

Institutional Review Boards, Contracting, and Other Legal Issues


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Building Research Capacity in the Dialysis Community

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Key Steps in a Typical Dialysis Research Study

Design

- Identify problem(s)
 - Formulate research question(s) and hypotheses
 - Design strategy
 - cohort study, clinical trial, interview/focus group(s)
 - Develop proposal outlining the protocol (plan)
 - recruitment, data collection, analysis, and dissemination plans
 - consider obtaining dialysis organization input
 - Secure research funding
 - Obtain Institutional Review Board (IRB)
 - Obtain dialysis organization approval to conduct study in clinic(s) including legal contracting
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Conduct

- Train clinic staff on protocol
- Recruit study participants
- Collect study data
 - Medical record information, blood samples, interviews
- Analyze study data and interpret findings
- During conduct, consider need for re-trainings of clinic staff and/or updates to participants and facilitators

Disseminate

- Share key findings with important stakeholders (e.g., patients, clinicians, administrators, policymakers)
 - Manuscripts published in journals
 - Presentations, conferences, and meetings
 - Tools and resources
 - Websites, social media
- Provide follow-up to participants and facilitators
- Identify areas for future research and potential collaborators, funders

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- Ongoing review by IRB and Data and Safety Monitoring Board

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What is an Institutional Review Board (IRB)?

A committee that is mandated by law to protect the rights and welfare of human subjects participating in research

Code of Federal Regulations
TITLE 45
PUBLIC WELFARE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
PART 46
PROTECTION OF HUMAN SUBJECTS

Why is an IRB Necessary?

IRB Members

- Not involved in study
- Have diverse expertise
- Include lay person(s)
- Have oversight authority

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What IRBs Review

- Protocol
 - Scientific rationale, risk, burden, sample size, analytic approach, protocol changes
- Consent forms
 - Readability, comprehension
- Study progress
 - Enrollment, retention
 - Adverse events
 - Protocol violations
 - Unanticipated events

All of this takes time and adds to the “cost of doing research”

Multiple IRBs

<i>Pros</i>	<i>Cons</i>
<ul style="list-style-type: none">• Lots of review• Local issues/context considered	<ul style="list-style-type: none">• Inefficient• Lack of agreement across IRBs• Paradoxical reduction in protections?

New NIH policy: for all multicenter trials, institutions must agree to use a single IRB of record

Elements of Consent Forms

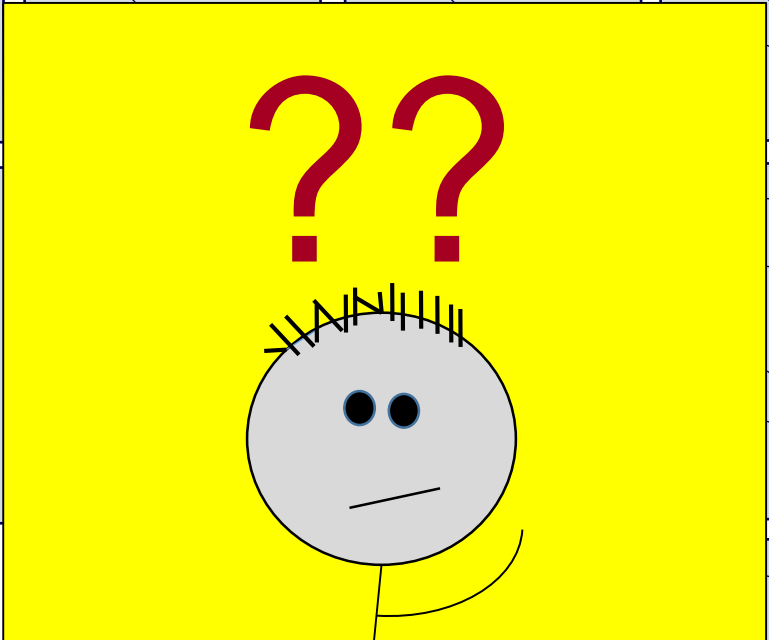
All Consent Forms

- A statement that the study involves research
- Purpose of research
- Duration of participation
- Description of experimental procedures
- Risks or discomforts
- Benefits
- Available alternatives
- Confidentiality protection

Greater than Minimal Risk Studies

- Compensation for injury
- Research participant rights
- Voluntary participation

Typical Consent Form

<p>Consent Form Protocol #557</p> <p>1</p>	<p>2</p>			<p>5</p>	<p>6</p>	<p>7</p>	
<p>8</p>	<p>9</p>				<p>12</p>	<p>13</p>	<p>14</p>
<p>15</p>	<p>16</p>	<p>17</p>	<p>18</p>	<p>19</p>	<p>20</p>	<p>My signature indicates my willingness to.....</p> <p>21</p>	

Lots of Interest in Simplifying Consent



What Do Contracts Address?

- Scope of Work
- Record keeping
- Data use and ownership
- Publishing and
- Authorship
- Budget
- Samples
- Intellectual property, discovery, inventions
- Study termination

Note: Researchers are NOT lawyers!

Data and Safety Monitoring Board

- Typically, but not always, needed for clinical trials
- Convened specifically for the study (in contrast to a standing IRB)
- Complements, but does not replace, IRB's activities
- Reviews safety and quality
- Reports provided to IRB and sponsor
- Some duplication with other oversight groups: e.g., adverse event review

Key Players in Regulatory Processes

- From the investigator's perspective
 - Home institution's IRB, Other sites' IRBs, Commercial IRB
 - Dialysis provider organization
 - Research "office"
 - Local facility's leadership (administrative, nursing, medical)
 - Contracting groups (home institution, dialysis provider organization, other participating sites, core facilities...)
 - Data and Safety Monitoring Board

Key Points

- Regulatory aspects of research are critically important for protecting rights and welfare of participants as well as other stakeholders
- Devoting time and effort to the regulatory aspects of research should be anticipated