Brief Steps to Obtaining Approval for Research Involving Human Subjects at Air University

1. AU Initial Process – If needed, an HRPP worksheet is completed by the Principal Investigator to determine the appropriate approvals of the research project.

   Complete the HRPP Worksheet to determine if the research meets the criteria under 32 CFR§219.102. "Research" means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

   Additionally, under 32 CFR§219.102., "Human Subject" means a living individual about whom an investigator conducting research obtains:
   (i) data through intervention or interaction with the individual, or
   (ii) identifiable private information.

   Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

   - *Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.*
   - *Interaction includes communication or interpersonal contact between investigator and subject.*

2. After completing the HRPP worksheet or if identified as meeting the definition of research, schedule an appointment with AU's HRPP POC. (Appointments may be conducted Teams, telephonic or in-person.)

3. After consulting with the HRPP POC, the complete protocol packet will be completed and returned to AU's HRPP POC. All current HRPP Templates are housed on AU's SharePoint site.

4. Once a complete packet is received, AU's HRPP POC may request additional supporting information.

5. A determination will be made and submitted to AFRL, AU's IRB if Record, for administrative completion and assignment of a Protocol Number. Please note, AFRL may review any IRB packet for review and concurrence. AFRL may seek additional information and will work through the AU HRPP POC to ensure a packet's completeness.

7. All AU protocols will be placed in the HRPP Tracking list maintained on the AU SharePoint site.

6. AF Review Processes Completed PRIOR to beginning research which may include additional steps outside of the HRPP determination process.
   a. Survey Control: (The use of a survey seeking to ascertain attitudes or opinions of AF members (to include Likert-scale surveys, questionnaires, interviews, focus groups, polls, etc),
      1. The AU Survey Office may provide a survey control number if the research population only includes Air University Students, Faculty, or Staff. Submit the survey through the AU Survey Approval Process.
      2. AF Survey Office (AFSO): If the research population is outside of AU, the survey must be submitted to AFSO. AF Form 4453 to the AF Survey Office workflow email as soon as possible. Reviews may take up to 20 days.
      3. Washington Headquarter Services (WHS): If a survey crosses branches of service, involves more than one government agency, or is going out to members of the public, which includes military family members and spouses of military members (unless the survey pertains to benefits) the approving authority is Washington Headquarters Services (WHS). AFSO will refer you to this agency for approval of the request. The link to their

website is https://www.esd.whs.mil/Directives/collections_pub/ and their workflow box is whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

b. Additional requirements, such as security review, may be required depending on the complexity of the research.