SMART TALK

A Community Forum to Explore Issues Surrounding Single IRB Review

Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, Federal Contract 75N95023C0008

FYI

Questions for the presenter or SMART IRB Team are welcome! Please post these under ‘Q/A’

Questions for fellow attendees should be posted under ‘Chat’

A link to today’s recording will be emailed to attendees. A recording will be posted on the SMART IRB website

Your feedback is valued! Please complete the survey at the end of the SMART Talk! The survey will be emailed as well.

What Is SMART IRB?

SMART IRB is…

A federally funded project to support institutions and researchers in the implementation of single IRB

SMART IRB provides…

A global IRB reliance agreement

An Online Reliance System to initiate and track reliance

Zero Cost Education, Guidance, and Resources

SMART IRB is NOT…

An IRB

An electronic system for Reviewing IRBs to receive studies for review

Reach out to a SMART IRB Ambassador

Aaron Kirby
Harvard Catalyst

Polly Goodman
Harvard Catalyst

Jeremy Lavigne
Harvard Catalyst

Ada Sue Selwitz
University of Kentucky

https://smartirb.org/ambassadors/

Carissa Minder
Washington University in St. Louis

Kathy Lawry
AAHRPP

Nichelle Cobb
AAHRPP

Stacey Goretzka

Lubabah Helwani
University of Southern California

An Update on SMART IRB Reliance Agreement V3.0

Today's presenters:

- **Barbara Bierer,** Principal Investigator and Program Director, SMART IRB; Program Director, Regulatory Foundations, Ethics, and Law Program, Harvard Catalyst
- **Emily Fogler,** Legal Counsel to SMART IRB, Epstein Becker and Green
- **Polly Goodman,** Sr. Associate Director, Regulatory Affairs Operations, SMART IRB
- **Jeremy Lavigne,** Senior SMART IRB Officer, SMART IRB

Moderator:

- **Nichelle Cobb**, Senior Advisor, SMART IRB; Senior Advisor for Strategic Initiatives, Association for the Accreditation of Human Research Protection Programs

