SMART IRB Reliance Agreement Version 3.0

Draft for Public Comment

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Agenda

- Drivers of Version 3.0
- Overview of key changes
- Public comment process
- Next steps

Drivers of Version 3.0

Recap of Versions 1.0 and 2.0

Version 1.0

- Original version
- Open to join 2016-2020

Version 2.0

- Current version
- Open to join 2020-present
- Identical to Version 1.0 but for limited changes to allow participation of NIH

Versions 1.0 and 2.0 co-exist and are compatible.

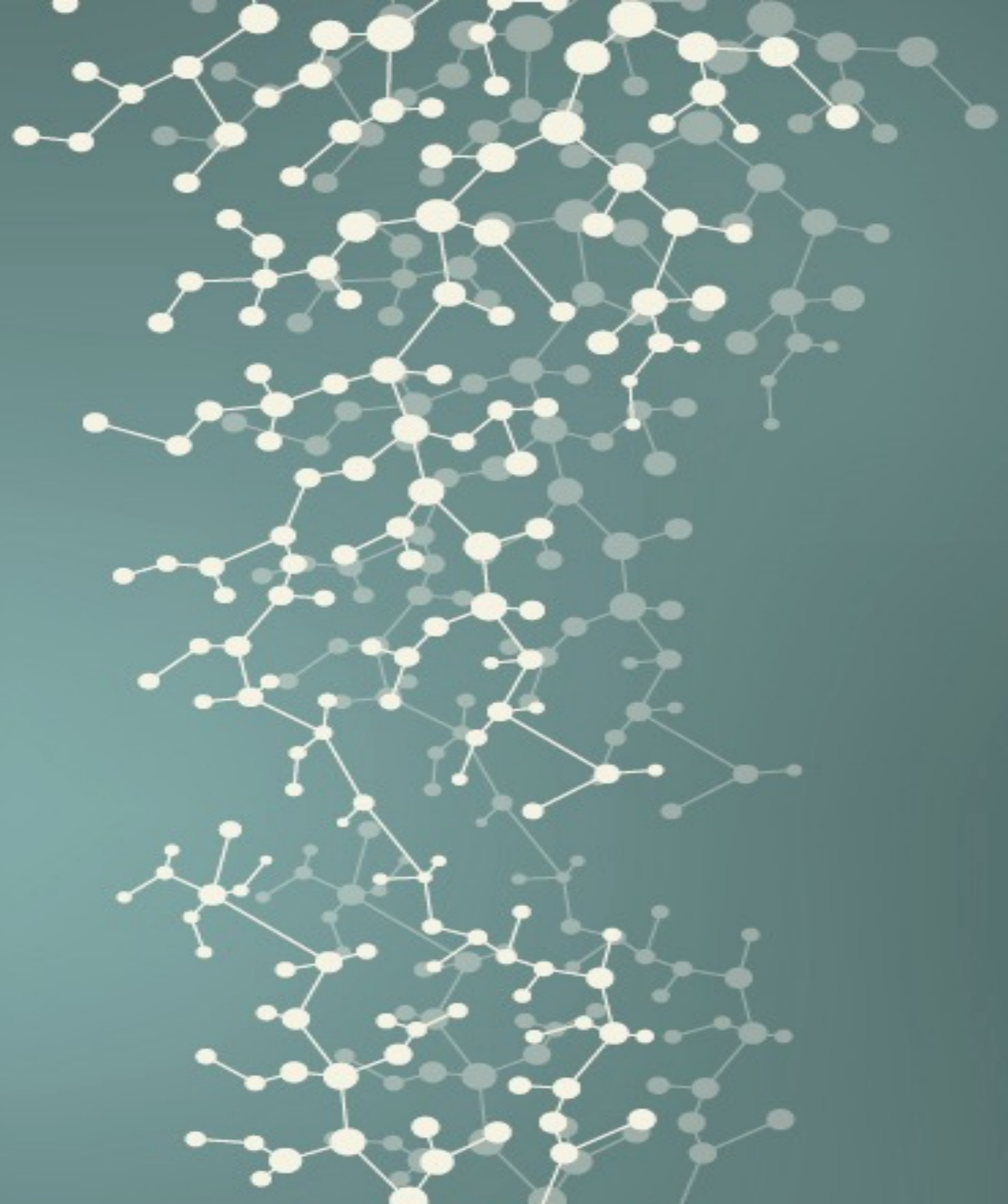
Drivers of Version 3.0

- 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)

