

SESSION II: MODELS FOR ASSISTING INSTITUTIONS RELYING ON sIRB

Incorporating sIRB Procedures into an Existing Research Network

University of Rochester CTSA Supplement
Carl T. D'Angio, MD and Kelley O'Donoghue, MPH
September 12, 2018

Who we are...

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

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



Grant Aims

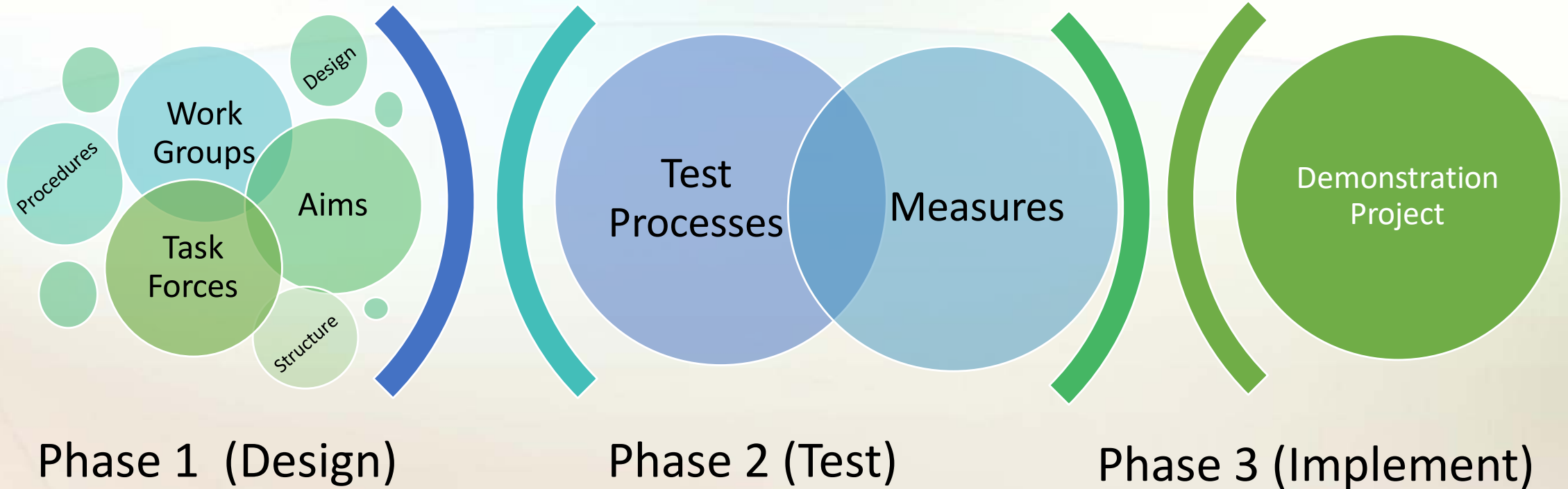
1. Establish responsibilities and relationships for the sIRB system in multi-site research network
2. Develop tools, procedures and standards for communication and data storage and handling
3. Develops standards for the cost structure of multi-site projects for a sIRB review



