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Single IRB
Standard Best Practices

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Video

- In an ideal sIRB world, all NIH funded research starts quickly - there is an efficient IRB review process, where information – data and documents are exchanged electronically from an sIRB to a participating site just as if they were ONE institution. Research teams experience an ease of submission using an interconnected system without double entry; Institutions have all the necessary information to track research their sponsored research. IRBs achieve consensus on standardized approaches to protocol and consent documentation, reliance agreements and ancillary review processes. In this sIRB world research begins

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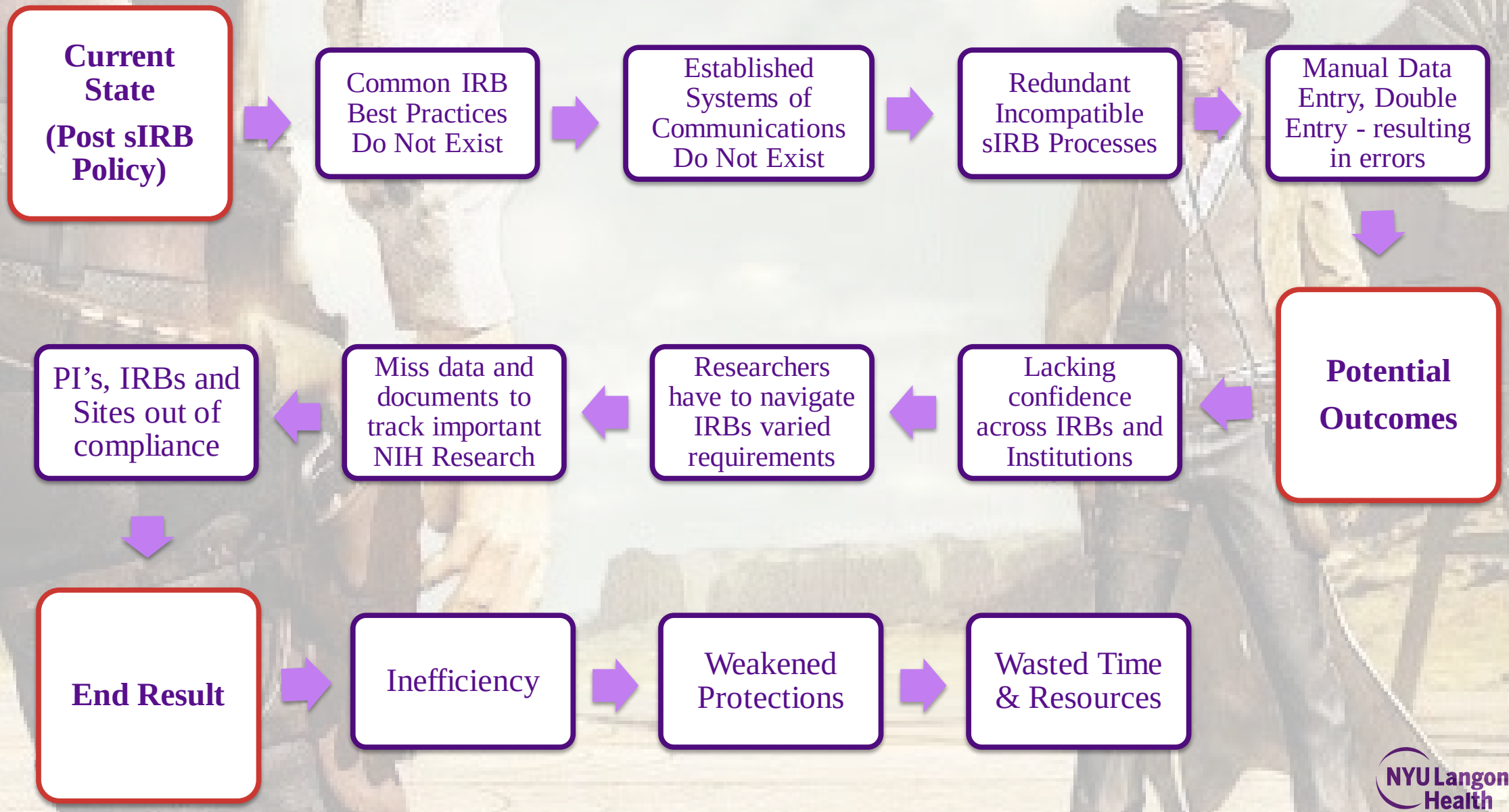
The Current Real World sIRB: Far From Ideal



