

# **SESSION II: MODELS FOR ASSISTING INSTITUTIONS RELYING ON sIRB**

## **Incorporating sIRB Procedures into an Existing Research Network**

University of Rochester CTSA Supplement  
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# Who we are...

Institution	Scientist/ Investigator	IRB Professional	Coordinator	IT Professional	CTSI Consultants
(NICHD)	(Higgins)		(Archer)		
Rochester	<b>D'Angio</b>	<b>O'Donoghue</b> Gommel Dauenhauer	Scorsone	Nguyen	Bennett Rubinstein
Case	Walsh	Reinhardt	Newman	Reinhardt	
Cincinnati	Poindexter	Bailey	Russell	Mark	
Duke	Cotten Fisher	Power	Finkle	Pittman	
Utah	Yoder	<b>Mumford</b>	Rau	Johnson	
UTSW	Brion	Al Shahrouri	Vasil	Bell	
<b>RTI</b>	<b>Das</b>	<b>Zaterka-Baxter</b>	<b>Palberg</b>	<b>Auman</b>	

6 of 15 institutions in multicenter, NICHD-funded Neonatal Research Network (NRN)



# Grant Aims

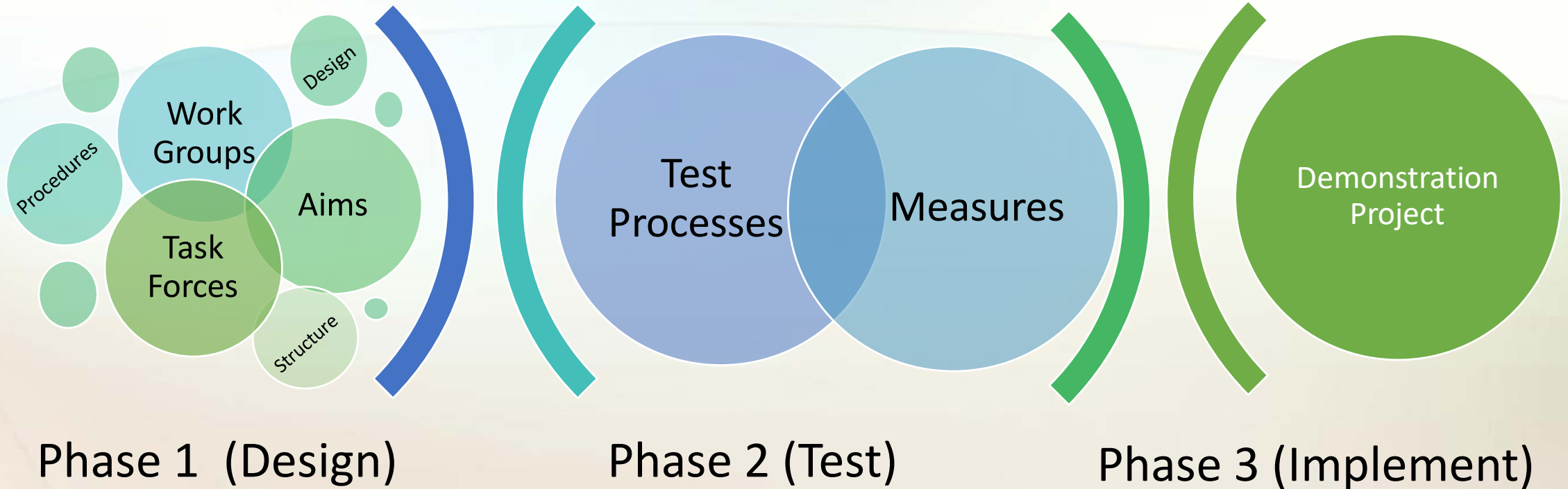
1. Establish responsibilities and relationships for the sIRB system in multi-site research network
2. Develop tools, procedures and standards for communication and data storage and handling
3. Develops standards for the cost structure of multi-site projects for a sIRB review



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# Timeline



Current Grant Cycle

Sep 2017   Oct   Nov   Dec   **Jan 2018**   Feb   Mar   April   May   June   July   Aug   Sep