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

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

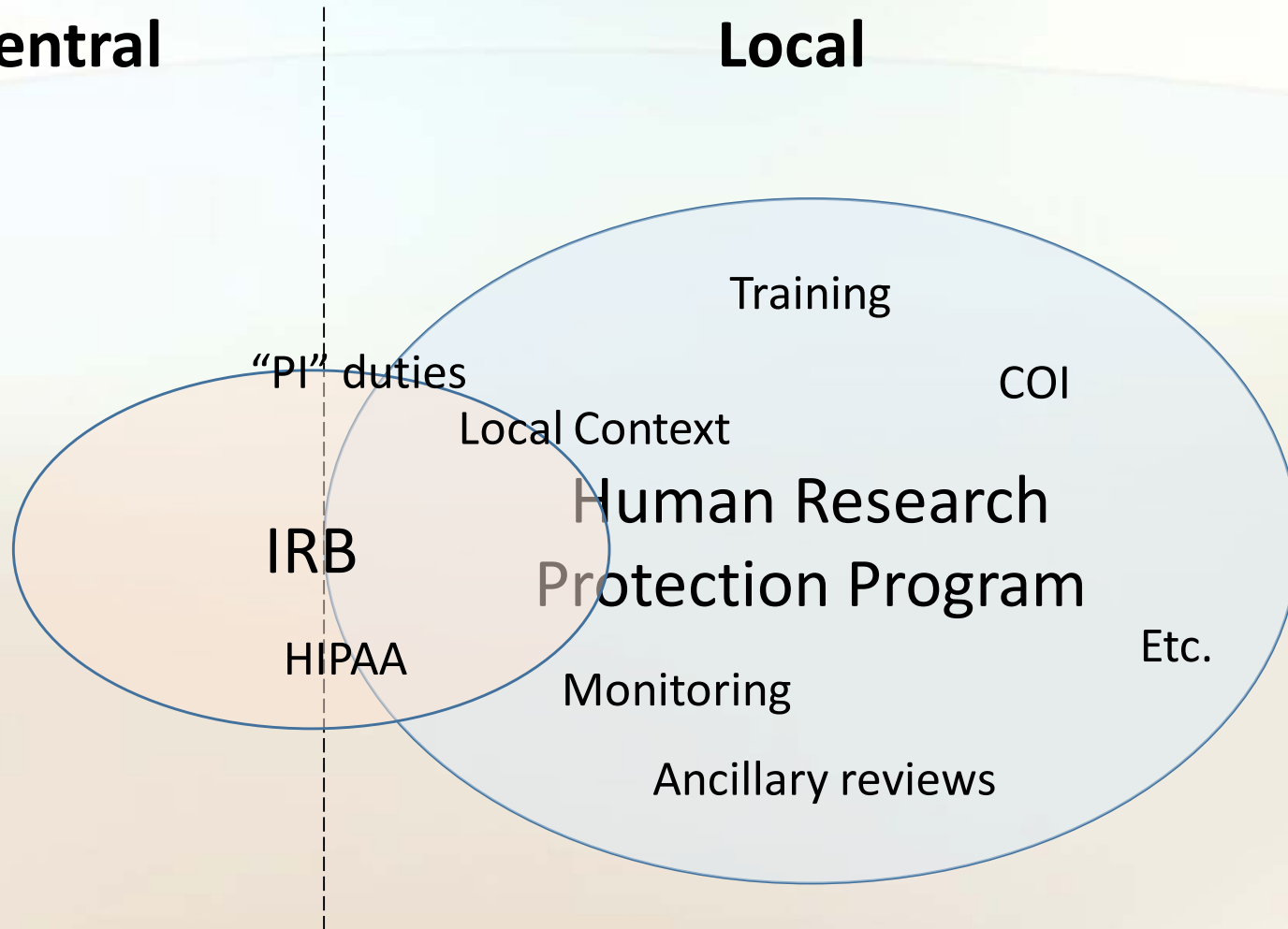
Themes

- 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

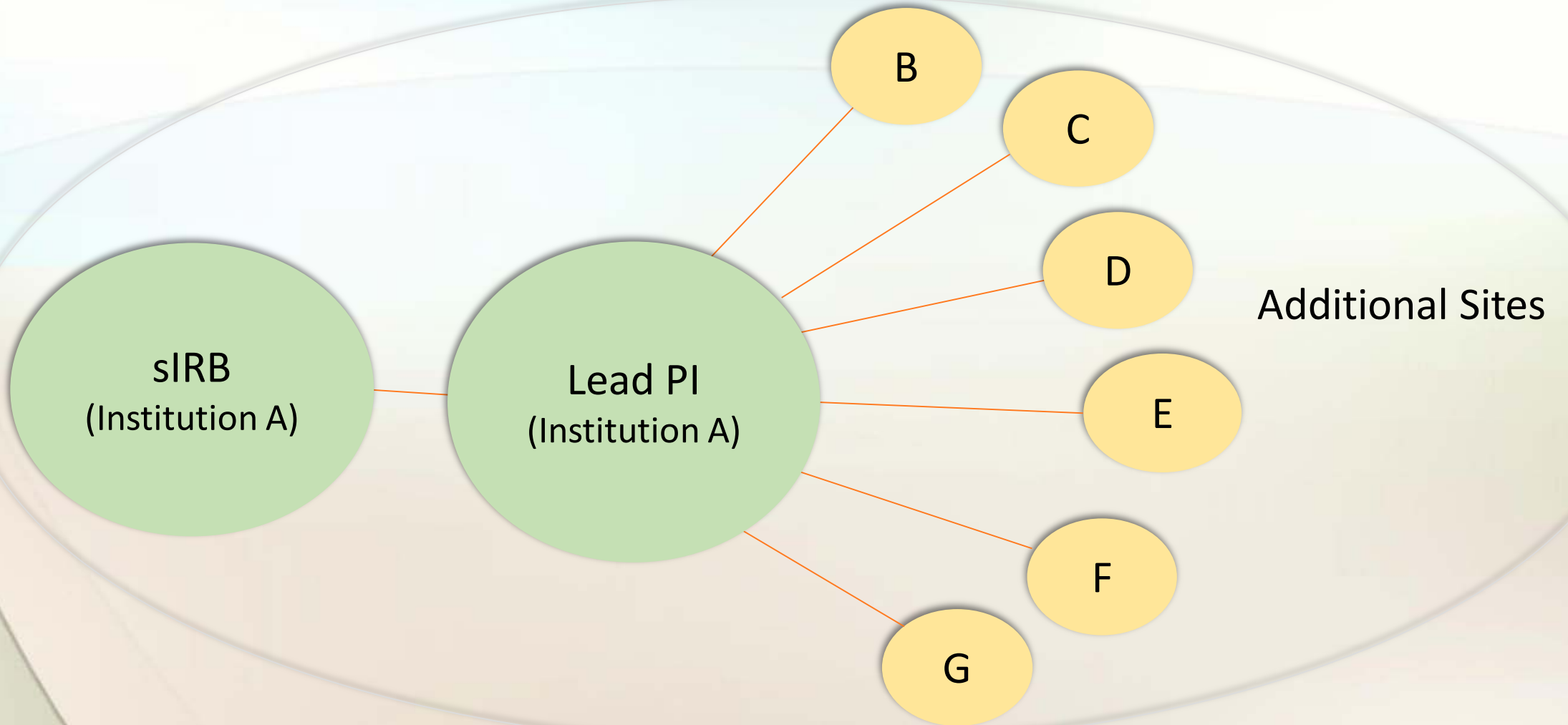
- Formal structure of communication
 - Communication is key and needs to be laid out early
 - When available, what role for a Data Coordinating Center or Coordinating Center?
- Information technology requirements and systems
 - Minimum requirements and specifications
 - Interoperability
 - Secure communication,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

