Reliance 101

UNC IRB MEMBER RETREAT JULY 2023

Objectives

- Provide historical context for reliance
- Describe overview of reliance processes
- Answer reliance questions

Historical Context

THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

Historical Context: sIRB Mandates

"sIRB" stands for "Single IRB": One single IRB reviews and approves the study, and other sites rely on that one IRB

- **NIH Single IRB Policy** – Effective January 25th 2018
  Applies to all NIH funded multi-site studies conducting the same protocol at each site.
- **Cooperative Research – Revised 'Common Rule'** – Effective January 20th, 2020
  Applies to federally funded, cooperative research involving more than one U.S. site.

Currently only *federally funded collaborative research* **requires** a single IRB review on behalf of all participating institutions

Reliance Process Overview

THE UNIVERSITY
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When is Reliance Involved?

UNC is the Reviewing IRB

- External Sites
  - Institutions
  - Organizations
- Independent Investigators

Requests for UNC to provide IRB review and oversight may be done as part of an **initial** submission, **or** as a subsequent **modification**.

UNC is the Relying IRB (aka "Ceded Review"):

- Relying on Commercial IRBs
- Relying on Institutional IRBs
- Relying on NCI CIRB

Requests for UNC to cede review and oversight to another institution or organization should be submitted as part of the **initial** application.

Criteria for Reliance

What do we consider for Single IRB requests?

- Whether single IRB review is required by the sponsor or applicable regulations or policies;
- UNC-Chapel Hill's role in the research;
- The risk level of the research;
- Where the research interventions will be performed, and by whom;
- Qualifications and experience of the researchers performing more than minimal risk interventions or procedures; and
- Whether the proposed Reviewing IRB is AAHRPP-accredited

UNC SOP 0901 Section 3.1.1.

When is Reliance Not Involved?

- Not Human Subjects Research
- Exempt Research
- International research that would require UNC to cede review, or accept review for international sites

UNC Reviewing: Multi-site IRBIS Application

When UNC accepts review for external sites, the reliance information is contained in section 2 (Project Personnel) and section 5 (Multi-site Study Information) of the IRBIS Multi-site application

Information about external sites and personnel can also be found using the IRBIS Options view -> CITI/COI & sIRB Attachments sections

Process as IRB of Record

1. UNC IRB reviews and approves the study for the UNC site
2. The study team submits a subsequent modification to activate external sites. The Reliance Team is responsible for this review, not the IRB.

*Note: External sites are not activated during the initial submission

Reliance Process for External Sites

The process for onboarding or activating a site involves 2 pillars:

1. The reliance agreement
2. The Activation Review – review of the site engagement, materials specific to the site, including local recruitment materials, local consent forms, and the Local Context Worksheet. These documents are housed in section 5 of the IRBIS application.

Reliance Process for External Sites

External Institution	Has or will the external institution agree to rely on the UNC-Chapel Hill IRB?	Local Consent Forms and Ads	Local Context Worksheet	Agreement
Institution Name	Yes			
Personnel	**Role**	**Ethics**	**CV**	**MD License**
Investigator Name	External Site PI			

External Institution	Has or will the external institution agree to rely on the UNC-Chapel Hill IRB?	Local Consent Forms and Ads	Local Context Worksheet	Agreement
Institution Name	Yes			
Personnel	**Role**	**Ethics**	**CV**	**MD License**
Investigator Name	Other			
Investigator Name	External Site PI			

External Institution	Has or will the external institution agree to rely on the UNC-Chapel Hill IRB?	Local Consent Forms and Ads	Local Context Worksheet	Agreement
Institution Name	Yes			
Personnel	**Role**	**Ethics**	**CV**	**MD License**
Investigator Name	External Site PI			

Reliance Process for Independent Investigators

View sIRB External Institutions and Attachments

Independent Investigators

Personnel	Role	Ethics	CV	MD License	Confirmation form	Agreement	Role in this study
Investigator Name	Research Assistant Independent Investigators						view
Investigator Name	Research Assistant Independent Investigators						view

Reliance Process for Independent Investigators

- Independent Investigators

	Full Name	Credentials	Role	Department	CITI HSP Training	CITI GCP Training	COI Training	COI WebID	COI Number	Initial COI Disclosure	Potential Conflict	COI Review Process	COI Review Result
	Investigator Name	--	Research Assistant		✓	✗	✓	1234567	23-01234	✓		Completed	No Conflict
	Investigator Name	--	Research Assistant		✓	✗	✓	1234568	23-12345	✓		Completed	No Conflict

Key: Faculty | Zero Salary | Inactive Status | Hospital Employee Only | External Personnel | Liaison

CITI/COI Responsibilities – External Sites

Who manages COI for external investigators and what, if any, responsibilities do IRB members have re: COI and training/CV review?

