EXTERNAL IRB REQUEST EDUCATION

Presented by Wayne State University Institutional Review Board (WSU IRB)

August 15, 2018

WSU IRB Presenters:
Monica Malian
Heather Park-May
Amanda Reese
Dawn Bielawski

Guest Presenter:
Christopher Gennai: Western IRB

- WIRB Hints and Reminders

Welcome!

Welcome and Introduction

Monica Malian
Human Research Protection Program Director
Wayne State University

AGENDA

- **9:35-10:30-** External IRB Overview, History, Status, Policies and Forms- Heather
- **10:30-11:15-** WIRB Hints and reminders- Christopher Gennai
- **11:15-11:30-** Break and Refreshments
- **11:30-12:00-** CIRB- Amanda
- **12:00-12:45-** NIH Single IRB (sIRB) Policy, Reliance Agreements, and the External IRB Process- Dawn
- **12:45-1:30-** Panel Discussion, Q&A with the speakers.

EXTERNAL IRB OVERVIEW

HISTORY, STATUS, POLICIES & FORMS

Heather Park-May, M.A, B.S
IRB Training Coordinator
Wayne State University

AN OVERVIEW OF EXTERNAL IRB'S

What does it mean to have a single IRB (sIRB) review?

In general, a single IRB is when a sponsor or PI collaborates with colleagues from outside institution(s) which then involves oversight from multiple IRB's.

IRBs from institution's engaged in the collaborative research agree to share the responsibilities of the oversight of research to ensure the rights and welfare of research participants are protected, thus reducing duplicative effort and inconsistency wherever possible.

IRBs carefully consider every sIRB agreement they enter into so as to not compromise the welfare of the local research participants.

When the WSU IRB agrees to rely on another IRB's review and oversight, we do so with the understanding that the reviewing IRB follows it's policies and procedures which are consistent with all applicable federal regulations, and holds their researchers to the same high standard.

The WSU IRB is still responsible for conducting local context reviews of the research.

AN OVERVIEW OF EXTERNAL IRB'S

An external IRB is any IRB other than the PI's local IRB that is responsible for overseeing the ethical conduct of human participant research.

- There are many different situations in which an IRB may rely on an external IRBs oversight of their research.

Terms used to describe the single IRB overseeing research being conducted at more than one institution.

- Central IRB
- Single IRB (sIRB)
- External IRB
- Reviewing IRB

❖ Relying IRB describes the local IRB ceding review to an external IRB.

Terms used to describe the institutional agreements executed when a single IRB oversees research being conducted at more than one institution.

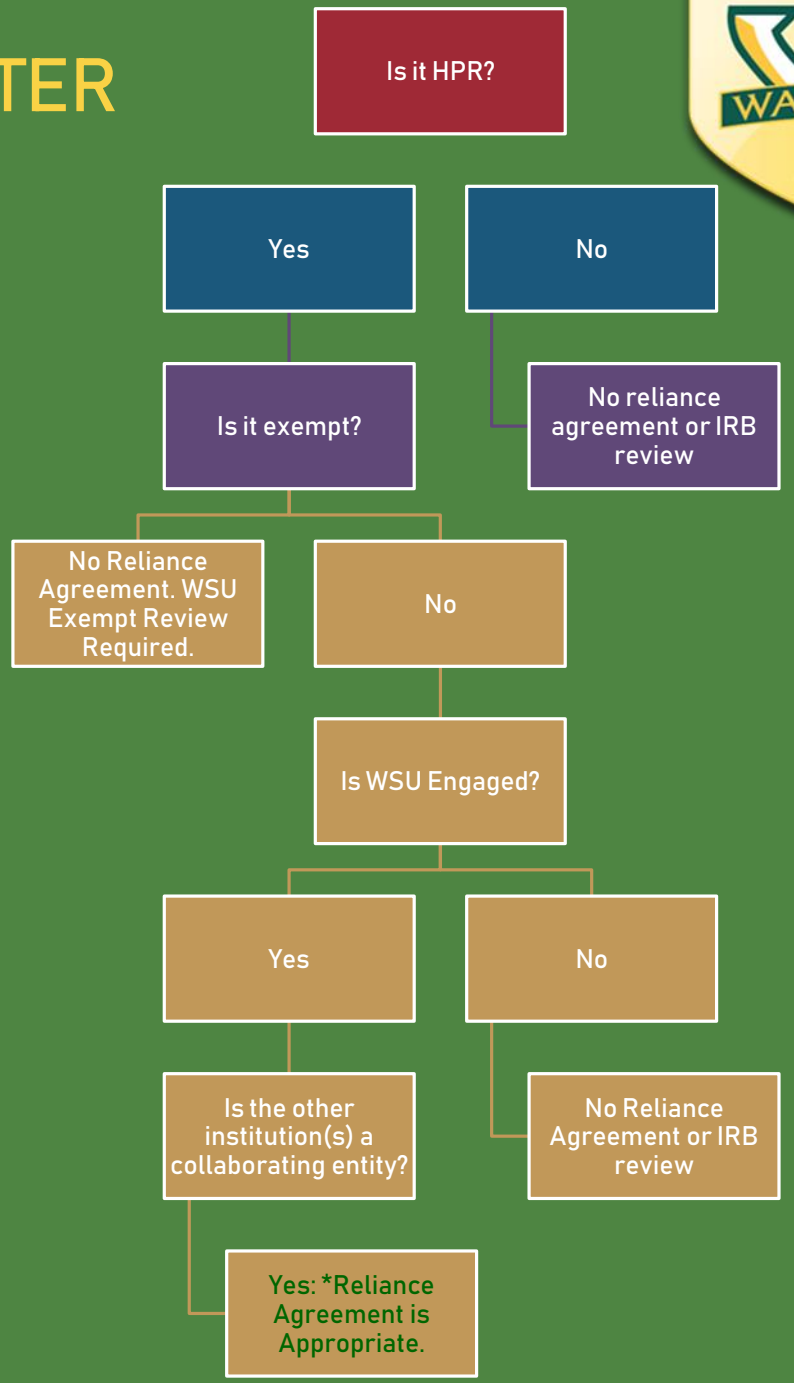
- Reliance Agreement
- Institutional Authorization Agreement (IAA)

