

Criteria for Approval for Certain Studies

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Outline

- Criteria for approval for certain studies
- References

Criteria for Approval When Applicable

Greater Than Minimal Risk Studies

- The research plan makes adequate provision for monitoring the data collected to ensure the safety of the subjects
- The protocol is scientifically valid and employs research procedures which are consistent with sound research design

Studies With Vulnerable Populations

- Additional safeguards have been included in the study to protect the rights and welfare of the vulnerable population

Clinical Trials

- Available non-clinical and clinical information is adequate to support the proposed clinical trial

Criteria for Approval When Applicable

Initial Review

- The researcher has the resources necessary to protect subjects
- The research is acceptable in terms of local context, applicable law, and standards of professional research conduct and practice

Initial Review of Multi-Site Research Where PI is Overall PI

- The plan for communication among sites is adequate to protect subjects

References

- [21 CFR 56.111](#)
- [45 CFR 46.111](#)
- [OIA-314](#)
- [OIA-320](#)