Expedited Review

Purpose

The purpose is to outline the policy and procedures for expedited review of research involving human subjects.

Definitions

Expedited is a classification of human subject research review which is performed outside of convened, monthly meetings of the Institutional Review Board (IRB) and is permitted by Federal regulations at 45 CFR 46.110 for certain non-exempt research involving no more than minimal risk, minor changes in approved research, or research for which limited IRB review is a condition of exemption.

Human subject (Participant) is a living individual about whom an investigator (whether professional or student) conducting research:

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens

Minimal risk means the probability of and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Policy

An expedited review procedure may be used for human research which involves no more than minimal risk but does not qualify for exemption. Qualifying research must fit into one or more Federal categories and not involve a prohibited population or activity.

Expedited review is carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB [45 CFR 46.110(b)(2)], including alternate members. Marywood University's IRB chairperson delegates review to all members at the beginning of each fiscal year. Individual review is assigned to one IRB member, who is chosen by the Director of Human Participants Protection and Research Compliance either on a rotating basis or after consideration of the reviewer's particular expertise. The Director assists with review to ensure regulatory and institutional compliance. The chairperson may serve as one of the assigned reviewers.

In examining the research, the expedited reviewer may exercise all of the authorities of the IRB <u>except</u> that the reviewer may not disapprove the research. A research activity may only be disapproved after review at a convened meeting of the IRB [45 CFR 46.110(b)(2)]. Research that has been approved by an IRB under this procedure may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB [45 CFR 46.112].

Any investigator who intends to conduct research involving human subjects, and who on the basis of the categories described below believes that research to be expedited, must submit an application package to Marywood University's IRB for review and approval prior to initiation of activities. The Director of Human Participants Protection and Research Compliance makes the final determination about review type, with consultation of the chairperson or other members of the IRB as needed. The investigator must transmit the research application through IRBNet, a web-based submission and management system, and include any necessary supporting materials. In most cases, an informed consent form is required. The form collects signatures, referred to as "documentation of informed consent," for the subject or legally authorized representative and the person obtaining informed consent. However, in certain circumstances, the requirement for documentation of informed consent or the entire informed consent process

itself may be waived or altered. Please refer to the Informed Consent policy for requirements and information about waivers or alterations.

The IRB office informs members about research proposals that have been approved under an expedited procedure through agenda and minutes documents, which are made available in IRBNet.

The IRB's website provides instructions, forms and templates, and the IRB checklist describes required documentation.

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Prohibited from Expedited Review

- Prisoners, unless only incidentally included
- Drugs*, internally taken substances, investigational devices, or biologics
- Research which may place subjects at greater than minimal risk

*The FDA considers dietary supplements to be drugs if intended to treat or mitigate disease. Please see our Dietary Supplements Policy for details.

While not all populations vulnerable to coercion or undue influence are excluded from expedited review, review type depends on specific research activities and the level of risk posed for the included population.

Federal Expedited Categories

45 CFR 46.110 (a)

The activities listed should not be deemed to be of minimal risk simply because they are included. Inclusion merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the

proposed research involve no more than minimal risk to human subjects. The most frequently used categories are 5 through 8.

The US Secretary of Health and Human Services will evaluate this list at least every eight years through the rulemaking process. The US Office of Human Research Protections has not yet updated its Decision Charts to reflect the Revised Common Rule when aiding in review type determinations.

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. (Note: 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.)

(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 participants, 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 participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, 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.

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Category 3 - Prospective collection of biological specimens for research purposes by noninvasive means, with some examples being:

(a) hair and nail clippings in a non-disfiguring manner;

(b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;

(c) permanent teeth if routine patient care indicates a need for extraction;

(d) excreta and external secretions (including sweat);

(e) 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;

(f) placenta removed at delivery;

(g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

(h) 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;

(i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;

(j) sputum collected after saline mist nebulization.

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.) Some examples are:

(a) 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 participant or an invasion of the participant's privacy;

(b) weighing or testing sensory acuity;

(c) magnetic resonance imaging;

(d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;

(e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

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). *(NOTE: Some research in this category may be exempt if it meets 45 CFR 46.104(d)(4). This listing refers only to research that is not exempt.)*

Category 6 - Collection of data from voice, video, digital, or image recordings made for research purposes.

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.*(NOTE: Some research in this category may be exempt if it meets 45 CFR 46.104(d)(2) and (d)(3). This listing refers only to research that is not exempt.)*

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

(a) where (i) the research is permanently closed to the enrollment of new participants; (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of participants; or

(b) where no participants have been enrolled and no additional risks have been identified; or

(d) 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.

