



THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

NIH Single IRB (sIRB) Policy Implementation

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NIH Single IRB policy for Multi-site Research

- Expectation that “a single IRB of record will be used in the ethical review of non-exempt human subjects research protocols funded by NIH” that are multi-site
- Effective date: applicable to awards received in response to applications/proposals submitted on or after **January 25, 2018**
- Scope
 - Limited to domestic sites of NIH-funded multi-site studies
 - Research supported through grants, cooperative agreements, contracts, or the NIH Intramural Research Program
 - Does not apply to career development, research training or fellowship awards



How will this policy impact UNC research?

- The UNC research portfolio currently includes 500+ active projects which are both NIH funded & multisite. UNC ranks in the top ten in total NIH research dollars. Impact to UNC could be significant. UNC will assume role of the IRB of record for some NIH multisite studies, and will cede review to another participating site for other studies.
- **Currently approved, ongoing NIH-funded multisite research:** There will be no action required and the research will continue to be reviewed both at UNC and the participating sites' IRBs for modifications and annual renewals until a competitive renewal is required to secure continued funding for the research after January 25, 2018. The UNC IRB will not review requests to implement sIRB review for currently ongoing research unless a competitive renewal is required to secure additional funding.



How will this policy impact UNC research?

- **NIH-funded multisite research yet to be IRB approved:** UNC investigators and research teams will need to identify a local study team member as the **IRB liaison**. This person will be the point of contact for the IRB and the study sites, and manage communications and materials to and from the sites. Investigators will need to plan for appropriate staffing if their UNC team will lead this sIRB effort for all sites, including sufficient budgeting for staff.
- Initial review at the UNC IRB (when sIRB) will focus on the protocol and approve a ‘model’ consent form. Participating sites are listed at initial review, but not approved to commence research activities until they are ‘on-boarded’ during a later modification. Onboarding a site will require a consent customized for the site, local context info, and other site-specific information relevant to the research



What **hasn't** changed regarding reliance arrangements?

- OHRE will continue to execute reliance agreements for individuals, industry sponsored research, non-profits, and other institutions
- OHRE typically executes about 300 reliance agreements each year.
- All reliance agreements will continue to be initiated via the IRBIS application. An application is required in both scenarios, when UNC will cede review and when UNC will be the Reviewing IRB.
- If UNC will cede review to another institution, that process will be similar to the current process when UNC cedes review to a central IRB



What **hasn't** changed regarding reliance arrangements?

- **IAA:** IRB authorization agreements (e.g., UNC relies on Duke IRB, Wake Forest relies on UNC IRB; can be executed between institutions when both have an FWA) ←→
- **IIA:** Independent Investigator Agreements (e.g., Bob Smith relies on UNC IRB; typically consultants, subcontractors, former students; UNC IRB extends our FWA to a small non-profit that does not have an FWA) →
- **Central** IRB Agreements (e.g., UNC relies on WIRB, UNC relies on the NCI CIRB; at UNC, 'central IRB' typically refers to a commercial IRB or NCI CIRB) →
- **Broad** Agreements (e.g. the joint NCSU/UNC biomedical engineering dept, EPA relies on UNC IRB for all HSR reviews) →



What **hasn't** changed in the IRBIS application?

All requests for reliance agreements will continue to be initiated and reviewed via the IRBIS application. The process begins in the screening questions.

General Information > 4. Screening Questions > question #6:

6. Are any personnel, organizations, entities, facilities or locations in addition to UNC-Chapel Hill involved in this research (e.g., is this a multi-site study or does it otherwise involve locations outside UNC-CH, including foreign locations)? You should also click "Yes" if you are requesting reliance on an external IRB, or that UNC's IRB cover another site or individual. [See guidance.](#) *

Yes No



- When screening question #6 = yes, section 5 (Multi-site Study Information) of the application opens and includes the following questions

1. Are UNC-affiliated researchers involved in research conducted at any locations outside of the United States? *

Yes No

2. Is UNC-CH the Lead Site or Coordinating Center or Sponsor of a multicenter project? *

Yes No

Required document(s): Lead Site/Coordinating Center addendum

[Lead Site/Coordinating Center addendum](#)





