

# Criteria for Approval for All Studies

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# Outline

- Criteria for approval for all studies
- References

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## Risks and Benefits (Beneficence)

- Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risks
- Risks to subjects are minimized by using procedures already being performed on the subjects for other purposes when possible
- Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result

## Selection of Subjects (Justice)

- Selection of subjects is equitable

# Criteria for Approval for All Studies

## Privacy and Confidentiality (Respect for Persons & Beneficence)

- There are adequate provisions to protect the privacy of subjects
- There are adequate provisions to maintain the confidentiality of the data

## Informed Consent (Respect for Persons)

- The informed consent process is adequate
- The documentation of informed consent is adequate

# References

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