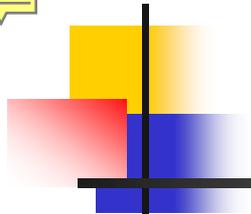


NIH Policy Mandate for a Single IRB of Record for Multi-site Research: Options for Implementation

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Emory University

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University of Michigan



Draft NIH Policy on the Use of a Single IRB for Multi-Site Research

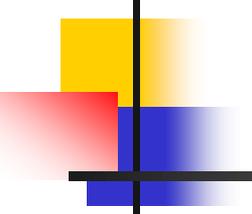
Scope

NIH generally will require all domestic sites of multi-site NIH-funded studies to use a single IRB of record.

While foreign sites in multi-site studies will not be expected to follow this Policy, they may elect to do so.

Responsibilities

All sites participating in a multi-site study will be expected to rely on a single IRB to carry out the functions that are required for institutional compliance with IRB review.

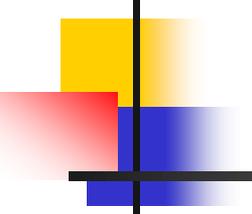


Draft NIH Policy on the Use of a Single IRB for Multi-Site Research

All participating sites will be responsible for meeting other regulatory obligations, such as obtaining informed consent and reporting unanticipated problems and adverse events to the single IRB of record, including local review for COI, IBC, Investigational Drug and Device Services, Radiation Safety, etc., and state or local requirements.

Agreements between the single IRB of record and other participating sites will be needed in accordance with 45 CFR part 46.

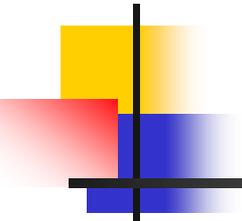
As necessary, mechanisms should be established to enable the single IRB of record to consider local context issues during its deliberations.



Draft NIH Policy on the Use of a Single IRB for Multi-Site Research

Identification of the IRB that will serve as the single IRB of record will be the responsibility of the extramural applicant or offeror, or the intramural principal investigator.

Use of the designated single IRB will be a term and condition of award. If the agreed-upon single IRB is a fee-based IRB, these costs will be included in the Notice of Award as a direct cost.

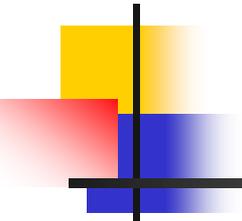


Exceptions to the Policy

Exceptions

Exceptions to the expectation to use a single IRB may be made with appropriate justification.

Exceptions will be allowed only if the designated single IRB is unable to meet the needs of specific populations or where local IRB review is required by federal, tribal, or state laws or regulations.



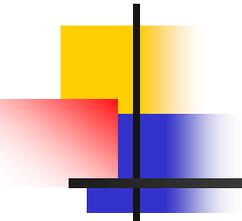
Problems We See With the Draft Policy

One-size fits all – may not result in the best IRB review model for the specific project.

Creates concerns about how and when a reviewing IRB is identified and about IRB and institutional HRPP protections that are impacted.

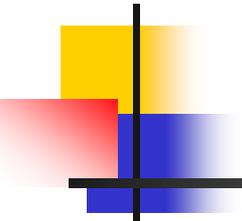
Has potential to adversely affect investigator timelines and to add burden in preparation of NIH funding proposals.

Single IRB review can create new cost burdens for the reviewing institution



Various Options

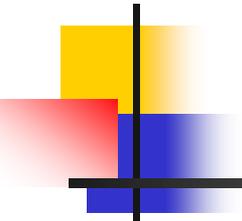
- Cede to Independent (Commercial) IRBs
- Modify standard IRB processes and systems
- Create new IRB process and systems
- Direct charge IRB costs
- Others?



Option 1 - Cede to an Independent (Commercial) IRB

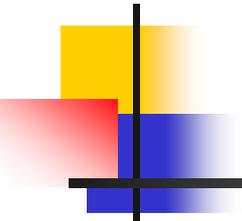
Benefits to academic institutions:

- The core business of Independent IRBs is to conduct reviews for external research sites.
- The business model of Independent IRBs is usually based on multi-site performance of research.
- Established, successful Independent IRBs have in-house or on-retainer legal counsel to evaluate local legal issues.
- Standard business practices for negotiating/managing reliance agreements.
- Standard business practices for institution-specific consent language.
- Software systems designed for external, novice users.



