# Introduction to the Columbia Human Research Protection Program

## Institutional Leadership

### A. Development

1. **Process for Revising Standard Operating Procedures**

## Institutional Culture

### B. Requirement for Submissions

### C. Definitions of Research and Human Subject

### D. Rascal

## Standard Operating Procedures

### I. Human Research Protection Program

#### A. Institutional Review Boards and IRB Office

1. **IRB Administrative Staff**
   - **Organization**
   - **Administrative Support to Review Panels**
   - **Compliance Oversight Team**
   - **Education and Training**
   - **Confidentiality and Conflict of Interest**

2. **Committees within the IRB Office**
   - **Education and Training Committee**
   - **Policy Committee**
   - **Accreditation Committee**
   - **Rascal Committee**

#### B. Privacy Board

#### C. Office of Sponsored Projects Administration

#### D. Clinical Trials Office

1. **Research Pharmacy**
2. **IND/IDE Assistance Program**
3. **Clinical Trials Monitoring Assistance Program**
4. **Spanish Translation Center**

#### E. Office of Research Compliance and Training

#### F. Joint Radiation Safety Committee, Radioactive Drug Research Committee, and the Radiation Safety Office

#### G. Institutional Biosafety Office

#### H. Protocol Review and Monitoring Committee

#### I. Irving Institute for Clinical and Translational Research

#### J. NYP Pharmacy

#### K. NYP Patient Services Administration

#### L. Center for Bioethics

#### M. Department Chairs, Investigators, and Departmental Administrators

## Institutional Review Boards

### A. 1. Guiding Principles, Regulations, Statutes, Standards, Policies

2. **Structure**
# Scope of Authority

## Autonomy

### Research Conducted by Columbia faculty, employees, and students

#### Constitution of the Columbia IRBs

- Membership
- Qualification of Members
- Membership Diversity
- Alternate Members
- Use of Consultants

### Appointments, Terms, and Responsibilities of IRB Chairs, Vice Chairs, and Members

#### Chair/Vice Chair

1. Selection and Appointment
2. Length of Term/Service
3. Duties
4. Resignation/Removal
5. Education and Training
6. Liability Coverage for IRB Chairs and Vice Chairs

#### IRB Members

1. Selection and Appointment
2. Length of Term/Service
3. Duties
4. Attendance Requirements
5. Removal, Resignation
6. Liability Coverage for IRB Members
7. Education and Training
8. Confidentiality and Conflict of Interest

### The Role of Non-Columbia (External) IRBs in the Columbia HRPP

#### Reliance Agreements

- Reliance on a Non-Columbia IRB
- Reliance on a Non-Columbia IRB for a multicenter study, consortium, or study program
- Columbia Serving as IRB of Record for Non-Columbia Entities

#### Research Conducted at CU by Investigators Affiliated with Other Institutions

### Preparation of Submissions to the IRB

#### Preparation of Event Submissions

#### IRB Abbreviated Submission Process

1. Industry-sponsored multicenter studies
2. Student-initiated research
3. Grant-funded research

#### Personnel

1. Principal Investigators
2. Eligibility
3. Research and Human Subject Determinations
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| E | 3 | Notification: Suspension |
| F | | Documentation of review and approval |

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### IRB Pre-review and Review Criteria

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| 1 | Pre-review: New Protocols |
| 2 | Pre-review: Renewals (Continuing Review) |
| 3 | Pre-review: Modifications |
| 4 | Pre-review: Unanticipated Problem Reports |
| 5 | Pre-review: Termination (Closure) Requests |

### B

| IRB Criteria for Review |
| 1 | Risks to Subjects are Minimized (applies the principle of beneficence) |
| 2 | Risk/Benefit Ratio is Acceptable (applies the principle of beneficence) |
| 3 | Selection of Subjects is Equitable (applies the principle of justice) |
| 4 | Informed Consent Process is Appropriate (applies the principle of autonomy) |
| a | Special Consent Situations |
| 1 | Consent from Non-English Speaking Subjects |
| 2 | Consent for Audio- and Video Recording |
| 3 | Consent for Live Case Procedures |
| 4 | Same Day Consent for Elective Procedures |
| 5 | Consent from Women in Labor |
| 6 | Enrolling Illiterate Subjects |
| 7 | Enrolling Individuals with Physical Limitations Related to Writing |
| 8 | Obtaining Consent for Future Use of Specimens |
| 9 | Obtaining Consent for Future Contact for Research |
| b | Waiver of Some or All of the Elements of Informed Consent |
| 5 | Documentation of Informed Consent is Appropriate (applies the principle of autonomy) |
| a | Waiver of Written Documentation of Consent |
| 6 | Data and Safety will be Monitored (applies the principle of beneficence) |
| 7 | Privacy and Confidentiality will be Protected (applies the principle of beneficence) |
| 8 | Recruitment Methods and Advertising Material are Appropriate (applies the principles of autonomy and justice) |
| 9 | Additional Protections are in Place for Vulnerable Subjects (applies the principle of beneficence) |
| 10 | Potential Conflict of Interest of Investigators is Eliminated, Mitigated or Managed |

## VI

### IRB Review of Specific Events, Types of Research, and Types of Documents

| A | IRB Review of Specific Events |
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