PROCEDURE

Effective Date: March 8, 2016
Approved By: President Bruce Shepard Authority: POL-U4520.08

PRO-U4520.08A PROTECTING HUMAN PARTICIPANTS IN RESEARCH

Action by:	*Action:*
Human Participants Researcher (Researcher)	1 **Submits** research protocol to Research and Sponsored Programs (RSP) utilizing the Human Participants Research Protocol Form . Researcher does not recruit or contact witnesses until IRB approval is secured.
	2 **Submits** protocol including: • Researcher's name, department, and title of protocol; • Answers to application questions including description of research methods, risks to individual participants, benefits to participants and field of research, • Describes recruitment method including all advertisements and flyers; • Citations supporting the research methodology as well as the data collection instrument, surveys, test instruments, or questionnaires; and • Signature of researcher and department chair and signature of faculty advisor if a student researcher.
	3 **Submits** copies of all survey instruments, tests, questionnaires, or interview questions.
	4 **Submits** the NIH or CITI ethics training certificates of all researchers on the project including all who design the research method, have contact with the human participants, or analyze data; • If the researcher is a student, submit the Ethics Training Certificate of faculty advisor;

- If research utilizes foreign data gatherers, submits an ethics training plan;
- Renews ethics training every five years.

5 **Submits** clearance correspondence from the leadership of the group being recruited permitting researcher to contact and recruit its members. For example, permission is required if the research involves an organization such as a club, a school or a Native American Nation.

Obtains written permission from any organizations providing names, emails, or contact information of potential participants. Organizations are under no obligation to permit access to their members or to provide their members' contact information.

Exception: No permission is required to recruit participants from a regularly scheduled WWU class.

6 **Submits** researcher's curriculum vitae or resume;

7 **Submits** explanation as to how the anonymity of the participants will be protected and how the data will be maintained to protect the confidentiality of the data;

8 **Submits** informed consent including one copy for researcher and one copy for participant or submits an explanation as to why consent should be waived.

Research Compliance Officer (RCO)

9 **Reviews** protocols and **determines** whether the package is complete and that it complies with federal regulations.

10 **Notifies** researcher if the protocol is not complete or requires revisions in order to comply with federal law and WWU policies.

11 **Reviews** protocol to **determine** if risk to human participants is minimal and falls within the exempt or expedited categories established by federal regulation.

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Researcher	12	**Submits** all revisions to RCO.
RCO	13	**Reviews** revised protocol. If the protocol is complete, qualifies as exempt, and complies with federal regulations and WWU policy, **sends** research approval memo to researcher. Exempt protocol approval extends for five years from the approval date.
	14	If the protocol does not qualify as exempt, **reviews** to determine whether the protocol falls within the expedited categories.
	15	If the protocol qualifies for expedited review, **sends** protocol to a primary reviewer. Expedited protocols can be reviewed and approved by a vote by primary reviewer and one additional IRB member.
Institutional Review Board (IRB)	16	**Reviews** protocol for compliance with federal regulations including: a) Risks to participants are minimized, b) Risks to participants are reasonable in relation to the anticipated benefits to participants, if any, and the importance of knowledge that may be reasonably expected, c) Selection of participants is equitable, i.e., the criteria for selecting certain groups or individuals to participate in a study are methodologically related to the goals of the research, d) Participants are adequately informed of their rights and informed consent is documented, e) Data obtained from the research are maintained in a manner that protects to confidentiality of the data and the privacy of the participants, and f) Appropriate safeguards are included in the study to protect the rights and welfare of the participants

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		especially when participants are likely to be vulnerable to coercion or undue influence.
	17	**Notifies** RCO if they request a full committee review of the protocol.
Designated Primary Reviewer	18	**Reviews** protocol for compliance with federal regulations. Sends requests for revisions to RCO. If reviewer disapproves of the protocol, the protocol is referred to full committee review.
RCO	19	**Sends** revision requests to researcher.
Researcher	20	**Submits** protocol revisions to RCO
RCO	21	**Sends** revisions to reviewer
Reviewer	22	**Reads** revisions and **approves** protocol if all the comments have been addressed and the protocol complies with federal regulations.
	23	**Sends** approval to RCO.
IRB	24	**Reviews** protocol distributed as a designated review and requests full committee review if deemed necessary.
RCO	25	**Sends** approval memo to researcher if no IRB member requests a full committee review. Approval of expedited protocols is for one year or less as determined by the committee.
	26	**Sets** time and date for full committee meeting if an IRB member requests a meeting or designated reviewer disapproves protocol.
Full IRB	27	**Meets and discusses** protocol. If there are revisions needed, RCO sends revision request to researcher.
Researcher	28	**Edits** protocol to address the IRB's requested revisions.
	29	**Sends** revised protocol to RCO.

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RCO	30	**Distributes** revised protocol to IRB.
IRB	31	**Reviews** protocol for compliance with federal regulations.
RCO	32	**Sets** a time and date for a full committee meeting.
IRB	33	**Meets** and votes on whether to approve the protocol. More than half of the committee membership must attend to constitute a quorum. A majority of a quorum must vote yes to approve a protocol.
RCO	34	**Notifies** researcher whether the protocol is approved. If approved, the RCO sends an approval memo to the researcher. Full review protocols are approved for a period of one year or less as determined by the IRB.
Researcher	35	**Submits** a protocol modification form to RSP if new researchers are added to the research team and submits the ethics training certificates of additional researchers.
	36	**Submits** a protocol modification form if the recruitment techniques change, the research methods change, or the data collection questions change.
	37	**Submits** annual request for protocol renewal.
RCO	38	**Reviews** modification and renewal requests and sends approval memo if the request is approved.
Researcher	39	If initial protocol, renewal request, or modification request is disapproved, may **appeal** the decision to the Vice Provost for Research within 30 days of the disapproval notification.
Researcher	40	**Writes** an appeal notice providing regulatory basis for reversing the committee's disapproval.
IRB	41	**Submits** a written explanation to the Vice Provost of Research as to why the protocol does not meet with the federal regulatory requirements.
Vice Provost for Research	42	**Determines** whether protocol is approved or disapproved. This decision is final.

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Researcher	43	**Reports** any unanticipated problems, possible non-compliance, and other information and incidents that might affect approval of the protocol or the participants' willingness to continue participation.
IRB	44	**Reviews** researcher files for protocol compliance as deemed relevant.
	45	**Orders** discontinuation of research if there are unanticipated problems, possible non-compliance, and other information and incidents that might affect approval of the protocol or the participants' willingness to continue participation.
Researcher	46	**Retains** all signed informed consents, transcripts, and data for six years following the completion of the research. These may be retained in electronic or print format.