

MATER Research – Policies for External Investigators

The MATER Research Committee recognizes the value of and welcomes the addition of studies judged to be of general interest and high scientific merit; that do not duplicate or interfere with existing MATER activities; that do not constitute an unacceptable burden on MATER clients, staff or faculty; and that are in line with MATER objectives and philosophies.

General Policies

The general policies include the review and approval of a proposal by the MATER Research Committee. More specifically, the following are mandatory:

1. **Involvement of MATER Faculty.** A MATER faculty researcher (Representative) must be involved as either the principal investigator (PI) or a co-investigator (co-I) on each study proposal. The MATER Representative is responsible for assuring the study's continuing compatibility with MATER. A list of eligible MATER Representatives is on MATER's website (<https://hospitals.jefferson.edu/departments-and-services/maternal-addiction-treatment-education-and-research/our-team.html>).
2. **Approval by the MATER Research Committee.** Proposals for studies are to be submitted to the Chair of the MATER Research Committee (Vanessa Short; Vanessa.Short@jefferson.edu), who will see that eligible proposals are reviewed by the Committee at the next scheduled MATER Research Committee meeting, which occur monthly. Study proposals should be submitted at least 1 month before submission for funding is planned. To allow sufficient time for an appropriate review, the completed proposal should be submitted to the Chair at least a week prior to the next scheduled MATER Research Committee meeting. Proposals received after that date may be deferred until the next meeting. The MATER Research Committee will review the scientific merit of the proposal and determine if it will interfere with other MATER research, if it conflicts with MATER philosophy, or uses excessive resources. (Please see Appendix 1, "*External Investigator Proposal Guide*", for guidance on required elements of the proposal.)
3. **Agreement to uphold tenets of MATER's philosophy.** Investigators agree to uphold the tenets of MATER's Philosophy (see Appendix 2, "*Tenets of Executing MATER's Philosophy*").
4. **Funding requirements.** MATER faculty and staff listed on a proposal will be funded for any funded studies where data are collected at MATER. In general budgets will be negotiated with the Research Chair in conjunction with the Director of MATER.
5. **Publication and presentation approval.** All publications, manuscripts, abstracts, and presentations derived from the study must be shared with the MATER Representative(s) listed on the proposal prior to submission. External study PIs are expected to include MATER Representative(s) in authorship decisions and participation. MATER Representative(s) who are co-Is on such studies will respect the PI's first and exclusive opportunity to analyze, present, and publish data collected under the auspices of their external study. The MATER Research Committee should be informed of journal submission (dates and journal name), results of reviews (acceptance, rejection or request for revision) and final acceptance by journal. If there are any changes to an approved manuscript prior to publication, whether required by the journal or not, these changes should be discussed with the co-authors.
6. **Specific Procedures and Requirements.** There are several specific requirements that need to be addressed for the submission of an external study proposal and the completion of the study:
 - a. **Funding.** External study investigators must agree not to enter into any verbal or written agreement or contract with entities that will provide funding for any research activity related to MATER without prior review and approval of the MATER Research Committee.
 - b. **Confidentiality of Individually Identifiable Data.** Maintenance of confidentiality as related to the potential identification of individual MATER clients and staff is a critical issue. Confidentiality of individually identifiable data about MATER clients and research subjects must be assured. External study investigators are to provide documentation that they have current certification of IRB and HIPAA training by their institution. They also need to sign and return the MATER Confidentiality Certification form. Certain data regarding drug and alcohol treatment is protected at the federal level by 42 CFR Part 2 and at the state level by PA 255.5. External partners and internal collaborators must make proper arrangements when such data and covered entities are involved.
 - c. **Changes after initial approval.** Once a study is approved, changes in the structure or concept of the study must be approved by the MATER Research Committee.

d. MATER staff approvals. If the proposed work requires the participation of specific MATER staff (non-faculty), the MATER Representative on the study will have the obligation to determine if staff will participate in the proposed project.

f. Participant burden. A careful and clear assessment of the participant burden created by the proposed study and the benefit of the information gained in light of this burden is required. The burden posed by the study will be assessed in the context of the overall participant burden created by other relevant study related activities.

g. Study burden. A careful and clear assessment of the burden the proposed external study will create for the overall study, its participating institutions and support activities is required; specifically, the burden on participants, and MATER clients, staff and faculty. This includes participant recruitment, obtaining consent, completing assessments, attaining IRB approval, data management, and other related activities.

h. Attendance at MATER research meeting. The external PI is expected to attend a MATER research meeting at the start of the project to provide details about the study.

Proposal Review Process

Study proposal applications are submitted to the Chair of the MATER Research Committee either by the external PI or by the MATER Representative listed on the proposal. Elements to be included in each proposal can be found in Appendix 1, *“External Investigator Proposal Guide”*. The MATER Research Committee reviews the application at their next scheduled meeting, which occur monthly. The review is based on scientific merit and interest, consistency with MATER philosophy, non-duplication or interference of ongoing research activities, and burden level on MATER clients, staff, and faculty. The study PI will be notified of approval.

External investigator’s signature below acknowledges that the individual understands and agrees to these policies. MATER faculty signature below acknowledges that the faculty has explained these policies, and the external investigator has demonstrated understanding and agreement to uphold these tenets.

External Investigator Signature

Date

MATER Faculty Signature

Date

External Investigator Printed Name

MATER Faculty Printed Name

Appendix 1

External Investigator Proposal Guide

Proposals for studies are to be submitted to the Chair of the MATER Research Committee (Vanessa Short; Vanessa.Short@jefferson.edu).

The study proposal must include:

- 1) Study title
- 2) Name and contact information of external PI
- 3) Name and contact information of external co-I(s)
- 4) Name of the approved MATER faculty researcher(s) serving as co-PI or co-I
- 5) Planned start date and funding plans
- 6) Abstract describing the study
- 7) Description of the study, including
 - a. Rationale and brief background
 - b. Specific aims
 - c. Design and Methods, including plans for recruitment and enrollment, data collection and management, and statistical analyses
 - d. Sample size justification
- 8) Confidentiality of individually identifiable data
- 9) Planned publications, including abstracts, manuscripts, and presentations

Appendix 2
Tenets of Executing MATER's Philosophy

1. We provide, or facilitate receiving, all services that meet an individual/mother-child dyad/family's needs related to all issues that surround substance use disorders.
 - a. This is inclusive of medical, psychiatric, behavioral, case management, etc.
2. We advocate for all individuals/mother-child dyads/families to receive the best services that meet their needs.
3. All individuals have equal and non-contingent rights to the services we provide.
 - a. One service is not withheld until compliance with another (e.g., therapy is provided whether or not medication was dispensed, and vice-versa).
 - i. Services may be scheduled to encourage positive behavior (e.g., medication for IOP-level clients provided only after IOP group time)
4. All services are provided or facilitated in a timely manner.
5. All staff, clients, families, collaborators, and stakeholders are met with respect and compassion.

External investigator signature below acknowledges that the investigator understands and agrees to uphold these tenets.

MATER faculty signature below acknowledges that the faculty has explained these tenets, and the investigator has demonstrated understanding and agreement to uphold these tenets.

External Investigator Signature	Date	MATER Faculty Signature	Date
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External Investigator Printed Name	MATER Faculty Printed Name
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