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Section C

Oversight

Oversight: REC

- Research ethics committees (RECs)
 - Responsibility for the rights and welfare of human subjects
 - ▶ Study design
 - ▶ Special protections for vulnerable subjects
 - ▶ Consent process
 - Local
 - ▶ Variability in review

Oversight: DMC

- Oversight
 - Data monitoring committees (DMCs)
 - ▶ Protect subjects from previously unknown adverse events
 - ▶ Avoid unnecessarily prolonged exposure to an inferior treatment
 - Interim analysis
 - Stopping rules

Summary

- Good study design is key to conduct of an ethical study