

Single IRB Alliance

Single IRB Solutions Through Consensus

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INTRODUCTION

As part of a yearlong project led by NYU School of Medicine’s Institutional Review Board and Clinical and Translational Science Institute (CTSI), various experts from research institutions across the country were asked to develop standardized best practices for successfully implementing the NIH’s sIRB model.



Our unified solution, the sIRB Alliance, was established thanks to the efforts of key stakeholders at NYU School of Medicine and those at a network of research institutions including 84 Huron client institutions and 62 institutions of the CTSA consortium.

A full list of collaborators, as well as the chosen solutions and information on future projects can be found on our website, SIRBAlliance.org.

PURPOSE

The sIRB Alliance aims to establish consensus on standardization of relevant policies, procedures, and information technology to support broad adoption of the NIH’s sIRB model. A universally accepted approach for review facilitates efficient study start up. Implementation of these solutions will reduce variations in sIRB review and enable institutions across the country to carry out the NIH’s vision for a streamlined sIRB model.

- To develop these standards, the sIRB Alliance enlisted the expertise throughout the country with a structured survey and working group meetings. Working groups were asked to weigh in on three approaches to major areas of sIRB review with an emphasis on a fully standardized approach, a local approach, and a hybrid of the two. These areas included:
- Roles and Responsibilities for sIRB and Local (relying) sites
 - Reliance Agreements
 - Informed Consent
 - Reportable Events
 - Subject Complaints
 - Ancillary Reviews
 - Study Team Training & Qualifications
 - Data Safety Monitoring
 - Plans Recruitment Materials
 - Vulnerable Populations
 - Financial Conflict of Interest