SMARTIRB.org

SMART IRB Agreement V3.0 Update

Public Comments and Next Steps

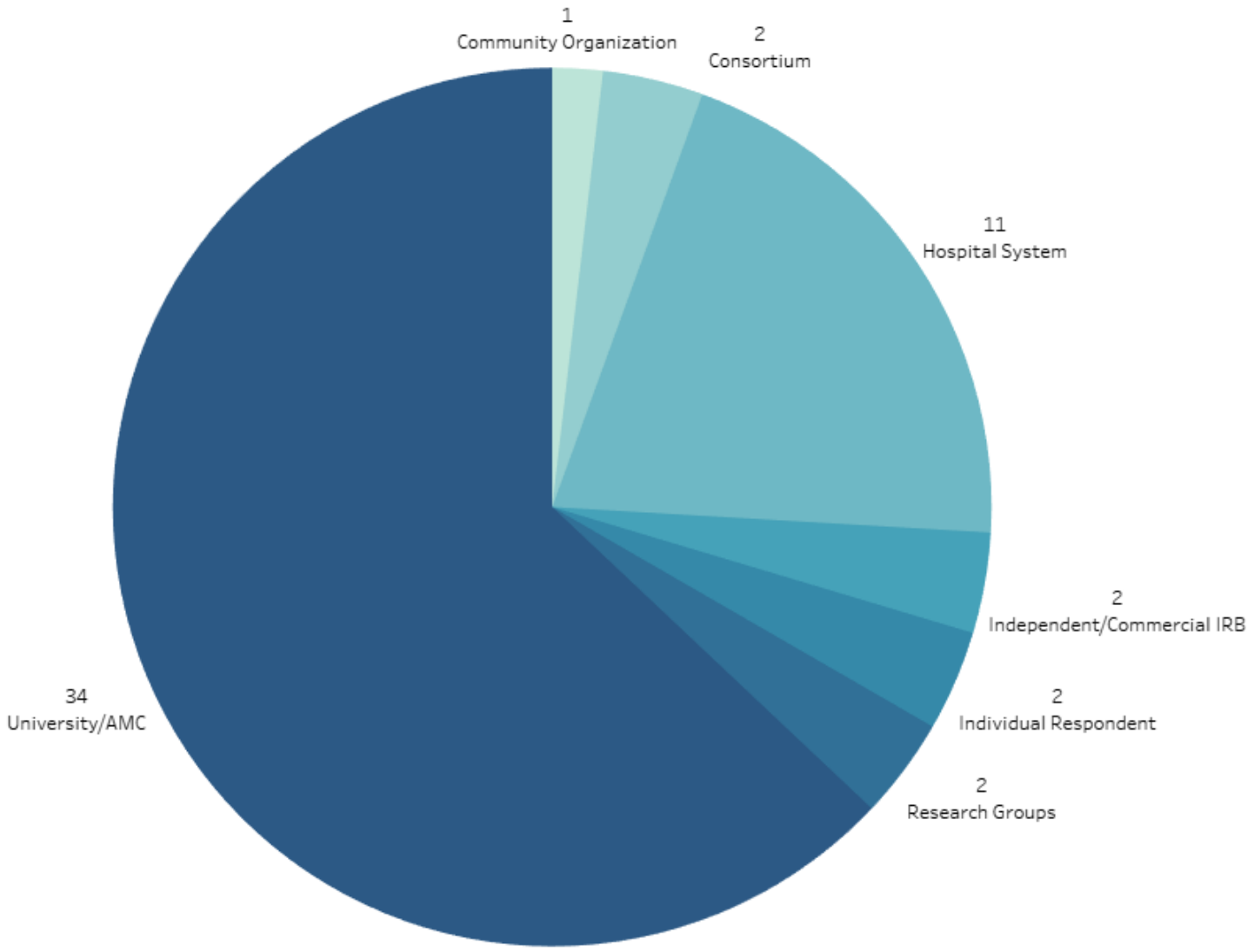
SMART IRB Reliance Agreement V3.0 - Public Comment Period