Version 3.0 Will Replace 1.0 and 2.0

- Version 3.0 is a significant amendment of the current agreement
- Version 3.0 is not compatible with Versions 1.0 and 2.0
- Once finalized, Version 3.0 will be the only option to join

Overview of Key Changes



All Sections Have Changes

- Eligibility to participate in the agreement (Section 1)
- Scope and application of the agreement (Sections 2 and 5)
- Collaborative processes for reliance requests and selection of Reviewing IRB (Section 3)
- Determination of applicable policies and procedures for conduct of reliance relationship (Section 3)
- Responsibilities of all Participating Institutions (Section 4)
- Indemnification options (Section 4)
- HIPAA (Section 4)
- Responsibilities of Reviewing IRBs / Reviewing IRB Institutions (Section 5)
- Responsibilities of Relying Institutions (Section 6)
- Termination (Section 7)
- Miscellaneous (Section 8)

Changes to Eligibility To Participate in the Agreement (Section 1)

Federal Assurance of Compliance

- Assurance of compliance with Common Rule still required for participation
- New: An FWA with HHS is no longer the only form of Assurance accepted - an Assurance issued by any federal Common Rule agency is sufficient (e.g., DoD)

Institutional Oversight of Exempt Research

- Institutions still must provide institutional oversight of *non-exempt* research
- New: Institutional oversight of *exempt* research is no longer a requirement for participation

Changes to Scope and Application of the Agreement (Sections 2 and 5)

Exemption Determinations

- Institutions may continue to use the agreement to obtain exemption determinations from a Reviewing IRB Institution or Reviewing IRB
- New: Any exemption determinations must be conducted in accordance with the Common Rule
- New: Explicit expectation for Reviewing IRBs to perform Limited IRB Reviews if required for an exemption determination

Withdrawal of Reviewing IRB

- New: Reviewing IRBs may withdraw from providing review and oversight of research for a Relying Institution based on “significant cause”
- Significant cause includes ongoing, uncorrected non-compliance by the Relying Institution with its obligations under the agreement
- Withdrawal requires prior notice (60 business days) and explanation to the Relying Institution

Changes to Collaborative Processes (Section 3)

Initiation/Consideration of Reliance Requests and Selection of Reviewing IRB

- Federal regulatory agency or federal funding agency processes on these topics ("Agency Processes") control when applicable to the research
  - Examples: Common Rule; NIH sIRB Policy
- New: Institutions must document among themselves when Agency Processes apply

Changes to Determination of Applicable Policies and Procedures (Section 3)

Policies and Procedures for Conduct of Reliance Relationship

- Federal agency/department policies and procedures for conduct of the relationship ("Mandated Policies") control when applicable to the research
  - Examples: VA, DoD policies
- In the absence of Mandated Policies, institutions retain flexibility to select other policies and procedures ("Other Policies")
- New: Institutions must document among themselves whether Mandated Policies or Other Policies apply
- New: In the absence of such documentation, the SMART IRB SOPs will be deemed to apply (unless Mandated Policies apply)

Changes to Responsibilities of All Participating Institutions (Section 4)

Training and Compliance

- New: Obligations to ensure adequate training, education, qualifications, and resources for personnel and to require compliance by personnel apply to all institutions (not just Relying Institutions)
- Institutions serving as Reviewing IRBs/ Reviewing IRB Institutions must ensure training and require compliance of IRB members

Correction of Non-Compliance

- New: Institutions must diligently address and correct any non-compliance with applicable laws, regulations, policies, and the agreement terms