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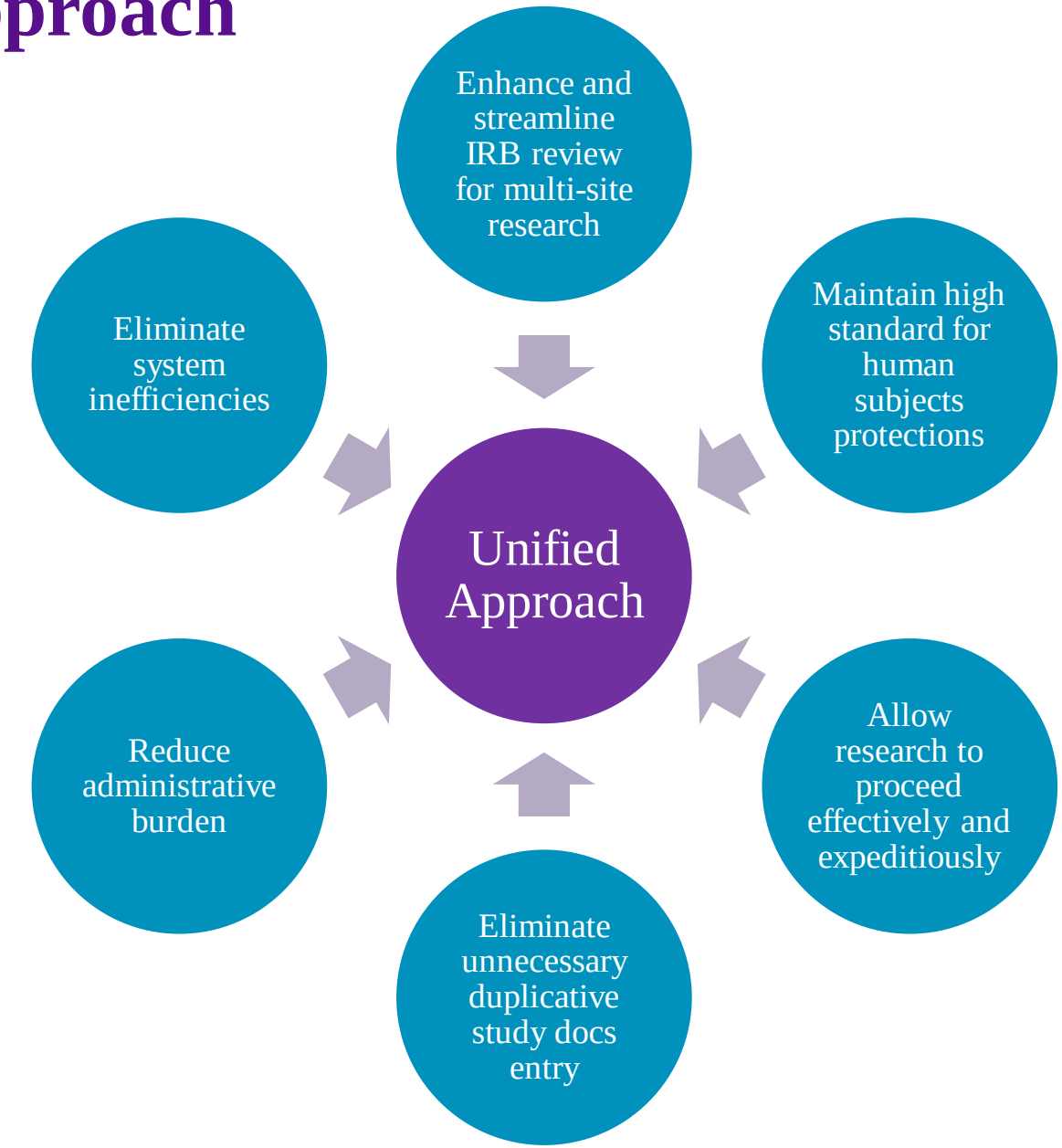
Building A Unified Approach



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Building on Existing Solutions

Existing Solutions		Our Goals
SMART IRB recommendations, guidance and reliance templates	→	Standardizing Additional Documents, Policies and Processes
Support primarily the Clinical and Translational Science Award (CTSA) network	→	Support All NIH Award networks
To date, work has been mostly delivered by large institutions	→	Promote collaboration across institutions of all sizes
Web-Based Submission System	→	End-to-End Cloud Service Connecting sIRB and pSites for Multi-site Studies

