NIH Single IRB Policy

Presentation to FDP
September 22, 2016

Presentation Overview

- Overview of the NIH sIRB Policy

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- Implementation

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  – Options for complying with the policy
  – What to put in grant applications to NIH
  – Cost Implications
  – Implementation Resources

- Model Reliance Agreement:

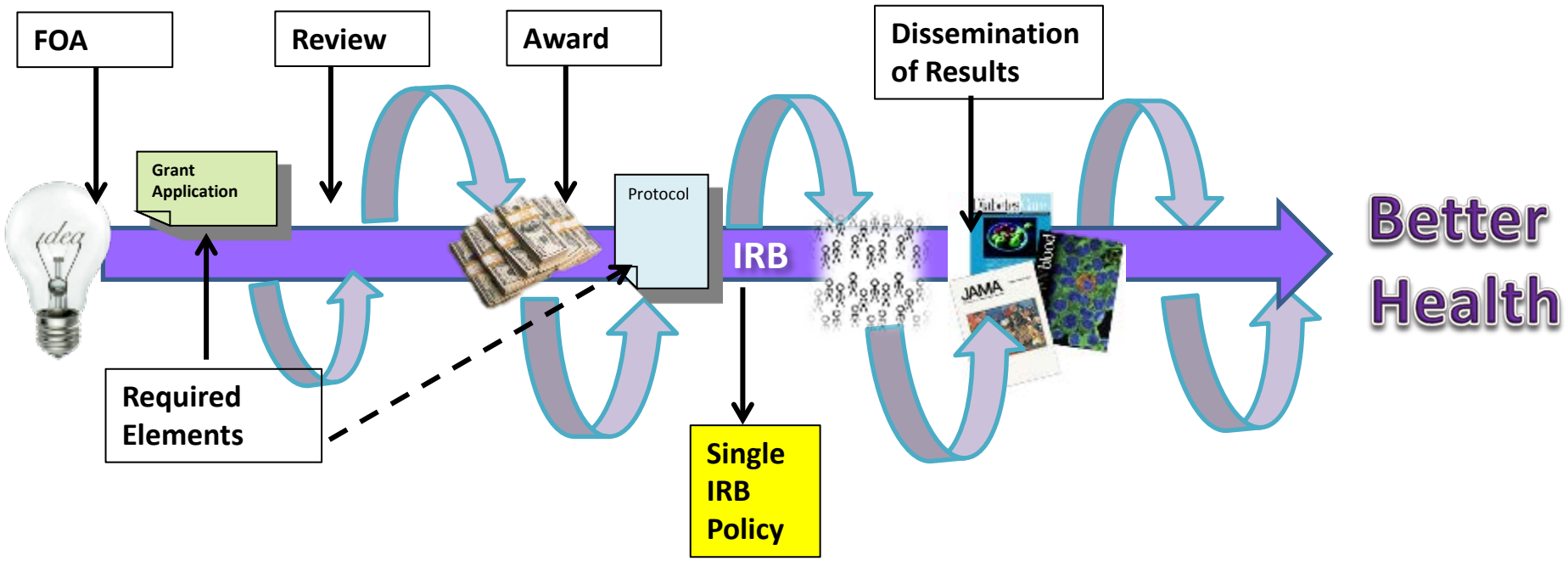
  Michelle Culp, NCATS

  – NCATS SMART IRB Reliance Platform

- Other Resources

Overview of the policy

Research involving Human Participants
Quality Critical at Every Point



NIH Single IRB Policy

Published in NIH Guide and Federal Register: June 21, 2016

- http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html
- https://www.federalregister.gov/articles/2016/06/21/2016-14513/final-nih-policy-on-the-use-of-a-single-institutional-review-board-for-multi-site-research

Effective Dates

- Competing grant applications

  Receipt dates on/after May 25, 2017

- Contract proposals

  Solicitations issued on/after May 25, 2017

- Intramural research

  Multi-site studies submitted for initial review on/after May 25, 2017

sIRB Policy Provisions

- Applies to domestic sites of multi-site studies
  - All sites conducting the same protocol

- Exclusions:
  - Foreign sites
  - Career development (K), institutional training (T), and fellowship awards (F)
  - When Federal, State, Tribal, local requirements require local review
    - Tribal regulations/policies given specific consideration in order to ensure that the importance of their role is recognized

- Exceptions may be considered:
  - May be requested when there is a compelling justification

NIH sIRB Policy – Implementation

- Implementation Efforts – IN PROGRESS
  - Implementation guidance (e.g., FAQs, Roles & Responsibilities)
  - Instructions for applicants/offerors and sample language
  - Resources for investigators and institutions
  - Exceptions process
  - Evaluation criteria