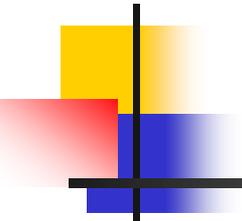
Option 1 - Cede to an Independent IRB (cont.)

- Responsibility for IRB oversight is shifted externally
- Flexible “sizing” of program
- Immediate access to skilled personnel
- Available resources: 20-30 staff per IRB
- Full reimbursement of costs per NIH statements – No costing analysis required



Option 1 - Challenges?

- Perception of the quality of the review; consideration of local context for each site may not be well-accounted for.
- Get over it!! The NIH Policy devalues the role of local context. This will be dramatically changed, irrespective of the model used.
- New “partner” institutions will need to initiate relationship with IRB – This is no different than what will need to happen with lead institution’s internal IRB.



Option 2 - Utilize Existing IRB Meeting Infrastructure at the NIH-awarded Institution

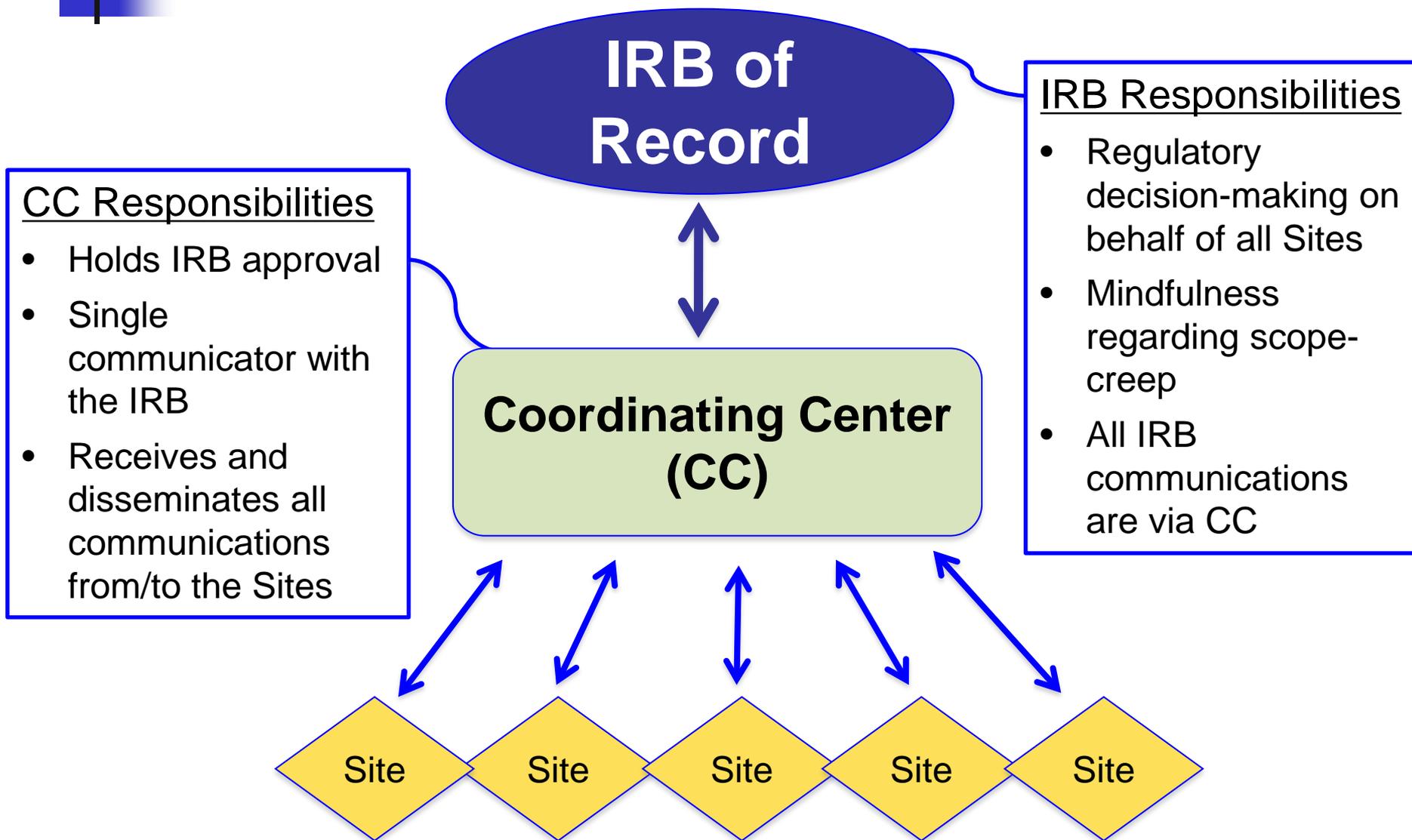
Benefits:

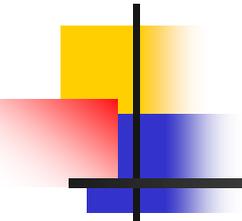
- IRBs are already constituted with trained members
- Standard SOPs already developed

Challenges:

- Reliance agreements must be developed and negotiated with each site
- Existing IRB membership may not represent necessary expertise or local context of the participating sites
- Multi-site SOPs must be developed
- Process and meetings frequency may not be flexible enough to support multi-site research (e.g. IT System limitations)
- Site monitoring must be developed and implemented
- Financial considerations (e.g. who does the work?)

Option 2 - Utilize Existing IRB Meeting Infrastructure at the NIH-awarded Institution

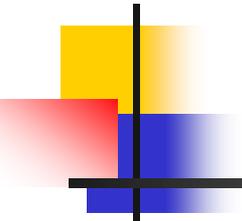




Option 3 - Create a Virtual IRB Meeting Infrastructure Hosted at the NIH-awarded Institution

Benefits:

- IRB staff are already trained and in place
- IRB membership may be easily amended via the use of alternates from participating sites to adjust for expertise and local context; a single IRB may be readily reconstituted on a study-by-study basis
- Virtual (teleconference) conduct will decrease costs/time associated with in-person meetings
- Meetings may be convened with flexibility of timing to accommodate multi-site time-sensitivity