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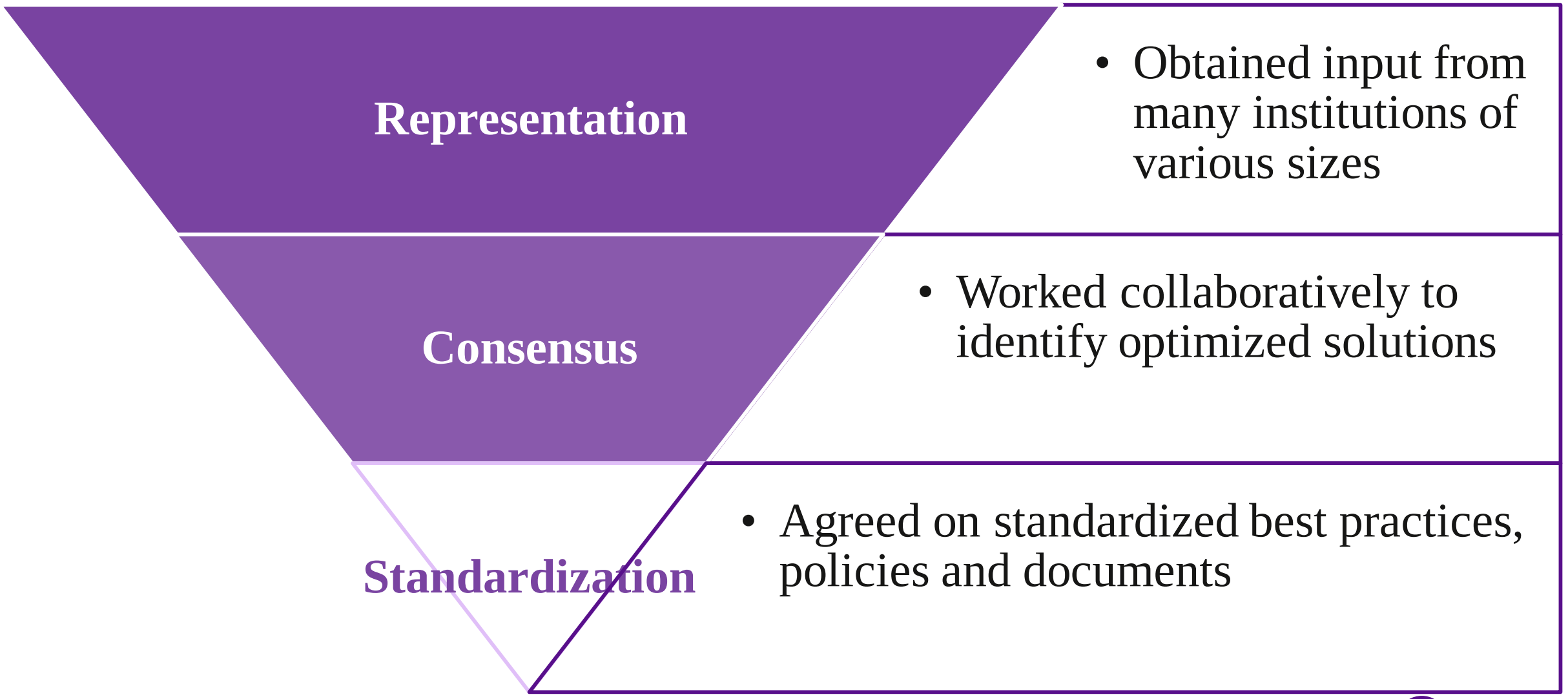
Our Philosophy