- NIH Guidance on Use of Direct and Indirect Costs

  NOT-OD-16-109

- Model Reliance Agreement
  - NCATS SMART IRB Reliance Platform

Policy implementation

Awardee implementation

Options for awardees:

- Existing IRB serves as sIRB
  - Either awardee or participating site
- Independent IRB
- Central IRB, when required in Funding Opportunity Announcement

sIRB must be registered with OHRP and must have membership to adequately review the proposed study

Information in Applications/Proposals

- Most likely in Protection of Human Subjects Section
  - Name and/or ORHP IRB Registration number for proposed sIRB
  - Statement that all applicable sites will use the sIRB
  - Statement that communication plans between participating sites and sIRB will be described in Reliance Agreement
- If applicant/offeror cannot identify sIRB in application/proposal
  - Statement that awardee will follow the policy and will provide information to NIH prior to initiating the study
- For legal, regulatory, or policy-based exceptions
  - Provide specific citation and indicate which sites are impacted

sIRB: Peer Review and JIT

- Information provided relating to sIRB will not be considered
  - in overall scoring OR
  - in overall rating of Protection of Human Subjects
- Peer reviewers should not suggest budget changes for sIRB
- JIT/Award
  - OHRP IRB Registration #
  - Use of sIRB will be a Term and Condition of Award
  - Restricted award if necessary prior to sIRB approval

Cost considerations

Cost Implications for the Single IRB Model

- NOT-OD-16-109: Guidance on sIRB costing issues
  - Describes various costs that may be associated with Single IRB activities
  - Primary activities & secondary activities
  - 12 scenarios illustrating how costs of sIRB activities may be included in grant budgets

IRB Costs as F&A/Indirect Costs

- Costs of IRB review of human research protocols are most commonly included in an organization's Federally negotiated F&A (indirect cost) rate agreement.

- If an institution has an affiliated IRB, the costs of running the IRB are usually included in the institution's F&A costs, since it is an institutional research resource that benefits a common purpose.

IRB Costs as Direct Costs

- Costs associated with IRB review of human research protocols are not allowable as direct charges to NIH-funded research, unless such charges are not covered by the organization's F&A rate. (See: NIH GPS 4.1.15)
  - If an institution does not have a Federally negotiated F&A rate, or has a Federally negotiated F&A rate that does not include IRB costs, then it may be allowable to charge IRB costs as a direct cost.
- If an institution elects to use an independent/unaffiliated IRB for a specific project, the independent IRB's fees can be charged as a direct cost.
  - This is because the independent IRB is not part of the institution's F&A rate agreement, and it is a **project-specific cost** that can be directly assigned as benefiting this project only.

Costs Associated with Single IRB Review

- **Primary activities**
  IRBs regularly perform these activities.

  - Ethical review of the proposed research protocol
  - Review of the template informed consent document

- These routine activities are usually included in an organization's Federally-negotiated F&A rate agreement.

Costs Associated with Single IRB Review

- **Secondary activities**
  Additional activities that the IRB performs in its capacity as the sIRB

  - Review of site-specific considerations for all participating sites, such as
    - investigator qualifications,
    - institutional capabilities,
    - state/local regulatory requirements,
    - community ethos
  - Oversight activities for all participating sites, such as
    - reviewing reportable events,
    - reviewing complaints,
    - notifying sites of serious non-compliance and other determinations,
    - communicating with sites

- These are project-specific activities that are “above and beyond” IRB review of human subjects research

How Are Costs Associated with Single IRB Review Treated?

In general…

- **Primary activities** should be charged as **indirect costs**, if IRB costs have been included in an institution's Federally approved F&A rate agreement.
- **Secondary activities** are severable from routine IRB activities, and may be charged as **direct costs**, with appropriate budget justification.

Key considerations:

- Institutions must make sure they are consistent in treatment of various IRB activities and costs
  - Need to avoid "double dipping"
- Determinations of whether sIRB costs are direct or indirect may be situational and project-specific
  - Must be well documented and justified
- Institutions will provide guidance to researchers within their policy framework and requirements.

Example 1

Recipient University and Subrecipient Hospital perform a study together:

They decide to use Recipient University's IRB as the sIRB

- Recipient University (RU) charges primary activities as F&A costs, and charges secondary activities as direct costs.
- Subrecipient Hospital (SH) relies on RU's IRB; therefore, SH has no IRB costs of their own.
- Grant funds for cost of sIRB review for SH are administered through the prime award to RU.

Example 2

Recipient University and Subrecipient Hospital perform a study together:

They decide to use Subrecipient Hospital's IRB as the sIRB.

- Subrecipient Hospital (SH) charges primary activities as F&A costs, and charges secondary activities as direct costs.
- Recipient University (RU) relies on SH's IRB; therefore, RU has no IRB costs of their own.
- Grant funds for the cost of sIRB review for RU are administered through the subaward to SH.