When UNC is the IRB of record for external sites and/or personnel, we have different policies for who is responsible for tracking CITI training and COI disclosures. UNC is responsible for tracking CITI/COI for Independent Investigators and *active* external sites that are set to "UNC Policy".

IRB members only need to track COI disclosures at full board renewal for Independent Investigators and *active* external sites that are set to "UNC Policy".

CITI/COI Responsibilities – External Sites

External Institutions

Personnel Management - External Site policies

Policy Undetermined - Default setting, policy will be set by IRB upon submission.
Policy TBD - Site policy has not been set by the IRB. May be set in a later submission.
UNC Policy - Site does not have an FWA, please list ALL engaged personnel from the site. The site's personnel will be required to complete UNC ethics training in CITI, a COI disclosure when applicable, upload their current CV and any medical licensures to Section 5 - Multi-Site.
Site Policy - Site has an FWA, please list ONLY the site PI and study liaison. The site will manage their own personnel requirements. No UNC trainings or COI disclosure required and no CVs or licensures collected.

External Institution						COI Policy						Assurance Letter	Management Plan
– Institution Name						**UNC Policy** (edit)							
	Full Name	Credentials	Role	Department	CITI HSP Training	CITI GCP Training	COI Training	COI WebID	COI Number	Initial COI Disclosure	Potential Conflict	COI Review Process	COI Review Result
★	Investigator Name	--	External Site PI	Forensic Nursing	✓	✓	✓	1234569	23-01235	✓		Completed	No Conflict
External Institution						**COI Policy**						**Assurance Letter**	**Management Plan**
– Institution Name						**Policy TBD** (edit)							
	Full Name	Credentials	Role	Department	CITI HSP Training	CITI GCP Training	COI Training	COI WebID	COI Number	Initial COI Disclosure	Potential Conflict	COI Review Process	COI Review Result
★	Investigator Name	--	External Site PI	Police Department	--	n/a	--		n/a	n/a			n/a
External Institution						**COI Policy**						**Assurance Letter**	**Management Plan**
– Institution Name						**Site Policy** (edit)							
	Full Name	Credentials	Role	Department	CITI HSP Training	CITI GCP Training	COI Training	COI WebID	COI Number	Initial COI Disclosure	Potential Conflict	COI Review Process	COI Review Result
★	Investigator Name	--	External Site PI		--	n/a	--		n/a	n/a			n/a

