

IRBMED Seminar Series

Spring, 2017

**Revisions to the Federal Policy for the Protection of Human Subjects
'Common Rule'
*Changes Ahead***

**“Unchecking the Box” and
Single IRBs for Multi-site Research, External IRBs**

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“Unchecking the Box”

- Current federalwide assurance (FWA) process allows institutions to indicate that the Common Rule applies to all research regardless of funding source
- Michigan ‘unchecked the box(es)’ as part of our Flexibility Initiative

We were the first institution to take full advantage of the “Flexibility”

2 year approval periods

New exemption categories

Many institutions followed our lead

FWA and the Boxes

- (b) *Optional for U.S. institutions:* This Institution voluntarily elects to apply the following to all of its non-exempt human subjects research regardless of the source of support, except for research that is covered by a separate assurance issued by another U.S. federal department or agency that has adopted the Common Rule:
- ***The Common Rule*** (see section 3 of the Terms of the FWA for a list of U.S. federal departments and agencies that have adopted the Common Rule and the applicable citations to the Code of Federal Regulations)
- ***The Common Rule and subparts B, C, and D of the HHS regulations at 45 CFR part 46***

“Unchecking the Box”

- Preamble confirms the elimination of the “check the box” option on the assurance mechanism
- Further simplifications to the assurance process:
 - No statement of ethical principles required
 - No IRBs designated on the FWA
- Federal regulations apply to federal research
- Non-federally sponsored research is not subject to the Common Rule and Subparts B, C, D
 - Apply equivalent protections / policies
 - This is not a freebie
 - Subjects expect to be safe

Single IRBs (Cooperative Research 45 CFR 46.114)

- Required by January 20, 2020 for multi-site research
 - Federally sponsored
 - Involves more than one institution
 - Located in the US
 - Reliance on a single US IRB for portion conducted in the US
- Not subject to the provision
 - Where one study/one IRB is required by law (tribal law)
 - Federal agency determines reliance on a single IRB is not appropriate*
 - *The nature of these determinations is unknown. OHRP indicated that agencies has substantial flexibility to remove single studies and broad groups of studies from this requirement.
- Options for use of a single IRB
 - Not federally sponsored
 - International sites

Single IRBs

- ...each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy.

This is existing language but takes on new meaning

- When relying on a single IRB, only IRB regulatory oversight is ceded to the single IRB – many of the study team obligations remain in-house such as:

All ancillary committee reviews (e.g., CRAO, Research Pharmacy)

Conflict of Interest review and management plans

Monitoring

Maintaining compliance with educational requirements

Contrast:

NIH Single IRB Requirement

- Implementation date of September 25, 2017
 - Applies to all NIH sponsored multi-site studies
 - This is not limited to clinical research
 - Applies to domestic research
- Not subject to the revision
 - Requests for exceptions that are not based on a legal, regulatory, or policy requirement will be considered if there is a compelling justification for the exception. The NIH will determine whether to grant an exception following an assessment of the need.

Single IRB

Naming Conventions for Agreements

- Reliance Agreements
- Cooperative Agreement
- IRB of Record Agreements
- Master Service Agreements

How do they work?

- Collaborating institutions complete the agreement document
- Roles and responsibilities are apportioned
- Assure all internal institutional documents are in alignment with the arrangements
 - Standard Operating Procedures
- Does not require OHRP or FDA signature or approval

Single IRB Benefits

- Reduces duplicative review across sites
- Reduces variability of the study design across sites
- Decreases cumulative review time
- Decreases burdens on local IRBs
- Costs are reduced locally and for the study as a whole

Preamble

- ...we believe it is likely that the institutional policies, procedures, and standard documents needed to implement this regulatory provision will, over time, become increasingly standardized, which will significantly minimize the burden on institutions associated with this requirement.
- This proposal was one of the most commented on in the NPRM, receiving more than 300 comments.
- Research institutions tended to oppose this proposal, while individuals (i.e., those who were not providing comment in an official institutional capacity) and scientific organizations tended to support the proposal.

Single IRB Challenges

- Quality and thoroughness of review
- Consideration of local context
- Apportionment of institutional liability
- Managing 'shared' control and accountability
- Developing / agreeing to different standardized procedures

- Cost models (direct costs can be separated from indirects)
 - Very difficult
 - Cost shifting to the Reviewing IRB
 - Some ease of burden for the Relying IRB
- Institutional risk/liability
- Larger institutions expected to disproportionately accept the Reviewing IRB role?

External IRBs

- Primarily
 - Commercial (independent)
 - Academic
 - Hospital based (AMC)
- Michigan Medicine has relationships with 4 commercial IRBs
 - Western
 - Schulman
 - Quorum
 - Chesapeake

IRBMED as the Single IRB?

Decisions are on a case by case basis

Do we hold the grant

Are we the coordinating center

How many sites

Academic merit

Monitoring requirements

Study team expertise

IRB expertise on topic

Subject risk level

Submit a request to IRBMED

For Fun – HHS by the numbers

- 202,617 annual reviews of multi-institutional protocols take place,
5 reviews per multi-institutional protocol,
- Therefore, 40,523 multi-institutional protocols are reviewed each year.
- 16,209 (40 percent) of these multi-institutional studies are funded by NIH already be subject to NIH's single IRB review policy.
- Elimination of 97,256 annual reviews
 - 32,211 would have undergone convened initial review
 - 14,472 would have undergone expedited initial review
 - 34,896 would have undergone convened continuing review
 - 15,678 would have undergone expedited continuing review
- Read more ~p. 108 of the Final Common Rule (Preamble)

Questions?

Seminar Series Wrap-Up

- Fill out note cards with any questions
- Provide recommendations relative to topics / format for upcoming educational delivery on the Common Rule

WE THANK YOU FOR COMING
STAY TUNED