Example 3

Recipient University and Subrecipient Hospital perform a study together:

They decide to use Independent IRB as the sIRB.

- Independent IRB's fee, which includes both primary and secondary activities, is charged to the award as direct costs.
- Neither RU nor SH have IRB costs of their own.
- Recipient University, as the prime recipient, handles the contractual arrangements with Independent IRB on behalf of both sites.

See NOT-OD-16-109 for more detailed scenarios.

Costs of Staff Salaries

- Project-specific IRB coordinator or other administrative personnel provide communication and oversight related to the sIRB
  - 45 CFR 75.413(c): Salaries of administrative and clerical staff may be charged as direct costs only if all conditions met:
    - Administrative or clerical services are integral to project;
    - Individuals involved can be specifically identified with the project or activity;
    - Costs are explicitly included in the budget, or applicants obtains prior written approval of Federal awarding agency; and
    - Costs are not also recovered as indirect costs.
  - These costs must be clearly described and appropriately justified in budget justification

Implementation Resources

- Mailbox for questions: SingleIRBPolicy@mail.nih.gov
- Webpage for links to resources: http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/clinical-research-policy/models-irb-review

NCATS **SMART** IRB Reliance Platform

Streamlined, **M**ultisite, **A**ccelerated **R**esources for **T**rials

Evolution to NCATS SMART IRB Reliance Platform

Sep 2014
- NCATS funded a CTSA IRB Reliance project to Dartmouth College
  - Harvard Medical School & University of Wisconsin

Apr 2015
- Initiated pilot study of IRBrely in PCORI

May 2016
- IRBrely → SMART IRB Reliance Platform

June 2016
- NIH Single IRB Policy

July 2016
- NCATS SMART IRB supplement awarded

What Is the SMART IRB Reliance Platform?

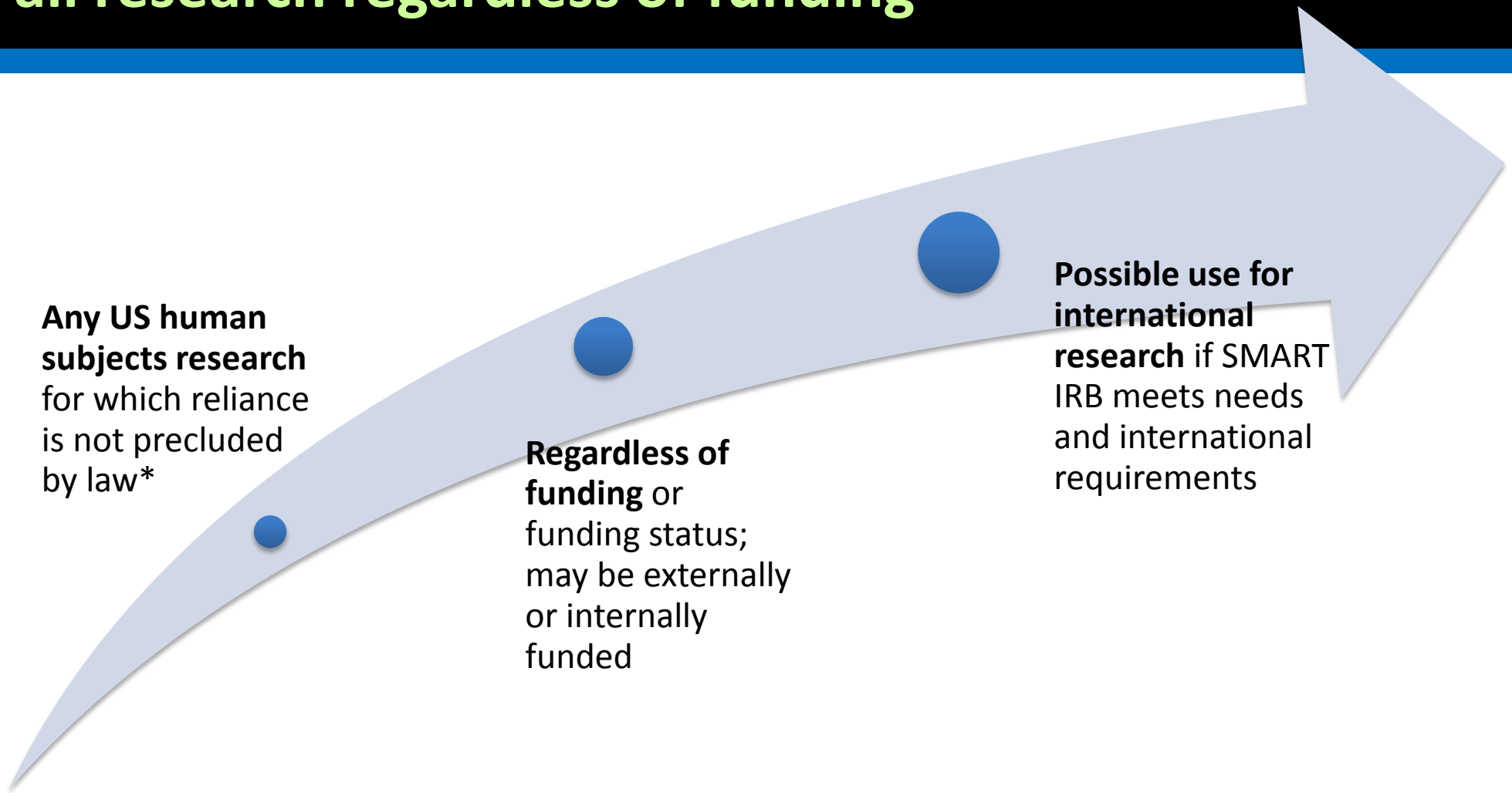
Initiative developed under an award from the National Center for Advancing Translational Sciences (NCATS) of the National Institutes of Health (NIH) to support single Institutional Review Board (IRB) review of multi-site human subjects research.