Public Comment Period

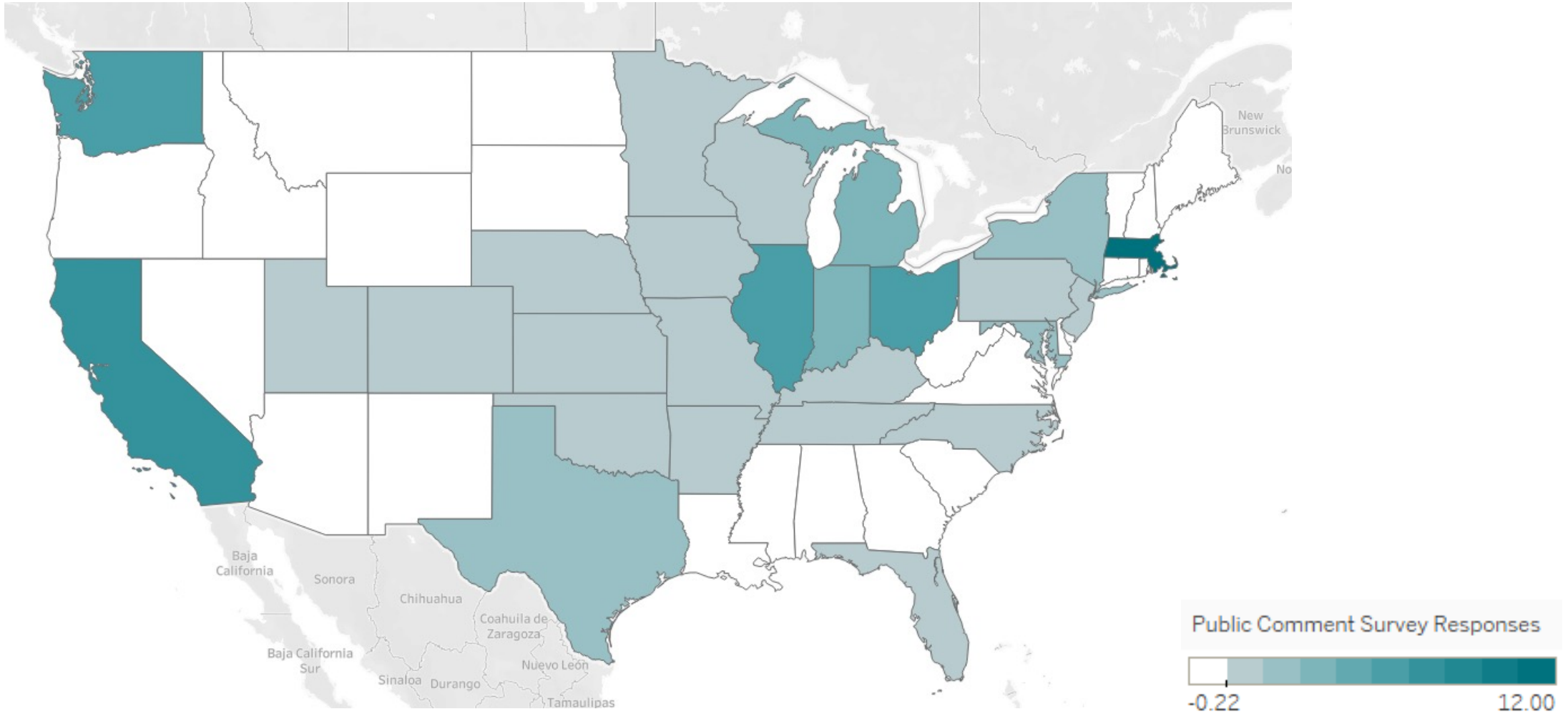
- Open from 11/15/23 – 2/15/24

Total Comments Received

- 250 unique comments received from 54 different institutions



SMART IRB Agreement V3.0 Public Comments



Summary of Topics for Public Comments Received

- Informatics Improvements
- Requirements for Joining SMART IRB
- Exemption Determinations / Exempt Research
- Grandfathering
- Definitions
- Mandated Policies
- Reliance Requests & Required Information
- Education/Training/Qualifications/ Resources
- Notifications
- Compliance with Applicable Laws, Regulations & Institutional Requirements
- HIPAA
- Confidential Information
- Insurance
- Consent Forms
- Local Considerations
- Injury Coverage
- Monitoring: Quality Assurance/Quality Improvement Function/ Program
- External Reporting
- Governing Law and Venue
- Force Majeure
- Termination
- Indemnification
- Other Editorial changes

