§46.109: IRB Review of Research

UNC | RESEARCH

The IRB is authorized to…

- Review information given to subjects
- Review continuing review of research
- Determine the frequency of continuing review based on risk
- Examine consent documentation and waivers
- Communicate with researchers
- Limited IRB Review
- Observe the consent process and research

§ 46.109: IRB Review of Research

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy, including exempt research activities under § 46.104 for which limited IRB review is a condition of exemption (under § 46.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7), and (8)).

§46.104: Limited IRB Review

(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with § 46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with § 46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by § 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and

(iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

Communications with Subjects

(b) An IRB shall require that information given to subjects (or legally authorized representatives, when appropriate) as part of informed consent is in accordance with § 46.116. (ICF regulations). The IRB may require that information, in addition to that specifically mentioned in § 46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

Document or Waive Documentation

(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with § 46.117.

Communications with Researchers

(d) An IRB shall notify investigators and the institution in writing of its decision to:

- approve or disapprove the proposed research activity, or
- of modifications required to secure IRB approval of the research activity.

If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

Continuing Review Requirement

(e) An IRB shall conduct continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk, not less than once per year, except as described in § 46.109(f).

Continuing Review Exceptions

(f)(1) Unless an IRB determines otherwise, continuing review of research is not required in the following circumstances:

(i) Research eligible for expedited review in accordance with § 46.110;

(ii) Research reviewed by the IRB in accordance with the limited IRB review described in § 46.104(d)(2)(iii), (d)(3)(i)(C), (d)(7), or (d)(8);

Consent Process & Research Observation

(g) An IRB shall have authority to observe or have a third party observe the consent process and the research.

Summary

- **What is the Authority and Scope of the IRB's Review of research?**
- Review information given to subjects
- Review continuing review of research
- Determine the frequency of continuing review based on risk
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- Limited IRB Review
- Observe the consent process and research