

Research Information Guide (RIG)

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This guide is meant for those interested in clinical research but is not fully sure on some or all processes.

Keep the principles of ethical behavior, transparency, communication, and protecting the research volunteers in mind. In order to start there are basic requirements which will be provided. The flow/stages of research are provided in this guide with further details of the process in the appendix.

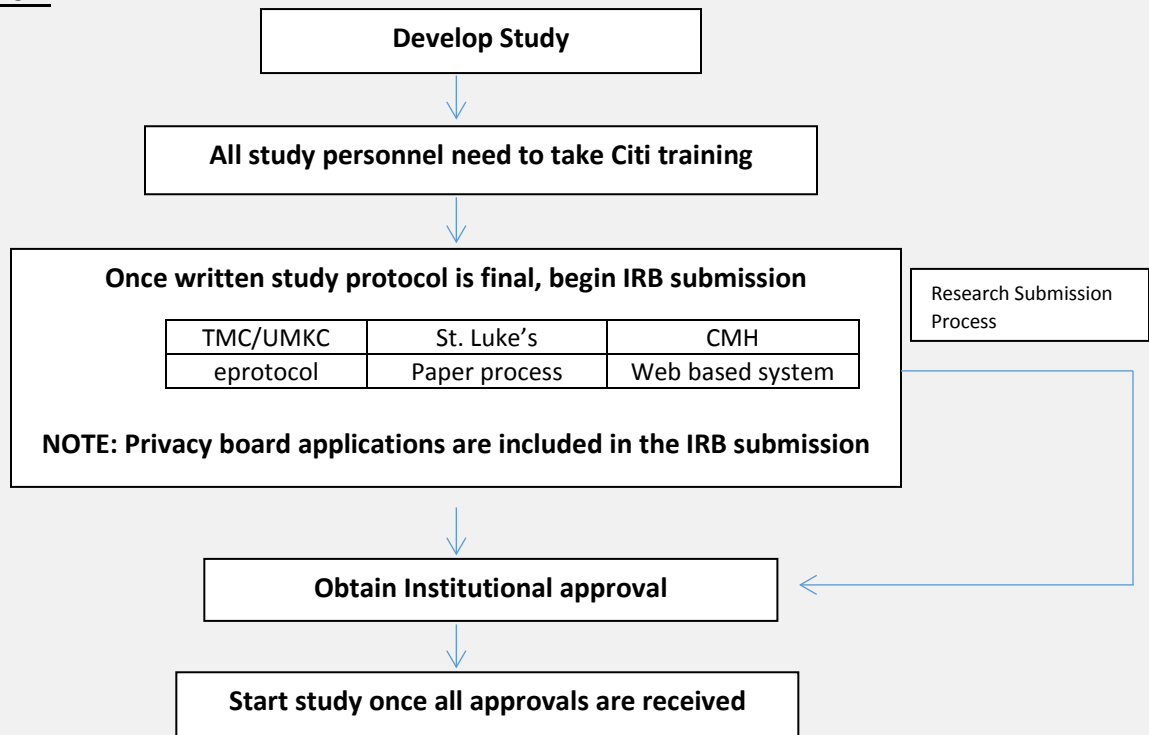
Research Support

Research Support is an office through Research Administration that provides guidance on the IRB submission/eprotocol process, privacy board & TMC applications. Additionally RS can guide on the IRB submission process at St. Luke’s and how to complete research forms. We understand that the process can be confusing; we are available to support medical students, residents and faculty mentors on the research submission process & can send “next step” emails along the way.

<http://med.umkc.edu/ora/research-support/>

Contact us at ResearchSupport@tmcmcd.org

A. Research Flow



B. Items applicable to anyone doing research

- Take Citi training Group 1 biomedical (other modules may be required depending on where the research is conducted and if the study has funding, this will be discussed in further sections). See appendix.

