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Revised Common Rule: Single IRB Requirement

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Objectives

- Review of regulatory drivers for sIRB review
- Overview of Common Rule agencies
- Implications for current studies
- Preparing for sIRB review [now and moving forward]
- VUMC IRB infrastructure for sIRB

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Review of Regulatory Drivers for SIRB Review

The Regulations

Jan 25, 2018
- Effective Date for NIH Policy on Single IRB

Jan 19, 2019
- Effective Date for 2018 Revised Common Rule

Jan 20, 2020
- ~~Compliance~~ EFFECTIVE! Date for Revised Common Rule Single IRB Requirement

NIH Policy for SIRB

- June 21, 2016: Policy requires single IRB (sIRB) review for multi-site NIH- funded research
- Effective Date: January 25, 2018

What types of studies does this policy apply to?

- NIH-funded multi-site studies that involve non-exempt research

  Multi-site Studies: The same protocol is being conducted at more than one site and the study is being funded wholly or in part by NIH
- New applications or competitive renewals submitted on or after the effective date

SIRB is the selected IRB of record that conducts the ethical review for participating sites of the multi-site study.

Requirements for SIRB Review under the Revised Common Rule

- The Revised Common Rule extends the Single IRB review requirement to all “cooperative research” [Research involving more than one institution]
- Required ~~compliance~~ **effective** date for this provision: **January 20, 2020**
- All research funded by any federal agency that is a signatory to the Common Rule must comply

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OHRP Exceptions to Single IRB Review

OHRP determined that for HHS cooperative research subject to the revised Common Rule (also referred to as the 2018 Requirements), and for purposes of 45 CFR 46.114(b)(2)(ii), an institution may continue to use multiple IRBs, in lieu of a single IRB, for the following research:

1) Cooperative research conducted or supported by HHS agencies other than the National Institutes of Health (NIH), if an IRB initially approved the research before January 20, 2020.

2) Cooperative research conducted or supported by NIH if either:
   a) the NIH single IRB policy does not apply, **and** the research was initially approved by an IRB before January 20, 2020, or
   b) NIH excepted the research from its single IRB policy before January 20, 2020.

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Overview of Common Rule Agencies

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Federal Agencies that are Signed Onto the Common Rule

https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html

- Department of Homeland Security
- Department of Agriculture
- Department of Energy
- National Aeronautics and Space Administration
- Department of Commerce (National Institute of Standards and Technology)
- Social Security Administration
- Agency for International Development
- Department of Housing and Urban Development
- Department of Justice (National Institute of Justice) – intends to become an official signatory
- Department of Labor
- Department of Defense
- Department of Education
- Department of Veterans Affairs – VUMC cannot serve as sIRB for VA sites
- Environmental Protection Agency (Research and Development)
- Department of Health and Human Services
- National Science Foundation
- Department of Transportation
- Office of the Director of National Intelligence
- Central Intelligence Agency
- Consumer Product Safety Commission

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Implications for Current Studies

What does this mean for my current projects?

The sIRB requirement applies to all cooperative research reviewed/approved by an IRB on or after January 20, 2020, regardless of funding date of the grant.

- Example: You received an NIH grant in 2017. Under this grant 3 discrete multi-site studies were planned. The first study was submitted to and approved under a multi-IRB model in 2017. The second study was approved in 2018. The third study is in final development with planned IRB submission February 1, 2020. This third study will require sIRB review.

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New Studies that are in process…

- Must have final IRB approval **BEFORE** the effective date: **January 20, 2020**
  - If you have a new study that is currently in a deferred or approved pending status, respond to your Committee Action Letter (CAL).
  - Due to number of outstanding CALs, our office cannot guarantee all affected studies will meet this deadline.

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Preparing for SIRB Review: Now and Moving Forward

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Identifying Your Studies that May Require SIRB Review

- **Question 1:** Is your study currently supported or will your study be supported by a federal agency that is a signatory to the Common Rule?
- **Question 2**: Is your study a true multisite study? *[Under the NIH Single IRB Review policy, "multisite" is defined as two or more sites. Multisite studies do not include studies that include more than one Vanderbilt site [e.g. VUMC and VCH]. Multisite implies that Vanderbilt and one or more non-Vanderbilt site are engaged in human subjects research.]*
- **Question 3:** Is your study expected to receive final IRB approval on or after **January 20, 2020?**
- **Question 4:** Has your program officer contacted you regarding the sIRB requirement? *[If not, contact them to confirm the requirement.]*

Asking Vanderbilt to Serve as the SIRB

- If Vanderbilt is the prime award site*, submit a **Vanderbilt Reliance Interest Form** to request Vanderbilt serve as the IRB of Record [this process is for existing and new studies]
- Once reviewed, you will receive email communication with the IRB's decision and next steps, including **required SIRB training**, as applicable

**Note: It is preferred that the prime award site also serve as the sIRB whenever possible.*

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What does this mean for my future grants?

