Full Review

Purpose

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

Definitions

Full review is a method of human subject research review required in the Code of Federal Regulations at 45 CFR 46, 21 CFR 50 and 21 CFR 56. It is performed at a convened monthly meeting of the Institutional Review Board (IRB) for research posing greater than minimal risk to subjects, clinical investigations regulated by the FDA, or for research involving any activities which are not allowed under an expedited process or exemption.

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.

Policies

Full review is performed at convened, monthly meetings at which a majority of the members of the Institutional Review Board (IRB) are present, including at least one member whose primary concerns are in nonscientific areas. The Director of Human Participants Protection and Research Compliance assists with review to ensure regulatory and institutional compliance. In order for research to be approved, it shall receive the approval of a majority of those voting members present at the meeting [45 CFR 46.108(b)], whether in person or via teleconference.

The IRB is given regulatory authority to review, approve, require modifications in (to secure approval), or disapprove all research activities involving human subjects [45 CFR 46.109(a)]. A research activity may only be disapproved after review at a convened meeting of the IRB. 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].

The IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB [45 CFR 46.107(f)].

When reviewing research proposals, the IRB is primarily interested in safeguarding the rights and well-being of human subjects and in assessing the ethical implications of the proposed procedures. In this context, the IRB may pass judgment on research design, but only to the extent that such design affects the subjects' rights or well-being. In analyzing the risk/benefit ratio of a research activity, both the stated goals and the scientific merit of the research will be considered.

Any investigator who intends to conduct research involving human subjects, and who on the basis of what is described believes that research to be full, must submit an application package to Marywood University's IRB for review and approval prior to initiation of research activities. The Director of Human Participants Protection and Research Compliance will make the final determination about review type, with consultation of the IRB Chair, members of the IRB, or the Assistant Provost, as needed.

Full submissions must be transmitted through IRBNet, Marywood University's online submission and management system, and include an IRB application form and all necessary attachments. 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 may be waived (FDA excluded except for emergency research). Alteration of informed consent or waiver of the entire

informed consent process itself may be requested (FDA excluded except for emergency research) only when the research fits into four criteria set forth in the regulations, the first of which is no more than minimal risk. Research with children involves specific requirements for parental permission and child assent.

The IRB must approve both the form and the process by which informed consent is to be obtained. This process begins with recruitment. Please see the Informed Consent policy for further information on the requirements of informed consent, alterations and waivers.

The research must be described to the IRB in a manner that allows adequate review of all of its aspects. The IRB requires research details to be provided on an IRB application form (dissertation or thesis chapters should not be submitted), which covers the following areas:

1. **OVERVIEW:** Describes the research planned and the rationale for the project, including: (a) purpose of the study (b) research questions(s) or hypothesis(es), (c) most recent relevant research in the area of inquiry (with citation), and (d) a list of references under c.

2. **PARTICIPANTS/SUBJECTS:** Includes characteristics and recruitment, specifying: (a) characteristics of the population (e.g. ages, minority population, special group whose ability to give consent is compromised, pregnant women, fetuses, prisoners), (b) inclusion and exclusion criteria, (c) approximate target number to recruit and enroll, along with justification for the number, (d) how and where subjects will be recruited (including any permissions for access), and (e) how research will be advertised, including any flyers, posters, or email scripts to be used; If using a flyer, how it will be used, such as posting, distributing via email, naming list-serves to be used, etc. (See permission letter template on the Forms & Instructions web page).

3. **RISKS & BENEFITS:** Addresses both potential benefits and risks to human subjects. Risks relate to the probability and magnitude of harm as a result of participating and can be physical, psychological, financial, social and

legal or may result from breaches of confidentiality. States (a) what the potential risks are to subjects, and whether or not they are greater than minimal, (b) if there are potential risks, how they will be minimized, (c) if there are risks, if they are reasonable when compared to the potential benefits, (d) potential benefits to the field of study, and (e) potential individual benefits to subjects, if any.