The new stuff



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Terminology

SMART IRB Reliance Agreement: *A national, master reliance agreement supporting single IRB review. AKA the ‘Smart IRB Master Common Reciprocal Institutional Review Board Authorization Agreement’. 23 pages long, signed by UNC December 2016. When someone refers to ‘using the SMART IRB’ they are likely referring to this specific, standardized agreement. Terms are not negotiable, but include some flexibility (COI, HIPAA, etc). Current UNC agreement template updated in March to resemble the Smart agreement.*

SMART IRB Exchange Portal: *A web-based platform developed by Vanderbilt to support IRB reliance initiation, documentation, tracking, and communication between participating IRBs and study teams. Note: study teams do not submit information for review via the SMART IRB Exchange, the SMART IRB Exchange is used to manage all of your approvals for the life of the study*



Exchange Portal

The screenshot displays the SMART IRB EXCHANGE portal. At the top, the logo "SMART IRB EXCHANGE" is visible, along with navigation links for Home, Contact Us, Your Profile, Resources, and Logout. A search bar is located in the top right corner. On the left side, a vertical sidebar for "UNC CHAPEL HILL" shows site statistics: 0 reviewers, 0 studies relying on the site, 5 participating studies, and 2 users. The main content area is titled "Site Studies" and includes an informational message about the study list and a "new study" button. Below this is a table of studies with columns for Study Title, Sponsor, Sites, and Reviewing IRB.

Study Title	Sponsor	Sites	Reviewing IRB
ECHO: eaRly dAta subMission Protocol - RAMP	NIH	20	VUMC
Efficacy of a Gluten-free Diet in Difficult-to-Manage Nephrotic Syndrome: Utility of Plasma Zonulin Levels as a Predictive Biomarker	NIH	3	VUMC
National Registry for Childhood Interstitial and Diffuse Lung Diseases	Investigator	5	VUMC
PETAL - Reevaluation of Systemic Early neuromuscular blockade (ROSE)	NHLBI	3	VUMC
PETAL - Vitamin D to Improve Outcomes by Leveraging Early Treatment (MOLET)	NHLBI	2	VUMC

Showing 1 to 5 of 5 entries



UNC CHAPEL HILL

- 0** reviewer
Your site is the reviewer for 0 studies
- 0** relying
Your site is relying on 0 studies
- 5** participant
Your site is participating in 5 studies
- 2** users
There are 2 users at your site

VERSIONS

1

Reviewing IRB

- VUMC (Pending)

Relying Sites

- Baylor Medicine
- OHSU
- U of Washington
- Utah
- Wake Forest

Registered/In Progress

- ACRI
- CCMC
- MUSC
- Miami
- Mount Sinai
- NorthShore
- Northwell Health
- Rochester
- Stanford
- Stanford U
- Tufts MC
- UCHealth
- UNC Chapel Hill
- Yale

ECHO: eaRly dAta subMission Protocol - RAMP [overview](#)

- Getting Started**
- Reviewing IRB Approvals
- Relying Site Approvals

Protocol Version: 1

University of North Carolina at Chapel Hill **aahrpp** **ctsa** **smart-irb**

Initial Study: Full Board **Current**

[Edit review](#)

Study Info

Role:
IRB Number:
Decision:
Submission Type: Initial Study: Full Board
Review Cycle:

Key Dates

Submitted for Local Review:
Local Review Conducted:
Local Review Completed:
Expires:

Documents

Type	Name	Size
Protocol [1]	DRAFT Protocol_ECHO RAMP_V0 9 14June2017.pdf DRAFT	232 KB

[Download all](#)



Terminology

- **Reviewing IRB = IRB of Record = Lead IRB = sIRB** => The IRB (including an IRB Organization) to which authority for IRB review and oversight has been ceded by another Participating Institution for an instance of Research under an agreement
- **Relying Institution = Relying site = participating site** => A Participating Institution that cedes IRB review to a Reviewing IRB for an instance of research under an agreement