C. Study Development stage:

- Prepare your research protocol (the plan you will follow to conduct the study) – Templates are available. <http://med.umkc.edu/em/research-resources/> Remember to add a date on your protocol header or footer, this helps with version control.
- Decide all the data endpoints that you are collecting (what you are looking at such as test results, age, etc.....) and put that in a spreadsheet and/or RedCap (a UMKC database system, discussed later in this guide). This will be your data collection sheet. Keep in mind that the IRB must approve all data collection variables.
- Check in with your mentor to develop and finalize protocol.
- Follow any Department specific guidelines regarding research.

D. Once you have a finalized protocol begin the steps for the Research Submission process outlined below:

- IRB / privacy board submission (done together) – also called Eprotocol (the IRB entry system and HIPAA forms), see directions in the appendix under eprotocol.
- TMC application (for studies using TMC subjects or conducted at TMC), see appendix for details.

E. Residents and Medical Students research

Residents and medical students should identify a mentor. The mentor is designated as the Principal Investigator on the study. Refer to the medical student section of this guide for more information.

F. Medical Students

- Go to the UMKC Link for steps about participating in research, see “Getting Started”.
<http://med.umkc.edu/student-research/>

Initial steps

- Complete the Student Research Information form
http://med.umkc.edu/docs/research/Student_Research_Information_Form.pdf
- Complete Citi training Biomedical Group 1 (if doing research at CMH or working with a grant, complete the COI training as well).
- Work with your investigator to be added as study personnel on the IRB application.

NOTE: before starting on a study, you must be IRB approved.

Research Faculty mentor/investigator information to add medical student/s to your TMC research study:

- Contact Research Administration (RA) at somresearch@umkc.edu
 - Email the name of the study which they will be added (provide IRB # if possible), medical student name and email
 - RA will make sure all the REQUIRED documents are in order. When patient interaction is involved this includes employee health information. For TMC users: Required documents are also located at: <http://centerpoint/sites/research/default.aspx>
- Once RA says the project is ready to go
 - Submit the project to the IRB using eprotocol for UMKC/TMC; St. Lukes and CMH have a separate system (instructions are provided in this guide).

G. IRB Information

Items requested by CMH IRB from the UMKC IRB:

1. Prepare the UMKC IRB Request to Rely (RtR) form for UMKC to rely on the CMH IRB:
<http://ors.umkc.edu/docs/default-source/irb/request-to-rely-form-2014-03-06.pdf?sfvrsn=16>
2. Complete the UMKC Financial Disclosure Form (FDF).
<http://ors.umkc.edu/docs/default-source/default-document-library/coi-disclosure-er.pdf?sfvrsn=0>
Note: if the study is not funded, under “sponsor” write none.
3. Email both documents (RtR & FDF) to umkcirb@umkc.edu The UMKC IRB will forward the approved RtR to CMH IRB.
4. Complete Citi training group 1 biomedical and #3 conflict of interest

Directions are posted here <http://med.umkc.edu/ora/process-to-conduct-research-at-the-childrens-mercy-hospital-and-clinics-cmh/>

St. Lukes – you will need to submit to the designated IRB. Contact researchsupport@tmcmcd.org for details.

Directions are here: <http://med.umkc.edu/ora/resident-research-process-at-saint-lukes/>

UMKC Institutional Review Board (IRB) - This is the IRB for TMC and UMKC. The UMKC IRB uses eprotocol to submit applications electronically. Instructions can be found in the appendix. Specific IRB information is located at

[http://ors.umkc.edu/research-compliance-\(iacuc-ibc-irb-rsc\)/institutional-review-board-\(irb\)](http://ors.umkc.edu/research-compliance-(iacuc-ibc-irb-rsc)/institutional-review-board-(irb))

IRB policy and procedures are here:

[http://www.ors.umkc.edu/research-compliance-\(iacuc-ibc-irb-rsc\)/institutional-review-board-\(irb\)/standard-operating-procedures](http://www.ors.umkc.edu/research-compliance-(iacuc-ibc-irb-rsc)/institutional-review-board-(irb)/standard-operating-procedures)

Obtain an Eprotocol password (for faculty, residents, and any staff working on the IRB application entry) by registering in order to enter the application.