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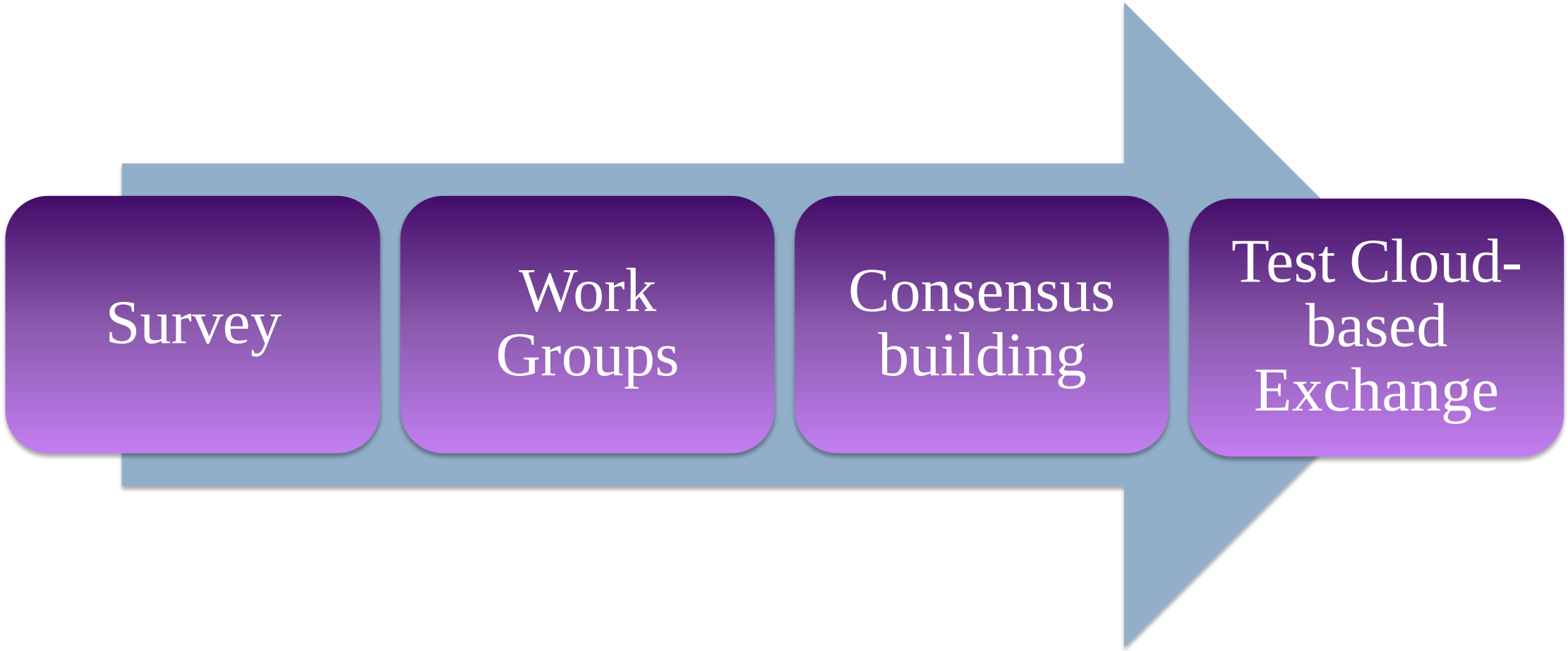
Establishing consensus for best practices



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Initial REDCap Survey: Community engagement

- **What was asked?**
  - characteristics of research institution
  - staffing and review volume
  - current local IRB data management practices
  - resources or experience for sIRB model
  - electronic IRB submission platform
  - standardization preferences on range of review topics in a main site and p-site context:
    - Informed Consent
    - Reliance agreements
    - Reportable Information
    - Ancillary Reviews
- **Who responded?**
  - 122 volunteers from 105 unique institutions
  - range of sizes and capabilities, including non-CTSA institutions
  - sites not on a Huron e-submission system, including homegrown systems
- **When?**
  - 01/26/2018 – 02/28/2018

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Survey Terminology

- **Category of Approaches**
  - **Standard** - the relying institution will accept standardized language/forms/processes with no local IRB/Institutional review
  - **Hybrid** - the relying institution will accept some standardized language/forms/processes but with option of limited IRB/Institutional changes
  - **Local** - the relying institution **requires IRB/Institutional review** of all language/forms/processes and would rarely approve a standardized (unmodified) study-wide instrument

Survey Topics and Results

- Informed Consent Language
  - Confidentiality of records
  - Experimental procedures
  - Subject renumeration
  - Risks related to genetics research
  - Research statement
  - NIH CoC Statement
  - Benefits to the subject
  - In case of injury explanation
  - Privacy Protection
  - Purpose of research
  - Alternate procedures and courses of treatment
  - Risks of discomforts to the subject
  - Duration of participation
- Study Team Training & Qualification
- Data Safety Monitoring Plan
- Recruitment Materials
- Definition of Vulnerable Populations
- Financial Conflict of Interest
- Defining IRB Reportable Events & Time Frames (including Subject Complaints)
- Defining ancillary reviews, timing of ancillary reviews
  - Outcomes of ancillary reviews and process for re-reviews
- Process and Addendum for Reliance Agreement
- Reliance Agreement and Addendum

■ Full sIRB Standardization ■ Hybrid Approach ■ Significant Local Modifications

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Building Consensus: Work Groups - Expertise, Representation