Lead Site/Coordinating Center Addendum

- **New** form intended to collect information needed for the review but not currently asked in the application, subject to updates
- Will be required when UNC is either the Lead Site, or the Data Coordinating Center (DCC) for multisite research, regardless of funding source (not just for sIRB applications)
- Required when a site that the UNC IRB review covers is the DCC. Example - UNC is the Reviewing IRB and Duke is the DCC, will need the form completed to provide information about the Duke DCC.
- UNC may be the lead site, and not the DCC. UNC may be the DCC and not the lead site. The form currently combines roles, so some questions will not be applicable to all studies



Lead Site/Coordinating Center Addendum

Questions:

Describe your plan for:

- selecting appropriately qualified study sites.
- ensuring that all collaborating institutions hold an OHRP-approved assurance
- providing study-specific training for personnel at all sites.
- collecting and maintaining critical documents, e.g., resume/CV, medical license, certification of training, laboratory certification, laboratory norms, etc.
- the review of each site's IRB approval notifications and consent documents.
- assuring that each site receives the current version of the protocol, and when applicable, protocol amendments and other study-related communications.
- assuring that informed consent is obtained and documents from each participant in compliance with federal regulations and local IRB requirements.
- tracking enrollment, and when applicable, randomization to treatment.



Lead Site/Coordinating Center Addendum

Questions, cont.

Describe your plan for:

- tracking, reporting and maintaining documentation of all of unanticipated problems involving risks to subjects and disseminating the information to all sites.
- auditing and monitoring on a periodic basis, to assess compliance and progress.
- securing compliance at external sites that are not adhering to the current approved protocol and/or good clinical research practices.
- designing data forms and providing instructions for the use of the forms.
- the collection and management of data across all sites/locations participating in the research.
- managing data and statistical analysis.
- overseeing secure data transmission and storage.





IRBIS Updates



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COMPLETED: Project Personnel section revised to accommodate Multiple Institutions and Independent Investigators. Personnel are grouped together by site. An additional Liaison designation coming soon to identify each sites liaison

Last Name	First Name	Department Name	Role		
University of North Carolina at Chapel Hill (UNC-CH)					
Hannah	Marcus	Office of Research Information Systems	Principal Investigator	edit	remove
Stephenson	John	Office of Research Information Systems	Faculty Advisor	edit	remove
Slattery	John	Office of Research Information Systems	Study Coordinator	edit	remove
Cowan	Laura	Office of Human Research Ethics	Regulatory Associate	edit	remove
Thornton	Michael	Office of Research Information Systems	Research Assistant	edit	remove
External Institutions					
Last Name	First Name	Department Name	Role		
North Carolina State University (NCSU)					
Smith	Dennis	Basketball ops	External Site PI	edit	remove
Ohio State University					
Miller	Braxton	Quarterback	External Site PI	edit	remove
Guinn, Jr.	Theodore		Co-investigator	edit	remove
Manning	Eli	Quarterback	Co-investigator	edit	remove
Elliott	Ezekiel	Running Back	Research Assistant	edit	remove
University of Alabama at Tuscaloosa					
Ingram	Mark		External Site PI	edit	remove
University of Florida					
Tebow	Timothy	qb	External Site PI	edit	remove
Leak	Christopher	Quarterback	Study Coordinator	edit	remove
University of Mississippi					
Manning	Eli	Quarterback	External Site PI	edit	remove
Oher	Michael	Offensive Tackle	Other	edit	remove
University of Tennessee					
Manning	Peyton	QB	Co-investigator	edit	remove
Independent Investigators					
Hart	Kevin		Regulatory Associate	edit	remove
Austin	Steve	Wrestler	Research Assistant	edit	remove



EXPECTED SOON: Updates to the Multi-Site Study Information section. Each external institution will have its own grouping. A place to access the Local Consent Form Template, Local Context Worksheet, and site agreement. Additionally, a place for personnel from that institution's ethics training, CV, and License (if applicable)

