provided to the IRB in English and in the appropriate translated language(s). All participant-relevant documents need to beat a literacy/numeracy level that is understandable by the enrolled participant population(s).
    b. In order to ensure that the translated materials convey the same meaning as the original in English, a completed Translator's Declaration form should be submitted with the protocol from the person or service providing the translation services.
    c. Additionally, if the Translator's Declaration and Back-Translator's Declaration apply, these must be completed, signed, and uploaded for the consent form(s) and recruitment materials. (May be required by the IRB when studies are more than minimal risk.)

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. HHS Uses and disclosures for which an authorization or opportunity to agree or object in not required 45 CFR 164.512 (i) (1)(ii)

Appendices:

Version/ Effective Date	Author	Section Changed & Reason for Revision
.00/6-7-17	M. McCarroll	New Standard Operating Procedure

.01/ 7-6-17	M McCarroll	6.1 Reference for the Payment SOP added; Removed bullet in 3.4 and 6.9.3. due to referring to consent process.; 6.4 added conditions preparatory to research.
.02/ 6-26-19	M. McCarroll	Put into new SOP Format and added Marketing responsibilities throughout the SOP
.03 / 4-3-2023	C. Case	Added preparatory to research language in item 4a; and a reference in the reference section for the Preparatory to Research regulations.
.04 / 6-27-2023	C. Case	Clarified language in item 6, that it includes language that would accompany an approved recruitment flyer; language in item 9 changed from should not include to must not include; Added two additional bulleted items for information that should not be included under item 9, any promise of free treatment or cure or use catchy words such as free or exciting. Added information that the IRB may require translation and back translation for studies that are more than minimal risk in item 12c.
.05 / 8-26-2024	J. Simmons	Removed reference to "waiver of FERPA authorization", administrative grammar/capitalization fixes

Sample Template:

Pacific Northwest University of Health Sciences

aacom AMERICAN ASSOCIATION OF COLLEGES OF OSTEOPATHIC MEDICINE

Research Study Participants Needed

Help Us Learn about Behavioral Health using Telesimulation!

Who is conducting the study?

- Lisa Munoz, MPH - Executive Director of Simulation and Dr. Bridget Beachy – Clinical Psychologist along with several family medicine physicians and counselors are conducting a research study assessing behavioral health using telesimulation.

What is the purpose of the study?

- The purpose of this study is to determine if practicing telesimulation enhances student's attitudes, proficiency, and confidence regarding telemedicine.

Who is eligible for the study?

- Any enrolled student at a participating program in the Yakima Valley Interprofessional Practice and Education Collaborative (YVIPEC)
- Age 18-33
- Able to read and speak English
- Have no pending litigation with any education entity in the YVIPEC

Who do I contact for questions and to get involved?

- Please contact the following:
  - Melissa Holm (YVIPEC IPE Manager) mholm@pnwu.edu 509-249-7894
  - Lisa Munzo, MPH (Principal Investigator) lmunoz@pnwu.edu 509-249-7852
- Testing will require one onsite session about two hours long
- Testing will take place at Pacific Northwest University of Health Sciences 200 University Parkway, Yakima WA 980901
- Participants will be asked to complete several surveys, participate in a training, and do a patient simulation