- Engaged in Research
- Collaborating Entity
- Coordinating Center
- Lead Institution
- Principal Investigator(PI) at Lead Institution
- Site Principal Investigator
- PI of the Grant
- Co-Investigator of the Grant
- PI of the Sub-Award

TERMS USED WHEN ARRANGING A RELIANCE AGREEMENT

HOW DO WE DETERMINE WHAT MULTI-CENTER RESEARCH REQUIRES A RELIANCE AGREEMENT?

- Is it Human Participant Research?
- Is it non-exempt research?
- Is WSU Engaged in Research?
- Are the other institution(s) collaborating entities?



* Reliance Agreement is mandatory for the single IRB review of all non-exempt NIH funded research for which NIH Single IRB policy applies.

HUMAN PARTICIPANT RESEARCH

- **Human Participant:** A living individual about whom an investigator (whether professional or student) conducting research obtains
  - (1) Data through intervention or interaction with the individual, or
  - (2) Identifiable private information.
- **Research:** A systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

ENGAGEMENT IN RESEARCH

A Collaborating Entity becomes "engaged" in human subjects (participants) research when its employees or agents:

1. intervene or interact with living individuals for research purposes or
2. obtain individually identifiable private information (that may be used) for research purposes [45 CFR 46.102(d),(f)].

COLLABORATING ENTITY

Collaborating Entity – An institution, practice plan, clinic, or individual that is participating in a cooperative research activity with the lead institution.

A Collaborating Entity is "engaged" in research when the entity or its employees or agents:

- Interact with individuals to draw blood, collect biological samples, administer treatments, dispense drugs, employ medical technologies, etc.,
- Conduct interviews, engage in protocol related communications, obtain informed consent,
- Maintain statistical, operational or coordinating centers for multi-site collaborative research, or
- Obtain, receive or possess private information about individuals such as names, information from medical records, etc.

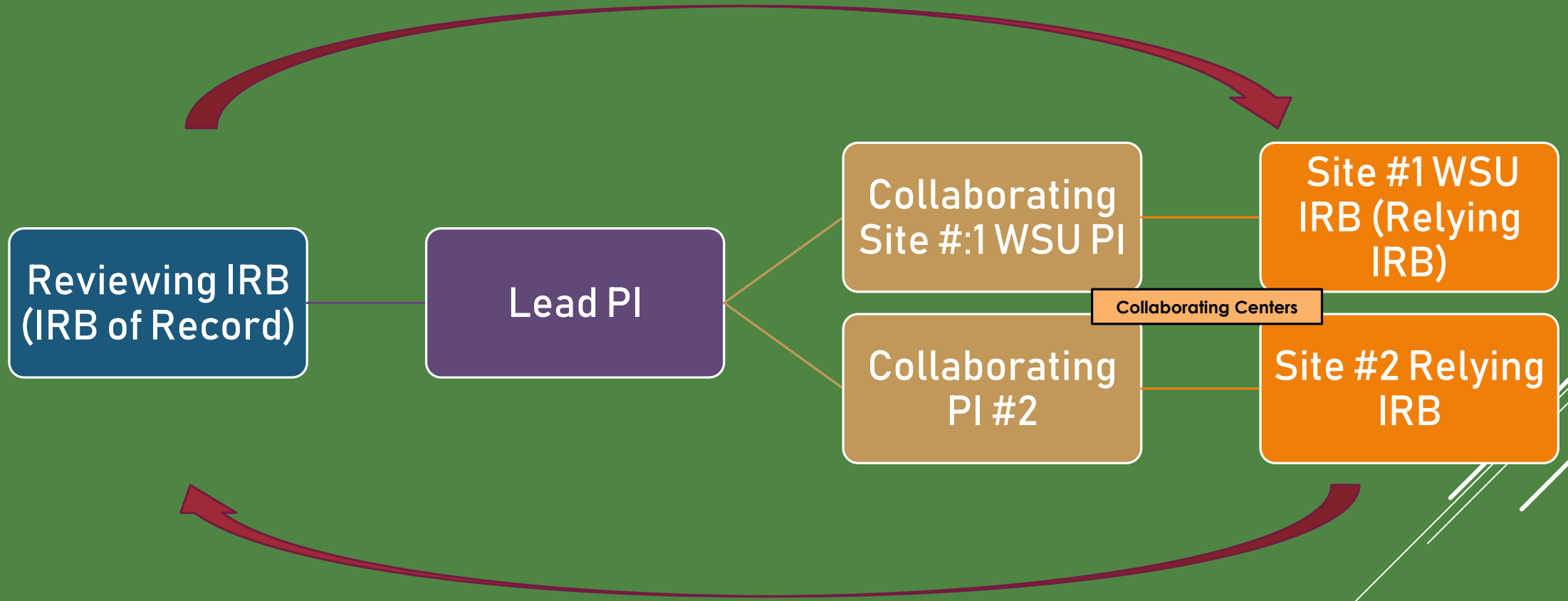
A Collaborating Entity is “not engaged” in research, when the entity or it’s employees or agents:

- Act as consultants on research but at no time obtain, receive, or possess identifiable private information,
- Perform commercial services meriting neither professional recognition nor publication privileges,
- Permit use of their facilities for intervention or interaction by research investigators, or
- Provide prospective participants (subjects) information about the availability of the research either verbally or in writing.

DIFFERENT STRUCTURES OF COLLABORATIVE RESEARCH WITH ONE REVIEWING IRB

- Investigator Initiated Collaborative Research
- Industry Sponsored Multi-Site Research

COMMON STRUCTURE OF INVESTIGATOR INITIATED RESEARCH COLLABORATING WITH OUTSIDE INSTITUTIONS



Examples:

1. WSU Principal Investigator (PI) collaborates on a study with colleagues from other academic institutions to increase diversity of sample, or sample size.

IRB RESPONSIBILITIES FOR INVESTIGATOR INITIATED RESEARCH COLLABORATING WITH OUTSIDE INSTITUTIONS

Reviewing IRB:

1. Conduct Initial and all subsequent reviews
    1. Continuing Reviews,
    2. Unanticipated Problems (UP's)
2. Oversight of ethical conduct of research for all sites
3. Provide IRB decision memos to lead PI and relying IRB(s)
4. Report all IRB determinations including protocol violations, adverse events and findings of non-compliance with associated local institutions.

Relying IRB:

1. Ensure safe and appropriate performance of research at local institution and affiliates.
2. Ensure qualifications of local research staff
3. Manage any major protocol violations and serious adverse events that occur locally.
4. Receive complaints about the research that may come from local research participants or community
5. Review Local UP's
6. Local oversight and review of research when it pertains to WSU policy, and all pertinent state and local laws and regulations including HIPAA regulations for applicable research data collection and use.

PI RESPONSIBILITIES FOR INVESTIGATOR INITIATED RESEARCH COLLABORATING WITH OUTSIDE INSTITUTIONS

Lead PI:

1. Submit initial and all subsequent reviews to reviewing IRB on behalf of all collaborating sites
2. Report UP's from all sites to reviewing IRB
3. Oversight of ethical conduct of research for all research sites
4. Provide IRB decision memo's to collaborating PI's
5. Ensure all collaborating sites adhere to the approved protocol
6. Adhere to all applicable institutional policies and state & Federal regulations

Collaborating Site PI:

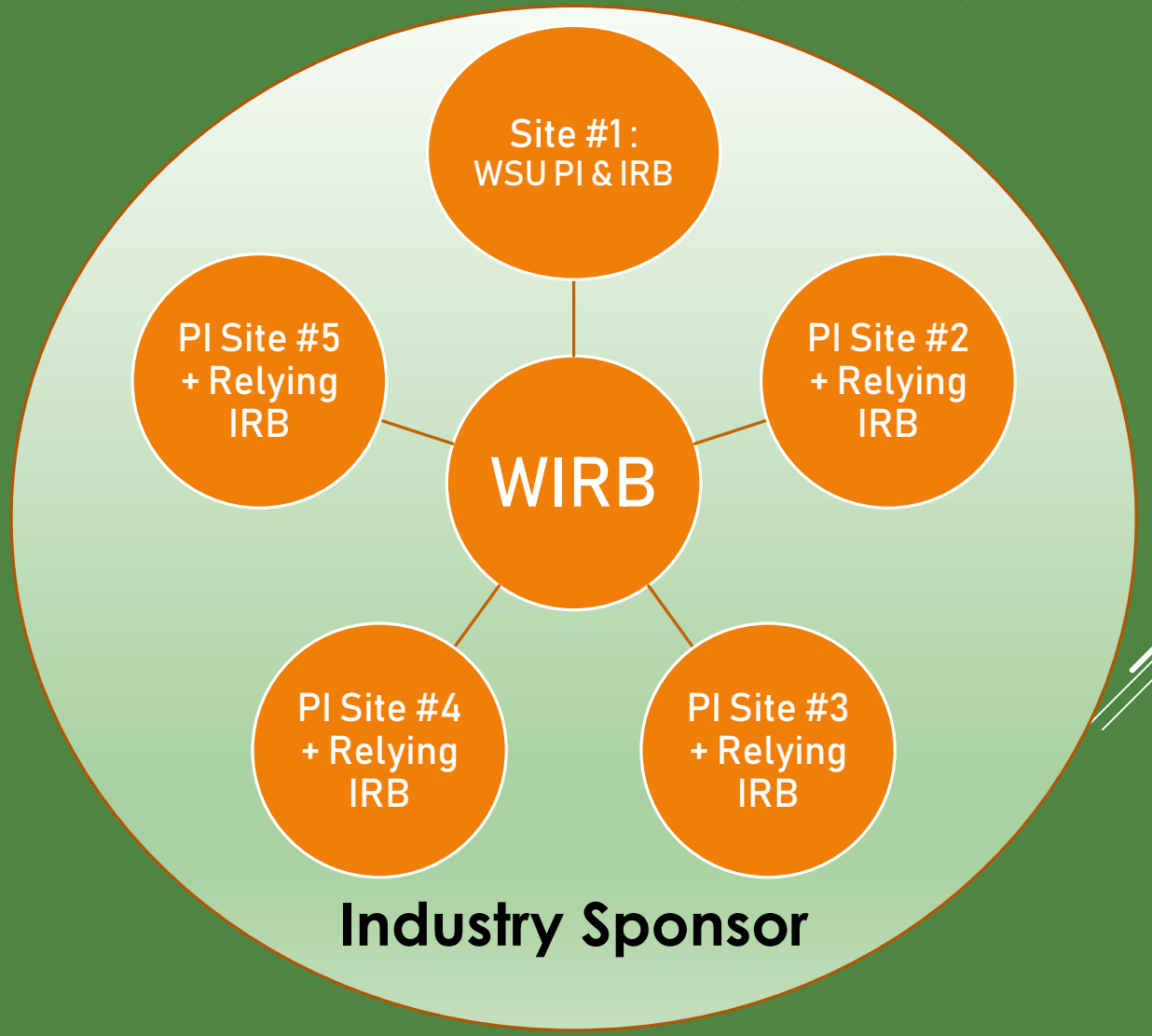
1. Follow the approved protocol
2. Report local UP's to Lead PI and local IRB
3. Adhere to all applicable institutional policies and state & Federal regulations

INDUSTRY SPONSORED MULTI-SITE RESEARCH WITH A COMMERCIAL CENTRAL IRB (WIRB)

Example:

WSU PI is selected by industry sponsor to conduct research at local site as one of many sites participating in a multi-center clinical trial.

- Industry sponsor requires IRB review by the Central IRB they have selected



Responsibilities for Industry Sponsored Multi-site Research with a Commercial Central IRB (WIRB)

Sponsor:

- All operational aspects of the clinical trials:

1. Select qualified investigators
2. Provide investigators with information needed to conduct trial
3. Ensure proper monitoring of trial
4. Ship supplies needed to conduct trial to sites
5. Report Serious Adverse Events and findings of non-compliance to federal agencies
6. Review and evaluate evidence relating to safety and effectiveness of test article

Site PI's:

1. Submit initial and all subsequent reviews to Central IRB
2. Report UP's to Central IRB
3. Maintain complete documentation
4. Ensuring all collaborating sites adhere to the approved protocol

IRB RESPONSIBILITIES FOR INDUSTRY SPONSORED MULTI-SITE RESEARCH WITH A COMMERCIAL CENTRAL IRB (WIRB)

Central IRB:

1. Initial and all subsequent reviews
    1. Continuing Reviews,
    2. Unanticipated Problems (UP's)
2. Provide oversight of the ethical conduct of research for all sites
3. Provide IRB decision memo's including protocol violations, adverse events/UP's and findings of non-compliance with associated local institutions, PI's and sponsor.

Relying IRB:

1. Ensure safe and appropriate performance of research at local institution and affiliates.
2. Ensure qualifications of local research staff
3. Manage any major protocol violations and serious adverse events that occur locally.
4. Receive complaints about the research that may come from local research participants or community
5. Review Local UP's
6. Local oversight and review of research when it pertains to WSU policy, and all pertinent state and local laws and regulations including HIPAA regulations for applicable research data collection and use.

WHY THE PUSH FOR SINGLE IRB REVIEW?

NIH IDENTIFIED PROBLEMS WITH MULTIPLE IRB REVIEWS

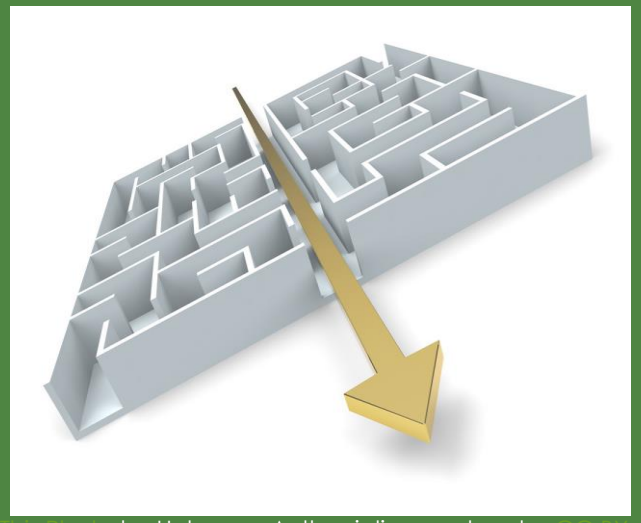
- Costly
- Unnecessarily duplicative
- Delays commencement of research
- Leads to inconsistency across all sites.