- **5 Work Groups**
  - Survey participants
  - Members from institutions of various sizes
  - CTSA and non-CTSA
- **Bi-weekly via teleconference** over several months
- Informed by the survey results, worked to **determine consensus for best practices for each major topic**

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Work Groups – Expertise, Representation

Informed Consent

Frederick More - NYU Langone Health
Helen Panageas - NYU Langone Health
Rania AlShahrouri - UT Southwestern Medical Center
Brian Moore - Wake Forest University Health Sciences
Julie Ozier - Vanderbilt University Medical Center
John Roberts - UNC Chapel Hill
Vanessa Smith - Rockefeller University
Lorena Smith - University of California San Diego
Amy Waltz - Indiana University
Daniel Jones - Partners Healthcare

Ancillary Review

Erik Mann - NYU Langone Health
Nida Cassim - NYU Langone Health
Karen Allen - University of California, Irvine
Hallie Kassan - Northwell Health
Kimberly Summers - University of Texas Health San Antonio
Elizabeth Witte - Harvard Medical School

Reliance Agreement

David Wallach – NYU Langone Health
Rui Ferreira - Albert Einstein College of Medicine
Raffaella Hart – BRANY
Thomas Street - University of Miami
Aaron Kirby - Harvard Catalyst

Other IRB Documents/Definitions

Marina Godina - NYU Langone Health
Kira Nightingale - NYU Langone Health
Catherine Raimond - NYU Langone Health
Aaron Kirby - Harvard Catalyst
Adrienne Meyer - University of Washington
Kelley O'Donoghue - University of Rochester
Sujatha Sridhar - University of Texas Health Science Center at Houston
Jenni Beadles - Vanderbilt University Medical Center
Ryan Washington - BRANY IRB

Reportable Information

Nadia Johnson – NYU Langone Health
Jessica Evans - Ohio State University
Nancy Green - Columbia University Medical Center
Stefanie Juell - Albert Einstein College of Medicine
Ginger Pomiecko - University Hospitals of Cleveland
Brenda Ruotolo - Columbia University
Megan Singleton - Johns Hopkins University School of Medicine
Nichelle Cobb - University of Wisconsin
Vanessa Hill - Ohio State University

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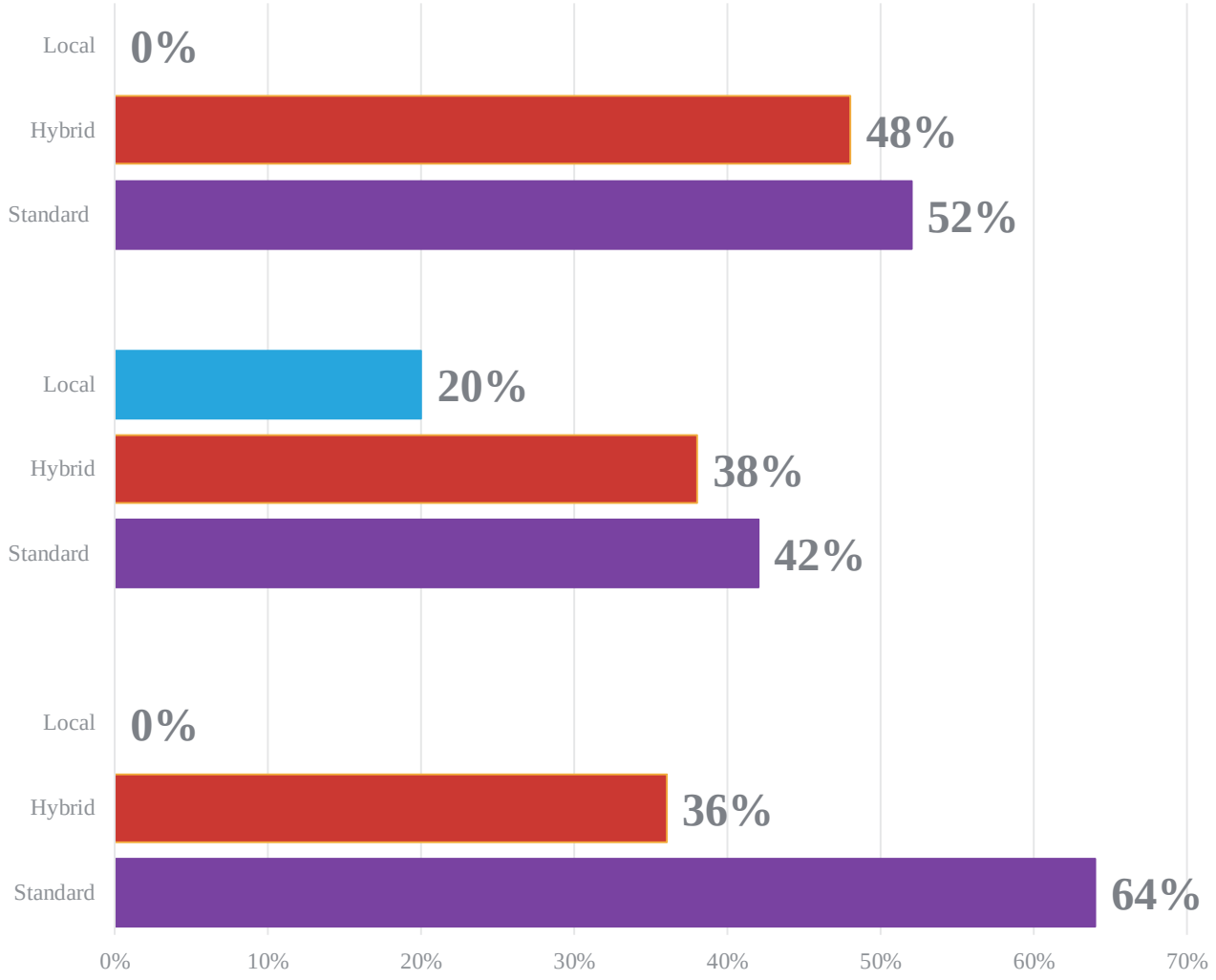
Work Group Results Summary