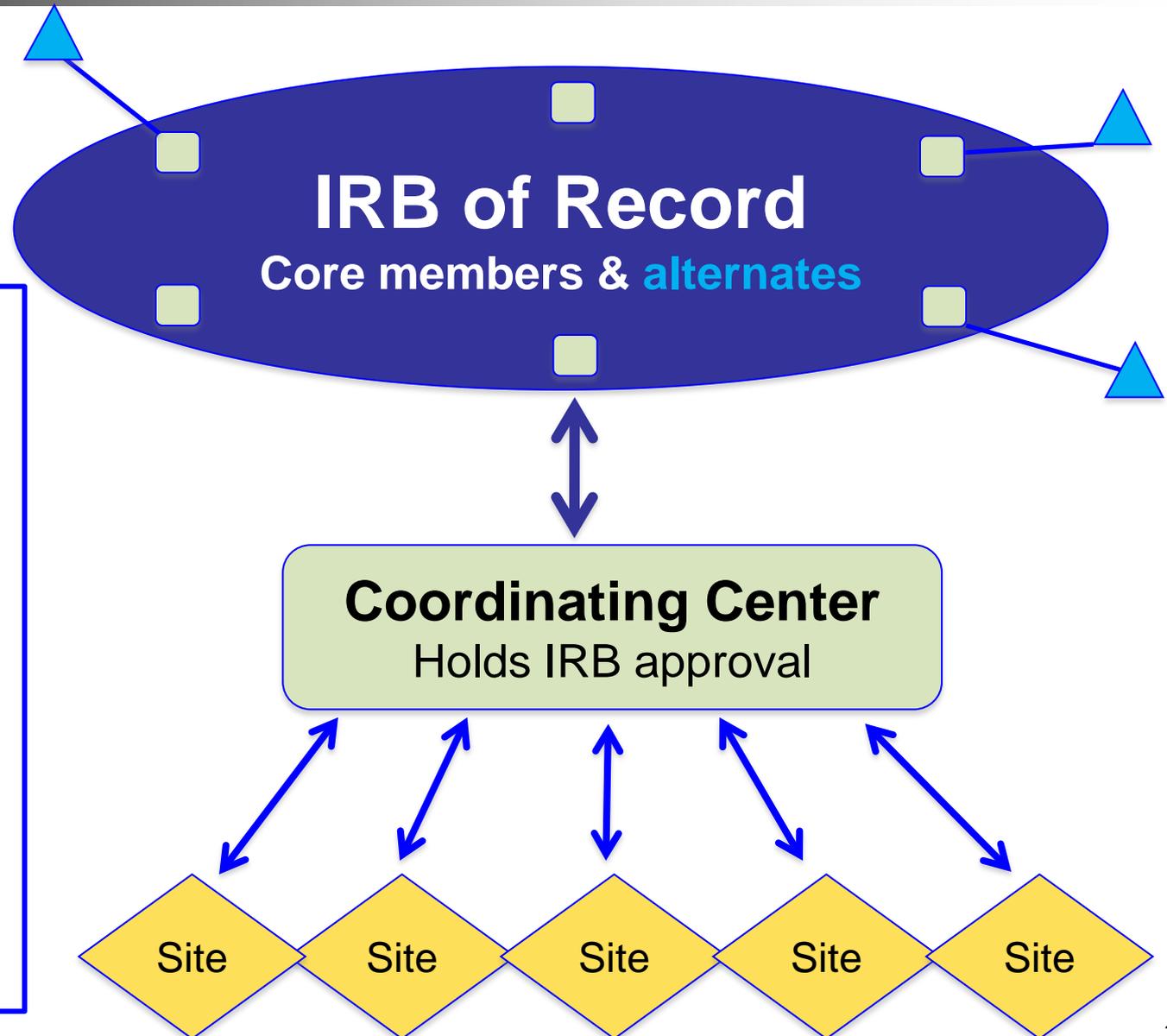


Option 3 - Create a Virtual IRB Meeting Infrastructure Hosted at the NIH-awarded Institution

Challenges:

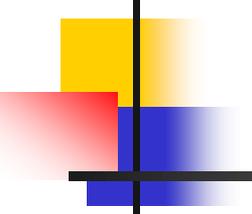
- Develop and negotiate a standard reliance agreement
- IRB members outside of the NIH-awarded institution will need appropriate training and awareness of SOPs and multi-site operations
- Multi-site SOPs must be developed
- Site monitoring must be developed and implemented
- Financial considerations (e.g. Cost to establish and maintain)

Option 3 - Create a Virtual IRB Meeting Infrastructure Hosted at the NIH-awarded Institution



Virtual IRB

- Flexibility of membership via expanded alternate pool
- Can be completely reconstituted
- Readily addresses local context/expertise
- Decreased facility costs (i.e., no lunches!)



Option 4: Direct Charge the Full Cost of Institutional IRB Review

Exclude IRB costs from the institutions F&A rate and direct charge IRB costs for federal studies as institutions do for industry studies.

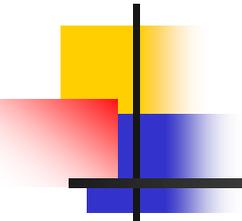
Is this inconsistent with the Uniform Guidance?

[Appendix III to Part 200—Indirect \(F&A\) Costs Identification and Assignment, and Rate Determination for Institutions of Higher Education \(IHEs\)](#)

C. Determination and Application of Indirect (F&A) Cost Rate or Rates

8. Limitation on Reimbursement of Administrative Costs

b. Institutions should not change their accounting or cost allocation methods if the effect is to change the charging of a particular type of cost from F&A to direct, or to reclassify costs, or increase allocations from the administrative pools identified in paragraph B.1 of this Appendix to the other F&A cost pools or fringe benefits.



Questions or Comments?