External Institution	Has or will the external institution agree to rely on the UNC-CH IRB?	Local Consent Forms	Local Context Worksteet	Agreement
Ohio State University	Yes			edit
Personnel	Role	Ethics	CV	MD License
Ezekiel Elliott	Research Assistant			
Theodore Guinn, Jr.	Co-investigator			
Eli Manning	Co-investigator			
Braxton Miller	External Site PI			
External Institution	Has or will the external institution agree to rely on the UNC-CH IRB?	Local Consent Forms	Local Context Worksteet	Agreement
University of Alabama at Tuscaloosa	Yes			edit
Personnel	Role	Ethics	CV	MD License
Mark Ingram	External Site PI			
External Institution	Has or will the external institution agree to rely on the UNC-CH IRB?	Local Consent Forms	Local Context Worksteet	Agreement
University of Florida	Yes			edit
Personnel	Role	Ethics	CV	MD License
Christopher Leak	Study Coordinator			
Timothy Tebow	External Site PI			
External Institution	Has or will the external institution agree to rely on the UNC-CH IRB?	Local Consent Forms	Local Context Worksteet	Agreement
University of Mississippi	Yes			edit
Personnel	Role	Ethics	CV	MD License
Eli Manning	External Site PI			
Michael Oher	Other			



Documents can be uploaded directly on the screen for each site/researcher.

External Institution	Has or will the external institution agree to rely on the UNC-CH IRB?	Local Consent Forms	Local Context Worksteet	Agreement
North Carolina State University (NCSU)	Yes			edit

Personnel	Role	Ethics	CV	MD License
Dennis Smith	External Site PI			

Upload CV for Dennis Smith at North Carolina State University (NCSU) ✕

>> Upload the "CV" document for Dennis Smith at North Carolina State University (NCSU)

Click [Browse](#) to locate the attachment on your computer and click [Upload Attachment](#).

Attachment: No file chosen

[Upload Attachment](#)

External Institution
Ohio State University

Personnel
Ezekiel Elliott
Theodore Guinn, Jr.
Eli Manning
Braxton Miller

External Institution
University of Alabama at Tus

Personnel
Mark Ingram



The Site information for each External Institution has been revised.

External Institution	Has or will the external institution agree to rely on the UNC-CH IRB?	Local Consent Forms	Local Context Worksteet	Agreement
Duke University	Yes			edit
Personnel	Role	Ethics	CV	MD License
No personnel available for this institution.				

External Institution	Has or will the external institution agree to rely on the UNC-CH IRB?	Local Consent Forms	Local Context Worksteet	Agreement
<p>close</p> <p>7. When a collaborator(s) outside of UNC-CH is (a) exercising authority or responsibility on behalf of a group or organization, (b) performing activities designated by a group or organization, or (c) using the collaboration for scholarly advancement (e.g., promotion, tenure) at a group or organization, complete the following information:</p> <p>Name <input type="text" value="North Carolina State University (NCSU)"/></p> <p>Has or will the external institution agree to rely on the UNC-CH IRB? *</p> <p><input checked="" type="radio"/> Yes <input type="radio"/> No</p> <p>If you have answered "Yes" please continue with the questions below. If you have answered "No", then please scroll down to the bottom of this screen and hit "Save". Note, additional sites can be added by repeatedly using the "Click here to add a response" option.</p> <p>Full legal name of external institution (e.g., University of Michigan-Flint): *</p> <p><input type="text" value="n/a"/></p> <p>Federalwide Assurance (FWA) number from external institution. If the institution does not have an FWA, enter 'N/A':institution does not have an FWA, enter 'N/A': *</p> <p><input type="text" value="n/a"/></p> <p>Contact information for any local IRB or ethics review committee representative who facilitates the execution of the IRB agreements. If there is no IRB or Ethics Review Committee, provide the contact information for an individual with knowledge of the institution's local context. (Name, Phone and Email):</p> <p>If you do not include all of the required information (name, phone and email) your application will be returned to you. If the signatory official is also the contact person, state that. *</p> <p><input type="text" value="n/a"/></p> <p>External institution signatory official (name, title, email):</p> <p>If you do not include all of the required information (name, title, email) your application will be returned to you. *</p> <p><input type="text" value="n/a"/></p>				<p> edit</p> <p>License</p> <p></p> <p>reement</p> <p> edit</p> <p>License</p> <p></p> <p></p> <p>reement</p> <p> edit</p> <p>License</p> <p></p> <p>reement</p> <p> edit</p> <p>License</p> <p></p>



The personnel tab has also been revised to better organize external institutions details regarding training and COI.