- **Produced Suggested Approaches for Standardization:**
  - Informed Consent templates (*shown on right*)
    - Biomedical and non-biomedical versions
  - Other IRB Documents/Definitions
    - Study Team Training and Qualifications (*shown on right*)
    - Data Safety Monitoring Plan
    - Recruitment Materials
  - Reportable Information
    - Reporting Definitions (*shown on right*)
    - Processing of Reporting and timelines
    - Review Process for Reportable Events



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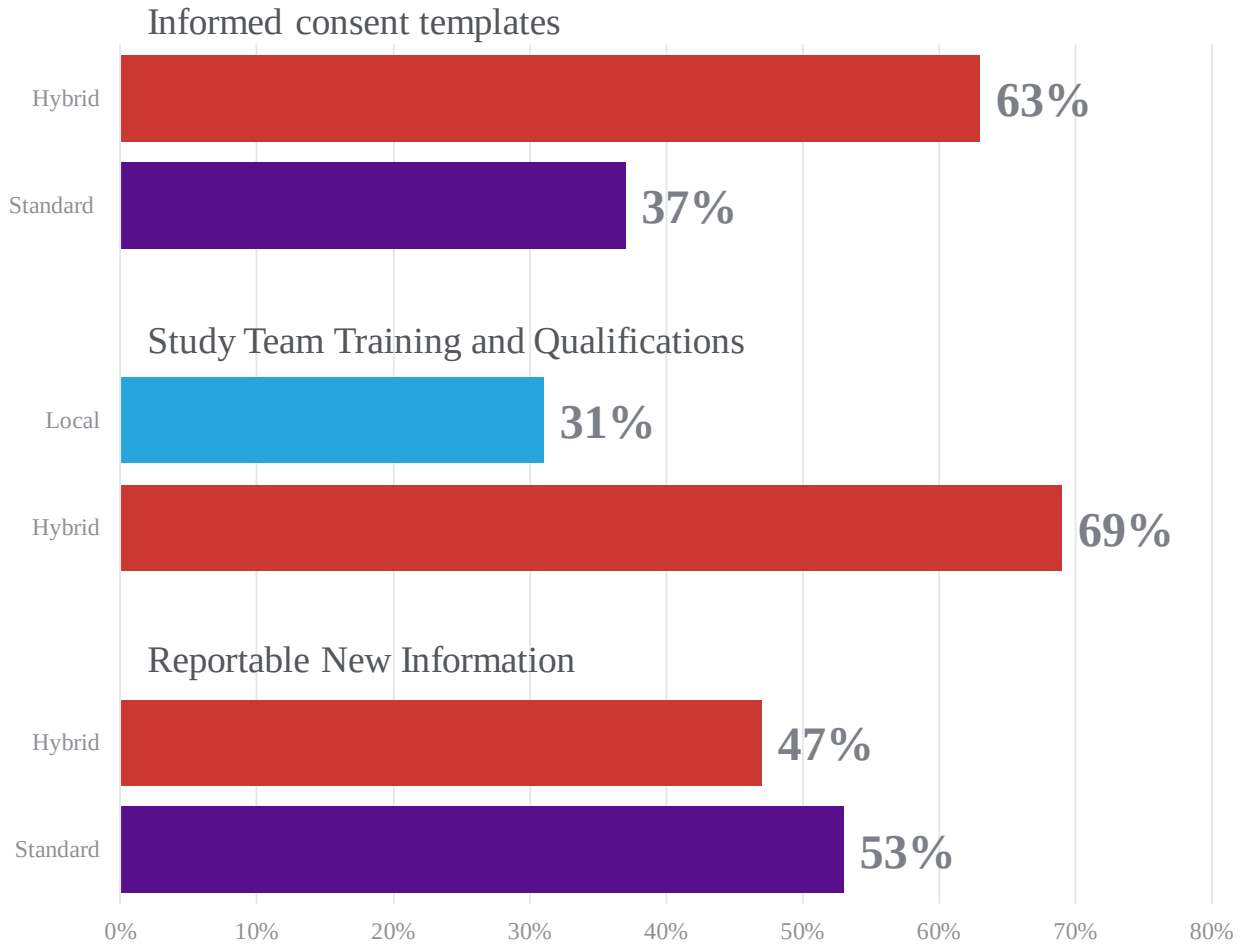
Consensus Building: REDCap Survey Preliminary Results