In January 2018 NIH enacted the single IRB mandate, meaning that all multi-site study with NIH grant applications due on or after January 25, 2018 must have a single IRB review. With some specific exceptions

- Multi-site studies with ongoing, non-competing awards will not be expected to comply with sIRB mandate until a competing renewal application is submitted.

EXPECTATIONS:

What NIH thought the sIRB mandate would do.



What investigators thought the mandate would do

What IRBs thought it would do: Discovering Uncharted Territory.

What the sIRB mandate actually did:

CHALLENGES:

The cost of a streamlined IRB review:

- Each institution must still maintain responsibility over researcher training, conflict of interest disclosures, HIPAA, ancillary reviews, and ensuring compliance with state and local laws.
- Adds to the lead PI's responsibility to manage communications and reporting among the sites and IRB's involved
- Increases the reviewing IRB's responsibilities for ethical oversight over multiple institutions.
- The burden of communication and reporting among multiple research sites and keeping track of reportable events falls to the lead PI.

RESPONSIBILITIES

- PI at Lead Institution- Responsible for the conduct of the research protocol at the lead institution and all other collaborating sites.
- Site PI- Responsible for the conduct of the research protocol at that site
- Coordinating Center- maintain an operations center to provide for the scientific oversight and protection of the human participants for all of the sites involved in the research. Functions include:
  - Data safety and monitoring
  - Data analysis
  - Protocol development
  - Adverse event reporting
  - Assurance verification

NEW EXTERNAL IRB FORMS

- **External IRB Request:** Use for all initial external IRB requests, and transfers of IRB oversight from WSU IRB to an external IRB.

- **External IRB Modification:** Use for subsequent submissions for any study being conducted at WSU or one of our affiliate institutions that is under the oversight of an external IRB. This includes the following changes:
  - Key Personnel Changes
  - Unanticipated Problem reports
  - Adverse Event reports
  - Changes to the reliance agreement
  - Or changes to the protocol or consent documents that affect local context of the study.
    - HIPAA Authorization/Waiver
    - Injury language in the consent form.

PI ATTESTATION

- When you sign either of these forms you are confirming that all of the following statements are true:
  1. Attest to the accuracy of the information provided in the application
  2. Agree to accept primary responsibility for the scientific and ethical conduct of the research, as approved by the IRB
  3. Agree to abide by the IRB's policies and procedures
  4. Agree to submit adverse event reports in a timely manner
  5. Agree to abide by the investigator responsibilities in the reliance/institutional authorization agreement

Remember:

Your project or modifications to already approved project cannot begin until you have received documentation of IRB review and final approval from the External IRB

CENTRAL IRB (CIRB) & WSU SUBMISSION

Amanda Reese, MA
IRB Operations Manager
Wayne State University

CIRB OVERVIEW

- Studies Eligible for CIRB Review
- Responsibilities of WSU & CIRB
- Initial Submission review by WSU Local IRB for Administrative Review
- Amendments
- Event Reporting & Local Oversight
- Resources
- Coming Soon

STUDY ELIGIBILITY

- Research studies currently reviewed and approved by the Central IRB
  - Phase 3 adult trials coordinated by the NCI Clinical Trials Cooperative Groups (ACOSOG, CALGB, ECOG, GOG, NCCTG, NCIC, NSABP, RTOG, and SWOG),
  - Phase 3 studies opened in the Cancer Trials Unit (CTSU), together with pediatric COG Phase 2, Phase 3, and Pilot studies.
  - Children's Oncology Group
  - Some studies that require CIRB submission

IRB RESPONSIBILITIES

Wayne State IRB

Responsible for:

- retaining local oversight to:
  - Monitor protocol compliance
  - Manage any major protocol violations
  - Ensuring qualifications of key personnel
  - Determine how assent is to be documented
  - Review of HIPAA (HIPAA remains the purview of local institution and IRB)

IRB RESPONSIBILITIES

CIRB

Responsible for:

- Regulatory IRB review of studies
- Conduct review of: Initial, Amendments & Continuations/Renewals
- Review unanticipated problems within the purview of the CIRB
- Report non-compliance determinations to appropriate agency
- Notify the local institution immediately of a suspension or restriction

INITIAL SUBMISSIONS

What to Submit:

- Consent Form (s) with HIPAA Authorization & Assent Form(s)
- HIPAA Summary Form
- CIRB Consent Template
- Sponsor's Consent Template if applicable
- All Study Participant Materials

Submit to cirb@wayne.edu

Local Administrative Review Tips:

- If requesting waiver of HIPAA Authorization-make sure waiver is signed
- HIPAA Authorization uses and disclosures matches HIPAA Summary Form
- Entities listed for question #8 of the HIPAA Summary Form are also in the Authorization and Consent Confidentiality section.
- Submit any additional required approvals (PRMC, DMC, McLaren)

