

# Appendix

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## A.1 Code of Federal Regulations

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| 45 CFR PART 46  | <a href="http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm">www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm</a>         |
| 21 CFR PART 11  | <a href="http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr11_02.html">www.access.gpo.gov/nara/cfr/waisidx_02/21cfr11_02.html</a>   |
| 21 CFR PART 50  | <a href="http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr50_02.html">www.access.gpo.gov/nara/cfr/waisidx_02/21cfr50_02.html</a>   |
| 21 CFR PART 54  | <a href="http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr54_02.html">www.access.gpo.gov/nara/cfr/waisidx_02/21cfr54_02.html</a>   |
| 21 CFR PART 56  | <a href="http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr56_02.html">www.access.gpo.gov/nara/cfr/waisidx_02/21cfr56_02.html</a>   |
| 21 CFR PART 58  | <a href="http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr58_02.html">www.access.gpo.gov/nara/cfr/waisidx_02/21cfr58_02.html</a>   |
| 21 CFR PART 312 | <a href="http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr312_02.html">www.access.gpo.gov/nara/cfr/waisidx_02/21cfr312_02.html</a> |
| 21 CFR PART 600 | <a href="http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr600_02.html">www.access.gpo.gov/nara/cfr/waisidx_02/21cfr600_02.html</a> |
| 21 CFR PART 812 | <a href="http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr812_02.html">www.access.gpo.gov/nara/cfr/waisidx_02/21cfr812_02.html</a> |
| 21 CFR PART 820 | <a href="http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr820_02.html">www.access.gpo.gov/nara/cfr/waisidx_02/21cfr820_02.html</a> |

## A.2 Good Clinical Practice Guidelines

FDA Device Advice

<http://www.fda.gov/cdrh/devadvice>

Guidance for Industry – Good Clinical Practice

[www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM129515.pdf](http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM129515.pdf)

## A.3 Medical Terminology, Dictionaries and Other Resources

NCI Common Terminology Criteria for Adverse Events (CTCAE)

[ctep.cancer.gov/reporting/ctc.html](http://ctep.cancer.gov/reporting/ctc.html)

MedicineNet.com

[www.medterms.com/script/main/hp.asp](http://www.medterms.com/script/main/hp.asp)

ECOG Performance Status

[www.ecog.org/general/perf\\_stat.html](http://www.ecog.org/general/perf_stat.html)

OHRS Common Language for Risks and Events Database

<http://www.dfhc.harvard.edu/ohrs/consent-documents>

## A.4 Suggested Reading

Nuremberg Code

[www.hhs.gov/ohrp/references/nurcode.htm](http://www.hhs.gov/ohrp/references/nurcode.htm)

Declaration of Helsinki

[www.fda.gov/oc/health/helsinki83.html](http://www.fda.gov/oc/health/helsinki83.html)

Belmont Report

<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>

QACT Clinical Trials Audit Manual

<http://www.dfhc.harvard.edu/clinical-research-support/quality-assurance-office-for-clinical-trials-qact/forms-policies-and-manuals>

DF/HCC Data and Safety Monitoring Plan

<http://www.dfhcc.harvard.edu/clinical-research-support/quality-assurance-office-for-clinical-trials-gact/forms-policies-and-manuals>

## **A.5 Useful Web Sites**

Office for Human Research Protections (OHRP)

[www.hhs.gov/ohrp](http://www.hhs.gov/ohrp)

Food & Drug Administration (FDA)

[www.fda.gov](http://www.fda.gov)

Instructions for Sponsor-Investigators Submitting IND Applications

<http://www.fda.gov>

National Institutes of Health (NIH)

[www.nih.gov](http://www.nih.gov)

Office for Civil Right (OCR) – HIPAA

<http://www.hhs.gov/ocr/privacy/index.html>

National Cancer Institute (NCI)

<http://www.cancer.gov>

Cancer Therapy Evaluation Program (CTEP)

[ctep.cancer.gov](http://ctep.cancer.gov)

Cancer Trials Support Unit (CTSU)

<https://www.ctsu.org>

Quality Assurance Review Center (QARC)

[www.qarc.org](http://www.qarc.org)

Office of Biotechnology Activities (OBA)

[oba.od.nih.gov](http://oba.od.nih.gov)

### **DF/HCC Specific Sites**

Clinical Research Unit (CRU)

<http://www.dfhcc.harvard.edu/clinical-research-support/clinical-research-unit-cru/>

Clinical Trials Education Office (CTEO)

[www.dfhcc.harvard.edu/cteo](http://www.dfhcc.harvard.edu/cteo)

Office for Human Research Studies (OHRS)

<http://www.dfhcc.harvard.edu/ohrs/>

Quality Assurance Office for Clinical Trials (QACT)

<http://www.dfhcc.harvard.edu/clinical-research-support/quality-assurance-office-for-clinical-trials-gact/>