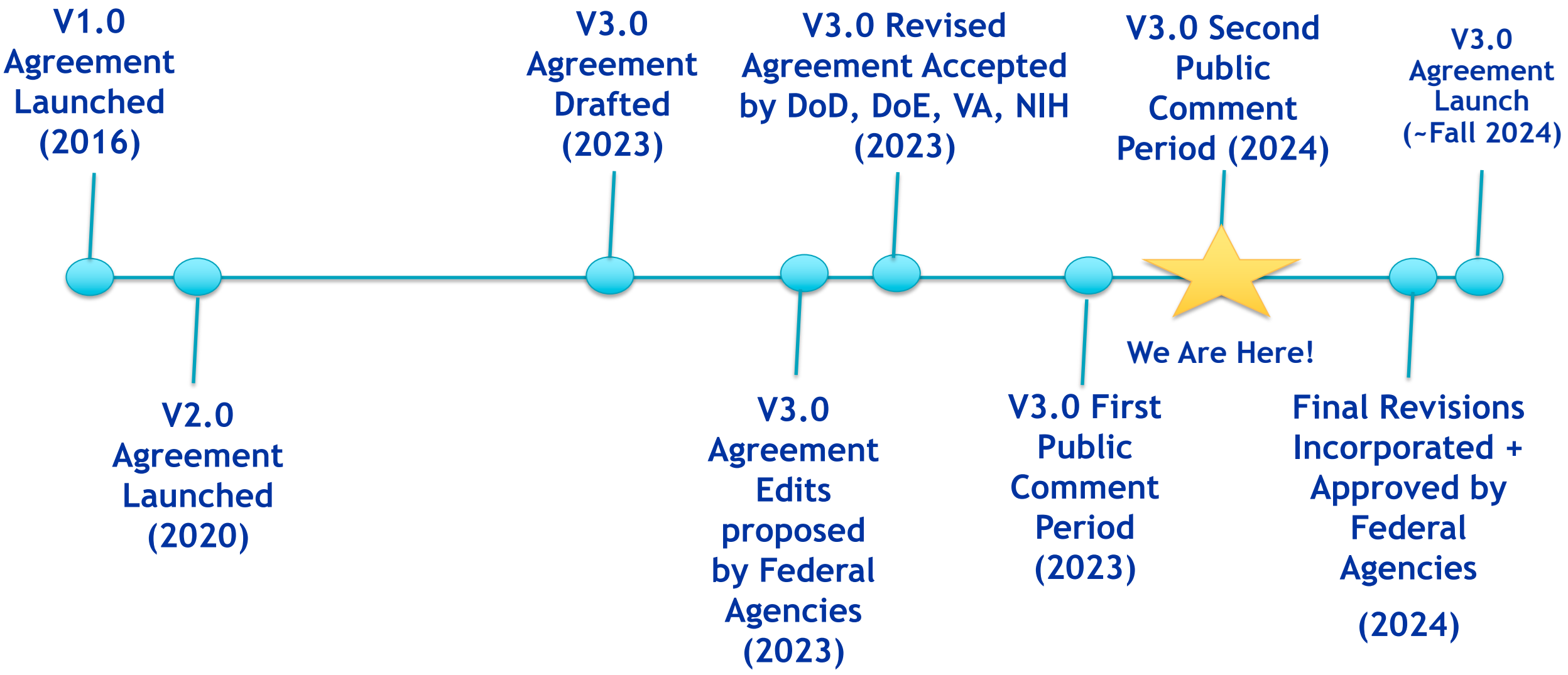
Next Steps

- SMART IRB team is following up with some commenters as needed for additional information/clarification on some of their comments
- SMART IRB team will discuss with federal agencies some specific issues that had been previously negotiated
- Version 3.0 is being updated to reflect comments as described today and will be re-posted for another brief public comment period (highlighting the updates from the previously posted draft)
- FAQs and Guidance will be developed to address areas of confusion

Drivers for Changes to Version 3.0

- To address feedback from current and potential Participating Institutions
- To capture the 2018 Common Rule changes to IRB review requirements
- To enable additional federal agencies to participate (e.g., VA, DoD & DOE)

SMART IRB Agreement: Progress Over Time



Transition to Version 3.0

Transition from Versions 1.0/2.0 to Version 3.0

- Received significant feedback on proposal to transition all Participating Institutions to Version 3.0 as of a cutoff date
- New transition proposal:
  - All institutions that are NEW to SMART after Version 3.0 goes live must join Version 3.0.
  - Current Participating Institutions that are added to an ongoing instance of reliance or that participate in a new reliance request after Version 3.0 goes live must join Version 3.0 at that time. In such cases, the Reviewing IRB Institution must also join Version 3.0.
  - If an ongoing instance of reliance or a new reliance request involves a federal agency that is new to SMART (i.e., a federal agency other than NIH), all Participating Institutions involved in that reliance must join Version 3.0 at that time.
  - Current Participating Institutions not falling into either of the above buckets may elect to join Version 3.0 at any time after it goes live.

Transition from Versions 1.0/2.0 to Version 3.0, cont.

- As a result of new transition proposal:
  - A current Participating Institution that either is required to or elects to join Version 3.0 may be under different versions of the Agreement with respect to different studies.
  - A current Reviewing IRB Institution may be under different versions of the Agreement with respect to different Relying Institutions in the same study.