E-mail Subject line should state "Initial Submission for _____(Study # and PI)

INITIAL SUBMISSIONS

Consent Form

Use the WSU IRB Consent Boilerplate when completing the study consent document for local context review

Key WSU Boilerplate Language:

- Research Related Injuries
- Confidentiality
- Study Costs
- Study contact information for PI and IRB
- HIPAA language

Recent CIRB Recommendations:

- No changes to NCI Consent Form Template
- Do not change section titles
- Do not delete required template language
- No wordsmith changes

AMENDMENT SUBMISSIONS

After WSU administrative (Local review) and approval is completed the CIRB assumes responsibility as the IRB of record

What to Submit:

- Modification Form
- HIPAA (If there are changes)
- Consent or HIPAA Authorization (If there are changes)

AMENDMENT SUBMISSIONS

- HIPAA
  - Changes to PHI used, shared or disclosed
    - i.e. may include new site additions
  - Requesting waiver of HIPAA Authorization
    - Make sure HIPAA waiver is signed

- Key Personnel Changes
  - Addition or Deletion of Key Personnel
  - Change in Principal Investigator

- A new modification request form is coming that will only address the above changes

CONTINUING REVIEWS

After initial administrative review and approval, the CIRB assumes the responsibility as the IRB of record.

Continuing Reviews/Renewals are not submitted to the WSU IRB.

EVENT & OVERSIGHT REPORTING

Local unanticipated problems occur at and are limited to a specific institution. The local institution is responsible for managing these according to our FWA procedures.

- Submit any local UP's to the WSU IRB
- WSU IRB should be informed of local site visits
- If WSU determines that an event meets the regulatory definition of non-compliance it is WSU responsibility to report to the OHRP/FDA

Unanticipated problems within the purview of the CIRB are those unexpected incidents, events, or outcomes which the sponsor identifies and which impact the trial nationally. These are reviewed by the CIRB and the CIRB accepts the responsibility to ensure reporting to the appropriate agency

COMING SOON

- Updated Initial Submission External IRB Request Form
- New Modification & Event Reporting Form for External IRB Requests
- Initial submission Formal Authorization memo

NIH SINGLE IRB (SIRB) POLICY, RELIANCE AGREEMENTS, AND THE EXTERNAL IRB PROCESS

Dawn Bielawski, PhD, CIP

Sr. IRB Review Specialist

Institutional Review Board

Wayne State University

SESSION OBJECTIVES

We will discuss:

- NIH Policy on single IRB usage
- External IRB Process (not WIRB or CIRB)
- Reliance Agreements
- SMART IRB

NIH POLICY ON THE USE OF A SINGLE INSTITUTIONAL REVIEW BOARD OF RECORD FOR MULTI-SITE RESEARCH

"…**establishes** the expectation that all sites participating in multi-site studies involving non-exempt human subjects research funded by the National Institutes of Health (NIH) will use a single Institutional Review Board (sIRB) to conduct the ethical review required by the Department of Health and Human Services regulations for the Protection of Human Subjects at 45 CFR Part 46."

NIH POLICY ON THE USE OF A SIRB OF RECORD FOR MULTI-SITE RESEARCH

- Covers all domestic sites of NIH-funded non-exempt multi-site studies. Doesn't apply to exempt studies and those get reviewed at each IRB still.
- Applies only to studies where the same research protocol is being conducted at more than one site.
- Not applicable if each site is doing a different piece of the protocol.
- Not applicable to training, fellowship, or career development applicants (T, F, K).

POLICY EFFECTIVE DATE

- Effective date: January 25, 2018
  - Grant applications - due on or after January 25, 2018
  - Contracts - all solicitations issued on or after January 25, 2018
  - Multi-site studies within ongoing awards will be expected to comply with the policy at competing renewal.

EXTERNAL IRB PROCESS

- The external IRB will provide ethical review
- WSU is still responsible for:
  - Ensuring adequate personnel training in Protection of Human Subjects and Good Clinical Practice.
  - Maintaining a compliance oversight role locally.
  - Ensuring that site specific requirements are in place and that a reliance agreement is in place.
  - Ensuring that required local ancillary reviews have been completed.

RELIANCE AGREEMENT

- A formal, written document indicating a collaborative arrangement between institutions that allows one or more institutions to cede human subjects research review to another IRB.
- Describes responsibilities of the relying institution and researcher & responsibilities of the reviewing IRB and its institution.
- May be for a specific study, or for specific classes or categories of research.

RELIANCE AGREEMENTS – TYPE 1

- Agreement already in place. Examples:
  - SMART IRB*
  - University of Utah
  - Henry Ford Health System
  - Commercial IRB such as Advarra or Quorum IRB.
  - The reliance agreement should be referenced with your request submission.

*For SMART IRB agreement use, please provide an acknowledgement form. There are 448 institutions signed on to the SMART IRB agreement, which can be checked at smartirb.org.