- **Prior to grant submission:**
  - Submit Vanderbilt Reliance Interest Form to ask Vanderbilt to be the IRB of record
  - Utilize resources: Vanderbilt-specific grant language for SIRB, budget estimates (e.g. SIRB review fees*, study personnel)

**Note: a review fee estimate will be provided upon acceptance of the reliance interest request.*

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sIRB Review + sIRB Coordination

sIRB Review	sIRB Coordination
IRB The initial and ongoing review of human subjects research activities for a multi-site study including the review of all activities at relying sites.	IREx, Lead Study Team, Coordinating Center The communications and support activities provided to relying sites *prior to and after* initial sIRB review to enable initial and ongoing approval of research at the site.

Project Initiation

Protocol Development	Site Selection	sIRB Selection
• Responsibility of Lead Study Team • Recruitment Plan • Consent Process • Data and Safety Monitoring	• Approximate number of and names of sites – as comprehensive as possible • Reliance Agreements • Site-Specific Procedures	• Lead/primary research institution • Study sponsor network chooses • Special requirements warrant using particular IRB • IRB has discretion to act as sIRB

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Single IRB Review ≠ Single Institutional Review

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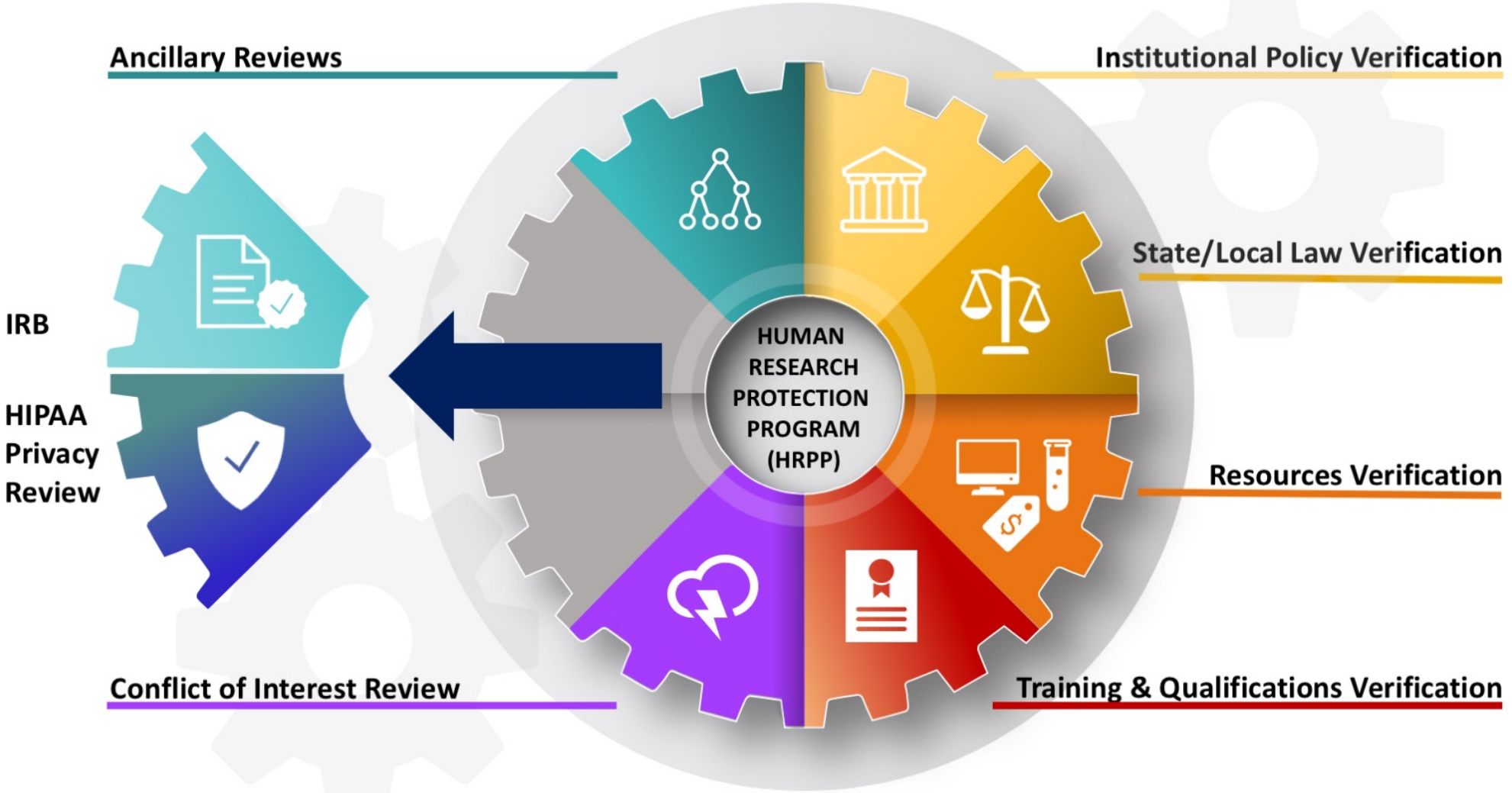
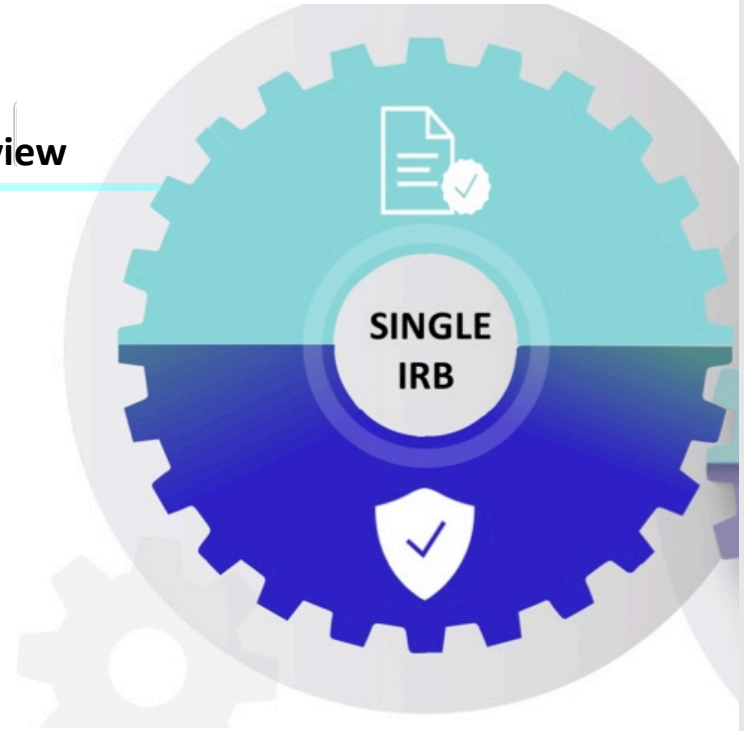
Single IRB Review ≠ Single Institutional Review



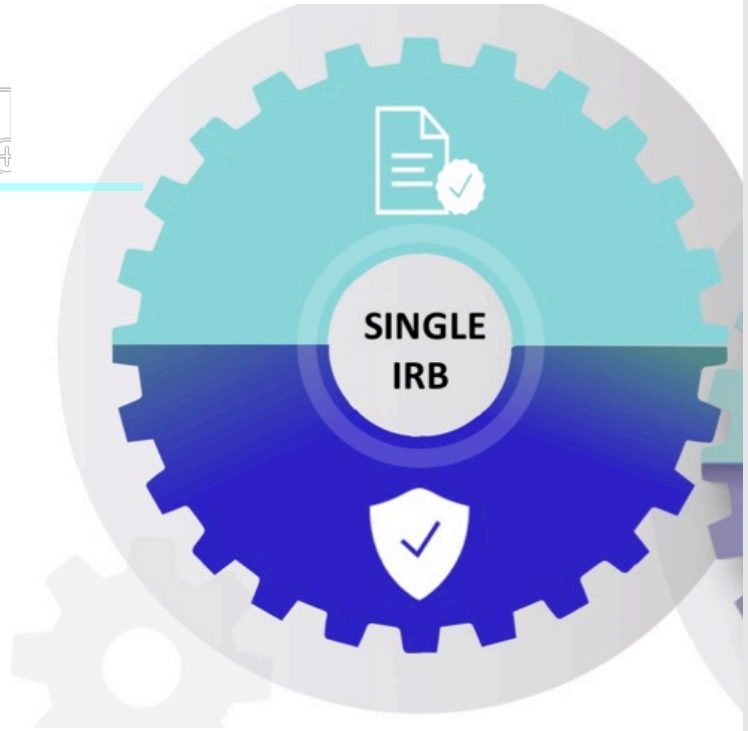
Single IRB Review Components



- Criteria for IRB Approval of Research *(45 CFR 46.111)*
  - Minimal Risk
  - Vulnerable Populations
  - Risk-Benefit ratio
  - Equitable Selections
  - Informed Consent
  - Privacy & Confidentiality
  - Data & Safety monitoring