- CTSA supplement to Harvard Medical School

Attributes of NCATS SMART IRB Reliance Platform

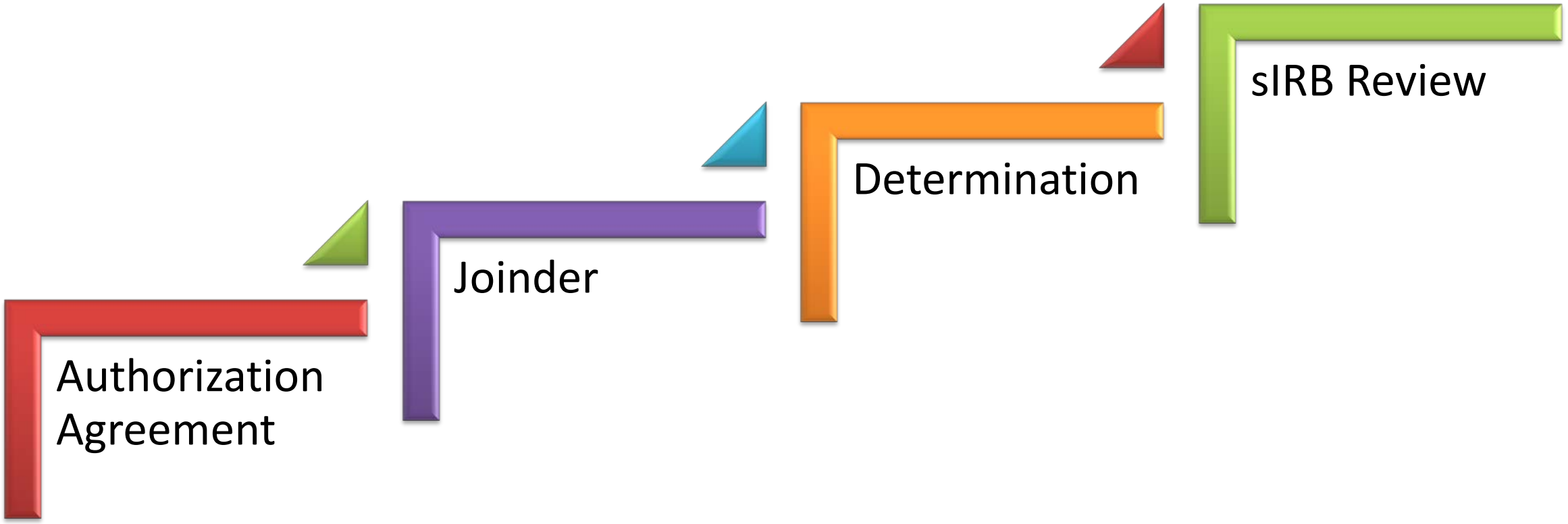
- A single national Authorization (reliance) Agreement that is pre-negotiated and signed by institutions once
- Flexible for large and small studies, networks and non-networks
- Harmonized and streamlined approach

