FAQ

1 – Consent

 This is a person’s voluntary agreement, based upon adequate knowledge and

 Understanding of relevant information, to participate in research or to undergo

 a diagnostic, therapeutic, or preventive procedure. In giving informed consent,

 subjects may not waive or appear to waive any of their legal rights, or release

 or appear to release the investigator, the sponsor, the institution, or agents thereof

 from liability for negligence.

2 – Assent

This is an agreement by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in research.

Mere failure to object should not, absent affirmative agreement, be construed

 as assent.

3 – Confidential

 This pertains to the treatment of information that an individual has disclosed in a

 in a relationship of trust and with the expectation that it will not be divulged to

 others without permission in ways that are consistent with the understanding of

 the original disclosure.

4 – Anonymous

Providing anonymity of information collected from research participants means that either the project does not collect identifying information of individual subjects (e.g., name, address, Email address, etc.), or the project cannot link individual responses with participants’ identities. A study should not collect identifying information of research participants unless it is essential to the study protocol.

5- Vulnerable populations

Because research can be a sensitive issue with certain populations, the IRB will thoroughly examine research conducted on these vulnerable populations: children, prisoners, pregnant women, mentally disabled persons, or economically/disadvantaged persons where coercion or other overriding issues may be a factor.

6 – Minimized risk

 This means that the probability and magnitude of harm or discomfort anticipated in the

 research will not be greater than situations ordinarily encountered in daily life or during

 the performance of routine physical or psychological examinations or tests.

7 – Human Subject

 A human subject is an individual about whom an investigator conducting research obtains

 data through intervention or interaction with an individual. Additionally, a human

 subject also has identifiable information from which he or she can be identified.

8 – Intervention

 This includes both physical procedures and active control by which data are gathered and manipulations of the subject’s environment that are performed for research purposes. Such interventions should be constructed to be considered minimal risk.

9—Ways to protect confidentiality

If it is essential to collect and link identifying information (e.g., subjects' names) to subjects’ responses (e.g., questionnaire answers), researchers must to provide the utmost confidentiality of subject data. The following are examples of practices that may be implemented to increase the level of confidentiality:

* Use study codes on data documents (e.g., completed questionnaire) instead of recording identifying information and keep a separate document that links the study code to subjects’ identifying information locked in a separate location and restrict access to this document (e.g., only allowing primary investigators access);
* Encrypt identifiable data;
* Remove face sheets containing identifiers (e.g., names and addresses) from survey instruments containing data after receiving from study participants;
* Limit access to identifiable information;
* Securely store data documents within locked locations (minimum of three years); and/or
* Assign security codes to computerized records.

COMMON ISSUES WITH THE APPLICATION PROCESS

A – “Share” submissions with other Co-PIs and faculty sponsors – anyone listed must electronically sign with in the IRBNet.org system. All members of the research team must first register through IRBNet.org to allow the submitting member of the team to “Share” access to the submission.

B – Consent forms require information to be explained on 6 points found in the sample WKU IRB consent: nature and purpose of the project, explanation of procedures, discomforts and risks,

benefits, confidentiality, and refusal/withdrawal (i.e., refusal to participate will have no

consequences to the participant).

C – Letters of cooperation must be included when working with outside organizations or institutions to approach or reach desired participant population. These letters must be verifiable and explicit in nature. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. The approval of the department or agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of other qualified IRB, or make similar arrangements for avoiding duplication of effort. Submitted letters of cooperation must be verifiable to assure department or agency head approval.

D—IRB process

* The principal investigator prepares the IRB application according to the IRB guidelines.
* ***The complete application packet is submitted through IRBNet.org***.
* The application is logged in and receives a unique identification number. The principal investigator is notified via e-mail of the number and receipt of the IRB application.
* The Compliance Officer conducts a Technical Review to determine that the IRB application is complete and contains the following:

Completed IRB application form;

Informed consent documentation (if informed consent is not required, verification of a request to waive informed consent is necessary);

A copy of the actual survey instrument, questionnaire, or data record form to be used in the project; (electronic) Signatures of the principal investigator (PI), faculty sponsor (if student project).

E - ***Revisions, Updates, or Modifications to the study after the initial application has been submitted.*** Submit updates and revisions by clicking on the "Project History" button in the IRBNet.org submission to add new documents. This creates a "-2" to the previous submission IRBNet ID, and the WKU IRB will get everything verified.

***Incomplete application packets will be returned to the principal investigator, with a memo stating deficiencies. Once corrected, these applications may be resubmitted for review.***

* Complete IRB applications will receive an Initial Evaluation by the Compliance Officer to determine content and impact of the project on human subjects. The Compliance Officer recommends to the IRB Chair one of the following categories:

**Exempt from Review** - the Compliance Officer provides written reasons for the exemption to the IRB Chair

**Expedited Review** - the Compliance Officer provides written reasons for expedited review to the IRB Chair (only recommended if there is minimal risk to human subjects)

**Full Board Review Required** - the Human Protections Administrator and Compliance Officer provide copies of the application to all members of the IRB for review at the next Institutional Review Board meeting.

* The full board meets once per month. (Typically the last working Friday of each month) If an application requires full board review, the principal investigator will be asked to make a brief presentation of the application at the meeting, and to respond to IRB inquiries.
* In all cases, disposition of the IRB application is forwarded to the applicant by the Compliance Officer within two weeks following the decision. Depending upon the type of review required, and whether or not any revisions must be made by the principal investigator, the decision may take from one day to one month or more.