Single IRB Review Components

IRB Review



Institutional/Community Profile

Information about the site's community and potential participant population that may need to be considered in order to evaluate the **Criteria for IRB approval**. This most often includes relevant characteristics of the local population, and applicable local laws and policies. SIRBs usually only need to ask for this information **once per site**.

HRP Review Components

A **study-specific review** that needs to occur at the local site. This includes **verification** that the site-specific information is incorporated appropriately for the site in the protocol and consent documents. It also includes the relying site **HRP's review responsibilities** as outlined in the reliance agreement.

This generally includes study-specific confirmation of:

- COI
- training/qualifications of local research staff
- ancillary reviews
- application of local laws and policies
- *HIPAA Authorization & Privacy Rule (*45 CFR 164)*

VUMC sIRB Infrastructure

Single IRB Agreements and Resources

Agreements are completed one time per institution to avoid lengthy negotiations on a study-by-by study basis

1. **SMART IRB Reliance Agreement:** A national, master reliance agreement supporting single IRB review

2. **SIRB Letter of Indemnification:** (LOI) for the SMART IRB Reliance Agreement may be required. The SIRB LOI is a separate agreement concerning indemnification and related terms that may be required by the sIRB.

IRB Reliance Exchange (IREx): A single IRB documentation and communication portal.

To access IREx, a human research protections administrator or IRB director/manager can request to create an account and accept the terms of use.

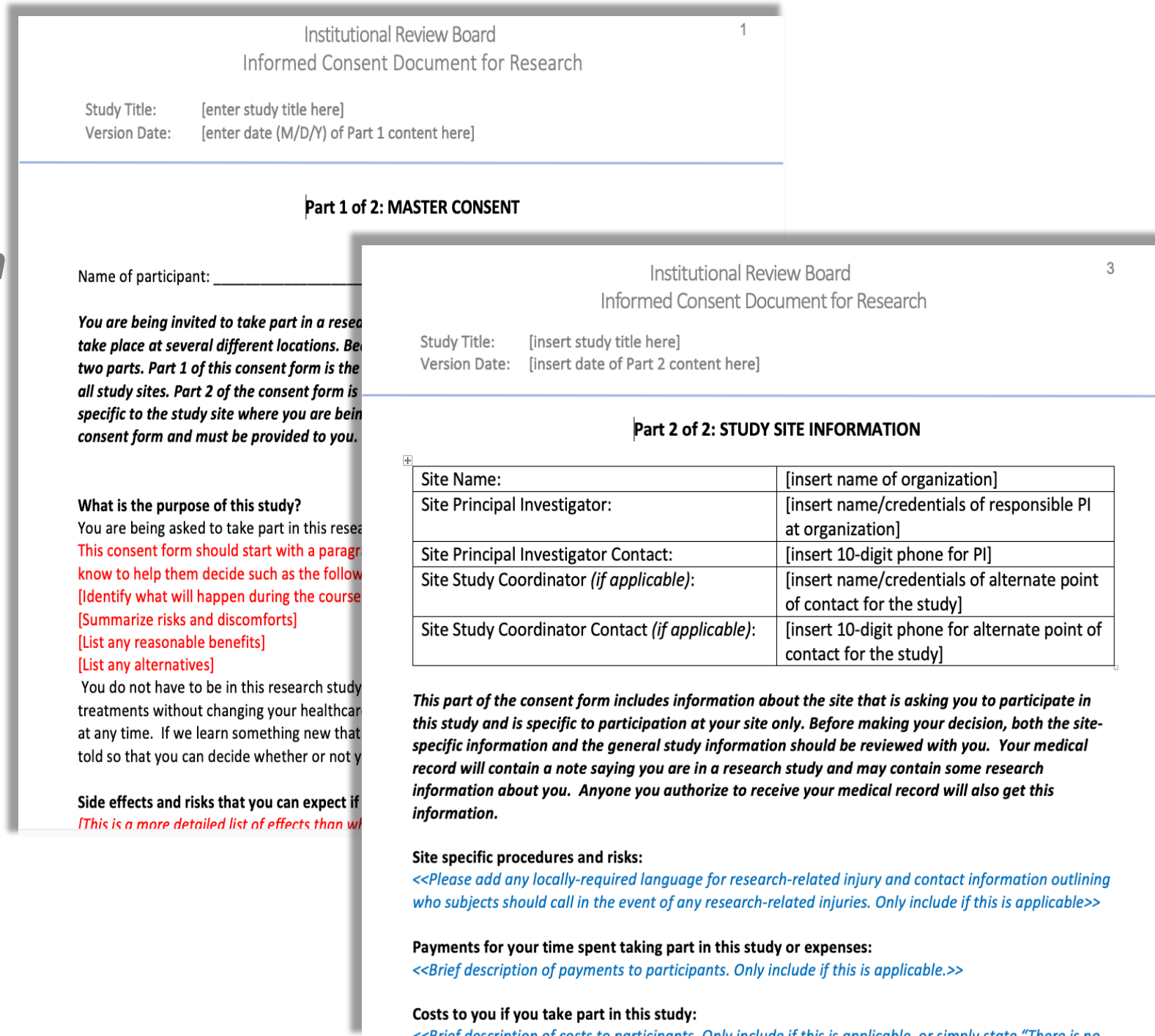
[A portal agreement is no longer required to join IREx.]