Routing	Routing Comments	Status History	Submitted Documents	Addenda	Personnel				
Training and Conflict of Interest entered for this Submission [-] collapse all									
Full Name	Role	Department Name	IRB Training	COI WebID	COI Number	Initial COI Disclosure	Potential Conflict	COI Review Process	COI Review Result
- University of North Carolina at Chapel Hill (UNC-CH)									
Michael Thornton	Research Assistant	Office of Research Information Systems	✗		n/a	n/a			n/a
John Stephenson	Faculty Advisor	Office of Research Information Systems	✓						
Marcus Hannah	Principal Investigator	Office of Research Information Systems	✗						
Laura Cowan	Regulatory Associate	Office of Human Research Ethics	✓		n/a	n/a			n/a
John Slattery	Study Coordinator	Office of Research Information Systems	✗						
External Institutions									
- North Carolina State University (NCSU)									
Dennis Smith	External Site PI	Basketball ops	✗						
- Ohio State University									
Braxton Miller	External Site PI	Quarterback	✗						
Theodore Guinn, Jr.	Co-investigator		✗						
Ezekiel Elliott	Research Assistant	Running Back	✗		n/a	n/a			n/a
- University of Alabama at Tuscaloosa									
Mark Ingram	External Site PI		✗						
- University of Florida									
Timothy Tebow	External Site PI	qb	✗						
Christopher Leak	Study Coordinator	Quarterback	✗						
- University of Mississippi									
Michael Oher	Other	Offensive Tackle	✗		n/a	n/a			n/a
Eli Manning	External Site PI	Quarterback	✗						



Effective January 1, 2017 – NIH expects all NIH-funded clinical investigators and clinical trial staff who are involved in the design, conduct, oversight, or management of clinical trials to be trained in Good Clinical Practice (GCP). Previously, GCP typically required when research was FDA regulated, now much more broadly required.

GCP training should be refreshed at least every three years in order to stay up to date with regulations, standards, and guidelines.

IRBIS update coming soon, adding column for GCP training to pull information from CITI:

Routing Routing Comments Status History Submitted Documents Addenda Personnel

Training and Conflict of Interest entered for this Submission

Full Name	Role	Department Name	IRB Training	GCP	COI WebID	COI Number	Initial COI Disclosure	Potential Conflict	COI Review Process	COI Review Result
University of North Carolina at Chapel Hill (UNC-CH)										
John Stephenson	Principal Investigator	Graduate School	✓	✓	212865	17-24528	✗		Unsubmitted	
John Slattery	Co-Investigator	Office of the Vice Chancellor for Research	✗	✓	212867	17-24530	✗		Unsubmitted	
Daniel Monson	Other	Office of the Vice Chancellor for Research	✗	✓		n/a	n/a			n/a
Gregory Johnson	Other	Office of the Vice Chancellor for Research	✗	✗		n/a	n/a			n/a
Andrew Johns	Study Coordinator	Office of the Vice Chancellor for Research	✗	✗	212863	17-24526	✗		Unsubmitted	
Laura Cowan	Study Coordinator	Office of Human Research Ethics	✓	✓	212866	17-24529	✗		Unsubmitted	





Challenges



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Understanding the Local Context