Communication Technical Issues

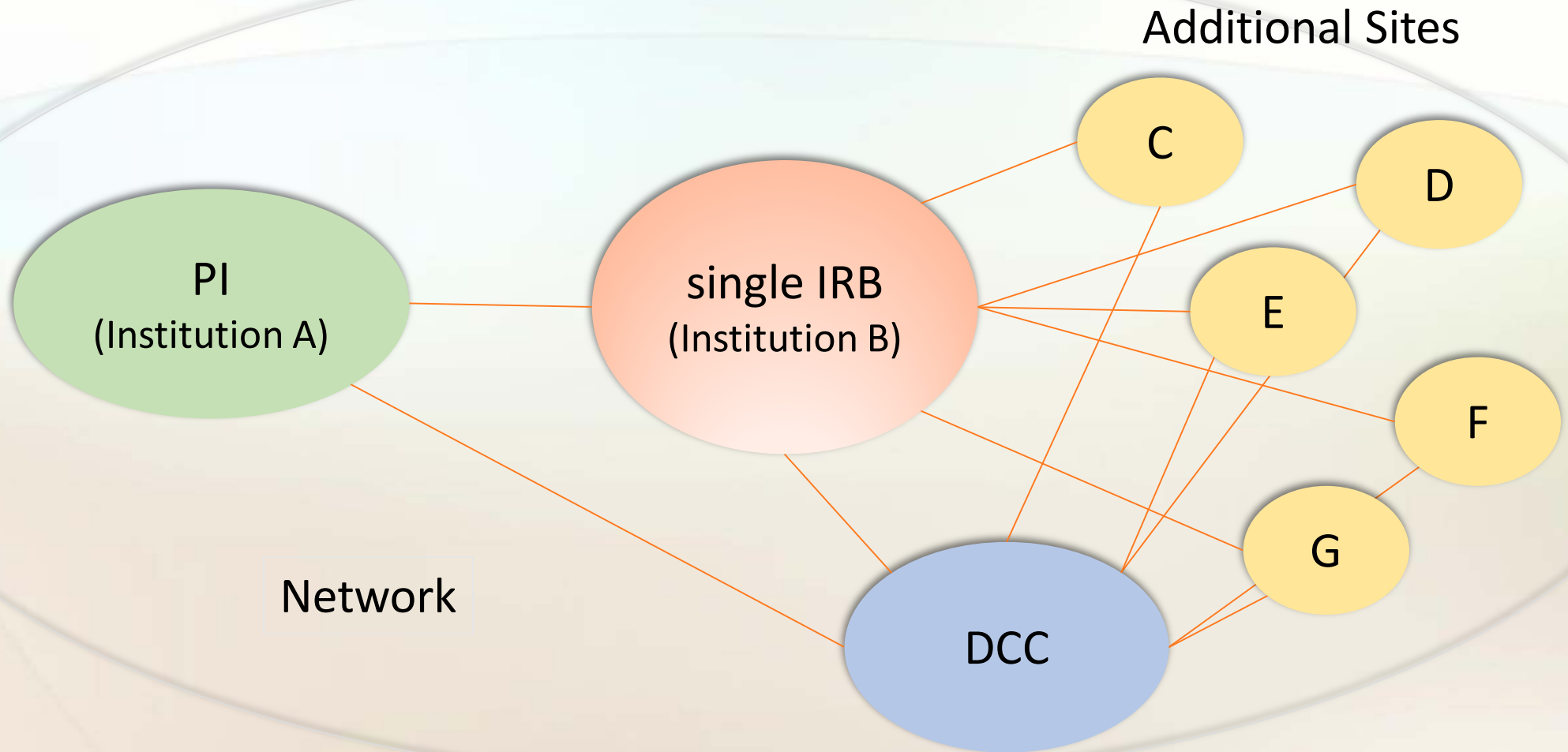
- Multiple IRB software systems
 - Poor interoperability
 - Not all can manage external submissions/investigators
- Most sIRB interaction systems new/incomplete
 - SMART IRB – reliance only
 - iREX (Vanderbilt) – gradually adding functions