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Expedited Review of Minor Changes to Approved Research

Federal regulations at 45 CFR 46.110 (b)(1)(ii) allow for expedited review of minor changes in research previously approved by the IRB during the period for which approval is authorized.

A change is minor if it falls into expedited categories 1-7 and does not:

- Exhibit a major change in aims, design or consent process
- Diminish scientific validity
- Increase risks or discomfort to subjects, or increase number of subjects at risk
- Expand eligibility criteria
- Add an element that may breach confidentiality (e.g., adding focus groups)
- Alter the willingness of subjects to enroll or continue
- Add sensitive information (e.g., questions about drug use, sexuality, etc.)
- Add a new consent form
- Alter study team qualifications in a way that would not be appropriate for the project
- Alter the facilities available to support the safe conduct of the research
- Create confusion or questions as to the full scope of the study (e.g., many revisions throughout study's length)
- Include any other factor that would warrant review by the convened IRB

Examples of Minor Changes

- Reduction of risk/discomfort to the participant
- Addition or removal of research personnel (e.g., research assistant) where team competence is still maintained
- Addition of a new recruitment site if all procedures and eligibility are the same
- Adding an instrument similar to the one already approved
- Addition of non-sensitive questions to interviews or surveys
- Removing questions from a questionnaire or instrument
- Corrections to documents that do not alter the meaning or procedure (clarification, typographical errors, grammar, etc.)
- Consent form changes that add or remove information so that it is consistent with an already approved IRB requirement
    - Defining a phrase more clearly in lay language
    - Updating to use IRB approved boiler plate language
- Alteration of the funding source

The investigator must submit minor changes using a Revisions to Approved Research Request form. The changes must be approved by the IRB prior to implementation.

The Director of Human Participants Protection and Research Compliance makes the final determination regarding eligibility for expedited review under these circumstances. Minor changes to approved research are reviewed by the chairperson or an experienced member of the IRB.

Procedures

1. The investigator and any research advisor, co-investigator and/or research assistant (RA) completes mandatory online training.
2. The investigator reads policies concerning research with human subjects, the IRB submission checklist, and instructions on how to submit (menu of four steps or downloadable PDF).
3. The investigator registers at www.irbnet.org, affiliates with Marywood University, and confirms registration via e-mail. If applicable, co-investigators or advisors do the same (RA registration optional).
4. The investigator downloads and completes necessary forms and templates, which are located on the IRB's website or in IRBNet's forms library.
5. The investigator proofreads and runs a spellcheck on all completed documents.
6. Following the written and/or video instructions for IRBNet, the investigator creates a new project, shares access to it with research team members (if applicable), applies an e-signature, has the advisor and/or co-investigators sign, and then submits it to the IRB.
7. The investigator monitors his/her e-mail account for a notice from the IRB, which informs of the decision letter's location for download by the investigator.
8. The IRB's decision letter describes requested actions, the requirement for tracking changes, and how to submit a response via IRBNet.
9. Once approved, the IRB emails an approval notice, prompting the investigator to download the approval letter and stamped materials (documents part of consent process) via IRBNet. Stamped versions of documents must be used in the research unless the IRB states otherwise.

10. The investigator submits via IRBNet any requests for revisions after approval, deviations from the approved research, or unanticipated problems or serious adverse events, should they occur. See appropriate policies and procedures about these topics.
11. The investigator submits a completed closure report form upon study conclusion, at or by the one-year approval anniversary. If activities haven't been completed at that time, the investigator submits either a continuing review/annual renewal form and attachments, or an annual check-in report form, depending on the research's progress and the date of the original approval (before or after January 21, 2019).

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Related Policies

- Closure or Withdrawal
- Continuing Review
- Dietary Supplements
- Full Review of Research
- Informed Consent and Assent
- Mandatory Reporting
- Records Retention

History

12/14/2012 - Revised to include minor change information and examples

05/21/2015 - Changed title of Asst. VP for Research to Dir. of Research and Sponsored Programs

05/25/2017 - Updated format, removed outdated staff references, added definitions and exclusions

05/30/2017 - Inserted link to Dietary Supplement Policy

06/08/2017 - Added related policies and regulatory references

05/23/2018 - Updated checklist link and examples of minor changes
06/07/2019 - Updated as a result of the Revised Common Rule
09/30/2019 - Corrected checklist link
01/21/2020 - Corrected checklist link