- Local Context Worksheet/Survey will be required for the participating sites (Relying sites), to provide information relevant to the review in terms of local and state laws and regulations (e.g. age of majority varies by state, reporting communicable diseases), institutional policies, standards (social or cultural) and other factors applicable to the research the Reviewing IRB will need to conduct a review. Review should adhere to laws and regulations **where the research is conducted**, so if UNC review covers a site in Texas, UNC IRB needs information about Texas laws and regulations, local considerations, etc
- Ancillary committee reviews will continue to be provided by the participating (Relying) sites. Example, even when UNC cedes review, UNC radiation safety sub-committee will review and provide language to be used in the UNC consent. UNC biosafety committee will review when necessary, UNC Investigational Drug Service (IDS) review when drugs administered.
- Local Context is being collected in a number of different ways. Each institution has their own set of questions, some are web-based surveys. UNC has it's own version of a worksheet which the liaison will send out to sites to complete prior to onboarding a site
- UNC has an 'Institutional profile' on the Smart IRB Exchange which documents some aspects of the local context information for UNC that do not need to be protocol-specific.



Customization of consent forms

The Reviewing IRB will review and approve a **model** consent form.

The Relying site will need to customize the model consent for their site.

Customization should be limited to a few areas:

- Contact information, header
- Research activities may differ between sites
- Number of subjects expected at each site may vary
- Compensation amounts may vary
- Injury language – contractual
- Other information that might be requested by the external site to be included in their consent form, per local context, ancillary reviews performed at the site, etc

Reviewing IRB receives customized consent and reviews/approves for use, and will need to review any subsequent revisions on behalf of the participating site as the study progresses.



Customization of consent forms

Examples of UNC specific language that may be included in UNC consents

Injury language is site-specific, here is UNC's injury language:

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from being in this study. If such problems occur, the researchers will help you to get medical care, but any costs for the medical care will be billed to you and/or your insurance company. The University of North Carolina at Chapel Hill has not set aside funds to pay you for any such reactions or injuries, or for the related medical care. You do not give up any of your legal rights by signing this form.



Customization of consent forms

- Mandatory reporting of communicable diseases in NC:

“Under North Carolina law, confidentiality does not extend to certain communicable diseases, such as TB, HIV, hepatitis, or other illnesses that put others at risk. If the researchers become aware that subjects have such an illness, they are required to report it to state authorities.”

- Mandatory reporting of child or elder abuse in NC:

“Under North Carolina law, confidentiality does not extend to information about abuse or neglect of a child or disabled adult. If the researchers become aware of such information, they are required to report it to state authorities.”



Customization of consent forms

UNC Radiation Safety Sub-committee basic language:

“This research study involves exposure to radiation from (insert maximum number scans and type of procedure). Please note that this radiation exposure is not necessary for your medical care and is for research purposes only. The average person in the United States receives a radiation exposure of 0.3 rem (or 300 mrem) per year from natural background sources, such as from the sun, outer space, and from radioactive materials that are found naturally in the earth’s air and soil. The dose that you will receive from participation in this research study is less than amount you receive from these natural sources in one year. The amount of radiation you will receive in this study has a minimal risk and is below the dose guideline established by The University of North Carolina Radiation Safety Committee for research subjects.”



Site Personnel

An important change in the reliance process involves site personnel. The **Relying site** will be responsible for managing their *own* staff with respect to their *own* sites institutional policies regarding:

- Conflicts of interest
- Ethics trainings/CITI
- Qualifications (CVs)



Conflicts of Interest (COI)

The SMART IRB agreement includes responsibilities of the Relying site:

6.6 Conflicts of Interest. Maintain policies regarding the disclosure and management of Research Personnel conflicts of interest related to Research and to share those policies with the Reviewing IRB, as requested. Unless the Reviewing IRB and the Relying Institution agree to an alternate approach in advance, the Relying Institution will perform its own conflict of interest analysis under its relevant policies. Relying Institution(s) will provide to the Reviewing IRB any resulting conflict of interest determinations, prohibitions, and management plans as well as any updates to such prohibitions, determinations, or plans, that the Relying Institution has determined to be necessary for the conduct and approval of the Research at the Relying Institution under such policies. The Relying Institution will abide by and will require its Research Personnel to abide by its institutionally required prohibitions or management plans related to the Research, as well as any additional prohibitions or conflict management

The agreement defaults to participating sites evaluating COIs for their staff according to their own policy, and provide the Reviewing IRB with assurances and any relevant COI management plans or consent language.