SMART IRB is Expansive in Scope
covers all research regardless of funding

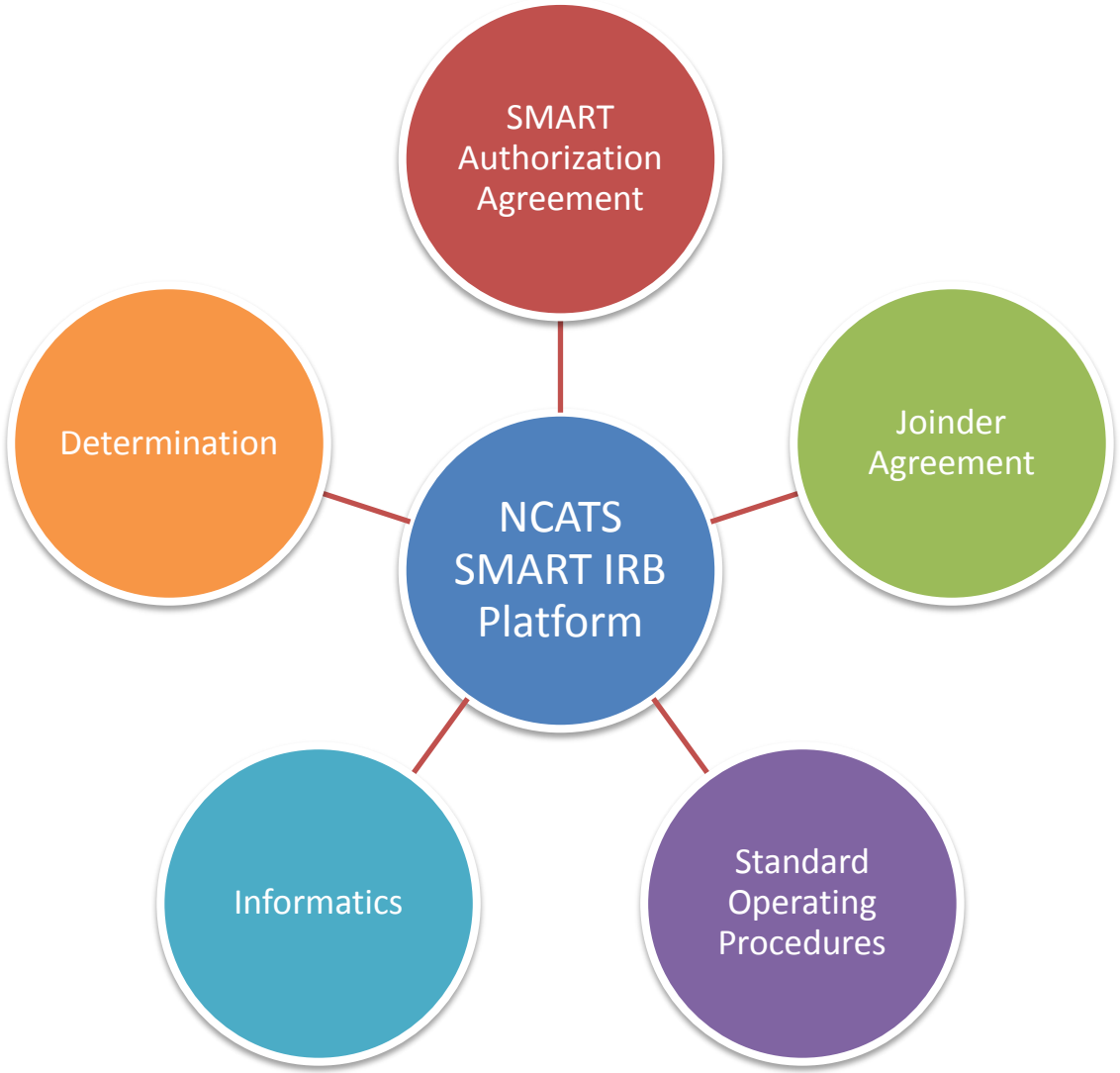


* Research for which local IRB review is required by law or otherwise is not eligible (e.g., certain FDA-regulated device trials)

NCATS SMART IRB Platform Steps



Components of NCATS SMART IRB Reliance Platform



Single IRB Review

SMART IRB Authorization Agreement

- An umbrella agreement
- Establishes an approach for roles and responsibilities of the single IRB and participating sites.

Joinder agreement

- Enables institutions to sign on to SMART IRB Reliance Platform authorization agreement