Exemption Determinations / Exempt Research

Section 2. Scope and Application of the Agreement – VERSION 3.0 PROPOSAL

2.1.2 Exemption Determinations. … In the case of Exemption Determinations, including those for which Limited IRB Review (defined in Exhibit A) is required, and with respect to Research that is subject to an Exemption Determination, all of the terms of this Agreement shall apply except for Sections 2.5, 5.4.1, 5.7 [Conflicts of Interest], 5.9, 5.10 [Notification of Serious and/or Continuing Noncompliance], 5.11 [Notification and Referral of Other Issues], 5.13 [External Reporting], 5.14 [Notification of Communications with Federal Agencies], 5.15, 6.4, 6.6 [Local Considerations], 6.8 [Conflicts of Interest], 6.9, 6.12, 6.13 [Notification of Noncompliance], 6.14, 6.16 [External Reporting], and 6.17 [Notification of Communications with Federal Agencies].

Public Comments Received

- Several respondents commented that Sections of the Agreement related to the following topics should apply to Exemption Determinations / exempt research:
  - Conflicts of interest
  - Local Considerations
  - Notification and reporting

Proposed Resolution

- Conflicts of interest
  - No change, not applicable to Exemption Determinations
- Local Considerations
  - Yes, applicable to Exemption Determinations “to the extent relevant to the criteria for the Exemption Determination”
- Notification and reporting of potential noncompliance (and notification of communications with federal agencies related to same)
  - Yes, applicable to exempt research if the noncompliance “could disqualify the Research from the relevant exemption”

Customization of Consent Forms

Section 5. Responsibilities of Reviewing IRBs/Reviewing IRB Institutions – VERSION 3.0 PROPOSAL

5.6 Consent Forms. … The Reviewing IRB will permit the Relying Institution(s)/Site Investigator(s)/other Personnel to customize limited site-specific sections of the form(s), and will consider requests from the Relying Institution(s) on other sections of the form(s) if necessary to address legal or regulatory issues or federal department- or agency-specific requirements. Any such customizations or requests will be subject to approval by the Reviewing IRB … .

Public Comments Received

- One respondent requested to reinstate list of site-specific sections of the form that can be customized (injury, research costs, local contacts) or to add “institutional policy issues” as a basis for Relying Institutions to request changes to the form.

Proposed Resolution

- Examples of site-specific sections can be addressed in SMART IRB FAQs
- Add “institutional requirements” to the provision:

> [The Reviewing IRB] “will consider requests from the Relying Institution(s) on other sections of the form(s) if necessary to address legal or regulatory issues, federal department- or agency-specific requirements, or institutional requirements”

Local Considerations

Section 6. Responsibilities of Relying Institutions – VERSION 3.0 PROPOSAL

6.6 Local Considerations. With respect to Research submitted for Ceded Review, a Relying Institution will identify, interpret (as necessary), and communicate to the Reviewing IRB the requirements of any applicable state or local laws, regulations, institutional policies, standards, or other local factors, including local ancillary reviews; any federal department- or agency-specific requirements; and the requirements of any applicable federal laws or regulations other than the Federal Policy, other federal human subjects protection regulations or policies, and the FDA Clinical Investigation Regulations that would affect the conduct by or approval of the Research on behalf of the Relying Institution ("Local Considerations"). … HIPAA and its requirements are not considered Local Considerations and are addressed separately in Section 4.4 hereof.

Public Comments Received

- Numerous respondents objected to the Relying Institution having the obligation to identify and interpret federal laws and regulations and federal agency requirements.
  - One respondent wrote "until federal agencies and departments provide an information sheet, a more workable approach might be to place upon the reviewing IRB the responsibility to review grant documents and identify which federal requirements apply. Where necessary, the Reviewing IRB could propose a uniform interpretation of these requirements for the study. Any relying site that disagrees with the interpretation could request clarification from the applicable department or agency and communicate those clarifications to the Reviewing IRB. Rationale: Shifting the responsibility of identifying federal department or agency-specific laws or regulations, other than the Common Rule and FDA regulations, away from Reviewing IRBs shifts significant responsibility for federal compliance review solely onto the relying institutions, undercutting the theoretical efficiency of sIRB review. Without clear summaries and guidance from federal departments and agencies regarding their requirements, laws and regulations applicable to a given study, undertaking the task of identifying and interpreting these requirements and regulations will be time intensive for each relying institution. This could potentially lengthen the time to approval and could lead to each relying site implementing and interpreting these requirements differently across one study."
  - Another respondent said "I heartily disagree with letting IRBs off the hook and requiring relying institutions to be solely responsible for identifying what regulations and laws apply to a study. The Reviewing IRBs need to take some responsibility and identifying the requirements should be a collaboration. I would really like to see this section revised to describe a collaboration."