Concerns About Non-Compliance with (Breach of) the Agreement

- New: Institutions must work together in good faith to resolve such concerns
- Options for resolution include:
  - Discussion through Institutional Officials
  - Consultation with regulatory agencies
  - Engagement of neutral third parties
- No waiver of rights to enforce agreement

Notification of Federal For-Cause Investigations

- New: Institutions must notify others with whom they are in a reliance relationship of any for-cause compliance investigations of the institution or its personnel by OHRP, FDA, NIH, or other federal human subjects research regulatory agencies or funding agencies when:
  - the investigation is related to the research under review or
  - the investigation could affect the conduct or the integrity of such research, the rights or welfare of participants, or the Reviewing IRB/Reviewing IRB Institution's authority or ability to perform its review and oversight obligations

Insurance Requirements

- New: Any institution (including private institutions) may rely on self-funded liability coverage (instead of or in addition to traditional insurance policies) to satisfy the agreement's requirement to maintain coverage for its activities
- New: All government/public institutions are exempted from the insurance provision

Changes to Indemnification Options (Section 4)

Indemnification Options

- Entering any indemnification arrangements continues to be optional (the agreement does not require institutions to indemnify one another)
- New SMART IRB Indemnification Addendum is offered as an optional indemnification agreement for institutions that wish to join it

SMART IRB Indemnification Addendum

- Attached to the agreement at Exhibit C, but requires separate joinder
- Developed by working group of Harmonization Steering Committee including representatives of public and private institutions
- Can help to further streamline reliance by reducing need for negotiation of individual indemnification agreements

SMART IRB Indemnification Addendum

- Different obligations for public vs. private institutions
- If joined, applies to all activities in which joining institutions are involved under the agreement, unless a more limited scope is agreed by the involved joining institutions
- If joined, replaces prior indemnification agreements between joining institutions except with respect to previously noticed claims

Changes to HIPAA Provisions (Section 4)

Role of Covered Entity Relying Institution

- Nothing in the agreement shifts regulatory responsibility for HIPAA compliance away from the Covered Entity Relying Institution
- Focus of HIPAA provisions is on which party will perform specific tasks required for the Relying Institution's compliance
- New: Relying Institution (not Reviewing IRB) drives that decision

Authorization Forms/Language

- New: Relying Institution may require its own authorization form/language to be used (does not need the agreement of Reviewing IRB/Reviewing IRB Institution)
  - Reviewing IRB/Reviewing IRB Institution provides authorization form/language (only) if Relying Institution does not
- New: Relying Institution may identify Local Considerations mandating authorization be separate from the ICF
  - Reviewing IRB/Reviewing IRB Institution may merge authorization and ICF (only) in absence of such considerations
- As currently, the party providing the authorization ensures it contains the required elements and statements and permits the use and disclosure of PHI as necessary for the research

Waivers of Authorization

- New: Relying Institution may perform/provide waiver of HIPAA authorization (does not need agreement of Reviewing IRB)
  - Reviewing IRB reviews waiver requests (only) if Relying Institution does not
- New: Relying Institution may identify Local Considerations preventing approval of a waiver
  - Reviewing IRB may approve a waiver (only) in absence of such considerations
- As currently, the party performing/providing the waiver does so in accordance with HIPAA's waiver criteria

Reviewing IRBs/Reviewing IRB Institutions That Do Not Address HIPAA

- New: Reviewing IRBs/Reviewing IRB Institutions that are federal departments or agencies, that are not HIPAA Covered Entities, or that otherwise do not provide HIPAA authorizations or waivers (for any reason) are not obligated to do so
- This is a somewhat broader exception than in the current agreement, which expects Reviewing IRBs/Reviewing IRB Institutions to perform these tasks unless they have policies prohibiting them from doing so

Changes to Responsibilities of Reviewing IRBs / Reviewing IRB Institutions (Section 5)

Research That Is Not Subject to Federal Human Subjects Requirements

- New: For research not subject to the Common Rule, FDA regulations, or other human subjects protection requirements, Reviewing IRB must apply Common Rule standards to the review (e.g., criteria for approval of the research and the elements of informed consent), unless Relying Institution and Reviewing IRB agree on a different standard
- The agreement does *not* require external reporting in connection with such research

