The Revised Common Rule

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Objectives

Describe the Changes that Affect the UU IRB

What does this mean for ERICA?

UPDATE: The postponement to January 2019…what does this mean for UU IRB?
Changes that Affect the UU IRB

Informed Consent Changes

- Defined concept of ‘broad consent’
- New concept of ‘concise summary’ and new items to disclose
- Public posting of consent documents
- Changes to waivers of consent
Informed Consent Changes

‘Broad Consent’

The new rule includes an option to obtain ‘broad consent for the storage, maintenance, and secondary research use of identifiable private information and identifiable biospecimens.’

**Impact @ UU IRB:**

- Though this was never formally defined in the regulations before 2018, the UU IRB has been employing this method for tissue banking and repositories for many years. The UU IRB Tissue Banking policy addresses nearly all of the new components of the rule; updates to this policy will be made.

- For leftover clinical samples, UU could make an institutional process for obtaining broad consent up front.
  - Waivers still acceptable for leftover clinical samples.
Informed Consent Changes

‘Concise Summary’

‘Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research.’

Prohibition on the ‘mere’ listing of ‘isolated facts’ in consent forms.

Impact at UU IRB:

- The consent template will be re-drafted to include a section for the concise summary.
- Example consent documents will be posted to illustrate good ways to present information.
- New requirements on the Informed Consent checklist.
Informed Consent Changes

New items to disclose in the Consent Document

A statement of whether or not identifiable private information or biospecimens may be used or distributed for future research.

A statement of whether or not clinically relevant research results will be disclosed to subjects, and if so, under what conditions.

**Impact @ UU IRB:**

- The consent template will be re-drafted to include these statement.
- Discussion on possible policy for release of clinically relevant research results (already exists for incidental genetic results).
- New requirements on the Informed Consent checklist.
Public posting of Consent Documents

‘For each clinical trial conducted or supported by a Federal department or agency, on IRB-approved informed consent form used to enroll subjects must be posted by the awardee on a publicly available Federal website…’

Time for posting: ‘no later than 60 days following the last study visit by any subject.’

Impact @ UU IRB:

- Unclear
- The ‘Federal website’ does not yet exist.
- Which consent form should be posted?
- Who is responsible for posting – investigator or institution?
Changes to waivers of consent

Waiver of Informed Consent now requires a finding that research could not be conducted with de-identified biospecimens or information.

No more waivers of consent for recruitment only.

Waiving signatures for members of ‘distinct cultural groups’ where ‘signing documents is not the norm.’

**Impact @ UU IRB:**

- IRB application updates to include the new changes
- Board member checklist updates to include the new changes.
Changes that Affect the UU IRB

Changes to the Definition of Research & Exemption Categories

- Addition of 4 defined activities to be excluded from ‘research’
- New IRB exemption categories
## Levels of IRB Review Authority

<table>
<thead>
<tr>
<th>No IRB Review</th>
<th>Some IRB Review</th>
<th>Full IRB Review</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Non-Human Subject Research</strong></td>
<td><strong>IRB Exempt Research</strong></td>
<td><strong>Minimal Risk Research &amp; Greater Than Minimal Risk Research</strong></td>
</tr>
<tr>
<td>= No humans</td>
<td></td>
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<tr>
<td><strong>And/or</strong></td>
<td></td>
<td></td>
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<tr>
<td>No research</td>
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</table>

Common rule changes or clarifies these two levels of projects.
Activities to be Excluded from ‘Research’

Research
A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

45 CFR §46.102(d)

Common Rule now officially says these are not to be interpreted as ‘Research’:
1. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship)
2. Public health surveillance activities
3. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or investigative purposes
4. Authorized operational activities…in support of intelligence, homeland security, defense, or other national security missions.

Impact @ UU IRB:
None. These were already in guidance as not research.
We have already been applying this standard.
Currently 6 Federal Exemption Categories

1. Common education settings
2. Surveys, interviews, focus groups, observation of public behavior
3. Surveys/interviews of public officials
4. Use of existing data/samples if recorded non-identifiably
5. Evaluation of public benefit programs
6. Taste and food quality evaluation

Common Rule now adds:

1. Benign behavioral interventions with adults – deception mostly excluded
2. Expands #4 to use identifiable information if protected according to HIPAA
3. Data and tissue storage and maintenance under ‘broad consent’; does not cover prospective collection
4. Data and tissue use if ‘broad consent’ was obtained, as long as results are not returned to participants
**Impact @ UU IRB:**

1. Extra category for federal studies. No impact on non-federal studies; local policy already covers this type of research under non-federal exemption.
2. Extra option for federal studies. No impact on non-federal studies...
3. Only useful if UU makes an institutional process for left over clinical samples.
4. Extra category for federal studies. No impact on non-federal studies...