How to register on eprotocol (obtain a password)

- Click on: <https://umkc.keyusa.net/> and login.
- Click “Register” and fill out the required information and submit.
 - Username format – last name first initial or last name first and middle initial
- You will receive an email from the IRB with your login and password within a few days.
- *Note: if there are medical students on this study that will not be working on the eprotocol application, they are be added to the study without applying for an eprotocol password. See Adding medical students to eprotocol in the Eprotocol entry section.*

The IRB applications to select in eprotocol are:

- Non-Human Subjects Research
- Exempt
- Expedited / Full review

See the appendix for information on each type of application and or the IRB website listed above.

H. Informed Consent for Research – Information is found at

[http://www.ors.umkc.edu/research-compliance-\(iacuc-ibc-irb-rsc\)/institutional-review-board-\(irb\)/informed-consent](http://www.ors.umkc.edu/research-compliance-(iacuc-ibc-irb-rsc)/institutional-review-board-(irb)/informed-consent)

Tips:

- Note the time of consent on documentation in order to show that consent occurred before research procedures. This can be written on ICF near the date.
- Review consent after it is signed to ensure there are no errors and all blanks are completed.
- Person that made errors can correct errors by line through the error then date and initial, no scratches and no white out.
- Know the IRB policy and procedures on consent. See Obtaining Consent from Research Subjects.

I. RedCap – data entry module

RedCap data base can be used for data entry and analysis and is designed to comply with HIPAA standards.

See information located at: <https://chi.umkc.edu/redcap/>

J. Statistics support

The Department of Biomedical and Health Informatics (DBHI) offers a research and statistical consulting service. Although the mission of the program is to foster innovative research by supporting faculty, residents, fellows, and students on the Hospital Hill Campus, this service will be available to others at UMKC on a space-available basis. This service will:

- Promote high-quality research by consulting on proper research design
- Support researchers in making sample size estimates
- Assist researchers in ethical and accepted methods of data analysis and interpretation.

See the appendix for specific details.

K. **i2b2** - This is a de-identified data base of patient information that can be used for feasibility, cohort discovery & hypothesis generation. TMC Cerner Millennium password is required. For more information go to: <http://chi.umkc.edu/i2b2/>

L. **Appendix**

Appendix 1: Research Contact Information

General IRB phone number umkcirb@umkc.edu	816-235-5927	*See web links section for full listing
Research Administration somresearch@umkcmed.edu		*See web links section for full listing
Research Support ResearchSupport@tmcmed.org	816-404-5087 816-404-4711	Laurie Kemble Hollie McKinney

Appendix 2: Research at CMH

All persons involved with research at CMH must meet the qualifications of CMH for research. The following is required for CMH to participate in research at CMH.

All students listed on research protocols must complete the following:

- Request to Rely Form (RtR)
- UMKC FDF
- Citi training group 1
- Citi training conflict of interest

Email the RtR and UMKC FDF to somresearch@umkc.edu , they will send the documents to the CMH IRB on your behalf. Then the IRB process can begin per CMH websites.

https://www.childrensmercy.org/Health_Care_Professionals/Research/Research_Integrity/

Appendix 3: Format for a Research Study Protocol

UMKC template http://med.umkc.edu/docs/research/templates/Research_Protocol_Format.pdf

- A. **Title:** Incorporate your primary study hypothesis.
- B. **Investigators:** Include the name of the PI/faculty advisor and all other investigators Decide early who will be the PI, first author, additional authors and corresponding author.
- C. **Introduction/background information:** Write your introduction as a logical argument for why your study needs to happen and what your study can contribute. This should introduce the research area and provide the rationale for the significance of your project. The protocol should include a background of research performed within this area (with cites) and the significance of these. For example what is known, but what gaps are left.

If applicable include any preliminary studies, pilot work, or preparatory work you have carried out specific to the area of the proposal. Include summary data about your practice and/or patient population that would lend to the significance of you carrying out this study in your patient population.

Close the last paragraph with the study's research goal.