- IRB community asked to choose from top two approaches as determined by work groups
  - IRB forum
  - CTSAs
  - Huron Listserv
  - NYC IRB Consortium Listserv
- 65 responses from 45 different institutions
  - Survey still open for participation



■ Full sIRB Standardization ■ Hybrid Approach ■ Significant Local Modifications

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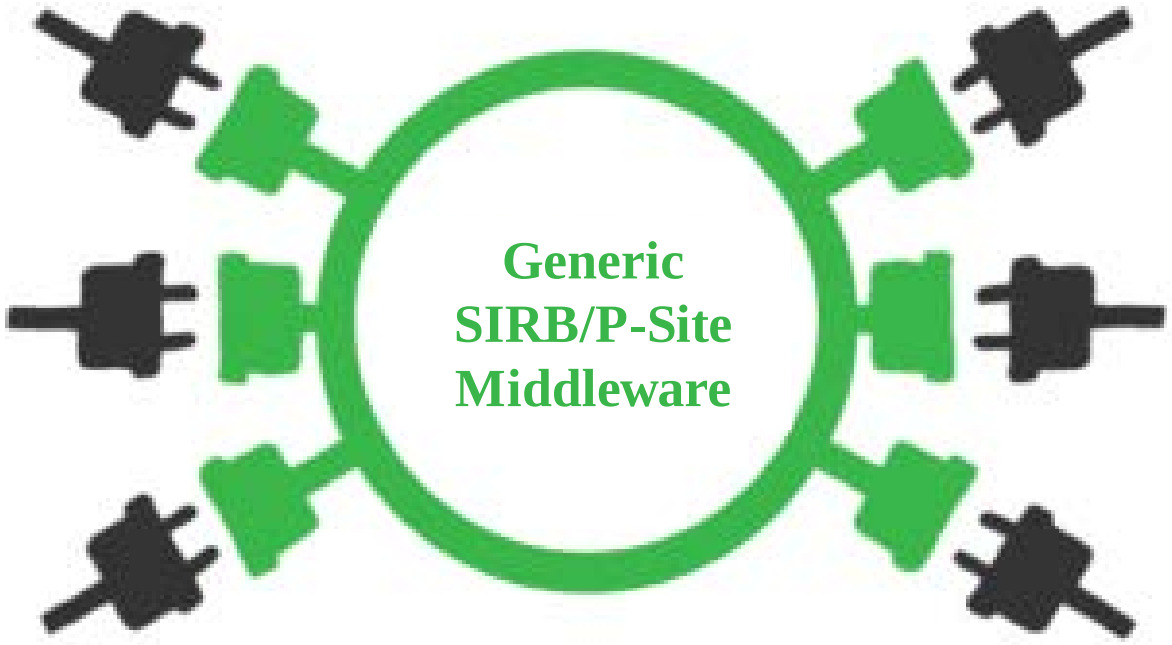
Generic SIRB/P-Site Middleware

Huron Native Clients
(100%)

Huron Free pSite Client
(40%)

Huron Rx Client
(25%)



