

SIRB/IAA template screen shots for initial submission –IRB of RECORD

(all other regular sections are completed by PI with addition of section “MSU IAA”)

Role: Analyst 172 Hila Berger

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Personnel ✓

Activity ✓

MSU IAA

Assurances

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Study Population

Study Design

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Conflict of Interest (COI)

ACTIVITY

* What type of activity is this submission for?

☒ Research Study

* Is this a multi-institutional study?

☒ Yes

* Is Montclair State University the Primary Contact Site for this multi-institution study?

☒ Yes

* Is the PI requesting that Montclair State University serve as the IRB of Record for one or more other study sites participating in this study?

☒ Yes, this study involves activity at MSU and at the collaborating institutions.

☐ No, each institution will conduct its own IRB review.

To find out if your study will qualify for an IAA (Institutional Authorization Agreement), please contact Amy Krenzer, krenzera@montclair.edu or 973-655-7583.

☐ No

☐ Secondary Data Analysis of de-identified data sets (where no Research Team Members hold linking codes or access to identifiers.)

☐ Activities Without a Plan to Conduct Research (Case Study, Phase1 Grant with no Human Subjects Research, or Quality Improvement project) requiring Human Subjects Research determination.

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MSU IAA

When is an IRB Authorization Agreement an option for MSU serving as the IRB of Record?

This procedure will be considered upon the agreement of the IRB chair, staff and Compliance Officer. They will evaluate the project to determine if the research or program evaluation project would be better suited for singular review by MSU IRB.

This will generally be considered under the following criteria:

- Unless federally funded, exempt category studies will not qualify for an IAA.
- The external IRB has a Federal-Wide Assurance from OHRP
- The funding is primarily allocated to the PI at MSU
- Any subaward language does not preclude this agreement
- The majority of the research leadership and design is to be conducted by MSU PIs or research team members
- Minimal risk research (greater than minimal risk research is not excluded but will require more review)

If you have any questions or concerns, contact the IRB office at reviewboard@montclair.edu

See the help button on the top right "?" for more information.

* If your study meets the above criteria, please complete the following information.

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- Additional Study Notes
- Attachments ✓

• If your study meets the above criteria, please complete the following information.

Collaborator's Institution and contact information

• IRB Director or Manager and contact information


• Collaborating Institution's FWA #


• Collaborating Institution's personnel and role(s) in research

Please list the personnel at the external site and briefly explain the roles, expertise and responsibilities of each investigator.

sIRB/IAA template screen shots for initial submission – External site is IRB of RECORD

(NOTE: your Cayuse study decision will be “Rely on External IRB”)



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ACTIVITY

* What type of activity is this submission for?

☒ Research Study

* Is this a multi-institutional study?

☒ Yes

* Is Montclair State University the Primary Contact Site for this multi-institution study?

☐ Yes

☒ No

* Will the Outside Contact Site be the only IRB reviewing this study?

☒ Yes. Please complete the Institutional Authorization Agreement (IAA) section in this submission.

☐ No, each institution will conduct its own IRB review.

To find out if your study will qualify for an IAA (Institutional Authorization Agreement), please contact Amy Krenzer, krenzera@montclair.edu or 973-655-7583.

☐ No

☐ Secondary Data Analysis of de-identified data sets (where no Research Team Members hold linking codes or access to identifiers.)

☐ Activities Without a Plan to Conduct Research (Case Study, Phase1 Grant with no Human Subjects Research, or Quality Improvement project) requiring Human Subjects Research determination.

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Outside Site IAA

An Institutional Authorization Agreement, or IAA, is required when an outside contact site will be the IRB of Record for a research study in which MSU will participate as a study site.

This will generally be considered under the following criteria:

- Unless federally funded, exempt category studies will not qualify for an IAA.
- The external IRB has a Federal-Wide Assurance from OHRP
- The funding is not primarily allocated to the PI at MSU
- The majority of the research is to be conducted off of MSU campus or sites
- When the expertise of the collaborating IRB is more suited to the review of the research (i.e. a medical or inpatient study at a medical facility)

If your study meets the above criteria, please complete the sections below. See the help button on the top right "?" for more information.

* Outside IRB of Record

Provide the name of the outside IRB of Record.

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Outside Site IAA

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* Outside IRB of Record

Provide the name of the outside IRB of Record.

* IRB Contact

Please include the IRB contact person and their phone number and email.

* Role of MSU PI in study

Please describe, in detail, the role of the MSU Research Team or MSU facilities in this study.



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* Application and/or Study Protocol

Attach the application and protocol for this study that was reviewed by the outside IRB.

ATTACH

Outside IRB Approval

Attach the IRB Approval from the outside IRB.

ATTACH

* Outside IRB Correspondence

Attach all additional correspondence concerning the review(s), amendments or adverse events of this study by the outside IRB.

ATTACH

