Reviewer Continuing Review/Renewal Checklist

Office of Research Integrity & Compliance | Version 2
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This document is intended to outline general areas that should be examined by IRB members when reviewing continuing review/renewal submissions. If further assistance or clarification is required, please contact the ORIC at 304-293-7073, or at IRB@mail.wvu.edu.

Please remember that all comments should be put into the 'Comments' section of the *Online Review* tab.

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Regulatory Criteria for Approval

This section outlines the federally required criteria for approval, found at §46.111.

1. Risks to subjects are minimized:
    i. By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.
    ii. Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research).
    i. The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
3. Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116. (or has previously been waived by the IRB)
5. Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117. (or has previously been waived by the IRB)

6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
8. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Full Board Renewal Issues

This section outlines common issues that are made when submitting/reviewing renewals to the Full Board. Please use this as a reference when conducting your reviews of Full Board Non-Clinical Trials and Clinical Trials.

- Preliminary results and interim findings are summarized adequately.
- Publications relative to the research are summarized adequately.
- Problems and/or changes to the research since the last IRB review are summarized adequately.
- The number of subjects enrolled corresponds to the number approved for enrollment
- Subject accrual is summarized adequately.
- A summary of any withdrawal of subjects from the research since the last IRB review is described adequately.
- A summary of any relevant information regarding this research, especially information about risks associated with the research is described adequately.
- Study-wide or multi-center trial reports received since the last IRB review are included with the continuing review.
- Data Safety Monitoring Reports received since the last IRB review are included with the continuing review.
- A summary of any unanticipated problems and available information regarding adverse events since the last IRB review is described adequately.
- A summary of any unanticipated problems and available information regarding adverse events (in many cases, such a summary could be a simple brief statement that there have been no unanticipated problems and that adverse events have occurred at the expected frequency and level of severity as documented in the research protocol, the informed consent document, and any investigator brochure) is described adequately.
- A summary of any complaints about the research since the last IRB review is described adequately.
- Any benefits experienced by the subjects are summarized adequately.
- The currently approved consent document is still accurate and complete.
- Overall, continuing review information is adequate.

Additional Documentation for Full Board Renewals

Additional information should be provided if significant new findings arise. The reviewer should consider the following:

1. Are there any new significant findings that may relate to the subject's willingness to continue participation in this research project?
2. Are the new significant findings stated in the informed consent form?
3. Should the PI notify currently enrolled subjects of this information?
4. What is the plan for notifying subjects?

Reviewer Recommendations

1. Device Category
    a. Not applicable
    b. Significant risk
    c. Non-significant risk
2. Continuing Review Frequency
    a. 12 months
    b. 6 months
    c. Other: Please indicate in the comments under the Online Review tab.

Criteria for Expedited Approval

1. The research is no more than minimal risk.

    Note: If the research is more than minimal risk, it is not eligible for expedited review.

2. The research is not classified.

    Note: If the research is classified, it is not eligible for expedited review.

3. Would identification of the subjects and/or their responses reasonably place them at risk of criminal or civil liability or be damaging to the subjects= financial standing, employability, insurability, reputation, or be stigmatizing. If yes, have reasonable and appropriate protections been implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal?

    Note: If No, the research is not eligible for expedited review.

Expedited Categories of Review

Category 1: Clinical studies of drugs and medical devices only when condition (a) or (b) is met:

a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required.

   i. Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.

Note: The WVU IRB has determined that any research that involves the use of a drug, whether FDA approved or not, must be reviewed at a convened full board IRB meeting.

b. Research on medical devices for which:

   i. An investigational device exemption application (21 CFR Part 812) is not required; or

   ii. The medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Category 2: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

a. 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

b. 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.

Category 3: Prospective collection of biological specimens for research purposes by noninvasive means. Examples include:

- Hair and nail clippings in a non-disfiguring manner;
- Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
- Permanent teeth if routine patient care indicates a need for extraction;
- Excreta and external secretions (including sweat);
- Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
- Placenta removed at delivery;
- Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
- Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
- Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
- Sputum collected after saline mist nebulization.

Note: This category includes the prospective collection of specimens by noninvasive methods. This includes methods not involving general anesthesia or sedation. Research involving tissue samples and body fluids require approval from the WVU Institutional Biosafety Committee (IBC).

Category 4: Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, *excluding procedures involving x-rays or microwaves*. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples include:

- Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject=s privacy;
- Weighing or testing sensory acuity;
- Magnetic resonance imaging;
- Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
- Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

Note: WVU includes physical exercise (i.e. research from C-PASS) and physical measurements (i.e. some engineering studies) as Category 4.

Category 5: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

a. Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.

Note: Often, this category is used for medical record review when the researchers are recording identifiable information (see the Guidance on HIPAA Identifiers and Data Protection). This category can also be used for social and behavioral studies whenever the investigator wishes to analyze previously recorded data that are identifiable, such as class grades and assignments.

Category 6: Collection of data from voice, video, digital or image recordings.

Category 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.

a. Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.

Note: Research qualifying for this category of expedited review usually involves an intervention with a pre- and post-test instrument (i.e. survey). Focus groups, surveys, and interviews are also common.

Category 8: Continuing review of research previously approved by the convened IRB as follows:

a. Where:
    i. The research is permanently closed to the enrollment of new subjects;
    ii. All subjects have completed all research-related interventions; and
    iii. The research remains active only for long-term follow-up of subjects; or

Note: All three (3) criteria need to be met in order to qualify for 8(a).

b. Where no subjects have been enrolled and no additional risks have been identified; or

c. Where the remaining research activities are limited to data analysis.

Category 9: Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Note: This category applies to protocols which include a device were originally reviewed by the convened full board. At that meeting, should the Board determine that the research presents no more than minimal risk, and no additional risks have been identified, the protocol's continuing review/renewal is eligible to be reviewed using expedited processes.