Public Comments Received, cont.

- One respondent requested to revise definition and separate truly “local” considerations from federal considerations:
  - “Harmonize with the working group's definition, which would include removing "any federal department- or agency-specific requirements; and the requirements of any applicable federal laws or regulations other than the Federal Policy, other federal human subjects protection regulations or policies, and the FDA Clinical Investigation Regulations that would affect the conduct by or approval of the Research". This language could be moved into a different/new section of the agreement. These are not local considerations in the way institutions think of them but requirements the Federal agencies are imposing as part of joining this agreement.”

Proposed Resolution

- Limit the definition of Local Considerations to state/local laws and institutional policies, and create a new term to refer to federal laws and regulations and federal agency requirements
- Obligate the Relying Institution to identify Local Considerations plus federal laws/regulations/agency requirements that the Reviewing IRB may not be able to identify from the protocol on its own or that are unique/specific to the Relying Institution

Section 6. Responsibilities of Relying Institutions – NEW PROPOSAL

6.6 Local and Other Considerations. A Relying Institution will identify and communicate to the Reviewing IRB/Reviewing IRB Institution (i) the requirements of any applicable state or local laws, regulations, institutional policies, standards, or other local factors, including local ancillary reviews ("Local Considerations"); and (ii) the requirements of any applicable federal laws or regulations or of relevant federal departments or agencies that may not be apparent from the Research protocol or that are specific to the Relying Institution ("Other Considerations") that would affect the conduct by or approval of the Research or the grant of an Exemption Determination on behalf of the Relying Institution. … HIPAA and its requirements are not considered Other Considerations and are addressed separately in Section 4.4 hereof.

Monitoring

Section 6. Responsibilities of Relying Institutions – CURRENT AGREEMENT

6.11 Monitoring; Quality Assurance/Quality Improvement Function/Program. A Relying Institution will maintain, implement, or have access to a human subjects research quality assurance/quality improvement ("QA/QI") process, function, program, or service that can conduct and report to the Relying Institution the results of for-cause and not-for-cause audits of the Relying Institution's and its Personnel's compliance with human subjects protections and other relevant requirements in the conduct of Research. Relying Institutions that do not have access to a QA/QI process, function, program, or service must have an alternate means of monitoring the conduct of Research as appropriate to ensure compliance. However, if requested by a Relying Institution, the Reviewing IRB/Reviewing IRB Institution may agree to waive the requirement for the Relying Institution to have access to a QA/QI process, function, program or service or alternate means of monitoring with respect to Research.

- Language has not been substantively revised
- Requirement was moved from Section 4 (Responsibilities of Participating Institutions) to Section 6 (Responsibilities of Relying Institutions) but has always applied by its terms only to Relying Institutions.

Public Comments Received

- Some comments suggested confusion whether this provision is addressing HRPP quality or the capacity to monitor specific Research (it is the latter).
- Suggestion also made to remove any provision on monitoring specific Research from the Agreement.
- Suggestion also seems to be to require all Participating Institutions (not just Participating Institutions with IRBs) to assess or have the capacity to assess HRPP quality.

Proposed Resolution

- FAQs will be written to distinguish between assessing HRPP quality and compliance monitoring of specific Research.
- Language of Section 6.11 will also be streamlined/tightened to help address confusion.
- Section 6.11 will remain in the Agreement and Relying Institutions will continue to be required to have the capacity to monitor specific Research (note that Section 6.11 already permits parties to agree among themselves to waive this requirement).
- The requirement for an HRPP quality assessment in order to participate in the Agreement will not be expanded; this requirement will continue to apply only to institutions that have an IRB.

