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Research Tools and Checklists

Tools and Checklists

FDA and OHRP Inspections

Tools and Checklists

Below is a collection of tools to assist in the conduct and management of clinical research:

[UCSF Routine On-Site Review Form](#) ^[1] [Quality Management Plans](#) ^[2] [?](#) ^[3]

[Regulatory Binder Requirements](#) ^[4] [??](#) ^[5] [Standard Operating Procedures](#) ^[6]

[Delegation of Authority Documentation Log](#) ^[7] [Drug or Biologic Dispensing / Accountability Log](#) ^[8]

Screening / Enrollment / Withdrawal Log ^[5]

- Example: Study Events Tracking Form ^[10]
- Example: Tracking System for Deadlines and Reporting ^[11]

FDA and OHRP Inspections

Please notify UCSF upon receiving the call or letter to schedule the inspection. See the UCSF Clinical Research HUB ^[12] for more information about whom to contact and how to prepare for the inspection.

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Links

[1] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/rsv-report-template.pdf>

[2] <http://hub.ucsf.edu/quality-management-practices>

[3] https://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/RSV_template_form.pdf

[4] <http://hub.ucsf.edu/regulatory-binder-requirements>

[5] <https://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/screening-enrollment-withdrawal-log.doc>

[6] <http://hub.ucsf.edu/sops>

[7] <https://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/delegation-of-authority-documentation-log.doc>

[8] <https://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/investigational-agent-accountability-record.doc>

[9] <https://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/investigational-device-accountability-log.doc>

[10] <https://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/example-study-events-tracking-form.doc>

[11] <https://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/example-tracking-system-for-deadlines-reporting.xls>

[12] <http://hub.ucsf.edu/fda-and-ohrp-inspections>