# Discussion Points – Aim 1

## Roles and Responsibilities

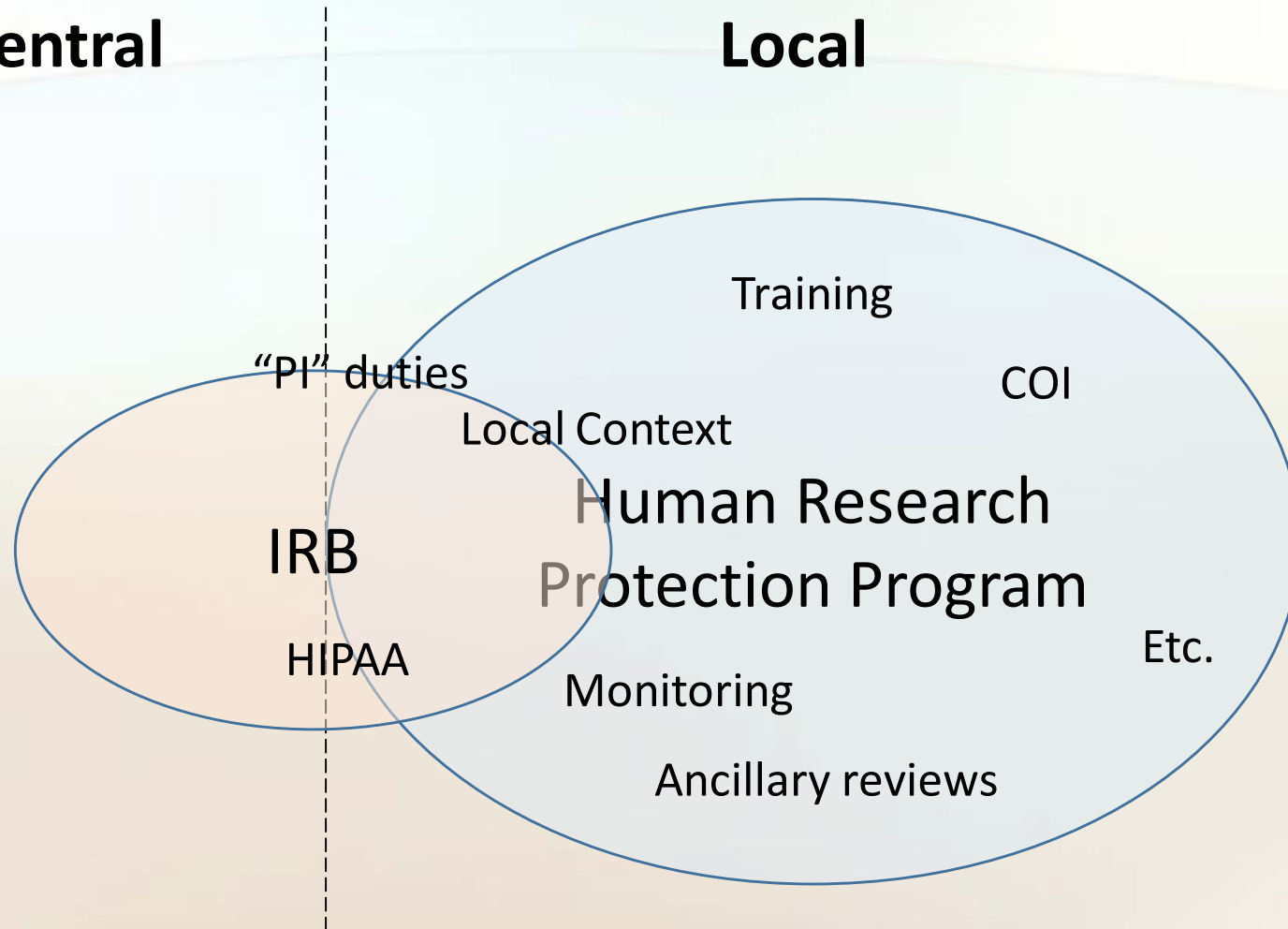
### Themes

- Responsibilities of the single IRB and its institution
  - Minimal requirements to act as a central IRB
  - Ensuring the lead PI understands responsibilities
- Responsibilities of relying IRBs and their institutions
  - Shape and extent of local institutional review
  - Avoiding overlap of responsibility with sIRB
- Role of Data Coordinating Center
- Relationships to Data and Safety Monitoring Committee
- Contingency planning for turnover of sIRB

# Roles and Responsibilities

**Central**

**Local**



# Discussion Points – Aim 2

## Communication

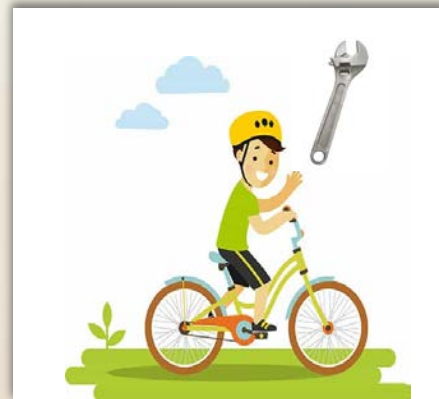
### Themes

- Formal structure of communication
  - Communication is key and needs to be laid out early
  - When available, what role for a Data Coordinating Center or Coordinating Center?
- Information technology requirements and systems
  - Minimum requirements and specifications
  - Interoperability
  - Secure communication, data storage and sharing
- Relationship to other communication platforms (SMART IRB, CTSA TIN, etc.)

