OREGON CLINICAL & TRANSLATIONAL Research Institute

OHSU

GCP and OHSU Research Documentation Standards eLearning Handout

This document is a companion to the eLearning OCTRI GCP and OHSU Research Documentation Standards. Learners should take the CITI GCP Training course prior to this training.

Acronyms:

- ALCOAC – Attributable, Legible, Contemporaneous, Accurate, Complete
- CFR – Code of Federal Regulations
- CITI – Collaborative Institutional Training Initiative
- CLIA – Clinical Laboratory Improvement Amendments
- CMS – Center for Medicare and Medicaid Services
- CRF – Case Report Form
- CRO – Clinical Research Organization
- DNV – Det Norske Veritas (Norwegian for "The Norwegian Truth)
- eCRIS – electronic clinical research information system
- EDC – Electronic Data Capture
- FDA – Food and Drug Administration
- GCP – Good Clinical Practice
- HIPAA – Health Insurance Portability and Accountability Act
- ICH – International Council on Harmonization
- IDE – Investigational Device Exemption
- IHR – Integrated Health Record
- IND – Investigational New Drug
- IRB – Institutional Review Board
- NDA – New Drug Application
- NIAHO – National Integrated Accreditation of Healthcare Organizations
- OCTRI – Oregon Clinical and Translational Research Institute
- PMA – Premarket Approval Application
- SOC – Standard of Care
- SOP – Standard Operating Procedure

eLearning References:

The list of references/resources follows along with the modules, so you may see the same link more than once if it is referenced more than once in the course. We included the full title of the policy or webpage so that you can search for the resource on 02 in the event that a link is broken. If you find a broken link, please email Bridget Adams adamsb@ohsu.edu so we can update the handout.

GCP & OHSU Research Documentation Standards:

- CITI GCP Training https://www.ohsu.edu/research-integrity/human-researcher-training#section-200431 Registration in Compass.

Consider Your Research Documentation Audience:

Other Care Providers

- Research Documentation in the Integrated Health Record (IHR) HC-MRM-123-POL
- Content of the Integrated Health Record Policy (IHR) HC-MRM-100-POL
- Designated Record Set/Legal Health Record (IPP-02)

Monitors/Sponsors

- 21 CFR 312.56 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.56
- 21 CFR 812.46 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.46

FDA Inspectors

- 21 CFR 312.68 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.68
- 21 CFR 812.145 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.145

FDA Regulations and GCP Documentation Standards

Adequate Case Histories

- 21 CFR 312.62 Investigator Recordkeeping and Record Retention https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.62
- 21 CFR 812.140(a) Records, Investigator Records https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=812.140
- E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) https://www.fda.gov/regulatory-information/search-fda-guidance-documents/e6r2-good-clinical-practice-integrated-addendum-ich-e6r1
- Electronic Source Data in Clinical Investigations https://www.fda.gov/media/85183/download

ICH Guidelines

- ICH E6 R2 https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf

ALCOA - +Plus

- OCTRI's Guidance for OHSU Principal Investigators and Study Teams: FDA Inspection Conduct and Responses https://www.ohsu.edu/sites/default/files/2019-07/FDA%20Inspection%20Guidance%202019-07-24.pdf
- Clinical trial regulatory file checklist https://www.ohsu.edu/octri/tools-templates-and-resources Look under the Study Conduct – Study conduct resources, tools, and example templates accordion.

Creating Case Report Forms

- OCTRI Research Forum Past Presentations "Case Report Form Development" (slides and recorded video of presentation are

available). https://www.ohsu.edu/octri/octri-research-forum-your-monthly-clinical-and-translational-research-event.

Electronic Data Capture Resources:

- 21 CFR Part 11 Electronic Records; Electronic Signatures – Scope and Application Guidance https://www.fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application
- OCTRI REDCap https://www.ohsu.edu/octri/redcap-your-complete-solution-online-databases-and-surveys-research
- Qualtrics https://o2.ohsu.edu/information-technology-group/software/qualtrics.cfm
- Advarra EDC (Knight Cancer Institute Only) For questions or to request this service, email kcri@ohsu.edu.
- Other 21 CFR Part 11 systems – consultation available by contacting OCTRI@ohsu.edu

OHSU Research Documentation Requirements

- Content of the Integrated Health Record (IHR) HC-MRM-100-POL https://ohsu.ellucid.com/documents/view/264
- Research Documentation in the Integrated Health Record (IHR) HC-MRM-123-POL https://ohsu.ellucid.com/documents/view/279
- The OHSU Designated Record Set (IPP-02) https://ohsu.ellucid.com/documents/view/15593

OHSU Systems and Resources:

eCRIS

- Studies Required to Use eCRIS flowchart https://o2.ohsu.edu/ecris/upload/eCRISrequiredflow-V4-march-2017.pdf
- eCRIS (Manuals, access, training, contacts) https://o2.ohsu.edu/ecris/
- Epic Research Indicator Workflow https://o2.ohsu.edu/ecris/upload/EPIC-RESEARCH-INDICATORS-final-3.pdf
- Research Subject Preconsent Request Form for Epic https://o2.ohsu.edu/ecris/manuals-and-guides.cfm
- To request Preconsent Research Association email ResIndicator@ohsu.edu
- eCRIS User Manual https://o2.ohsu.edu/ecris/upload/eCRIS-User-Manual-with-gridless-final-9-23-20.pdf
- eCRIS Training https://o2.ohsu.edu/ecris/

Epic Research Documentation Tools

- Virtual: Epic Training for Research Staff – Register in Compass https://ohsu.csod.com/LMS/catalog/Welcome.aspx?tab_page_id=-67&tab_id=-1
- Epic for Research Bridge site https://bridge.ohsu.edu/cs/itg/projects/eri/Public/ITG%20Epic%20for%20Research.aspx.

- Requesting SmartSets/Order Sets https://bridge.ohsu.edu/cs/itg/projects/eri/_layouts/15/WopiFrame.aspx?sourcedoc={f1b7e1c4-a412-454b-af9e-2d5e979666cf}&action=default
- Epic order Entry for Research Staff User Guide https://bridge.ohsu.edu/cs/itg/projects/eri/_layouts/15/WopiFrame2.aspx?sourcedoc={8bc3d775-3a29-442a-b58e-2d7bb4ea3ae1}&action=default

Research Subject Tracking Features in Epic

- Epic for Research Bridge site https://bridge.ohsu.edu/cs/itg/projects/eri/_layouts/15/WopiFrame.aspx?sourcedoc={13a7556b-cea9-4530-9ff0-4ebc4bdba66f}&action=default

Research Applications, Systems, Services

- Security Review - https://o2.ohsu.edu/information-technology-group/information-privacy-security-ips/security/security-review.cfm
- Initiate a security review - https://wiki.ohsu.edu/display/HHT/Initiate+a+Security+Review

Sponsor Monitor/Auditor Epic Access

- Epic Access for Monitors/Auditors instructions https://www.ohsu.edu/octri/tools-templates-and-resources (Open the "Study Conduct" accordion to find document).

Research Documentation Retention

- 45CFR74.53.b https://www.govinfo.gov/content/pkg/CFR-2007-title45-vol1/pdf/CFR-2007-title45-vol1-sec74-53.pdf
- 21 CFR 312.62.c https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=312.62
- 21 CFR 812.140.d https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=812.140
- ICH GCP 4.9.5 https://ichgcp.net/4-investigator
- 45 cFR 164.530 (j)(2) - https://www.govinfo.gov/content/pkg/CFR-2014-title45-vol1/pdf/CFR-2014-title45-vol1-sec164-530.pdf