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[Application Appendix A, Co-Investigators and Study Staff](#)

[Application Appendix B, Additional Protections for Children](#)

[Application Appendix C, Drugs and Biologics](#)

[Application Appendix D – Request for Waiver of Informed Consent/Authorization](#)

[Application Appendix E – Excess Human Material](#)

[Application Appendix F – Nursing Implementation and Planning](#)

[Application Appendix G – Devices](#)

[Application Appendix H – Nonionizing Radiation](#)

[Application Appendix I – Radiation Exposure Form](#)

[Application Appendix J – Additional Protections for Neonates](#)

[Application Appendix K – Additional Protections for Pregnant Women and Fetuses](#)

[Application Appendix L – Research Limited to Use of Medical Records](#)

[Application Appendix M – Additional Protections for Individuals with Impaired Decision-Making Capacity](#)

Claim of Exemption from Institutional Review Board Review

[Expedited Review Application Form](#)

[Protocol Summary](#)

**Amendments (Changes to Approved Research)**

[Amendment Form](#)

[Co-Investigators and Study Staff Amendment Form](#)

**Continuing Review**

[Continuing Review Application](#)

[Adverse Event Log](#)

[Deviation / Violation Log](#)

[Protocol Summary](#)

**Reporting Adverse Events Occurring at Sunrise Health Sites**

[Serious and/or Unexpected Adverse Events](#)

**Reporting Adverse Events Occurring at Non-Sunrise Health Locations**

[IND / IDE Safety Report Form](#)

**Appendix**

1. [Department of Health and Human Services](#)
  - a. [The Belmont Report](#)
  - b. [Title 45 Code of Federal Regulations Part 46 Protection of Human Subject](#)
  - c. [Research That May Be Reviewed Through an Expedited Procedure](#)
  
2. [Food and Drug Administration \(FDA\)](#)
  - a. [21 CFR 50- Protection of Human Subjects](#)
  - b. [21 CFR 54- Financial Disclosure by Clinical Investigators](#)
  - c. [21 CFR 56 - Institutional Review Boards](#)
  - d. [21 CFR 312 - Investigational New Drug \(IND\) Applications](#)
  - e. [21 CFR 812 - Investigational Device Exemptions \(IDE's\)](#)
  - f. [FDA ICH Good Clinical Practice Consolidated Guidelines](#)
  - g. [FDA Examples of Nonsignificant Risk and Significant Risk Devices](#)
  
3. [National Institutes of Health \(NIH\)](#)
  - a. [Office of Grants and Contracts](#)
  - b. [Office of Recombinant DNA Activities](#)
  - c. [NIH Policy on Reporting Race and Ethnicity Data](#)
  - d. [NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research](#)
  - e. [National Human Genome Research Institute](#)

4. **Office for Human Subject Research Protection (OHRP)**
  - a. IRB Guidebook
  - b. OHRP Guidance (listed by topic)
  - c. OHRP Compliance Oversight Procedures