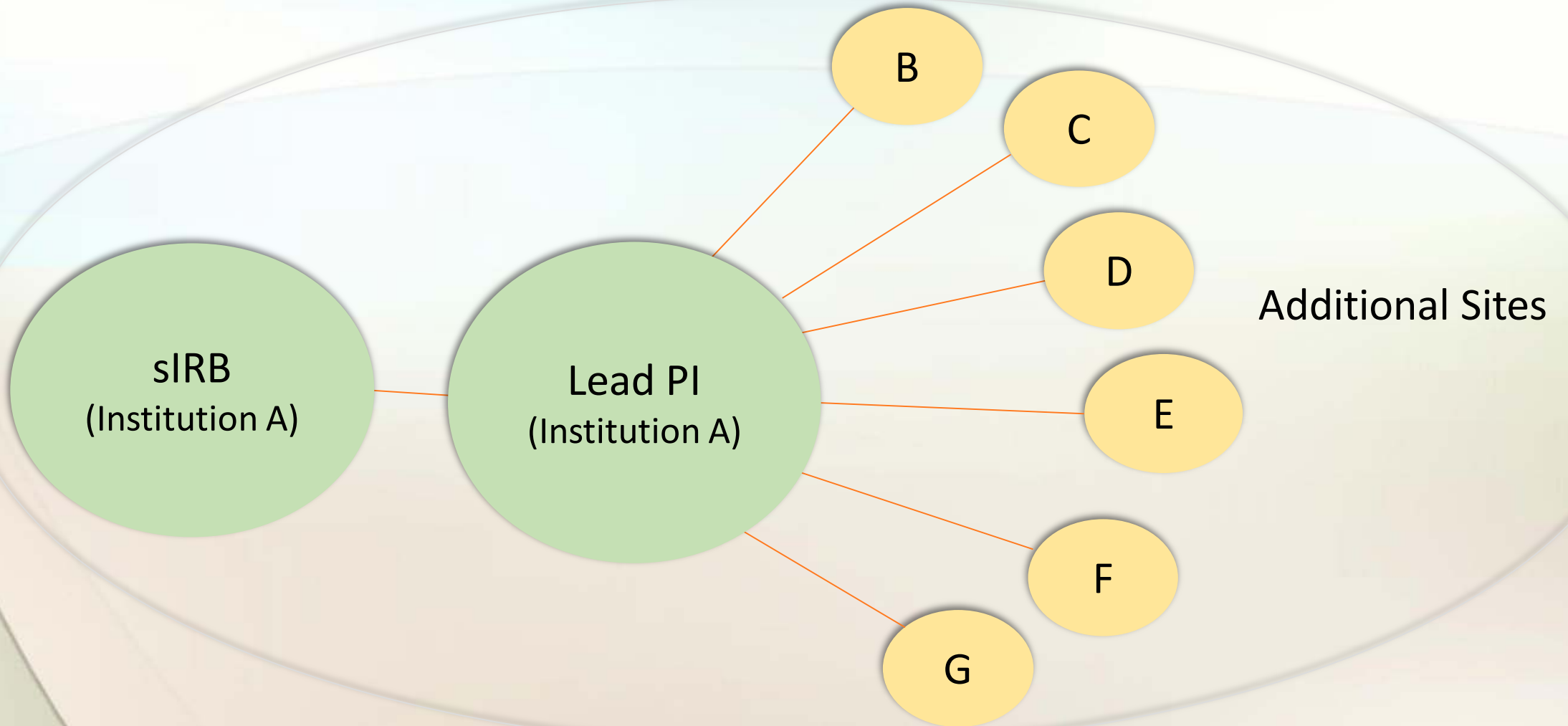


# Communication Technical Issues

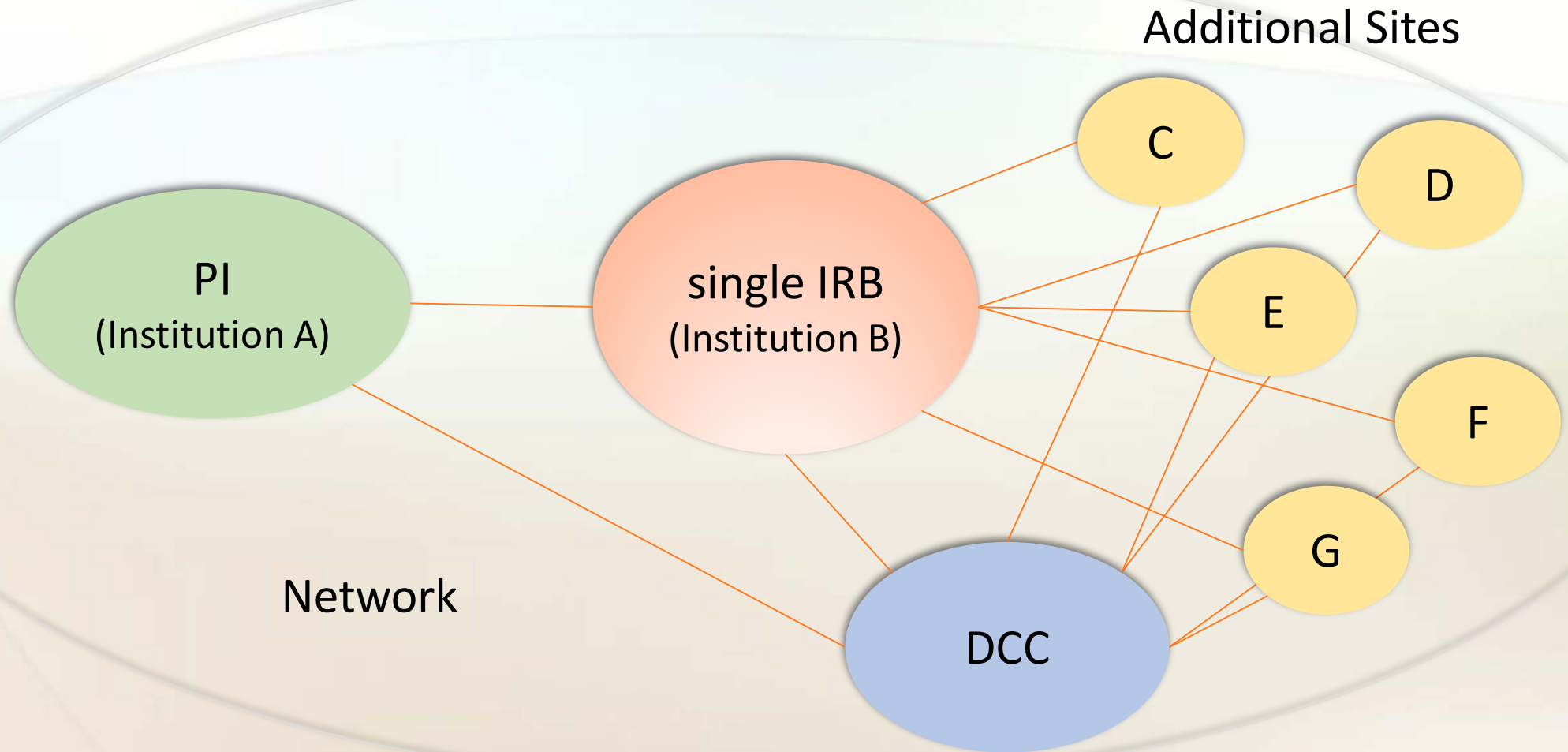
- Multiple IRB software systems
  - Poor interoperability
  - Not all can manage external submissions/investigators
- Most sIRB interaction systems new/incomplete
  - SMART IRB – reliance only
  - iREX (Vanderbilt) – gradually adding functions



