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

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

- Projects that do not meet the federal definition of research = non-human subjects research (NHSR) or activities determined by the IRB as not research ***DO NOT*** require a TMC Research Application Form.
- The Principal Investigator (PI) or co-PI must be a member of the current TMC Medical Staff or TMC employee.
- Attach the appropriate items (study protocol, consent form, etc., listed on pg. #**3**) with the Application Form.
- 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/***
- To avoid bias and assure objectivity in research, researchers and staff submit a signed disclosure form for all sponsored projects: ***http://www.ors.umkc.edu/office-of-research-services/financial-conflict-of-interest***
- 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.
- TMC research policies are posted on the TMC ***intra***net: ***http://tmcpolicy*** Research FAQs at TMC and federal regulations are listed at: ***http://research.tmchost.com/***

Research Administration Office e-mail = *SOMResearch@umkc.edu* or call (816) 235-6247. **The office is located in the UMKC School of Medicine.**

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

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

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.

- Research proposals with adult participants, contact the UMKC IRB: ***http://ors.umkc.edu/research-compliance/irb***
- Research proposals that involve children - contact Children's Mercy Hospital IRB**:** ***www.childrensmercy.org/irb***

Both UMKC and CMH IRBs utilize an electronic IRB submission system.

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.

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Application for Approval of Research Protocol and Document Review (research application)

1. **Research Protocol Title**

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

3. **Research site** ☐ TMC-HH ☐ 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 <u>not</u> '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.

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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)** ☐ Study Budget (if applicable).
- **(4)** ☐ TMC Research Expense Worksheet for funded projects (if applicable).
- **(5)** ☐ Informed Consent form (if applicable). *Send the final IRB approved version when available.*
- **(6)** ☐ Financial Disclosure/Conflict of Interest form for all research staff for sponsored projects (if applicable).
- **(7)** ☐ Investigator's Drug Brochure for pharmacy review (if applicable).
- **(8)** ☐ Reviewed by Privacy Board.
- **(9)** ☐ IRB Approval or Exemption Letter* (send IRB approval letter when available).

* If the IRB submission is approved before review and approval of the TMC Research Application is complete, the IRB may not release the approved Informed Consent and final approval until this application has received administrative approval at TMC and receipt of this completed/signed form by Research Admin.

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:
- **(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 at 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 http://tmchost.com/research/?page_id=22

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Principal Investigator (*Signature)* Date **Co-Principal Investigator** (*Signature)* Date
(TMC Medical Staff Member or Employee if PI is not)

Address (for inter-office mail) Phone Pager

Email
Inter Office Mail Address

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Laboratory Approval

14. Any lab tests/procedures (central or local), including Point-of-Care testing, to be performed for this study project?

☐ Yes
☐ No

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TMC Lab Director Date

Please indicate the **local** lab tests requested to be performed **AND** any point-of-care tests (i.e., urine pregnancy test, blood glucose, etc.) to be performed by study staff.

Pharmacy Approval

15. Any use of a drug (approved or investigational) or drug-eluting device?

☐ Yes
☐ No

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TMC Pharmacy Director Date

Comments/Concerns

Department Approval

16. ....
Department Manager Date **Department Chair** Date
(Program Director if resident's study)

Comments/Concerns

Final Approval

17. Financial and Administrative Review **Estimated Revenue** $_____

Funds will be administered by: ☐ TMC ☐ UMKC ☐ Other_____

Comments _____

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Director of Clinical Research Date **TMC Legal Counsel** Date
(As to Legal Form and Insurance)
(Not applicable for non-sponsored research studies)