From: https://www.aahrpp.org/resources/for-accreditation/tipsheets/criteria-for-approval

To approve research, the IRB must determine that all of the following criteria are satisfied:

Risks to Participants

- Risks to participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk.
- Risks to participants are minimized whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.
- Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.

Selection of Participants

- Selection of participants is equitable taking into account the purposes of the research, the setting in which the research will be conducted, the special problems of research involving vulnerable populations, the selection criteria, and the recruitment procedures.

Safety monitoring

- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.

Privacy

- When appropriate, there are adequate provisions to protect the privacy of participants.

Confidentiality

- When appropriate, there are adequate provisions to maintain the confidentiality of data.

Vulnerable Populations

- When some or all of the participants 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 are included in the study to protect the rights and welfare of these participants. (Note: Subpart B of the DHHS regulations specifies additional protections for pregnant women; Subpart C of the DHHS regulations, for prisoners; and Subpart D of the DHHS and FDA regulations, for children.)

Consent

Consent will be sought from each prospective participant or the participant's legally authorized representative in keeping with the criteria outlined below.

From: https://www.aahrpp.org/resources/for-accreditation/tipsheets/criteria-for-approval

The process for obtaining consent must incorporate all of the following:

- The Researcher will obtain the legally effective informed consent of the participant or the participant's legally authorized representative.
- Consent will be sought only under circumstances that provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate.
- Consent will be sought only under circumstances that minimize the possibility of coercion or undue influence.
- The information that is given to the participant or the representative shall be in language understandable to the participant or the representative.
- The informed consent does not include any exculpatory language through which the participant or the representative is made to waive or appear to waive any of the participant's legal rights.
- The informed consent does not release or appear to release the Researcher, the sponsor, the institution, or its agents from liability for negligence.

Information that must be provided as part of the interaction with the participant and in the documentation of the consent process, unless waived or altered:

- A statement that the study involves research.
- An explanation of the purposes of the research.
- The expected duration of the participant's participation.
- A description of the procedures to be followed.
- Identification of any procedures which are experimental.
- A description of any reasonably foreseeable risks or discomforts to the participant.
- A description of any benefits to the participant or to others which may reasonably be expected from the research.
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.
- A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained.
- An explanation of whom to contact for answers to pertinent questions about the research.
- An explanation of whom to contact for answers to pertinent questions about the research participant's rights.
- An explanation of whom to contact in the event of a research-related injury to the participant.
- Contact information for the research team for questions, concerns, or complaints. (AAHRPP Standard III.1.G)
- Contact information for someone independent of the research team for problems, concerns, questions, information, or input. (AAHRPP Standard I.4.A)
- A statement that participation is voluntary. A statement that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled.
- A statement that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.