SMART IRB Provides the Ability to Negotiate

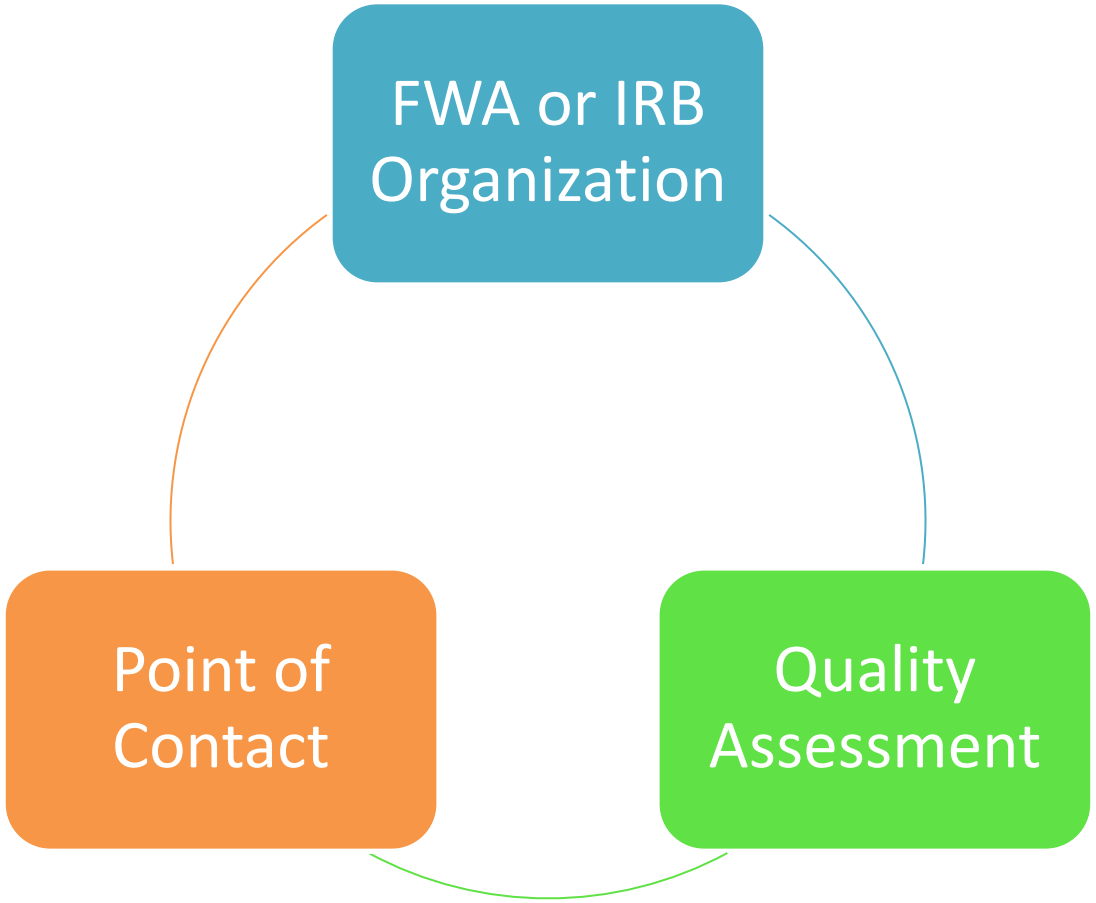
Terms:

Sets a default allocation of responsibility but permits parties to reach individual agreements on certain terms