3rd Party IRB Systems
(n/a)

Home Grown pSite Client Systems
(n/a)

API Middleware
(n/a)

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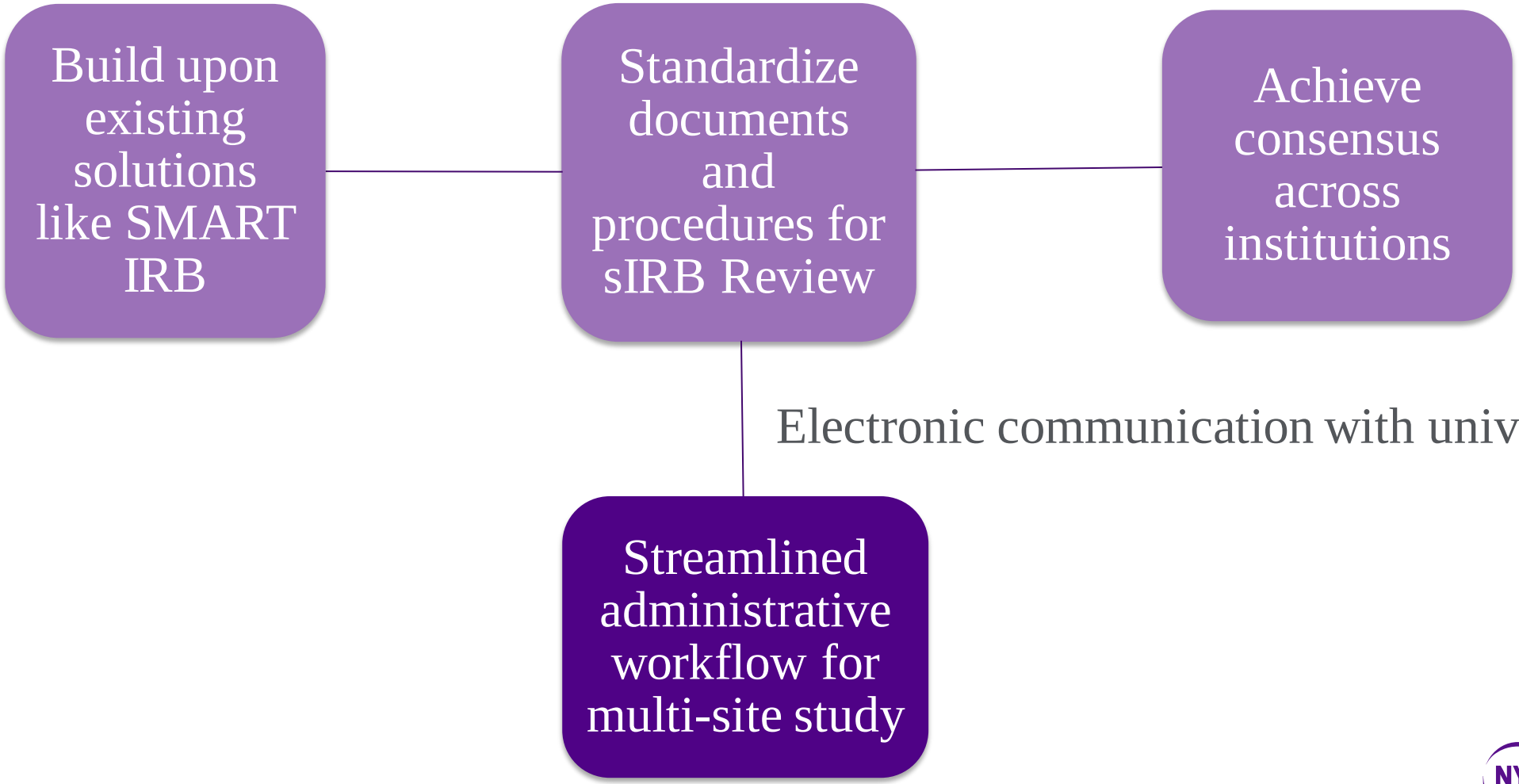
Impact for the sIRB model



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Impact: Dissemination and Sharing of Results

- sIRB Alliance and next steps
  - Publish all consensus documents to sIRB Alliance website
  - Create Public Access Forum for ongoing dialogue
  - Create universal API for exchanging sIRB/pSite information between different IRB administrative systems (currently in draft)
- Standardize Best Practices to expand the exisitng SMART IRB's standard template for reliance agreements and broaden to the concept of harmonization for sIRB efficiency for all study related document review.

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