IRB Criteria for Approval
Why talk about the approval criteria?

- Reminds us of our mission to protect the safety and welfare of research participants
- Refresher for some, newer information for others
- Keeps us focused and aligned with each other
Approval Criteria

Operationalize the ethical principles described in the Belmont Report

• Respect for Persons
  • The right to individual autonomy and protection for populations with compromised autonomy
  • Voluntariness, freedom from coercion or undue influence
  • Informed consent
  • Privacy and confidentiality

• Beneficence
  • Risks are reasonable in relation to the benefits of the research
  • Research is designed to minimize risks
  • Study design is sound

• Justice
  • Risks borne equally by members of society who are likely to benefit
  • Study does not select specific classes of individuals due to ease of their availability

Provide focus for IRB review

• Helps avoid committee diversion in directions that may not be related to the rights and welfare of research participants
45 CFR 46.111 & 21 CFR 56.111 Criteria for Approval

To approve research, the following requirements must be satisfied

1. Risks to participants are minimized (sound research design and acceptable procedures)
2. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants and the importance of knowledge that may reasonably be expected to result
3. Selection of participants is equitable (considering purpose and setting of research)
4. Informed consent will be sought and documented (unless waived) accordingly
5. There are adequate provisions for data monitoring to ensure safety of participants if appropriate
6. There are adequate provisions to protect the privacy of participants and to maintain confidentiality of the data if appropriate
7. There are additional safeguards to protect the rights and welfare of participants likely to be vulnerable to coercion or undue influence
45 CFR 46.111 & 21 CFR 56.111 Criteria for Approval

1) Risk to Participants are Minimized
   - Risks can be both time and situation specific
   - Risks can be subjective and relevant to specific populations, or even individuals
   - Possible type of harm
     - Social, physical, economic, legal, dignity and respect

2) Risk to Participants are Reasonable in Relation to Anticipated Benefits
   - Consider only the risks and benefits that may result from the research
   - Do not consider possible long-range effects of applying knowledge gained from the research (e.g., possible effects on public policy)

3) Selection of Participants is Equitable
   - Inclusion/exclusion criteria are adequate
   - Research purpose and setting are appropriate
   - Recruitment process is fair
   - Special requirements for vulnerable populations are addressed, if applicable
4) Informed consent will be sought and documented (unless waived) accordingly
   • Each participant, or their Legally Authorized Representative (LAR) will sign an informed consent
   • Will be appropriately documented
   • OR will be waived

5) There are adequate provisions for data monitoring to ensure safety of participants if appropriate
   • For greater than minimal risk research, there is an adequate plan describing how the study will be monitored to ensure safety (e.g., sponsor, data monitoring committee, data safety monitoring board, independent medical monitor)
6) There are adequate provisions to protect the privacy of participants and to maintain confidentiality of the data if appropriate

• **Privacy**
  • Evaluate the methods used to identify and contact potential participants
  • Consider the settings in which participants will interact with the study team and the appropriateness of all personnel present for research activities
  • Look at the nature of information obtained about participants (is it the minimum amount necessary to achieve research goals)
  • Is information obtained about individuals other than the participant (family members, etc).

• **Confidentiality**
  • What protections are in place to minimize the likelihood that information about participants will not be inappropriately divulged
  • Do the safeguards to protect confidentiality align with the potential of harm from unauthorized, inappropriate or unintentional disclosure
7) There are additional safeguards to protect the rights and welfare of participants who may be vulnerable to coercion or undue influence

- Consider the scientific and ethical reasons for including vulnerable participants in research
- Determine if additional safeguards are required (including but not limited to regulations regarding risks to children, considerations for individuals without decision-making capacity, )
Where Can I Find These Criteria in More Detail?

- USC HRPP Website
  - Policies
  - IRB Member Toolbox

- IRB Member Regulatory Reference Guide (attached with meeting agenda)

- Code of Federal Regulations
  - 45 CFR 46.111
  - 21 CFR 56.111

- IRB Member Handbook (Amdur/Bankert)

- iStar (Continuing Review/Expedited Review)
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Thank You!