RELIANCE AGREEMENTS – TYPE 2

- Agreement not yet in place, this adds several steps to the process:
  - Creation or negotiation of the reliance agreement
  - Review by IRB Staff
  - Review by Office of General Counsel
  - Signatures of the Institutional Officials (IO's) at both institutions
  - External IRB Request can't be approved until the agreement is in place

THE PROCESS WHEN WSU RELIES ON AN EXTERNAL IRB REVIEW:

1. Site PI completes all necessary forms and applicable forms and documents:
   - Protocol
   - Reliance agreement document or SMART IRB Acknowledgement
   - Local Context Worksheet required by Reviewing IRB (If applicable)
   - Consent document with HIPAA Authorization
   - HIPAA Summary Form

2. Send completed documents to relyirb@wayne.edu

THE PROCESS WHEN WSU RELIES ON AN EXTERNAL IRB REVIEW:

3. WSU will conduct a one time internal review consisting of:
    3. Local context considerations: HIPAA, targeted population and related cultural issues
    4. Michigan, local regulations
    5. WSU regulations and policies
    6. Local investigator and key personnel credentials
4. WSU indicates agreement to recognize the external IRB as the IRB of record and works with PI to execute the appropriate agreement with the reviewing IRB.
5. The PI serves as the middle-person between the reviewing and relying IRB, and other site PI's.

Communication is Key!

EXTERNAL IRB PROCESS

Provide the following to relyirb@wayne.edu:

- WSU-External IRB Request Cover Sheet and Review Authorization Form (new version soon)
- Consent document with HIPAA Authorization
- HIPAA Summary Form
- Research Protocol (most recent version)
- Reliance agreement document or SMART IRB Acknowledgement
- Local Context Worksheet required by Reviewing IRB (if applicable).

SELECTING THE AGREEMENT TYPE

Please select the External IRB you wish to utilize

- ☐ WIRB®
- ☐ Smart IRB** Participating Institution (specify): _____
- ☐ Other Institution (specify): _____

*If you selected **NCI CIRB** above, please select your site preference(s) from the following:

- ☐ Wayne State University / Karmanos Cancer Institute *(CIRB Signatory)* MI020
- ☐ Detroit Medical Center-HCC *(CIRB Affiliate)* MI053
- ☐ Huron Valley-Sinai Hospital *(CIRB Affiliate)* MI127
- ☐ Weisberg Cancer Treatment Center *(CIRB Component)* MI220
- ☐ McLaren Site(s)..... specify Site Number(s): _____

**A list of Smart IRB participating institutions is available at smartirb.org

AGREEMENT TYPE – NEW FORM

1.Please select the External IRB you wish to utilize

☐ WIRB®

☐ Other Commercial IRB, Academic or Hospital IRB? Specify: Point of contact name and email:	**Please select all that apply to your "Other Commercial IRB, Academic or Hospital IRB"** ☐ Smart IRB** Participating Institution (specify with point of contact): ☐ IRB Reliance Exchange Institution (Formerly Smart IRB Exchange)**: Specify Smart IRB Institution: **A list of Smart IRB participating institutions is available at smartirb.org
☐ National Cancer Institute CIRB	**Please Select your Site Preference(s) from the following:** ☐ WSU / Karmanos Cancer Institute *(CIRB Signatory)* MI020 ☐ Detroit Medical Center-HCC *(CIRB Affiliate)* MI053 ☐ Huron Valley-Sinai Hospital *(CIRB Affiliate)* MI127 ☐ Weisberg Cancer Treatment Center *(CIRB Component)* MI220 ☐ McLaren Site(s) specify Site Number(s):

ANCILLARY REVIEWS – CURRENT FORM

10. Other Compliance Considerations Does the research require any of the following approvals? If **Yes**, must provide approval letter with this submission.			
Embryonic Stem Cell Research Oversight Committee (ESCRO)	☐ No	☐ Yes	(*If "**Yes**" provide letter*)
Institutional Biosafety Committee (IBC)	☐ No	☐ Yes	(*If "**Yes**" provide letter*)
Radiation Safety Committee (RSC)	☐ No	☐ Yes	(*If "**Yes**" provide letter*)
Materials Transfer Agreement (MTA)	☐ No	☐ Yes	(*If "**Yes**" provide letter*)
Karmanos Cancer Institute Protocol Review & Monitoring Committee (PRMC)	☐ No	☐ Yes	(*If "**Yes**" provide letter*)
McLaren Health Care review	☐ No	☐ Yes	(*If "**Yes**" provide letter*)
Detroit Medical Center (DMC) Review	☐ No	☐ Yes	

ANCILLARY REVIEWS – NEW FORM

10. Ancillary Reviews Does the research require any of the following approvals? If ***Yes***, must provide approval letter with this submission.	
Embryonic Stem Cell Research Oversight Committee (ESCRO)	☐ No ☐ Yes *(If "**Yes**" provide letter)*
Institutional Biosafety Committee (IBC)	☐ No ☐ Yes *(If "**Yes**" provide letter)*
Radiation Safety Committee (RSC)	☐ No ☐ Yes *(If "**Yes**" provide letter)*
Materials Transfer Agreement (MTA)	☐ No ☐ Yes *(If "**Yes**" provide letter)*
Karmanos Cancer Institute Protocol Review & Monitoring Committee (PRMC)	☐ No ☐ Yes *(If "**Yes**" provide letter)*
McLaren Health Care review	☐ No ☐ Yes *(If "**Yes**" provide letter)*
Veterans Administration	☐ No ☐ Yes *(If "**Yes**" provide letter)*
Department of Psychiatry	☐ No ☐ Yes *(If "**Yes**" provide letter)*
Detroit Medical Center (DMC) Review https://www.dmc.org/for-health-professionals/clinical-translation-research-office **Note:** Research Occurring at DMC must copy jchehab@dmc.org on ALL communications with WSU IRB.	☐ No ☐ Yes *If "**Yes**" DMC Approval can be gained concurrently, but is required for IRB Administrative* authorization.

