IRB Guidelines and Policies

Section 1: Ethical Principles and Regulations

1.1 Statement of Ethical Principles and Regulatory Requirements for Human Subject Protection

Section 2: Definitions

2.1 Research and Human Subject Definition
2.2 Innovative Therapy Toolkit
2.3 Identifying QI/Education/Competency Evaluations as Clinical Research
2.4 Case Studies/Series

Section 3: Lines of Authority and Responsibilities

3.1 Jurisdiction of the Institutional Review Board
3.2 Institutional Review Board Autonomy and Functions
3.3 Institutional Official: Selection and Responsibilities
3.4 Institutional Review Board Chairperson: Selection, Responsibilities and Evaluation
3.5 IRB Member Selection and Evaluation
3.6 Consultants, Observers and Guests
3.7 Legal Counsel
3.8 Principal Investigator Responsibilities
3.9 Institutional Review Board Administrative Office Resources
3.10 Records and Files
3.11 Storage of Research Data and Informed Consent Documents
3.12 Reliance Agreements

Section 4: Credentials, Education and Training

4.1 Who May Participate on the Clinical Research Team
4.2 Education and Training: Investigators and Research Staff
4.3 Education and Training: Administrative Staff, IRB Members and Others
4.4 Who May Serve as Principal Investigator

Section 5: Research Activity Review

5.1 Operational Review Procedures: Full Committee Review
5.2 Department/Division Scientific Review of Human Subject Research
5.3 Exemptions
5.4 Expedited Reviews
5.5 Amendments and Revisions
5.6 Protocol Exception Requests
5.7 Continuing Review
5.8 Activation/Release and Approval Dates
5.9 Verification of No Material Changes Since Prior IRB Review
5.10 Additional Human Subject Protection Review
5.11 Emergency Exemptions
5.12 Disapprovals and Appeals
5.13 Data and Safety Monitoring Plans

Section 6: Reporting, Unanticipated Problems, Noncompliance

6.1 Reporting
6.2 Unanticipated Problems Involving Risks to Research Subjects and Others Including Adverse Events
6.3 Noncompliance: Investigations and Determinations
6.4 Suspensions, Terminations, Administrative Closures, Investigator-Initiated Voluntary Suspension or Termination
6.5 Research Related Injury
6.6 Managing Research Participant/Family Concerns and Complaints
6.7 Communication of Research Staff Concerns Raised During Clinical Research
6.8 Coordination Between Program for Patient Safety and Quality and Institutional Review Board Office

Section 7: Informed Consent/Assent

7.1 General Information - Informed Consent and Parental Permission
7.2 Special Considerations - Assent and Parental Permission
7.3 Waivers and Alterations of Informed Consent/Parental Permission/Assent Children
7.4 Informed Consent with Non-English Speakers
7.5 Decision Monitoring Program for Parents and Children Who Participate in Research
7.6 Obtaining Consent Remotely: Process and Documentation
7.7 Exception from Informed Consent Requirements for Emergency Research

Section 8: Drugs and Biologics

8.1 Drugs, Biologics and Dietary Supplements Regulations
8.2 Patients Hospitalized with Investigational Drug from Another Institution/Investigator or with Supply of Drug Not Approved in United States
8.3 Requirements for Investigators Who are Also Considered Sponsors of New Drugs

Section 9: Devices

9.1 Investigational Devices
9.2 Requirements for Investigators Who are Also Considered Sponsors of Investigational Devices
9.3 Humanitarian Use Devices

Section 10: Vulnerable Populations

10.1 Children
10.2 Incarcerated Youth and Prisoners
10.3 Women
10.4 Pregnant Women, Human Fetuses and Neonates
10.5 Wards of the State
10.6 International/Cross Cultural/ Community Based Participatory Research
10.7 Guidelines for Review of Research Involving Vulnerable Populations
10.8 Research Involving Adults with Decisional Impairment

Section 11: Guidance for Special Topics/Procedures

11.1 Extending Anesthesia and Sedation for Research Purposes
11.2 Skin Biopsy Guidelines
11.3 Research Blood Drawing Guidelines
11.4 Guidelines for Using the Internet to Conduct Research Activities
11.5 Guidelines for Research Funded by the Department of Education and School Based Research
11.6 Certificates of Confidentiality
11.7 Excess/Discarded Human Biological Specimens
11.8 Medical Record and Database Review Requests
11.9 Special Confidentiality Issues When Performing Research Related Imaging
11.10 Multi Site Research When a Children's Investigator Oversees an Operations, Coordinating or Statistical Center
11.11 Research Involving Department of Defense Funding
11.12 NIH Genomic Data Sharing Policy and Procedures
11.14 Extra Endoscopy Biopsies for Research Guidelines
11.15 Investigator Self Experimentation
11.16 Research Involving Department of Justice Funding
11.17 Requirements for Mental Health Safety Plans in Research Protocols

Section 12: Recruitment and Remuneration

12.1 Recruitment
12.2 Providing Remuneration to Research Subjects

Section 13: Process for Funding Agency Certifications

13.1 Coordination of Certification of Institutional Review Board Review and Acceptance of Grants and Contracts for Sponsored Research

Section 14: Conflict Of Interest

14.1 Institutional Review Board Conflict of Interest Policy
14.2 Conflict of Interest and Commitment Policy
14.3 BCH Public Health Service Investigator Conflict of Interest Policy
14.4 Residual Funds in Corporate Sponsored Clinical Research Activities