Requests for Modifications to Informed Consent Forms

- New: Reviewing IRB must consider Relying Institution's requests for modifications of the ICF that are necessary to address legal or regulatory issues or federal department- or agency-specific requirements
- This is a somewhat broader obligation than in the current agreement, which only requires Reviewing IRBs to permit customization of limited site-specific sections of the ICF identified by the IRB

Changes to Responsibilities of Relying Institutions (Section 6)

External Reports

- Reviewing IRBs/Reviewing IRB Institutions will continue to draft and send external reports of UAPs, serious/continuing non-compliance, and suspension/termination of IRB approval to federal human subjects research regulatory agencies (OHRP, FDA), unless the parties agree on an alternate procedure
- New: Regardless which party makes such reports to *regulatory* agencies, any and all other reports, including reports to federal *funding* agencies, state agencies, private sponsors, and other authorities, are the sole responsibility of Relying Institutions

Local Considerations

- New: Local Considerations that Relying Institutions must identify, interpret, and communicate to Reviewing IRBs include not only state or local factors but also requirements of *federal* laws and regulations other than the Common Rule and FDA regulations and federal department- or agency-specific requirements
- Reviewing IRBs only expected to be familiar with Common Rule and FDA regulations (HIPAA addressed separately)

Changes to Termination Provisions (Section 7)

Loss of Assurance or IRB Registration

- New: Rather than face *immediate* termination of its participation in the agreement in the event its Assurance is suspended, restricted, terminated or expires or its IRB registration is lost or lapses, an institution may continue to participate in its *ongoing* activities under the agreement for *30 business days* after such event (the affected parties may agree to extend this grace period to 60 business days)
- Termination of participation occurs after the grace period if the Assurance or IRB registration has not been fully reinstated
- The institution may not participate in *new* activities during the grace period

Changes to Miscellaneous Provisions (Section 8)

Joinder Agreements

- New: Joinder Agreements will be electronic and will be executed using electronic or digital signatures
- Systems designed with attention to 21 CFR Part 11 and federal department- and agency-specific security requirements

Governing Law and Venue

- New: Agreement includes a provision specifying governing law and venue for disputes between Participating Institutions – governing law and venue will be the law/courts of the state of the defending Participating Institution
- Provision does not apply to federal agencies or to public institutions where limited by law

Public Comment Process

Why Review and Comment on Version 3.0?

- Agreement requires that material changes proposed to the agreement be open for written comments
- Agreement also requires re-execution of Joinder Agreements when there are significant amendments
- Version 3.0 meets these standards and, once finalized, will be the only option to join (Versions 1.0 and 2.0 will not be available)
- Critical for current Participating Institutions to review and comment if they wish to continue participation

