PROCEDURE

Effective Date: May 27, 2021
Approved By: Vice Provost, RSP Authority: POL-U4520.08

POL-U4520.08 PROTECTING HUMAN SUBJECTS IN RESEARCH

Vice Provost for Research	1	**Selects, interviews, and appoints** members of Institutional Review Board (IRB)
Investigator	2	**Submits** application packet to Research and Sponsored Programs (RSP) utilizing the human subject research form on the RSP webpage.
	3	**Includes** the following in the submission:

- A completed application form, including:
- Investigator's name, department, and title of protocol,
- (Optional) the research category,
- Description of study purpose, procedures, research participants, research risks and benefits,
- Description of the recruitment methods,
- Description of the consent process, and
- Description of the type and sensitivity of data and the data management plan, (unless the research is exempt).
- Include all applicable attachments, including:
- Recruitment text(s),
- Informed consent document(s) or a consent wavier supplement,

PROCEDURE

Action by:		*Action:*
		• Copies of all survey instruments or tests, questionnaires, interview questions, • Other attachments as needed, including supplements, debriefing form, assent form, K-12 clearance letter, Tribal IRB or leadership approval, etc., and • Signature of investigator and department chair as well as faculty advisor if investigator is a student.
	4	**Completes** CITI Social & Behavioral Basic/Renewal Ethics Training or an IRB approved alternative. • All researchers recruiting subjects, collecting data, designing the research method, or analyzing identified data must complete ethics training. • Does not submit certificates with their applications but Investigator is responsible for maintaining all records of research team. • Renews ethics training every five years.
	5	**Cannot recruit** until IRB approval is secured. However, researcher may contact a community or organization representative to obtain permission to conduct research with the participant population.
Research Compliance Officer (RCO)	6	**Reviews** protocol and determines whether the application is complete.
	7	**Determines** review category.
	8	**Notifies** Investigator with any needed revisions

PROCEDURE

Action by:		*Action:*
		or missing elements.
	9	**Reviews** protocol to determine if risk to human subjects is minimal and falls within the exempt categories and protocol is complete.
	10	**Sends** approval memo to Investigator if protocol complies with federal regulations.
	11	**Reviews** to determine whether the protocol meets the expedited categories if the protocol does not fall within the exempt category.
	12	**Designates** primary and secondary reviewers and sends the protocol to the reviewers for expedited category review. The RCO can serve as one of the designated reviewers.
Primary/Secondary Reviewers	13	**Review** protocol to assess whether it complies with federal regulations. Sends any change requests or missing document requests to RCO.
RCO	14	**Sends** revision requests to Investigator.
Primary/Secondary Reviewers	15	**Contact** RCO if request full review.
	16	**Contacts** RCO with revisions request.
RCO	17	**Contacts** Investigator with revisions request.
Investigator	18	**Revises** and resubmits protocol if changes were requested.
RCO	19	**Sends** revised protocol to designated reviewers.
Primary/Secondary Reviewers	20	**Review** and communicate approval to RCO if the protocol complies with all federal regulations.

PROCEDURE

Action by:		*Action:*
RCO	21	**Sends** approval memo to Investigator if approved.
	22	**Sends** protocol to full IRB committee for review if protocol does not qualify for exempt or expedited review or is not approved by the expedited reviewers.
	23	**Sets** meeting date and notifies all IRB of the meeting time and date.
IRB	24	**Meets** and **votes** whether protocol is approved or disapproved. Approval requires a majority vote of a quorum of the committee.
RCO	25	**Sends** approval memo to the investigator if the protocol is approved.
Investigator	26	May **appeal** IRB non-approval to the Vice Provost for Research explaining the regulatory basis for the appeal.
Vice Provost for Research	27	**Determines** whether research protocol is approved or not approved. This decision is final.
Investigator	28	**Submits** protocol modification to RCO if any changes are made to protocol including: • The subject population • The maximum number of subjects • Recruitment plan or materials • Study instruments • The lead investigator or any investigators working with human subjects or their identifiable data.
RCO	29	**Reviews** modification and send it for expedited review to a primary and secondary reviewer. **Review** and notify RCO if protocol complies with federal requirements.

PROCEDURE

Action by:		*Action:*
		Sends approval if modifications comply with federal requirements.
Investigator	32	**Submits** status report (full board applications only) describing any adverse events, and whether the protocol should be closed.
	33	**Reports** any unanticipated problems, possible non-compliance, and other Information and incidents that might affect its approval of the protocol or the subjects' willingness to continue participation.
RCO	34	**Orders** discontinuation of research if there are unanticipated problems, possible non-compliance and other information or incidents that might affect approval of the protocol or the subjects' willingness to continue participation.
Investigator	35	**Retains** all signed informed consents and data for six years following the completion of the research unless the protocol specifies otherwise. These may be retained in electronic format.