Ethics Trainings & Qualifications

The SMART IRB agreement includes responsibilities of participating sites:

4.1 Education/Training/Qualifications. To ensure that its Research Personnel have adequate education, training, and qualifications to perform the Research and safeguard the rights and welfare of research subjects. This includes, but is not limited to, having any locally institutionally required professional staff appointments, credentialing, insurance or other liability coverage, training in human subjects protections, and background checks for their assigned role in the Research. A Participating Institution's selection of appropriate education/training requirements and other qualifications for its Research Personnel is at its discretion. A Participating Institution shall provide information or documentation regarding its Research Personnel's education, training, and qualifications in connection with a Ceded Review as requested by the Reviewing IRB.



NIH Guidance on Costs Associated with sIRB review

- **NIH GPS 4.1.15:** *Costs associated with IRB review of human research protocols are not allowable as direct charges...unless such charges are not covered by the organization's F&A rate.*
- **NOT-OD-16-109:** NIH Costing Scenarios
 - Defines **Primary Activities:** continue as indirect costs
 - Defines **Secondary Activities:** can be separated from routine IRB activities and charged as direct costs
 - Allows direct charging of independent/commercial IRB fees



Primary vs Secondary Activities

- **Primary**
 - Ethical review of proposed research protocol
 - Review of template informed consent document
 - Routine activities usually included in F&A rate
- **Secondary**
 - Project specific activities that are “above and beyond” IRB review of human subjects
 - Examples: establishing reliance agreements, review of site specific requirements, reporting unanticipated problems, protocol deviations; addressing serious/continuing non-compliance.
 - Incremental costs not in F&A rate



Preliminary Plans for Costing

- UNC OHRE has NEVER charged fee for federally funded research, only industry sponsored research
- UNC OHRE has not been recovering costs associated with providing IRB review on behalf of other institutions
- It is likely that UNC OHRE will begin to charge as a direct cost, when UNC is the Reviewing IRB. The costs will possibly be determined on a per-site basis.
- Grant application should reflect both costs for potential IRB review fees and staffing such as for the IRB liaison role.



NIH FAQs

NIH has released FAQs which will be helpful to review:

https://grants.nih.gov/grants/policy/faq_single_IRB_policy_research.htm#I

Frequently Asked Questions Single IRB Policy for Multi-site Research

Initial Posting: August 4, 2017

Last Revised: August 4, 2017

On This Page:

- A. Policy Background and General Requirement
- B. Policy Terms and Definitions
- C. Policy Applicability
- D. NIH Grant Application/Contract Proposal Preparation
- E. Reliance Agreements
- F. Responsibilities of the Single IRB and Participating Sites
- G. Award Considerations (Just-in-Time)
- H. Exception to the NIH Single IRB Policy
- I. Costs



NIH Relevant Documents & Resources

Office of Science Policy

<https://osp.od.nih.gov/clinical-research/irb-review/>

- Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research
- Federal Register Notice on the Final NIH sIRB policy
- Federal Register Notice on sIRB Effective Date Extension
- NIH Guide Notice on the Final sIRB policy
- NIH Guide Notice on sIRB Effective Date Extension
- NIH Director's Statement on the NIH sIRB policy
- OSP-OER Blog on the sIRB policy
- NCATS SMART IRB Reliance Platform
- Frequently Asked Questions about the Implementation of the sIRB policy
- NIH Guide Notice on Scenarios Illustrating the Use of Direct and Indirect Costs for Single IRB Review Under the sIRB Policy
- NIH Policy on the Use of a Single IRB for Multi-Site Research FAQs on Costs
- Request for Comments on the Draft NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research
- Public Comments on the Draft Policy
- New Federal Register Notice regarding the extension of the effective date for the Single IRB policy



IRB Contacts for Reliance Agreements:

<http://research.unc.edu/human-research-ethics/reliance/>

IRBReliance@unc.edu – dedicated email for all things related to reliance

OHRE main line 919-966-3113

John Roberts

Reliance Manager, UNC OHRE

jtr@unc.edu

Direct line: 919-966-2748





Time for Questions



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