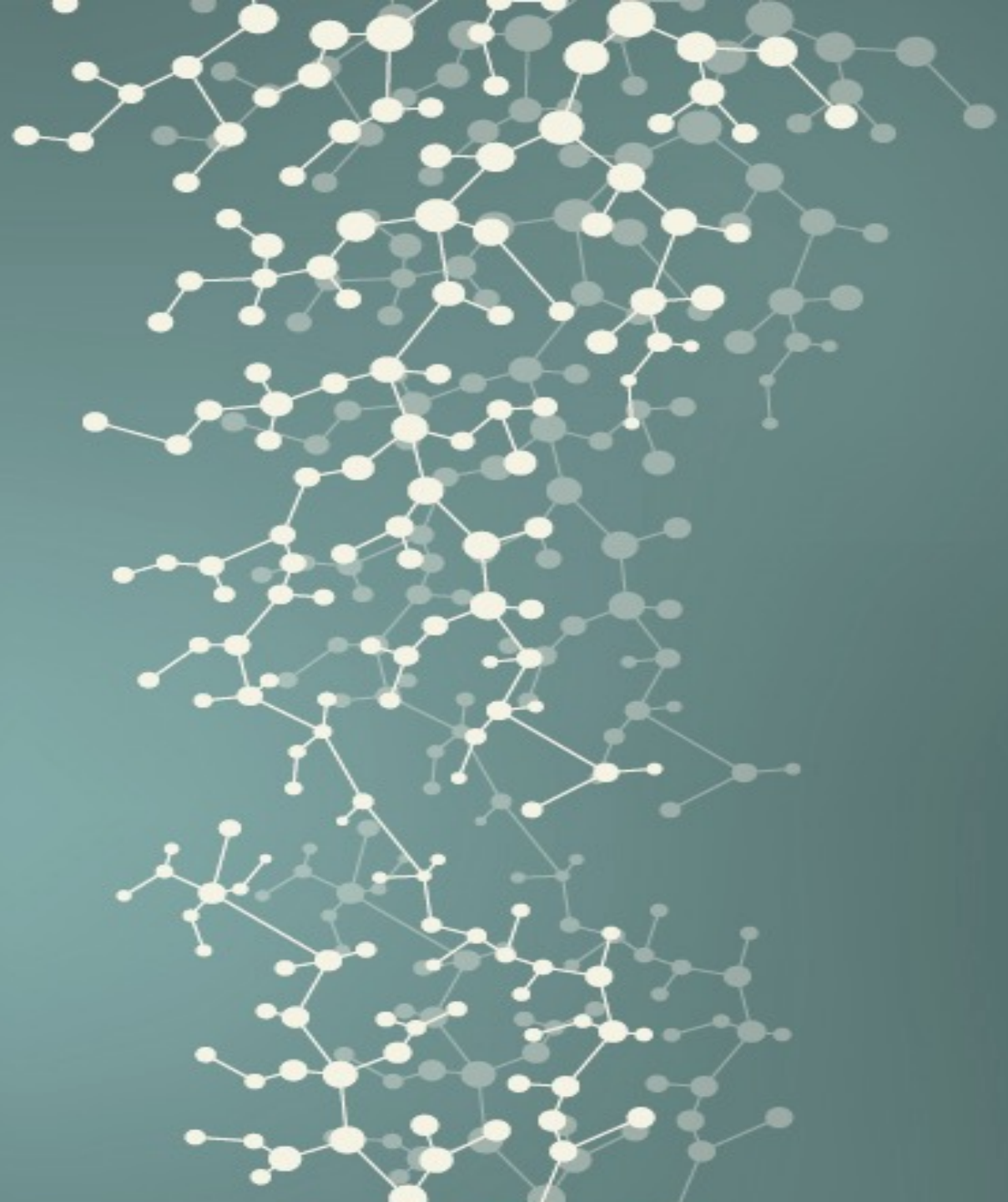
Public Comment Process

- Two ways to make and submit comments:
  - Use comment form available on SMART IRB website: https://smartirb.org/agreement/ (preferred)
  - Email comments to help@smartirb.org
- Deadline for submitting comments: February 15, 2024

Resources To Assist With Review

- Version 3.0 – clean and redlined against Version 2.0 - clean
- Executive Summary of key substantive changes
- FAQs on comment and transition processes
- This slide deck
- SMART IRB Ambassadors

Next Steps



Review of Comments

- All written comments received by the deadline will be considered
- Further changes to Version 3.0 may be made based on the comments

Joining Version 3.0

- Once ready, the final Version 3.0 will be posted ("go live") on smartirb.org
- Participating Institutions will be notified (through their Points of Contact) that Version 3.0 has been posted and is available for signature
- A reasonable period of time (TBD) will be provided for signature
- A Participating Institution that does not sign Version 3.0 within that time period will be considered to have terminated its participation in the agreement

What Happens to Studies Falling Under 1.0/2.0?

- If all involved parties timely sign Version 3.0: reliance continues under Version 3.0 terms
- If some but not all involved parties timely sign Version 3.0: reliance continues under Version 3.0 terms for those parties that signed; non-signing parties no longer covered
- If no involved parties timely sign Version 3.0: reliance ends

Versions 1.0/2.0 do not survive even for existing studies!

Questions?