Choice of Law/Venue

Section 8. Miscellaneous – VERSION 3.0 PROPOSAL

8.12 Governing Law and Venue. In the event of a legal proceeding or other dispute between any Participating Institutions with respect to the provisions of this Agreement, then as between the Participating Institution initiating the proceeding/dispute and a Participating Institution that is a defendant, the law of the state of the Participating Institution that is the defendant will govern the interpretation of this Agreement and the resolution of the dispute between those parties. In addition, each Participating Institution that brings a legal proceeding or other dispute against another Participating Institution with respect to the provisions of this Agreement hereby consents to the exclusive jurisdiction of the state and federal courts in the state of the Participating Institution that is the defendant with respect to the proceeding/dispute between those parties. This Section 8.12 applies to a Participating Institution that is a Public Institution only to the extent not limited by applicable law, regulation, or constitution in the jurisdiction in which such Public Institution serves as a Public Institution; provided, however, that this Section 8.12 does not apply at all to any Participating Institution that is a Federal Institution, with respect to which U.S. federal law, as applied by U.S. federal courts, shall govern.

Public Comments Received

- Nearly a dozen respondents requested that the Agreement not include this provision and instead remain silent on governing law and venue.
  - One respondent articulated concern that the provision does not provide sufficient predictability as to what law or location will apply and that it may promote "gamesmanship" because the applicable law and location will depend on which party files suit first.
  - One respondent noted that in a suit with multiple defendants, the provision would seem to require each defendant to be sued separately in their home venue under their home laws.
  - One respondent suggested the provision could be retained as a default if the parties do not agree otherwise but that it should be revised to allow for the parties to agree among themselves to an alternate selection of law and venue.

Proposed Resolution

- Remove this provision from the Agreement; the Agreement will remain silent on choice of law and venue.
- Include the provision in the Indemnification Addendum (only).

Indemnification Addendum

Definition of Losses:
Public Comment Received and Proposed Resolution

- Comment: Expand the definition of covered Losses to include not only damages and costs arising out of (private) third-party claims, but also governmental/regulatory/administrative penalties/fines.
- Proposed Resolution: No change.

Notification of Losses: Public Comments Received and Proposed Resolution

5. Notification

An Indemnified Party or Other Party will notify the Indemnifying Party/Responsible Party promptly in writing of any Losses for which it is seeking indemnification/reimbursement pursuant to this Indemnification Addendum. The Indemnifying Party/Responsible Party will not be responsible for any attorney's fees or expenses of litigation that are incurred by the Indemnified Party(ies)/Other Party(ies) prior to the provision of notice of the Losses hereunder.

- Comments: An indemnifying party should be responsible for litigation expenses and other costs incurred by a party seeking indemnification before such party has provided notice to the indemnifying party of the Loss, except to the extent the delay in providing notice or lack of notice has jeopardized the indemnifying party's ability to defend the claim.
- Proposed Resolution: Under consideration.

Authority to Agree to Settlement: Public Comments Received and Proposed Resolution

3.2 Defense. An Indemnifying Party will have the sole right to control the defense and financial settlement of any Losses for which it is providing indemnification hereunder, including the selection of legal counsel, except that the Indemnifying Party must not agree to any non-financial settlement or term of settlement (including but not limited to any acknowledgement of liability or responsibility) of any Losses without the prior consent of the relevant Indemnified Party(ies).

- Comment: The Indemnifying Party should be prohibited from agreeing to *any* type of settlement without the Indemnified Party's consent.
- Proposed Resolution: No change.

Insurance Coverage:
Public Comments Received and Proposed Resolution

- Comments: Remove the Indemnification Addendum's requirement to have insurance coverage for indemnification and defense obligations, on the grounds that an insurance requirement specific to indemnification obligations is not critical and may be a barrier to participation in the Addendum (depending on an institution's insurance coverage/exclusions).
- Proposed Resolution: Remove the insurance coverage requirement from the Indemnification Addendum.
  - Note that the Agreement has a general insurance coverage requirement, under which institutions can ask one another for evidence of specific coverages, and which institutions can agree among themselves to waive.

Federal Institutions:
Public Comments Received and Proposed Resolution

- Comment: Because Federal Institutions are not required to indemnify, other Participating Institutions should not be required to indemnify Federal Institutions (suggestion is to make the exception reciprocal).
- Proposed Resolution: To be discussed with Federal Institutions.