- D. **Study Question/Hypothesis:** Concisely state what question you are answering. Ideally, do this in one sentence. Can be stated as hypothesis or research objective(s). What is primary objective and are there any secondary outcomes?
- E. **Methods:** Consider consulting the SOM DBHI dept. for the Research and Statistical Consult Service, to assist in project design and data analysis - <http://med.umkc.edu/dbhi/consultation/>
 - 1. **Research study design-** randomized controlled trial, observational cohort, etc. May include rationale or justification for selecting that design. ?
 - 2. **Population:** describe the study population and the rationale for studying this population.
 - a. **Sample size:** How many subjects do you intend to enroll/ or subject records to access. Use a number please.
 - b. **Inclusion/exclusion criteria:** *use a bulleted format.*
 - c. **Recruitment:** Where will study participants be recruited/selected? Describe the step-by-step procedure for identifying and recruiting potential research subjects or requesting data.

3. **Consent-** If applicable, describe in detail how you will consent subjects? Verbal or written consent? Who will consent the subjects? *See sample consent forms at:*
[http://ors.umkc.edu/research-compliance-\(iacuc-ibc-irb-rsc\)/institutional-review-board-\(irb\)/informed-consent](http://ors.umkc.edu/research-compliance-(iacuc-ibc-irb-rsc)/institutional-review-board-(irb)/informed-consent)
 4. **Procedures:** Describe the step-by-step procedures for what will happen to the subject or data being reviewed. How many study visits? What will happen at each visit? Total time commitment?
 5. **Data Collection:** what data will be collected? Will PHI be collected? The IRB will need to see *your data collection sheet for submission*. Data to be collected needs to be very specifically stated to IRB. This sheet can be completed through RedCap or Excel and submitted to the IRB.
 6. **Confidentiality:**
 - a. Who will have access to the data? How will it be stored?
 - b. Coded Data (code linking data to PHI): Is the data coded? If yes, explain where the key to identifiers will be stored, how will it be protected, and who will have access to it.
 - c. Explain why, where, in what format, and for how long data/specimens will be retained.
- F. Analysis:** Describe your data analysis process. What statistical test you will use to test each research objective that you listed? Perhaps you will only summarize the data and provide descriptive statistics. How did you arrive at your sample size estimate? Describe your sample size justification and your recruitment strategy to achieve this. Include the resources used to estimate the sample, such as anticipated effect size. **Consider consulting the SOM DBHI dept. for the Research and Statistical Consult Service, to assist in project design and data analysis -**
<http://med.umkc.edu/dbhi/consultation/>

Appendix 4: CITI - Collaborative Institutional Training Initiative Directions

All research investigators and others listed on the project that will conduct research shall complete relevant educational courses through the Collaborative Institutional Training Initiative (CITI) program.

- **Group 1 (Biomedical Investigator- Human Subjects Research)** - Group 1 training is required by UMKC and Truman Medical Centers for clinical trials research, surveys or retrospective chart reviews conducted at TMC. This training is good for 2 years and then researchers complete a Refresher Course. *Additional courses are available that are applicable to your research.*

CITI Instructions: Select the CITI link: www.citiprogram.org

For first-time users:

1. Click on **Register**.
2. In Section 1, select your organization affiliation: **University of Missouri-Kansas City** and check the box to agree to the Terms of Service.

3. In Section 2, enter your personal information.
4. In Section 3, create a user name, password and security question.
5. In Section 4, enter country of residence.
6. In Section 5, CEU credits, select **No**.
7. In Section 6, enter additional personal information.
8. In Section 7, select **curriculum**.
 - For Question 1, select **Group 1 Biomedical Investigator (UMKC)**.
 - For Question 2 & 8, select **Not at this time**.
 - Leave the rest of the questions unanswered. Scroll to the bottom and hit **Complete Registration**.
 - Click **Finalize Registration**.
9. The Main Menu will appear. The assigned course(s) will be listed under the Course section. Click the title of the course to start the training.

For returning users:

1. Click **Log-In**, enter user name and password.
2. The Main Menu will appear. The assigned course(s) will be listed under the **Course** section. Click the title of the course to start the training.
3. If you do not see the course you want to take, click **Add a Course**.

At the end of the session:

1. **Please save a copy of your certificate.** You will need to supply the date of completion for your CITI training to the IRB.

Appendix 5: TMC Research Application

Required for studies using TMC patients. If the application is NHR, a TMC research app is not needed.