CONSENT CLARITY

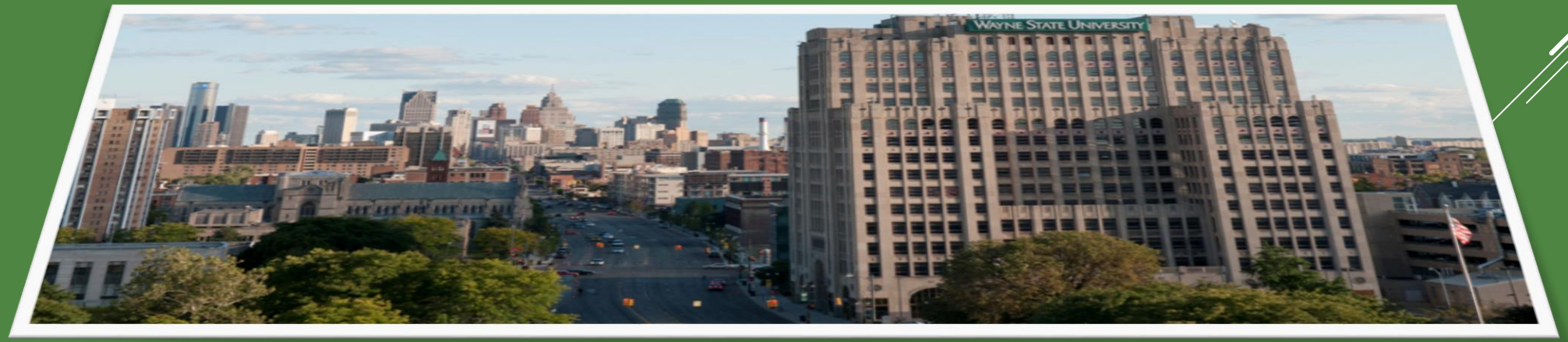
- Do not use the WSU template when relying on another IRB
- Use the main site's approved form(s)
- WSU site-specific (local context) language to be inserted or added as an appendix
- Other sites sometimes push back against using our local wording, if so IRB staff will work with the reviewing IRB to resolve this

HIPAA

- HIPAA Summary Form & HIPAA Authorization
- “Use” items must match on both
- “Disclosure” items must match on both
- Location(s) PHI will be disclosed to must match on both
- Justification is needed for disclosures
- HIPAA Summary Form requires PI’s signature on p. 1, and also on waiver page (if waiver requested)

LOCAL CONTEXT DOCUMENT

- Many IRBs have different versions of this
- Includes info about local laws and policies
- Many questions only the study team could answer – they are study-specific
- Please fill out as much of the form as you can, and include it with your submission
- The IRB staff will fill the IRB policy and MI law questions we can answer



SMART IRB
(STREAMLINED, MULTISITE, ACCELERATED RESOURCES FOR TRIALS IRB RELIANCE PLATFORM)

- Despite the name, it isn't an IRB
- Intended to help with sIRB policy implementation
- Master agreement between IRBs (448 participating institutions so far), can use the existing agreement if other site is willing
- Standard Operating Procedures (SOPs) used nationwide
- Wide range of resources

ARE REQUESTS ALWAYS APPROVED?

- Relying on an outside IRB isn't always appropriate. Examples:
  - WSU not engaged
  - International IRBs
  - Non-AAHRPP accredited IRBs (limits apply)
  - Single IRB policy doesn't apply. Examples:
    - Exempt study
    - K Award
    - All recruitment, consent, and participant activities are being done at WSU, but data is analyzed elsewhere

AFTER RELIANCE REQUEST APPROVAL

- Don't forget – Wait until the Reviewing IRB gives approval for the local site to begin.
- Use the modification form to update us about staff changes, COI changes.
- Most study changes do not need to be submitted to WSU IRB, because we are not the IRB of record. If not sure, ask. ☺
- PI is responsible to abide by responsibilities stated in the reliance agreement.

Remember:

Your project or modifications to already approved project cannot begin until you have received documentation of IRB review and final approval from the External IRB

WHERE TO GET IRB HELP

IRB web site: http://research.wayne.edu/irb/

Email for general questions: irbquestions@wayne.edu

IRB administrative office: 313-577-1628

Single IRB/External IRB Requests/Reliance Agreements: relyirb@wayne.edu or dawn.bielawski@wayne.edu or 313-577-2901

REFERENCES

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