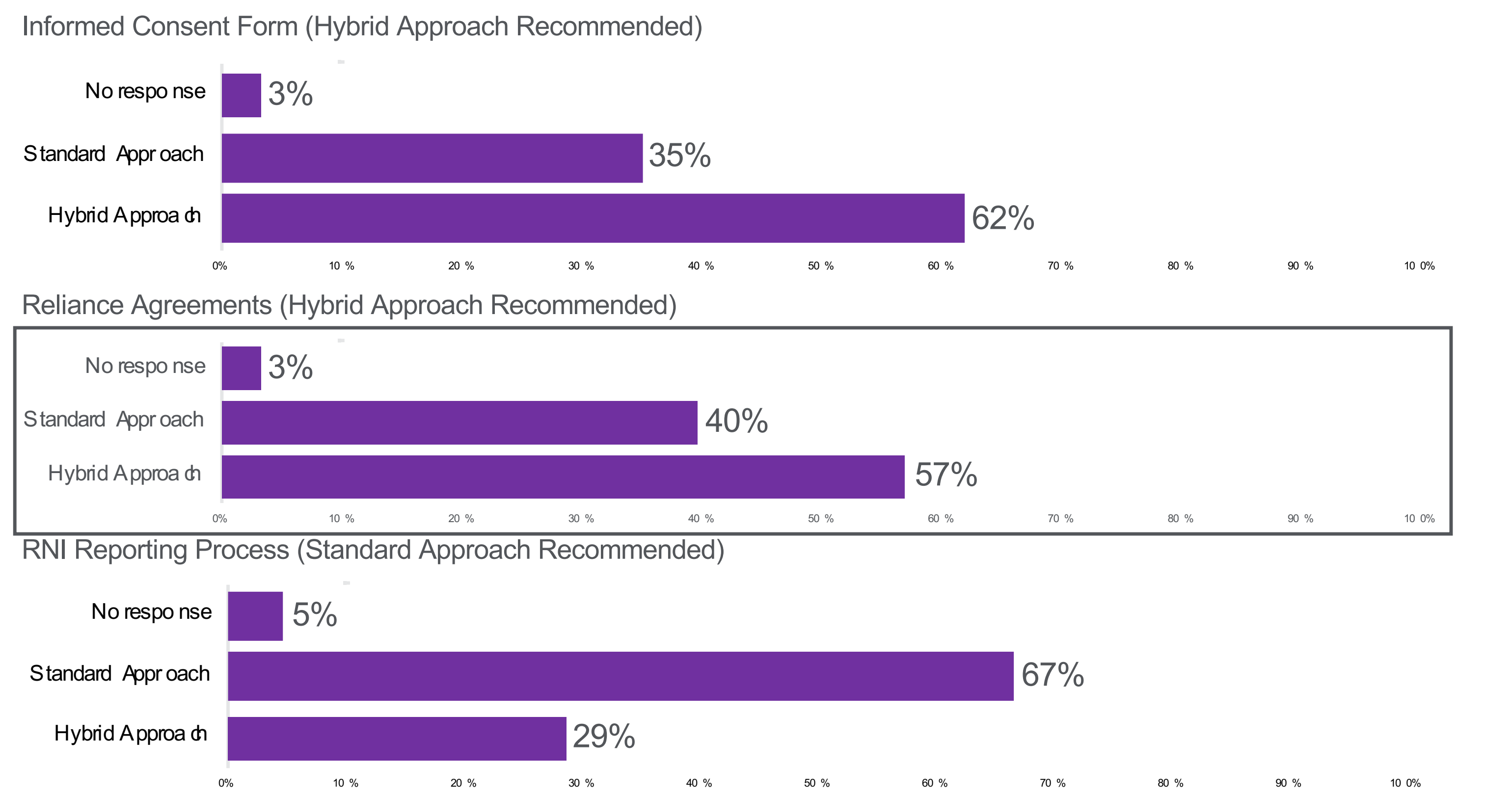
METHOD

Through structured surveys, working groups, and consensus meetings, the sIRB Alliance worked with the IRB community on standardizing sIRB practices intended to guide processes for sIRB review of NIH-funded multisite studies. Informed by the results of an initial survey polling 105 unique institutions, the sIRB Alliance at NYU School of Medicine invited individuals from CTSA and non-CTSA sites to address local context issues in a series of working group teleconferences.

The working groups characterized a range of practices to be considered for adoption as best practices in several areas. For each topic related to standardization of the sIRB best practices, two options were provided in a consensus survey voted on by convened Working groups):

- **Standard Approach:** psite will accept sIRB standards with no local IRB review (local IRB **will not review** instruments to adapt to the local environment).
- **Hybrid Approach:** psite accepts some sIRB standards after local IRB review. (local IRB **will review** instruments and may modify instruments for the local environment)
- **Local Approach:** psite **requires review** of all language/forms/processes and would rarely approve a standardized (unmodified) study-wide instrument.

EXAMPLES OF RESULTS



RESULTS

A consensus survey was distributed to the national IRB community upon selection of two approaches to each topic by working groups. 63 participants from 57 unique Institutions responded to the survey. Out of the 57 Institutions, 25 are CTSA affiliated institutions.

- Results for all twelve topics are summarized below:
- Reliance Agreements – Hybrid – 57%
 - Informed Consent Form – Hybrid – 62%
 - RNI Reporting Definitions – None – 49%
 - RNI Reporting Process – Standard – 67%
 - RNI Review Process – Standard – 52%
 - Communication of RNIs – Hybrid – 52%
 - Suggested Approach to Ancillary Review – Hybrid – 68%
 - Study Team Training and Qualifications – Hybrid – 60%
 - Recruitment Materials – Standard – 54%
 - Data Safety Monitoring Plan and Charter – Standard – 57%
 - Vulnerable Populations – Standard – 70%
 - Individual Financial Conflicts of Interest – Hybrid – 60%

CONCLUSIONS

Hybrid or fully standardized were the preferred approaches to standardizing these topics, with 11 out of 12 solutions receiving consensus on a hybrid or standard approach.

These findings demonstrate that establishment of consensus for standardization of best practices in support of the sIRB model remains a challenge. More work is required to engage all stakeholders in the conversation and encourage new standardized approaches to realize the full potential and benefits of the sIRB model.

MOVING FORWARD

The sIRB Alliance has additional consensus building projects in the works, including:

- **Standardizing Key terms for Electronic submission**
An upcoming consensus-building initiative to build a national index of key terms for electronic review submission.
- **Middleware**
A free-to-download system that would allow electronic submission systems to communicate seamlessly among institutions of varying sizes, means, and electronic submission systems.