1. Complete application
2. Obtain signatures from your department and services being used
 - a. PI signs #13
 - b. Department Manager and Department Chair sign #16
 - c. Other services as applicable sign #14 (Lab), #15 (Pharmacy)
3. Email to somresearch@umkc.edu along with study related documents described under #12 (i.e. protocol...)

Conducting research at TMC directions: <http://med.umkc.edu/ora/conducting-research-at-tmc/>

Appendix 6: Request to Rely on an External IRB

CTSA (Clinical and Translational Science Awards)

The CTSA regional partners (UMKC/TMC, CMH, St. Luke's Hospital, and the Univ. of Kansas Med Center) have signed an umbrella IRB reciprocity agreement that will streamline the approval process for joint research. Only

one IRB review is needed for projects involving these institutions. The partners have established an algorithm to determine which IRB will be the IRB of record. Investigators from these institutions are encouraged to contact their home IRB office to request a single IRB review for their collaboration. **You will need to submit a Request to Rely form to your institution's IRB to notify them of the reciprocal IRB review.**

What is a "Request to Rely"?

The Request to Rely form starts the process by which an investigator may submit their request to an external IRB. The IRB will ask the investigator questions about the proposed study which will allow the IRB to determine whether the study meets the criteria to allow the investigator to rely on an external IRB.

As the Reviewing Institution, an Institution is responsible for IRB review and continuing oversight. As the Relying Institution, an Institution cedes IRB review and continuing oversight to the Reviewing Institution. The Principal Investigator is responsible for providing the Relying Institution with copies of all official documentation (approvals, etc.) from the Reviewing Institution's IRB. This document must be kept and available upon request.

UMKC/TMC Request to Rely Submission Process

- ❖ For the CTSA regional partners (UMKC/TMC, CMH, St. Luke's Hospital, and the Univ. of Kansas Med Center) complete this form: [Request to Rely Form](#).
- ❖ For any other institution, complete this form: [IRB Authorization Agreement](#)
- Email the applicable form to: UMKCIRB@UMKC.edu

CTSA Contact Information:

- ❖ KUMC IRB Office: (913) 588-1240/ humansubjects@kumc.edu
- ❖ Children's Mercy: (816) 458-4428/ irb@cmh.edu
- ❖ St. Luke's Hospital: (816) 932-3661/ irb@saint-lukes.org

Appendix 7: Statistical and Consulting Services

The Department of Biomedical and Health Informatics (DBHI) offers a research and statistical consulting service. This service will:

- Promote high-quality research by consulting on proper research design
- Support researchers in making sample size estimates
- Assist researchers in ethical and accepted methods of data analysis and interpretation.

Guidelines for Using the Consulting Service

The RSCS staff must be consulted at the beginning of the project; usually this should be before data collection has started. In some cases where secondary data are analyzed this condition would be waived.

1. The recipient of the consult service must submit the following documents to the RSCS office:
 - o A draft project abstract of 250 words that specifies the **Objectives, Methods, Anticipated Results, and Potential Conclusions** of the Project. *If the project is a clinical trial, a brief (250 words maximum) project summary using the PICO format if it is applicable to the particular study must also be submitted.*
 - o the population being studied,
 - o the intervention or exposure,
 - o the comparison or control group, and
 - o the primary outcome measure(s).

We understand that not every project will fit neatly into this format, but any abstract for different types of research should provide a comparable level of detail.

2. For students, residents, and fellows a **letter of support for the project** from the program director or faculty mentor will be required to verify that the project has been reviewed at the program level.
3. If the project requires **Human Subjects approval**, documentation of this must be forwarded to the office prior to data collection and analysis.
4. To request service, submit required information and documents online [here](#).

The users of this service need to perform their own data collection and analysis.

If you are faculty and using the DBHI staff to develop a grant for extramural funding we would encourage you to have our statistician included in the programs proposed budget as a certain percentage FTE for the project. In such cases, details will be worked out with the DBHI staff in order to establish appropriate work/payment levels.