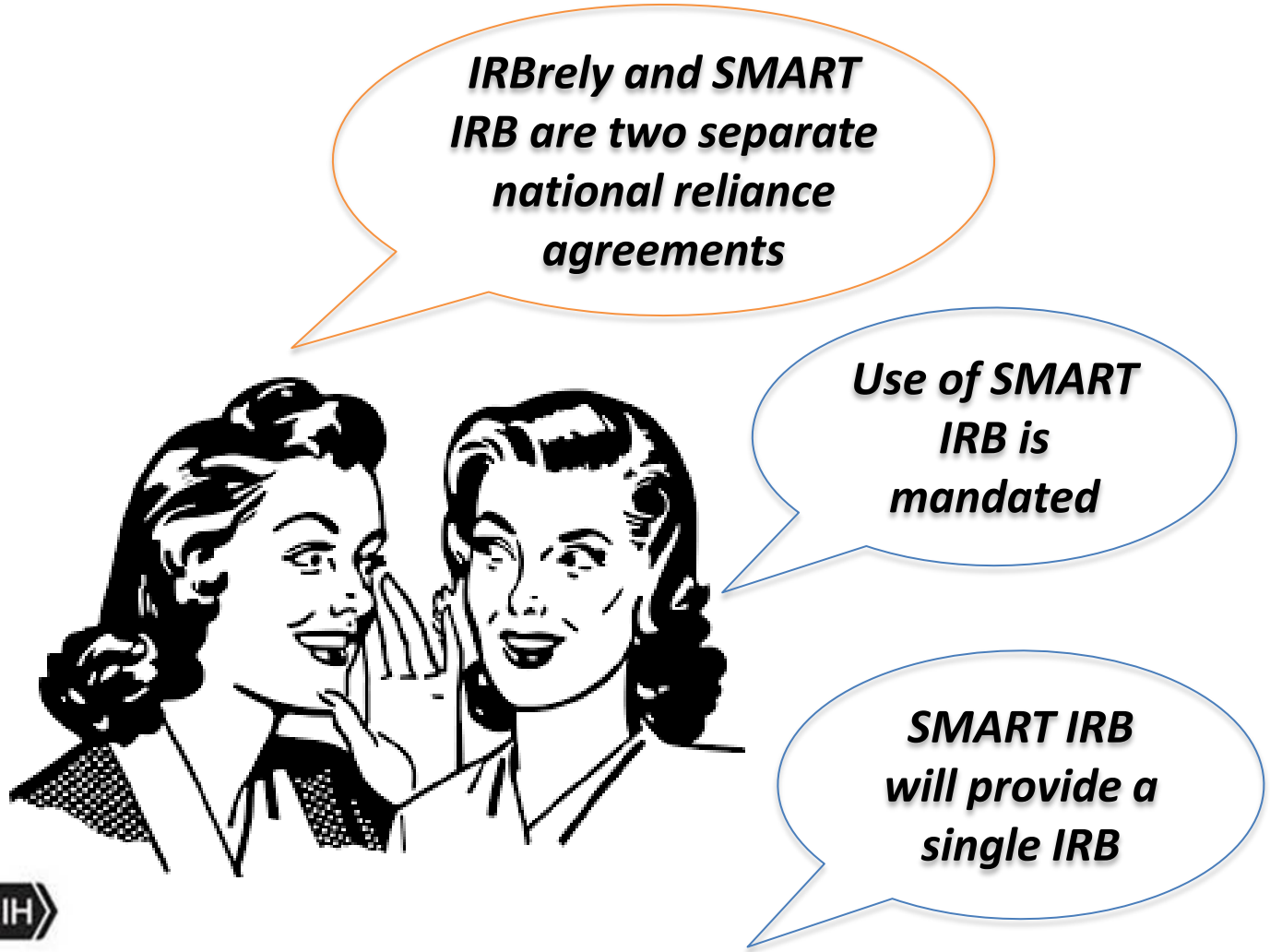
Takeaway:

Aims to standardize; a site is done negotiating the agreement once it has signed SMART IRB

NCATS SMART IRB Authorization Agreement Eligibility



Rumor has it…



SMART IRB is an *extension* of IRBrely, and remains a "treaty" model.

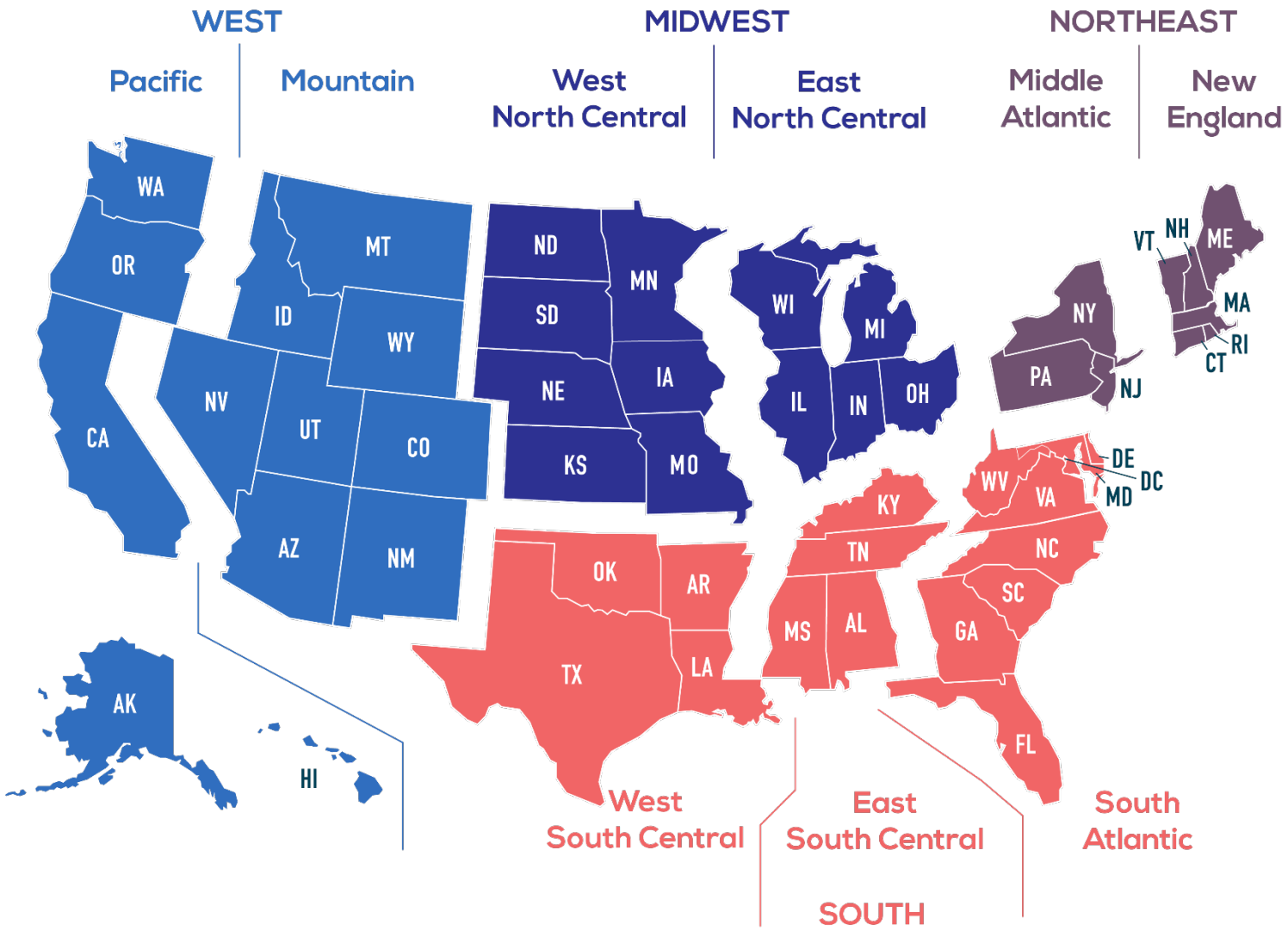
Participation is NOT mandated, nor is it exclusive.

