

Table of Contents

Section 1: General Human Research Protection Program Policies

1.1 Human Research Protection Program

1.2 Authority Granted by the Organization

1.3 UNMC Serving as Central IRB

1.4 UNMC Ceding Review to an External Central IRB

1.5 Requirements for Research Conducted at International Sites

1.6 IRB Composition, Leadership, Qualifications, & Responsibilities

1.7 IRB Member, Consultant, Staff COI Identification & Management

1.8 Investigational Activities Requiring IRB Review & Approval

1.9 Resources Necessary to Protect Subjects

1.10 Scientific and Other Committee Review of Research

1.11 HRPP Access to Legal Counsel

1.12 Sponsored Research

1.13 Compliance with ICH-GCP Guidelines

1.14 Research Subject to Department of Defense Regulatory Requirements

1.15 Research Subject to Department of Justice Regulatory Requirements

1.16 ORA Record Keeping Requirements

1.17 Retention of Research Records

1.18 Review and Approval of HRPP Policies and Procedures

1.19 IRB Signature Authority

1.20 Community Involvement in Research & Outreach Activities

1.21 Post-Approval Monitoring of Research

1.22 Assessment of the Effectiveness and Efficiency of the HRPP

1.23 HRPP Training Requirements and Opportunities for Research Personnel

1.24 HRPP Training Requirements for IRB Members

1.25 Financial Conflicts of Interest

1.26 PI Qualifications & Responsibilities

1.27 Research Personnel Qualifications and Responsibilities

1.28 External Investigator Assurance

1.29 ClinicalTrials.gov Reporting

1.30 Use of the Rapid Response IRB

1.31 Observers at IRB Meetings

1.32 Confidentiality of the Review Process

Section 2: Process of Review

2.1 Submission of Items for Review by the IRB

2.2 Full IRB Review

2.3 Expedited Review

2.4 IRB Review of Changes in Previously Approved Research

2.5 Criteria for IRB Approval

2.6 Exempt Research

2.7 Continuing Review of Research

2.8 Limited IRB Review

2.9 Closure of On-Going Research

Section 3: Special Issues

3.1 Assessing the Need for Increased Monitoring, Interim Continuing Review, and Verification from Sources Other than the PI

3.2 Data and Safety Monitoring

3.3 Privacy Interests and Confidentiality of Research Data

3.4 Use of Protected Health Information in Research

3.5 Subject Recruitment Through Advertisements

3.6 Subject Recruitment Through Direct Invitation

3.7 Finder's Fees and Recruitment Bonuses

3.8 Research Subject Compensation

3.9 Contraception Requirements

3.10 Pregnancy Testing

3.11 Collecting Data from Pregnant Partners of Research Subjects

3.12 Ethical Access

3.13 Use of Placebo or Wash-Out of Effective Therapy in Clinical Trials

3.14 Phase I and First-in-Human Studies

3.15 Managing Radiographic Incidental Findings in Human Subjects Research

Section 4: Vulnerable Populations

4.1 Additional Protections for Vulnerable Populations

4.2 Research Involving Pregnant Women, Human Fetuses, and Neonates (Nonviable or of Uncertain Viability)

4.3 Research Involving Prisoners

4.4 Research Involving Children

4.5 Local 407 Panel Review of Pediatric Research

4.6 IRB Review of Research Involving Subjects with Impaired Decision-Making Capacity

4.7 Research Involving Employees of the Organization and Students as Subjects

Section 5: Informed Consent

5.1 Obtaining Informed Consent from Research Subjects

5.2 Waiver or Alteration of Informed Consent and HIPAA Authorization

5.3 Use of a Telephone Consent Process

5.4 Waiver of the Requirement to Obtain Signed Consent Form

5.5 Use of the Short Form Consent Document

5.6 Exception from Informed Consent Requirements for Emergency Research

Section 6: FDA Regulated Research/Drugs & Devices

6.1 Research Involving Investigational and Marketed Drugs

6.2 Research Involving Investigational and Marketed Devices

6.3 Humanitarian Use Device (HUD)

6.4 Emergency Use of a Test Article

Section 7: Human Biological Materials and Data Registries

7.1 Banking Human Biological Materials

7.2 Use of Human Biological Material in Research

Section 8: AEs, Unanticipated Problems and Compliance

8.1 IRB Review of Adverse Events and Adverse Device Effects

8.2 IRB Review of Study Related Complaints

8.3 IRB Review of Unanticipated Problems Involving Risk to the Subject or Others

8.4 Review of Noncompliance Involving the PI and Study Personnel

8.5 Noncompliance by the IRB or Other Components of the HRPP

8.6 Study Hold, Suspension, and Termination

8.7 Reporting Incidents to Institutional Officials and Federal Agencies

Revision #6

Created 30 October 2019 18:11:27 by Autumn M Eberly

Updated 17 October 2023 17:10:51 by Robert A Lewis