Lead PI and sIRB at the same institution

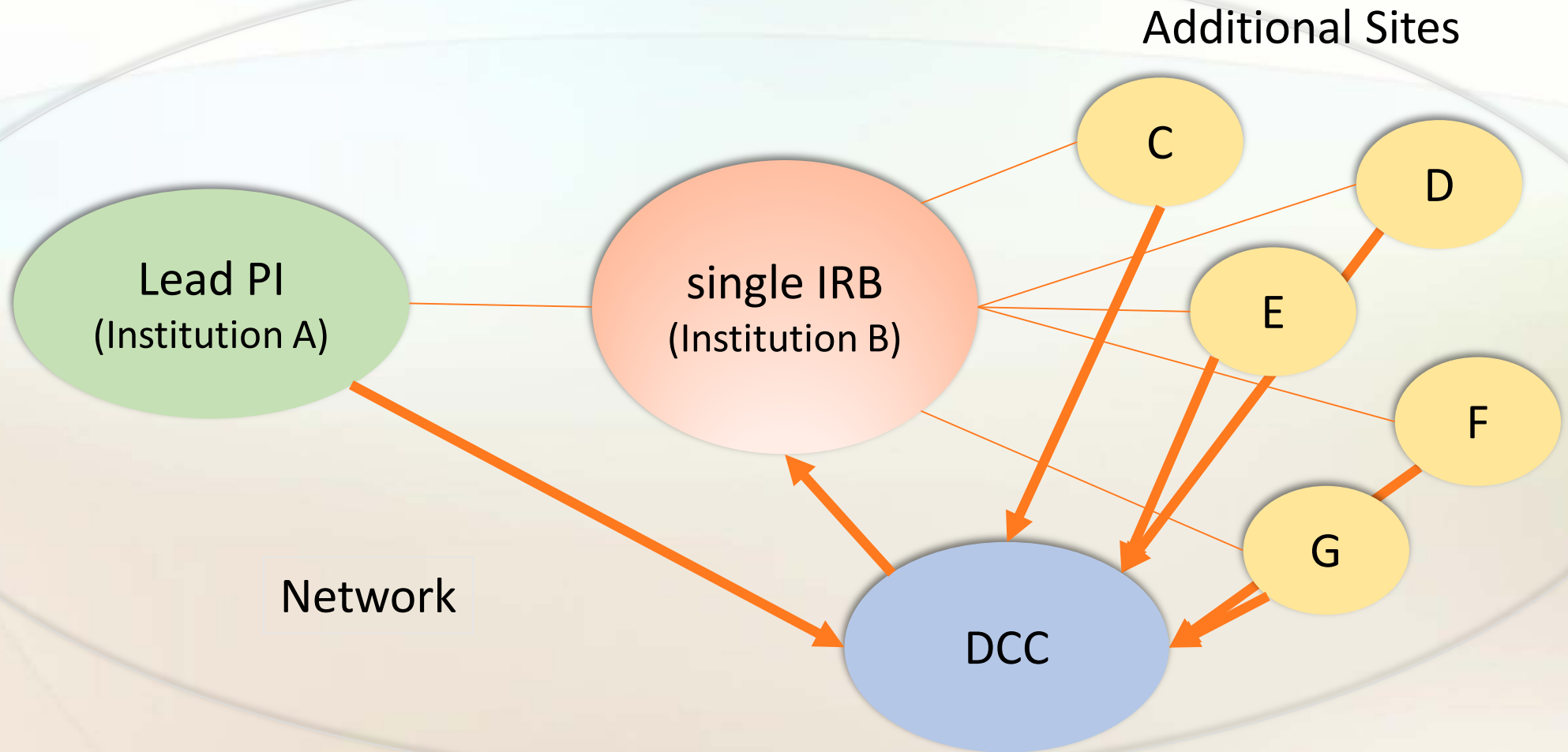


Lead PI and sIRB at different institutions



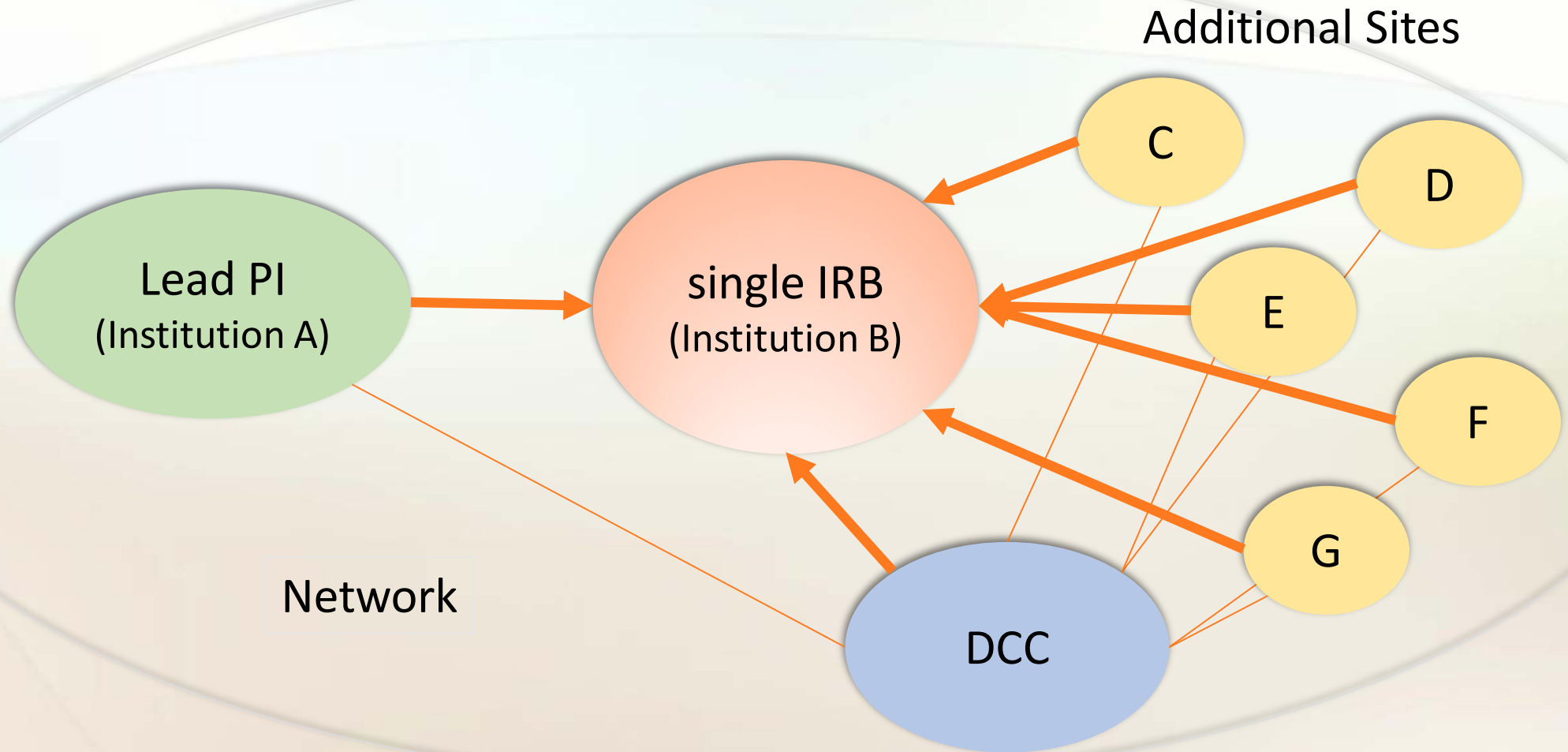
Lead PI and sIRB at different institutions

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