SMART IRB does NOT establish a single IRB.

How do Institutions Join SMART IRB?

- Institutions join SMART IRB through the SMART IRB Joinder System www.smartirb.org
- Priority is to have all CTSA Hub institutions and their affiliates sign-on first
- SMART IRB Ambassadors will contact CTSA Hubs and affiliates to answer questions regarding the Agreement and SOPS
- CTSA Trial Innovation Network cIRBs will use the NCATS SMART IRB Authorization Agreement

SMART IRB Ambassadors Assigned to CTSA Hubs by Region



sIRB Determination / Cede Review

Reviewing IRB

- A Lead Investigator, Study Team or Network identifies the IRB that will serve as the IRB of Record

Participating Institutions

- Participating Institution / Site cedes review to the reviewing sIRB

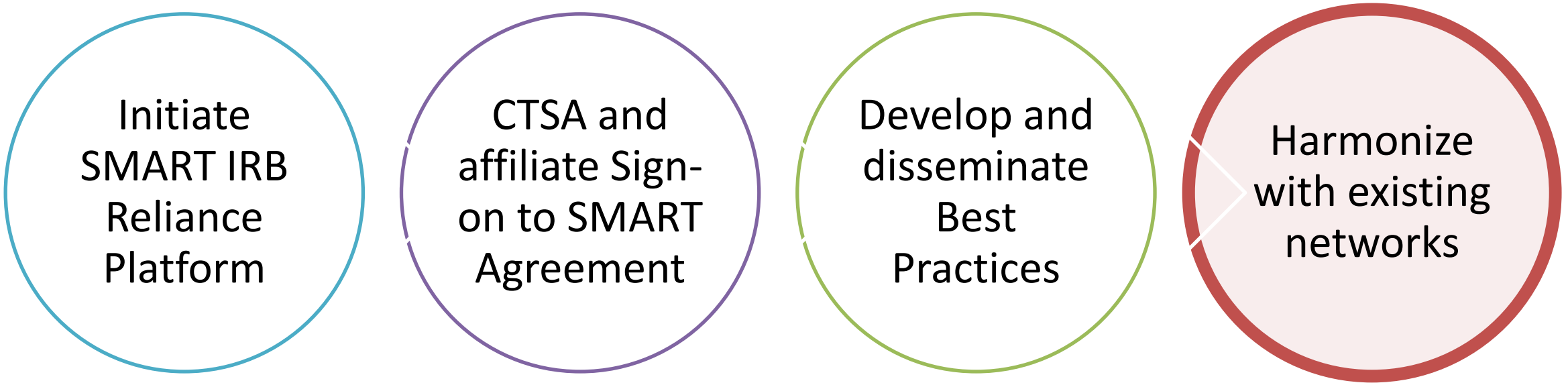
Documentation

- Determination of the sIRB and Participating Institutions must be documented
- Electronic systems are in development to support determination documentation

Value of SMART IRB Reliance Platform

- National platform that will support all types of multi-site clinical research studies regardless of the size of the study or from where the research study originates.
- Leverages expertise from CTSAs and NIH networks to support an evolving IRB reliance network
- Signatories agree to serve as either the reviewing IRB or relying Institution

SMART IRB Reliance Platform Timeline



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QUESTIONS?