Ability To Enter Separate Indemnification Agreements: Public Comments Received and Proposed Resolution

- Comment: If institutions join the Indemnification Addendum for specific studies only, can they still enter separate indemnification agreements among themselves for other studies?
- Proposed Resolution: Yes. Clarify in Indemnification Addendum that this is permissible.

Effect on Existing Indemnification Agreements: Public Comments Received and Proposed Resolution

7. Effect on Existing Indemnification Arrangements

This Indemnification Addendum represents the entire understanding of the Indemnification Participating Institutions with respect to the subject matter hereof, and supersedes any prior separate agreements, whether written or oral, on such subject matter to the extent that the relevant parties to such agreements both become Indemnification Participating Institutions; provided, however, that the obligations and rights of such parties with respect to requests for indemnification/reimbursement that have been noticed or otherwise made between such parties prior to the date that this Indemnification Addendum is effective as to both such parties will continue to be governed by and subject to the terms of their prior separate written agreement, and the terms of this indemnification Addendum will apply only with respect to requests for indemnification/reimbursement that are noticed on or after such date.

- Comments: Several respondents indicated that they will not join the Addendum if it supersedes their prior separate indemnification agreements.
- Proposed Resolution: Remove the “superseding” language and permit the prior separate indemnification agreements to remain in place for reliance requests initiated prior to joining the Indemnification Addendum.

Other Areas of Revisions (not exhaustive lists)

Definition of HRPP

- Comments reflected confusion/questions regarding what is meant by the term “HRPP” as used in the current Agreement (IRB? accreditation?)
- Will revise definition as follows: “An Institution’s policies, procedures, and oversight mechanisms for addressing human research protections”

Federal Processes for Initiating Reliance and Determination of Reviewing IRB (Section 3.1)

- Received comments seeking to clarify terminology and reduce burden regarding federally mandated processes for initiating reliance and determination of the Reviewing IRB
- Will change term proposed to reference these processes from “Agency Processes” to “Mandated Processes”
- Will only require Participating Institutions to document when Mandated Processes apply if such documentation does not exist elsewhere

Processes for Initiating Reliance in Research Not Subject to Mandated Processes (Section 3.2)

- Received comments seeking to:
  - retain certain details in the Agreement that were proposed to move to the SMART IRB FAQs
  - make these processes a suggestion rather than a requirement
- Will restore language from current Agreement regarding ability of a Site Investigator to make a reliance request when there is no Overall PI or the Overall PI is not making (but does not object to) a reliance request
- Will revise language throughout Section 3.2 to shift from "will" to "should"

Research Personnel and IRB Member Education/Training/ Qualifications (Section 4.1)

- Received comments seeking to remove current requirement for Participating Institutions to provide documentation of their Personnel and IRB Members' education/training/ qualifications
- Will remove requirement to provide documentation; requirement remains to provide "information" (i.e., a description)

Notification to IRB of Agreement Obligations (Section 4.3)

- Received comments seeking to refine proposed provision requiring notification to IRB members about obligations under the Agreement
- Will limit notification requirement to notification of "relevant IRB leadership, administrators, and staff"

HIPAA Waivers/Alterations of Authorization (Section 4.4.2)

- Received comments seeking the Agreement to state that a Reviewing IRB/Reviewing IRB Institution is not obligated to ensure that a HIPAA waiver/alteration of authorization obtained by a Relying Institution complies with HIPAA's waiver/alteration requirements
- Will include this statement (matches similar statement in Agreement regarding HIPAA authorizations provided by a Relying Institution)

Termination of Participation (Section 7.2.1.3)

- Received comments seeking longer timeframe before automatic termination of participation in Agreement when there is a suspension/restriction/termination of Assurance or loss/lapse of IRB registration
- Will change timeframe from 30 to 60 business days

Questions and Discussion

Save the date for the next SMART Talk on Pondering Post-Approval Monitoring for Single IRB: FDA-Regulated Research Edition

July 17, 2024
2:00-3:30 pm ET

Questions?
Contact
help@smartirb.org

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