AAHRPP
Association for the Accreditation of Human Research Protection Programs, Inc.®

Tip Sheet 20: Sufficient Information to Determine Whether the Criteria for Approval are Met

Related Accreditation Elements: II.2.D., II.2.E., II.3.A., II.3.B., II.3.C., II.3.D., II.3.E., II.3.F., II.3.G., II.4.A., II.4.B., and II.4.C.

For initial and continuing review of research by a convened IRB or EC, all IRB or EC members (including alternate members) should review sufficient information to determine whether the criteria for approval of research are met. For initial and continuing review of research using the expedited procedure, the reviewer should review the same information as the convened IRB or EC would have reviewed.

Recommended Content:

1. Purpose of the research.
2. The scientific or scholarly rationale.
3. Procedures to be performed.
    a. A description of the procedures being performed already for diagnostic or treatment purposes.
4. Risk of harms.
5. Potential benefits.
6. Inclusion and exclusion criteria.
7. Setting of the research.
8. Provisions to monitor the data for the safety of participants.
9. Whether the research will involve individuals vulnerable to coercion or undue influence.
    a. When some or all participants are vulnerable, a description of additional safeguards included to protect their rights and welfare.
10. Recruitment methods.
11. Advertising materials.
12. Amount and schedule of all payments.
13. Provisions to protect the privacy interests of participants.
14. Provisions to maintain the confidentiality of data.
15. Consent process.
    a. The person who will conduct the consent interview.
    b. The person who will provide consent or permission.
    c. Any waiting period between informing the prospective participant and obtaining consent.
    d. Steps taken to minimize the possibility of coercion or undue influence.
    e. The language used by those obtaining consent.

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f. The language understood by the prospective participant or the legally authorized representative.

16. Consent document or consent script.

Note:

1. This information might exist in different sources, such as an application or research protocol or plan, and does not have to have to be located in one source.
2. Some of the recommended information might not be relevant to a particular research protocol or plan.

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