CITI/COI Responsibilities – External Sites

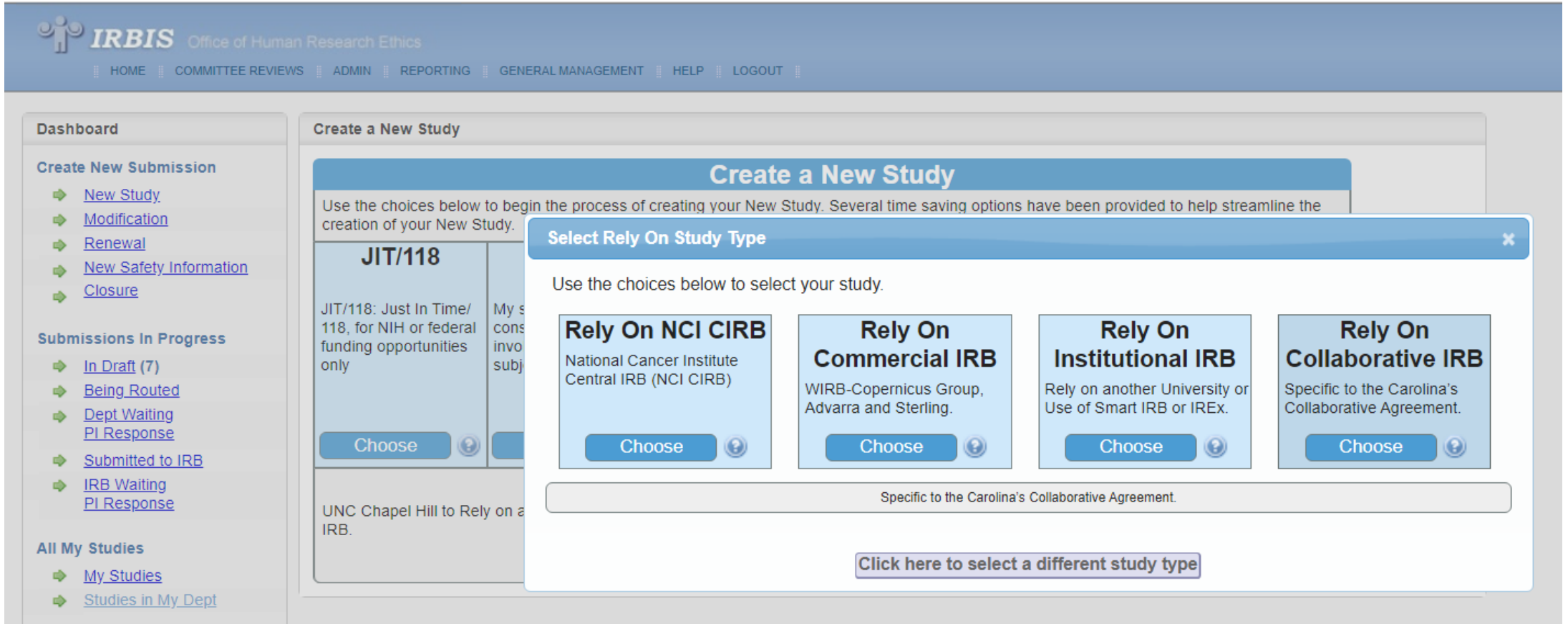
External Institution	Has or will the external institution agree to rely on the UNC-Chapel Hill IRB?	Local Consent Forms and Ads	Local Context Worksheet	Agreement
Institution Name	Yes			
Personnel	**Role**	**Ethics**	**CV**	**MD License**
Investigator Name	External Site PI			

External Institution	Has or will the external institution agree to rely on the UNC-Chapel Hill IRB?	Local Consent Forms and Ads	Local Context Worksheet	Agreement
Institution Name	Yes			
Personnel	**Role**	**Ethics**	**CV**	**MD License**
Investigator Name	External Site PI			

External Institution	Has or will the external institution agree to rely on the UNC-Chapel Hill IRB?	Local Consent Forms and Ads	Local Context Worksheet	Agreement
Institution Name	Yes			
Personnel	**Role**	**Ethics**	**CV**	**MD License**
Investigator Name	External Site PI			

Rely On Application Types & Workflow

4 types of Rely On applications, which contain different information and have separate processes based on the type of institution or IRB that UNC is relying on



In Draft	5645	215
Being Routed	347	8

Minutes / Agenda

Committee: ... Review Date: ... View Review Dates:

Message Center

You have 0 Unread Messages

Submitted To IRB — View All

	Total
Study	0
PRI (Reportable)	2
PRI (Not Reportable)	0
Rely On	1
NHSR	0
Personnel Modification	10
Admin Review	0

Accepted By IRB — View All

	TBD	FB	NFB
Study	26	5	105
PRI	1	0	3
Rely On			20
NHSR			4
Personnel			58
Admin Review			5
Admin Closure			17
Administrative Study Suspension			0

Waiting PI Response — View All

	Total
Study	656
PRI	7
Rely On	149
External IRB	18

PI Responses — View All

	TBD	FB	NFB
Study	38	14	9
PRI	0	0	5
Rely On			26
External IRB			0
NHSR			2
Personnel			4
Admin Review			3

My Bucket

	Total
Recently Viewed	7
All	114
Waiting PI Response	52
Accepted By IRB	44
PI Responses	18
IRB Chair Reviews	0

IRB Chair Reviews — View All

	FB	NFB
Study	0	38
PRI	0	0
Rely On		14
NHSR		0
Admin Closure		0
Administrative Study Suspension		0

PI Response Reviews — View All

	FB	NFB
Study	4	19
PRI	0	0
Rely On		11
External IRB		0
NHSR		0

Questions Submitted

- When should a study team close the UNC application when a study is relying on the external IRB?
- How do we know if/when a student or visiting scholar needs to be covered when they leave UNC?

Any additional questions?

Thank you!

Thank you to everyone who has been helping the Reliance Team!

Resources

Reliance webpage (forms, templates):
https://research.unc.edu/human-research-ethics/reliance/

Reliance SOPs:
901: Article - Office of Human Research Et... (unc.edu)
3401: Article - Office of Human Research Et... (unc.edu)

IRBReliance@unc.edu
General Inbox for Reliance issues and questions

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