VUMC sIRB Infrastructure

The Two-part Consent Form

- **Part 1 – Master Consent** contains all the elements of consent and is the same for all sites

- **Part 2 – Study Site Information Pages** are added to the end of the master consent and contain all locally required language for a site.



Institutional Review Board 1
Informed Consent Document for Research

Study Title: [enter study title here]
Version Date: [enter date (M/D/Y) of Part 1 content here]

Part 1 of 2: MASTER CONSENT

Name of participant: _____

You are being invited to take part in a resea
take place at several different locations. Be
two parts. Part 1 of this consent form is the
all study sites. Part 2 of the consent form is
specific to the study site where you are bein
consent form and must be provided to you.

What is the purpose of this study?
You are being asked to take part in this resea
This consent form should start with a paragr
know to help them decide such as the follow
[Identify what will happen during the course
[Summarize risks and discomforts]
[List any reasonable benefits]
[List any alternatives]
You do not have to be in this research study
treatments without changing your healthcar
at any time. If we learn something new that
told so that you can decide whether or not y

Side effects and risks that you can expect if
[This is a more detailed list of effects than wh

Institutional Review Board 3
Informed Consent Document for Research

Study Title: [insert study title here]
Version Date: [insert date of Part 2 content here]

Part 2 of 2: STUDY SITE INFORMATION

Site Name:	[insert name of organization]
Site Principal Investigator:	[insert name/credentials of responsible PI at organization]
Site Principal Investigator Contact:	[insert 10-digit phone for PI]
Site Study Coordinator *(if applicable)*:	[insert name/credentials of alternate point of contact for the study]
Site Study Coordinator Contact *(if applicable)*:	[insert 10-digit phone for alternate point of contact for the study]

This part of the consent form includes information about the site that is asking you to participate in this study and is specific to participation at your site only. Before making your decision, both the site-specific information and the general study information should be reviewed with you. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Site specific procedures and risks:
<<Please add any locally-required language for research-related injury and contact information outlining who subjects should call in the event of any research-related injuries. Only include if this is applicable>>

Payments for your time spent taking part in this study or expenses:
<<Brief description of payments to participants. Only include if this is applicable.>>

Costs to you if you take part in this study:
<<Brief description of costs to participants. Only include if this is applicable, or simply state "There is no

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Resources

- Single IRB Help Page: https://www.vumc.org/irb/single-irb-help
  - Vanderbilt Reliance Interest Form
  - Grant Resources
  - Additional Guidance (e.g., relying on another IRB)
- DISCOVR-e: https://irb.mc.vanderbilt.edu/login
  - Performance Sites enhancement March 2019
  - COMING SOON: funding enhancement to streamline and track funding agencies
- IRB Reliance Exchange (IREx): https://www.irbexchange.org/p/
  - Reviewing IRB
  - Relying Institution
  - Study Manager
- Vanderbilt Coordinating Center (VCC): https://vcc.vumc.org/

Questions?