# Lead PI and sIRB at the same institution

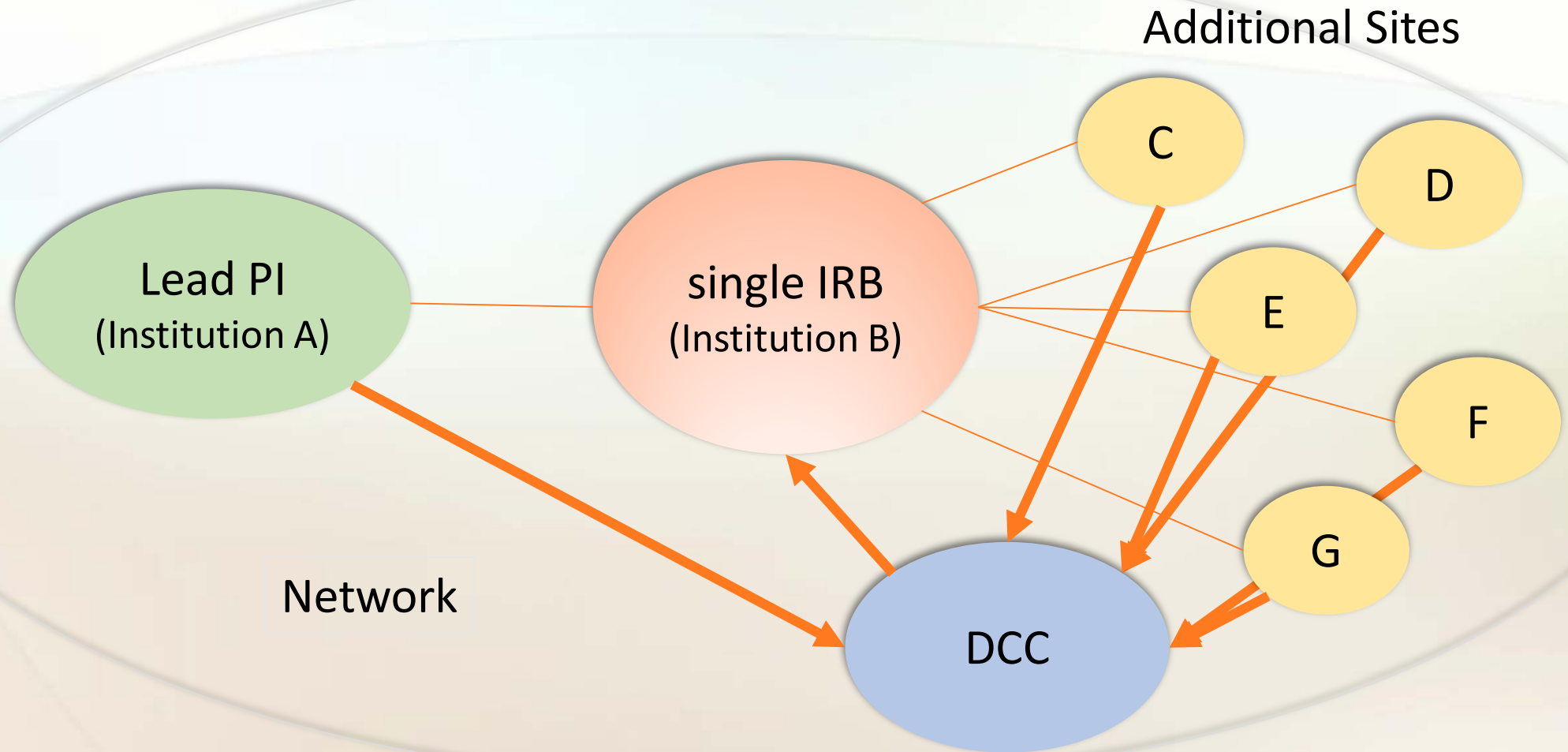


# Lead PI and sIRB at different institutions



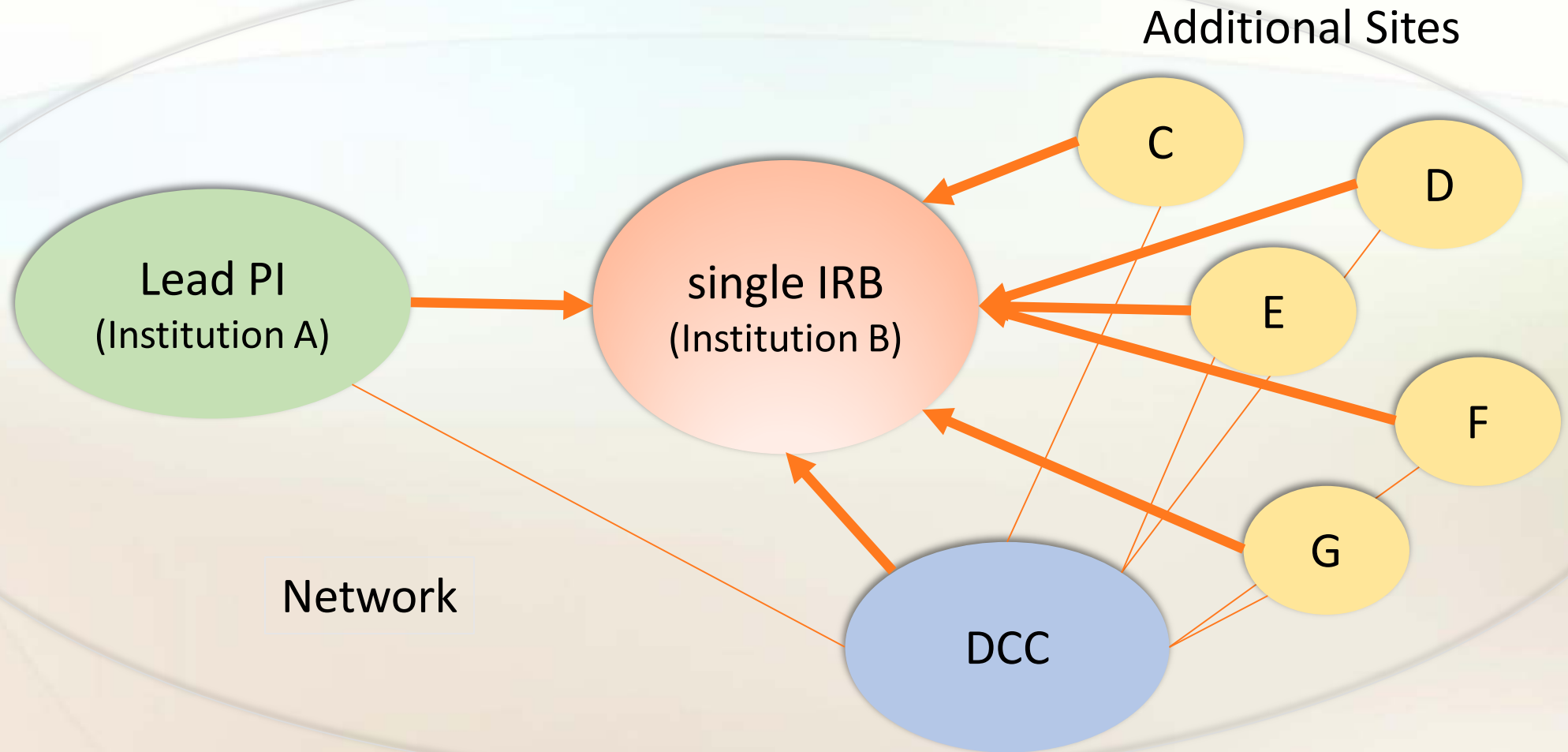
# Lead PI and sIRB at different institutions

*DCC hub for communication*



# Lead PI and sIRB at different institutions

*sIRB hub for communication, but DCC information center*



# Phase II

- Originally planned as mock reviews of existing studies
  - Advantages – comparability to actual pace of review
  - Disadvantages – duplication of effort, resources for “mock” reviews
- Altered to review of two upcoming randomized, controlled trials
  - Testing DCC-centric and sIRB-centric models
  - Advantages – effort is “real”
  - Disadvantages



# Different Perspectives on Relying IRB - Rochester



- Long history of use central IRB's
- Use own IRB application platform to manage institutional portion of external sIRB applications = two (or one-and-a-half) applications
- Clear institutional guidelines
  - Sensitive investigator information doesn't leave UR
- Considers qualities of sIRB
  - AAHRPP accreditation
- "IRB Exchange (iREX)"
  - Cloud-based, multi-institutional capability

# Different Perspectives on Relying IRB – UT Southwestern Medical Center



- Separate reliance team
  - Both for IRB of record and relying IRB applications
  - Pre-reliance meeting
- Separate system (REDCap) for intent-to-rely application
- Multiple inter-institutional agreements
  - Like all other centers, encourage SMART IRB
  - Clear delineation of responsibilities
- All documents leaving institution to go to sIRB (e.g. amendments) are first reviewed by UTSW



# Conclusions

- **Impact** – Developing/testing standards for sIRB review for multi-site, existing research network
- Resources and infrastructure partly **generalizable** to other institutions that might serve as or rely on a sIRB of record
  - Every system is different
- **Best practices** for information flow for facilitating sIRB review for multi-site research may emerge from Phase II
- **SMART IRB** and other platforms facilitate multicenter work, rather than vice-versa

Thank you

