Expedited Categories

Expedited studies are those studies that involve no more than minimal risk (Minimal risk studies would include non-sensitive surveys, focus groups, giving classes on how to brush teeth correctly, ultrasounds, measuring blood pressure after running around a track, blood draws, and registry studies), AND fall under a category on the list below, in addition to not being classified research for the federal government.

If the study is more than minimal risk, or does not fall under one of these categories, or is classified research it cannot be expedited.

1. Clinical studies of medical devices – if a commercially used device that is being used in accordance with its cleared/approved labeling or when no investigational device exemption is needed.
2. Blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: from healthy, non-pregnant 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 from other adults and children, 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.
3. Prospective collection of biological specimens by noninvasive means, such as urine, throat swabs, or already extracted teeth. Remember tissue samples and body fluids require an IBC approval.
4. Collection of data through noninvasive procedures routinely employed in clinical practice. (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. This would also include C-PASS and Engineering studies for physical exercise and physical measurements.
5. Research involving material that have been collected for non-research purposes. Often this category is used for medical record review with identifiers. In that case the PI must also submit a consent form waiver, as well as a HIPAA waiver.
6. Collection of data from voice, video, digital or image recordings.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies
8. A protocol that was originally reviewed per full board procedures and is up for continuing review where
   a) no enrollment has begun
b) enrollment is complete and only long term follow-up is conducted or 3) study is only open for data analysis. These remain categorized as full board protocols, but can be reviewed per expedited review.

9. A protocol that was originally reviewed by the full board for review of a device, where the Board determined at the meeting that the research is no greater than minimal risk and no additional risks have been identified may be reviewed as expedited continuing review.

**Personnel**

All personnel including students and residents need to be listed in the Personnel Section. Only persons working with de-identified data need not be included. There are some cases where study personnel are so numerous that the PI can attach a list of these persons, which will be checked by ORIC staff for training. The investigators and co-investigators must be listed in the Personnel Section of the protocol application.

**The consent form should name the investigator and co-investigators. If the PI intends to use other personnel to obtain consent and they are not numerous they should also be named on the consent. On the other hand, if there are numerous persons obtaining consent, the consent form should state “the consent has been explained to me by ____________________” and the qualified person’s name should be added in that space. That person should sign on the signature line for the PI as Designee. If anyone other than the PI or Co-I is obtaining consent, this needs to be indicated in the Questionnaire under the Consent Procedures section. The PI needs to confirm that all personnel obtaining consent have been trained, are well-versed in the study and can answer questions.**

**Vulnerable Populations**

The target group is vulnerable if pregnant women, fetuses, children, prisoner, or cognitively impaired persons are the focus of the research. If the target is the general population and one of these groups (except prisoners) participates there is no need to list them on the Questionnaire of the KC submission.

- If the population is cognitively impaired then the researcher has to explain how cognition is assessed. If mental capacity is over 7 years of age, an assent is needed with a guardian consent.
- If prisoners, the study must be reviewed via full board and a prisoner representative must be consulted.
Vulnerable Population Review

The PI should identify the potential to enroll vulnerable subjects in the proposed research at initial review and provide the justification for their inclusion in the study.

1. If the research involves adults unable to consent, the IRB evaluates the proposed plan for permission of legally authorized representatives.
2. The IRB evaluates and approves the proposed plan for the assent of participants.
3. Be aware that the IRB evaluates the research to determine the need for additional protections and consider the use of a data and safety monitoring board or data monitoring committee as appropriate.
4. The PI should provide appropriate safeguards to protect the subject’s rights and welfare, which may include the addition of an independent monitor. The independent monitor is a qualified individual not involved in the research study who will determine the subject’s capacity to provide voluntary informed consent.
5. Examples of studies that warrant independent monitoring include those involving schizophrenic patients who will be exposed to placebo, and/or drug washout, and/or treatment with agents that are not approved by the Food and Drug Administration (FDA). Populations requiring independent monitoring would include individuals with schizophrenia, other psychotic disorders or conditions characterized by lack of reality testing (i.e., psychosis). Populations not usually requiring independent monitoring would include those with substance use disorders.

WVU students and employees are considered a vulnerable population, if the intent is to enroll current students or employees that are being taught by the researcher team or are employees under someone on the research team. The main concern is perceived coercion.

- If students, the PI must state that students are informed in the cover letter or consent that the study is completely voluntary and their grades will not be affected.
- If employees, the consent should say their employed status is not affected.

There are methods that can be used to alleviate the concern of coercion. Some suggestions are:

1. Making participation completely anonymous
2. A person who is not giving the class or is not the employer can recruit
3. The faculty or employer can recruit, but make it very clear that the class status, grades or employee status will not be affected by non-participation or withdrawal.
4. Conducting the research after class grades have already been given.
5. You may develop other methods, such as having someone not involved with the study de-identifying the data.