**Common Rule now adds:**

1. Benign behavioral interventions with adults – deception mostly excluded
2. Expands #4 ← to use identifiable information if protected according to HIPAA
3. Data and tissue storage and maintenance under ‘broad consent’; does not cover prospective collection
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Changes that Affect the UU IRB

Changes to the Study
Review Requirements

- Cooperative research must use a single IRB
  (Next presentation)
- Fewer continuing reviews
Changes to the Study Review Requirements

No longer need continuing review if...

- the study qualifies for expedited review
- the study has research the state of involving only the analysis of data or accessing follow-up clinical data from procedures that the subjects would undergo as part of clinical care.

Impact @ UU IRB

- Further reduce the number of continuing reviews; we have already ‘field tested’ this for non-federal studies.
- Updates to checklists in ERICA
- More reminders for study closure
Changes that Affect the UU IRB

What does the 1-year postponement mean for UU IRB?

- There are some changes that reduce burden on IRBs:
  - No expiration dates for expedited research.
  - Expanded exemption categories
  - No waivers of consent for recruitment needed

We are already doing this for non-federal studies and will keep this practice until the Common Rule changes are effective.

Unfortunately, we will still have to use waivers of consent for recruitment for VA studies until the Common Rule changes are effective.
Objectives

Describe the Single IRB (SIRB) Model

Describe the Human Research Protection Program (HRPP)

Describe the roles & responsibilities for the SIRB Model

University of Utah Collaborations
The Single IRB (SIRB) Model

Multi-Site | Cooperative Research
The Single IRB (SIRB) Model

When is it required?

NIH POLICY
Required for all multi-site, domestic, non-exempt NIH research with grant application receipt after January 25, 2018.

COMMON RULE
Required for all domestic, cooperative research that is ready for IRB submission on or after January 20, 2020.

### The Single IRB (SIRB) Model

#### Choosing a SIRB

<table>
<thead>
<tr>
<th>Study by study</th>
<th>Lead study team’s home institution’s IRB</th>
<th>Selection by the study sponsor</th>
<th>IRB with specialties or experience with a type of research</th>
<th>No IRB is required to act as a SIRB</th>
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<tbody>
<tr>
<td>-- or --</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Network specific</td>
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</table>
# The Single IRB (SIRB) Model

## When is it not required?

<table>
<thead>
<tr>
<th>Exempt research</th>
<th>If the designated SIRB is unable to meet the needs of specific populations</th>
<th>Where local IRB is required by federal, tribal, or state laws</th>
<th>Research conducted under career development, research training or fellowship awards</th>
<th>Studies that involve more than one site but the sites have different roles in carrying out the research</th>
</tr>
</thead>
</table>
The Single IRB (SIRB) Model

Costs of SIRB – NIH Policy

**INDIRECT COSTS**
Institutions may use indirect costs to fund their site-specific costs for IRB review

**DIRECT COSTS**
Institutions can charge for additional costs incurred for SIRB review
The Human Research Protection Program
Human Research Protection

Human Research Protection Program (HRPP)

- IRB
- HIPAA Privacy Office
- Conflict of Interest
- Training, Qualifications, & Resources
- Ancillary Reviews
- State Law & Institutional Requirements
SIRB Roles & Responsibilities
SIRB Process Stakeholders & Roles

1. Single IRB
2. Relying Site HRPP
3. Lead Study Team
4. Participating Study Team
Stages of SIRB Reliance & Review

1. Protocol & Consent Development
   - Consent/authorization document and process
   - Recruitment plan
   - Data and safety monitoring plan

2. SIRB Reliance Decision

3. Initial Review

4. Ongoing Review & Oversight
Public Training Modules
IRB Website → Single IRB Review → SIRB Learning Videos

Training Module for UU Credit
RATS Program
www.education.research.utah.edu
RATS Online Classes: UU IRB, Single IRB Model

Reliance Consultation
IRB Website → Single IRB Review → Reliance Consultation Request
University of Utah
Collaborations
National Collaborations on the SIRB Model

**Trial Innovation Network**
- National SIRB Education Plan
- Electronic Systems Development
- Electronic Informed Consent Builder

**CTSA SIRB Supplements**
- Electronic Systems Model for SIRB
- Establishing a CIRB for an NIH Research Network

**SMART IRB & Harmonization Committees**
- Standard Reliance Agreement (SMART IRB Agreement)
- SIRB Cost & Charging Model
- Common Consent Templates
- Harmonizing IRB Reporting Policies