

# IRBrely

Where we started, where we are, where we're heading...

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# Today's IRBrely Conversation

- Quick Review: Origins and Aims
- Current Status
- Next Steps

# What are we talking about?

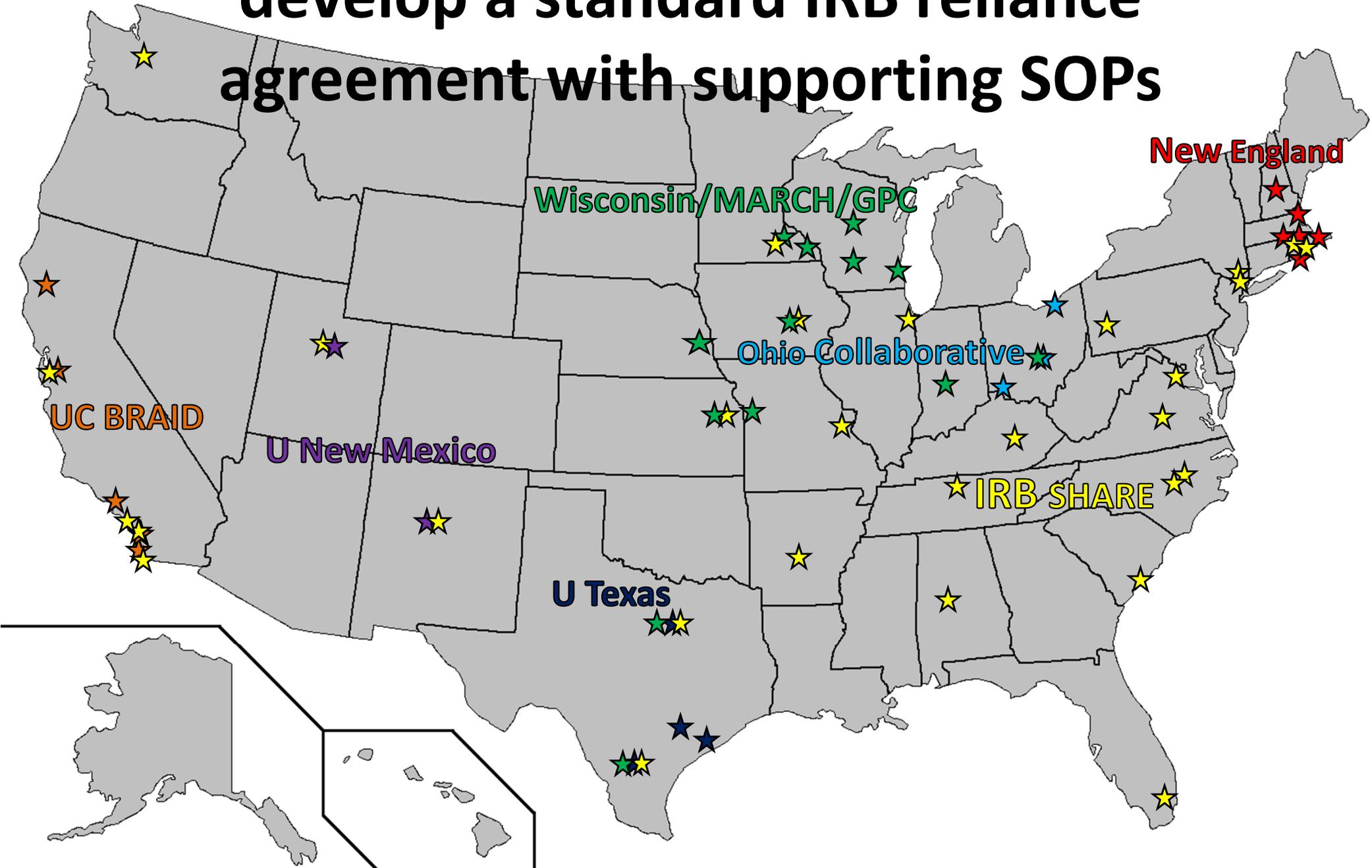
## Toward a National IRB *Reliance* System

*October 2014 – August 2015*

**Develop a standard IRB reliance agreement with supporting SOPs and informatics that:**

- is not specific to a research area or region
- can be used for small and large-scale studies
- can be applied to a range of research areas
- can be expanded beyond CTSA sites
- can allow FWA only institutions and IRB organizations to participate

# Major IRB networks working together to develop a standard IRB reliance agreement with supporting SOPs





# The National IRB System

## IRB *Reliance* Project is a standard reciprocal IRB reliance agreement with supporting SOPs

The IRB reliance agreement and supporting SOPs are NOT:

- A template – this is an executable master agreement
- A Central IRB model, but can be used to support central IRBs
- Limited to CTSA sites – open to all who meet the requirements
- Limited to AAHRPP accredited sites – other ways to demonstrate quality
- Set in stone – iterative learning and development

# Components and Activities of IRBrely

OCT-DEC 2014

JAN-APR 2015

MAY-AUG 2015

## IRB Master Reliance Agreement

- **A Single IRB authorization form** that all sites can use to cede review
- **Reliance model:** single IRB of record, chosen on study-by-study basis, for life of study; a “reviewing IRB” and “relying institutions”
- Build on expertise of existing models
- Engage PCORI to harmonize efforts

## Standard Operating Procedures (SOPs)

- **Spell out roles and responsibilities:**
  - Reviewing IRB
  - Relying Site(s)
  - Lead PI & Lead Study Team
  - Relying Study Team(s)
  - Lead Regulatory Contacts (aka POCs)

## Informatics Support

- [IRBrely.org](http://IRBrely.org) (Informational website)
- **Mechanism to join**
- **End-to-end, workflow-based platform** (in development) for study teams and sites to request and determine IRB reliance

## Pilot

- **Demonstrate feasibility** of proposed national IRB reliance model by piloting with a low-risk multi-center clinical trial
- CARRA Registry used to test components of IRBrely
  - Duke University served as Reviewing IRB; 15 sites ceding review
  - Obtaining feedback from participating sites on agreement and SOPs for roll out beyond the pilot
  - Testing forms and workflows developed in support of reliance to revise and enhance processes



# Next Steps for IRBrely

## Finalize and Expand

- Finalizing the edits from the 48 institutions
- Sending the agreement for final review
- SIGN
- Expand agreement to other sites
- Ensure that we have participation from all states

## Look to the Future

- Identify sustainability funding
- CTSA Network - Trial Innovation Centers (TICs)
  - “TICs will be lead centers of excellence in clinical trials and will facilitate the implementation of multi-site clinical studies by the CTSA Program network.”

<http://grants.nih.gov/grants/guide/rfa-files/RFA-TR-15-002.html>

# Next Steps for YOU

We are learning as we go! Contact us to:

- Review and join the agreement and SOPs
- Set up meetings and presentations to discuss the agreement and SOPs
- Identify studies to pilot the study and workflow
- Identify opportunities to harmonize with other existing IRB networks
- Commiserate and share stories and wisdom to inform and influence the final products! 😊

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