4. **PROCEDURES:** Describes the methods and procedures to be used with the subjects in the research, in non-technical language. States: (a) exactly what subjects will be asked to do, including all activities, (b) where research will take place, (c) what standardized tests, tools, or measures will be used, and includes instrumentation or questions, and discusses reliability and validity; if tools are older than 10 years, discusses rationale for choice, (d) if a researcher-developed instrument or set of interview questions is used, provides documentation that tool has been reviewed by 1 professional in the field of study (Master's degree or higher; from individual not affiliated with the current study). If uses professionals, supplies names, degrees held and contact information, (e) what data/information will be collected, (f) how data will be collected and by whom, (g) how data will be analyzed and by whom, (h) the approximate time commitment for subjects, as well as overall project length, and (i) whether or not subjects will be compensated. If so, discloses method and rationale (payment cannot be considered a participant benefit).

5. **INFORMED CONSENT:** (See templates on Forms Page) Describes the process for obtaining the informed consent of subjects. States: (a) how informed consent will be obtained (hard copy, verbal, etc.) and (b) how informed consent will be documented (e.g., signature or waived signature). Informed consent should convey that the project is research, purpose of study, how subjects were selected, procedures, length of study and time required of subjects, risks/benefits of participation, voluntariness of participation, procedure for withdrawal and what happens to data, confidentiality of data, data destruction, investigator and advisor/sponsor (if applicable) contact information and contact information concerning research integrity.

6. **RECORDS MANAGEMENT:** Records must be kept for as long as the applicable regulations require (at LEAST 3 years; See Records Retention). States: (a) how and where records will be kept (e.g. locked file in researchers' office), (b) who will have access to records (i.e., investigator, advisor, research assistant, outside transcriptionist, etc.), (c) whether or not data will be shared, and if so, with whom and to what extent (e.g., sharing de-identified/aggregate data with an agency), and (d) length of retention of records; if keeping longer than required, provide justification; if destroying, state how.

The IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research [45 CFR 46.109]. A new application for review is required for each research project that differs significantly in terms of research aims, procedures or subject populations from a previously approved application.

Please see the IRB checklist for required documentation, and the IRB's website for instructions, forms and templates.

The US Office of Human Research Protections provides a series of Decision Charts to aid in determination of review type.

Procedures

1. The investigator and all research team members (co-investigators, research assistants and advisors/sponsors) complete mandatory online training.
2. The investigator reads policies and procedures concerning research with human subjects, the submission checklist, and instructions on how to submit (center of page).
3. The investigator visits www.irbnet.org to register (affiliating with Marywood University), and confirms registration via e-mail. Co-investigators and

research advisors/sponsors must also register. Registration by research assistants is optional.

4. The investigator downloads necessary forms and templates, completes them, and gathers supporting documentation, as needed. IRB forms and templates are available on the IRB's website or via IRBNet's forms and reference library.
5. The investigator proofreads and runs a spellcheck on all completed documents.
6. Following the written instructions for IRBNet (video tutorials are also available), the investigator creates a project, shares it with research team members (if applicable), applies an electronic signature, and then submits it to the IRB.
7. The investigator monitors his/her e-mail account for communications from the IRB. Once the IRB publishes its decision letter at IRBNet, it will email a notice containing instructions on how to access the letter.
8. The IRB's decision letter will communicate required modifications, if any, how to apply tracking to documents prior to modifying them, and how to submit the modifications via IRBNet.
9. Once approved, the IRB will email a notice about approval, prompting the PI to access the approval letter and all stamped documents (documents part of the consent process) in IRBNet. Stamped versions of documents must be used in the research, unless otherwise noted.
10. The investigator submits to the IRB any requests for revisions after approval, deviations/violations from the approved protocol or materials, unanticipated problems or serious adverse events, should they occur. See appropriate policies and procedures about these topics.
11. The investigator submits a status report six months after approval, or a closure report if the study is completed prior to this period. The due date may be found in the approval letter and in the email message sent by staff upon approval.
12. As approval is granted for one year only (unless otherwise noted), the investigator submits either a closure report upon completion (at or by expiration date), or if not closing, a continuing review application to the IRB, allowing enough time so there is no lapse.

Related Policies

- Closure or Withdrawal
- Continuing Review
- Expedited Review of Research
- Informed Consent, Parental Permission and Child Assent
- Mandatory Reporting
- Records Retention

History

06/08/2017 - Updated format and added definitions, regulatory authorities and procedures

06/12/2017 - Small formatting change made

05/24/2018 - Corrected checklist links

09/30/2019 - Corrected checklist link

07/06/2022 - Small formatting change made