

A. Complete the TMC Research Application Form (the following 3 pages)

Completion and review of the application ensures department and administrative approval is obtained.

- Projects that do not meet the federal definition of research = non-human subjects research (NHSR) or activities determined by the Institutional Review Board (IRB) as not human subjects research ***DO NOT*** require a TMC Research Application Form. The research process at TMC: <http://med.umkc.edu/ora/conducting-research-at-tmc/>
- The Principal Investigator (PI) or co-PI must be a member of the current TMC Medical Staff or TMC employee.
- All researchers and study personnel must complete the CITI education course for the protection of human research subjects (**Group 1-Biomedical**) and renew every **3** years. http://med.umkc.edu/ora/human_subjects/
- Attach the appropriate items (study protocol, consent form, etc., listed on pg. #3) with the Application Form.
- To avoid bias and assure objectivity in research, for all sponsored research projects - researchers and staff shall disclose any potential conflicts and significant financial interests in accordance with the TMC Code of Conduct, the sponsor's requirements, and University of Missouri System conflict of interest disclosure requirements.
- For funded research projects, please forward the sponsor's draft study agreement/contract and budget to Research Administration for review and negotiation as soon as the contract drafts are received.
- Research policies are posted on the TMC *intranet* – <http://intra/default.aspx> click the **Policy Medical** icon.
- Research FAQs and links to federal research regulations: <https://tmcmed.sharepoint.com/sites/Research>

Office of Research Administration e-mail = HSDResearch@umkc.edu or call (816) 235-6015. **The office is located in the UMKC School of Medicine** on the 4th floor (M4-308).

B. Obtain approval from the Institutional Review Board (IRB)

Per an assurance with the U.S. Office of Human Research Protections, and institutional policies - research conducted at TMC requires approval by the appropriate IRB. The IRB will not provide final approval to conduct the research until verification of administrative approval at TMC has been obtained.

Most research at TMC is reviewed by the UMKC IRB: <http://ors.umkc.edu/research-compliance/irb> The UMKC IRB website has additional info about collaborative IRB review for projects that involve multiple institutions. The UMKC IRB utilizes an electronic IRB submission system.

Research requiring access, review, use, recording, or disclosure of any patient protected health information at TMC also requires review to ensure compliance with HIPAA Privacy Rule requirements. The Privacy Rule requirements will be reviewed during IRB review.

Please contact the IRB directly for questions about reviews, submission forms, or meeting information.

You may submit/apply to A & B above at the same time.

Application for Approval of Research and Document Review (Research Application Form)

1. **Research Protocol Title:**

2. **New project** **On-going project** **Date of planned study initiation**

3. **Research site** TMC-HSD TMC-LW TMC-BH

4. **Is this a sponsored research project?** Yes No
Study Sponsor or separate research organization (if any)

5. **Principal Investigator**

Phone Pager Email

Faculty Mentor (if this is a resident's or student's research project)

6. **Study Coordinator(s)**

Phone Pager Email

List all other staff that will work directly on this project:

7. **Please indicate who will pay the costs of treatment in the event a study participant suffers an injury during the conduct of this research project.**

8. **Indicate the study protocol procedures that are not 'standard of care' for this research project.**

9. **Will any advertisements (newspaper, radio, TV, internet, flyers, posters, etc.) be utilized?**

Yes No

If Yes, the ad(s) requires approval by the IRB. In addition, TMC Public Relations must approve the info as well.

10. Will study participants receive compensation for study participation? Yes No

If Yes, please indicate compensation method:

- Check or TMC Cash Office stipend from TMC research study account
- Gift certificate or gift card. Indicate source:
- Other:

Please note, the amount and method of compensation also require IRB approval.

11. Is the study sponsor providing any study recruitment incentives or bonuses to the site that are not mentioned in the study agreement/contract or budget? Yes No

If Yes, please describe:

12. Attach copies of these items with this application:

- (1) Current Research Study Protocol.
- (2) Study Contract / Grant Application (if applicable).
- (3) Sponsor's study Budget (if applicable).
- (4) TMC Research Expense Worksheet for funded projects (if applicable) – "internal budget".
- (5) Informed Consent form (if applicable). *Send the final IRB approved version when available.*
- (6) For sponsored projects, every project staff member that has a significant financial interest or potential conflict of interest shall submit a Disclosure Form.
- (7) Investigator's Drug Brochure for pharmacy review (if applicable).
- (8) Review by Privacy Board and IRB Approval/Determination* (send IRB approval when available).

* If the IRB submission is approved before review and approval of the TMC Research Application, the IRB may not release the approved Informed Consent and send final IRB approval until this Application has received administrative approval at TMC.

Please obtain the signatures of the appropriate individuals (items #14 – #16 on the next page) before submitting this application.

13. As the Principal Investigator or TMC employee/workforce member signed below, we/I certify that we/I have reviewed the applicable policies and requirements:

- (1) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research,
- (2) U.S. DHHS regulations for the Protection of Human Subjects at 45 CFR Part 46,
- (3) US Food & Drug Administration (FDA) Regulations located throughout 21 CFR, and
- (4) The relevant TMC institutional policies and procedures for the protection of human research subjects, clinical trials, research privacy, and research integrity.

For reference see the TMC *intranet* ([TMC policies](#) page) and <https://tmcmed.sharepoint.com/sites/Research>

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Principal Investigator (Signature)

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 Date

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Co-Principal Investigator (Signature)

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 Date

Address (for inter-office mail)

(TMC Medical Staff Member or Employee if PI is not)
 Phone
 Email
 Inter Office Mail Address

