**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- Generalizable Knowledge

In order to contribute to generalizable knowledge, the activity’s conclusions are intended to be extended beyond the sample or internal program. The dissemination of findings to an external or scientific audience is a sufficient criterion for identifying generalizable knowledge.

6- 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.

7 – 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.

8 – 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.

9 – 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.

10- 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.

11- Pilot testing

Defined by NIH; “A small-scale test of the methods and procedures to be used on a larger scale.” See – Generalizable Knowledge.

## 12- Feasibility studies Feasibility Studies are investigations done before a broader research study in order to answer the question "Can this study be done?". Feasibility Studies are used to assess important parameters that are needed to design the main study. Evaluations are considered by the researcher before approaching the IRB using the following examples.

* standard deviation of the outcome measure, which is needed in some cases to estimate sample size;
* willingness of participants to be randomized;
* willingness of clinicians to recruit participants;
* number of eligible patients or other appropriate participants
* characteristics of the proposed outcome measure and in some cases feasibility studies might involve designing a suitable outcome measure;
* follow-up rates, response rates to questionnaires, adherence/compliance rates, cluster randomized trials (CRTs), etc.
* availability of data needed or the usefulness and limitations of a particular database
* time needed to collect and analyze data

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:

**Levels of Review are not determined or requested by the researcher.** Applications will be evaluated by the Compliance Committee and Compliance Officer within one of the three categories below.

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

Although the category is sometimes referred to as "exempt," this type of research does require IRB review and registration. The exempt registration process is much less rigorous than an expedited or full-committee review. To qualify, research must fall into one of six federally-defined exempt categories. These categories present the lowest amount of risk to potential subjects because, they involve either collection of anonymous or publicly-available data, or conduct of the least potentially-harmful research experiments. The following are examples of Exempt Research:

* Projects that use existing data, documents, records, or specimens properly obtained and either:

\* subjects cannot be identified in the research data directly or statistically, and no one can track subjects' identities

\* the sources are publicly available.

* For research not involving vulnerable subjects the intent is to observe public behavior, or conduct interviews or surveys or educational tests and either:

\* the subjects cannot be identified, directly or statistically; or

\* the responses/observations could not harm the subjects if made public; or

\* federal statute completely protects all subjects' confidentiality;

\* all respondents are candidates or elected or appointed public officials.

* In educational settings, research or evaluation of normal educational practices.
* To be categorized as Exempt from Full Board Review the research project must also meet the following criteria:

\* If potentially exempt because subjects cannot be identified, the research must protect anonymity; and

\* If subjects give information about others, inadvertent disclosure presents no more than minimal risk to those others.

**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)

Expedited review as defined by federal regulations allows the IRB chairperson, or one or more experienced reviewers among members of the IRB to evaluate and approve specific types of research. Reviewers conducting an expedited review may exercise all of the authority of the IRB except that they may not disapprove a study. When a subcommittee cannot approve the research under expedited review, the study is referred to the full Committee for review.

 To qualify for an expedited review, research must fall into one of nine federally-defined expedited categories. These categories involve collection of samples and data in a manner that is not anonymous and that involves no more than minimal risk to subjects. Some examples of expedited research are:

* collection of existing data, documents, records, or specimens that was originally approved at the expedited level
* moderate exercise by healthy volunteers
* drugs or devices not needing investigational new drug or device exemptions
* individual/group behavior or characteristics without manipulation or stress, recording data from adults by non-invasive clinical procedures, e.g., weight, height, eye-color
* collection of blood samples from ambulatory non-pregnant adults (Not more than 2x/wk, less than 550ml in 8 wks)
* collection of hair, nail clippings, deciduous or permanent teeth needing extraction
* collection of supra-/sub-gingival dental plaque/calculus by prophylactic scaling
* non-invasive collection of excreta - e.g., sweat, saliva, placenta, amniotic fluid
* voice recordings for research - e.g., investigation of speech defects

**Full Board Review Required** - the 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.

All projects that do not fall into either the Exempt or Expedited Review categories, or deal with special concerns or vulnerable populations go to the full IRB for review. This is the most rigorous level of review. Full Board Review Research involves the following:

* Research projects that have special concerns or involves vulnerable populations.

\* Children: Both assent of child and permission of parents is required. Research with more than minimal risk but no direct benefit to the child is restricted.

\* Pregnant women or fetuses: Research is severely restricted; the IRB must assure appropriate process to select, inform, and obtain consent of subjects.

\* Subject selection is from individuals considered to be representative of an ethnic minority group or are unable to speak English.

\* Prisoners: Severely restricted research. Prison IRBs typically take authority over the application process.

\* People with mental impairment: No regulations apply, but because informed consent is problematic, and the subjects are vulnerable, this type of research should be limited.

* Projects that involve possible coercion or undue influence that induces or entices consent, e.g., excessive compensation, inequitable relationship, etc.
* Sensitive information is being gathered, e.g., child abuse, violence, sexual conduct/misconduct, mental health/status information, AIDS, alcohol, compulsive disorders, etc.
* Does the research present more than "minimal risk?" "Risk" means both magnitude of harm, and the probability of incurring harm. "Minimal risks" means risks a non-vulnerable person ordinarily encounters in daily life in routine medical, dental, or psychological exams. For research with greater than minimal risk, the IRB should ensure that the researcher's benefits are maximized and risks minimized and compare its scientific merit to its risks.
* For genetic research, and research using blood and other body tissues: the protocol must:

a. discard the blood/tissue without doing tests beyond the protocol, or have no personal identifiers; and

b. either promise not to grow perpetual cell lines, or mention that possibility in the consent process.

* Major deception, e.g., intentionally misleading subjects about their status, giving false information about the researchers or the research purpose.
* Minor deception, e.g., incompletely disclosing the full purpose of the study, to avoid biasing the results.

**Other IRB Issues and Concerns: Items to be considered.**

* + In situations when there is more than minimal risk, the IRB determines if the scientific merit outweigh risk, and if the benefits are maximized and the risks are minimized?
  + Should the IRB require reports from the principal investigator and review this project at shorter intervals than annually?
  + “Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children2, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.”