In return the DBHI Office will provide the following support:

1. One two-hour consultation at the start of the project to help with study design, data collection issues, and establish timelines. We will make every attempt to schedule this appointment within one month of the initial request or sooner if possible. But it must be realized that a good number of the people supporting this service are volunteers.
2. Email support in follow-up for statistical issues as they develop.
3. One two-hour consultation at the end of the project to help review findings and conclusions.
4. Review of drafts of papers to be submitted to medical or other peer reviewed journals. We would anticipate that the staff person who works on the project will be listed as one of the co-authors to the publication.

Contacts:

For questions about completing the REDCap form, please contact Erin Gilmore. Email: gilmoree@umkc.edu.
For general questions about the service, please contact Dr. Julie Banderas. Email: banderasi@umkc.edu

Links:

DBHI website: <http://med.umkc.edu/dbhi/consultation/>

To request consulting service: <https://redcap.umkc.edu/surveys/?s=3EPTDHLAK4>

Appendix 8: IRB APPLICATION TYPES

QA/QI projects do NOT require IRB review. To determine whether or not IRB review is required, there are two steps. The first step is to determine whether or not the study is research. The next step is to determine whether or not the study involves human subjects. **If your study meets the Research and/or the Human Subject definition it will require IRB review.**

1. **Research:** a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes.

Indicate whether the activity meets the following criteria for research:

A. The activity is a systematic investigation: an activity that involves a prospective research plan which incorporates data collection, both quantitative and qualitative, and data analysis to answer a research question

B. The activity is designed to develop or contribute to generalizable knowledge: designed to draw general conclusions (i.e. knowledge gained from a study may be applied to populations outside of the specific study population) inform policy, or generalize findings

If you did not check A or B, the activity is “not research”.

If you checked both A and B, the activity is “Research”.

2. **Human subject:** 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*

- **Intervention** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. **Interaction** includes communication or interpersonal contact between investigator and subject.
- **Identifiable private information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably

expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Indicate whether the activity meets the following criteria for research:

C. The research involves living individuals

D. The investigator will obtain data information about those individuals

E. the investigator will obtain EITHER of the following:

E. 1. Collect data through **intervention or interaction** with an individual, including interviews, surveys, physical procedures, manipulations of the subjects environment, and any other direct contact or communication with the subject (regardless of whether resulting data is identifiable or not).

E. 2. Obtain, view or otherwise handle any **private information** which identifies individual subject(s) through the use of either direct identifiers (name, address, etc.) or indirect identifiers in the form of a code that links back to the identity of the subject through an existing key.

If "Yes" to C, D **AND** either E.1 or E.2, the activities involve human subjects.

What if I still don't know if I need IRB review?

- **Submit an application for Determination of Human Subjects Research** and/or contact umkcirb@umkc.edu if you are still uncertain how to proceed. (See Instructions below)

Exempt Application

For a study to be eligible for exemption all of the research activities must fit in one or more of the six categories listed on the website below. In some cases, all but one of the activities will fit in the categories.

Risk Assessment Considerations for Exempt studies

Research eligible for exemption usually involves little or no risk to subjects. Some reviews apply the “minimal risk” standard when conducting exempt review. When determining “minimal risk” all the risks associated with the study must be identified. Department of Health & Human Services defines “minimal risk” to mean “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests” [45 CFR 46.102(2)(i)].

[http://ors.umkc.edu/research-compliance-\(iacuc-ibc-irb-rsc\)/institutional-review-board-\(irb\)/exempt-determinations](http://ors.umkc.edu/research-compliance-(iacuc-ibc-irb-rsc)/institutional-review-board-(irb)/exempt-determinations)

Expedited Full Review Application

Expedited does not mean that the review is less rigorous or happens more quickly than convened review. It refers, instead, to certain types of research considered to involve minimal risk.

Expedited review shall be conducted by the IRB chairperson or by one or more of the experienced IRB members designated by the chairperson to conduct the review. The IRB member conducting the expedited review may exercise all of the authorities of the IRB except that the reviewer may not disapprove the research. The reviewer shall refer any research protocol which the reviewer would have disapproved to the Full IRB for review. The reviewer may also refer other research protocols to the Full IRB whenever the reviewer believes that Full IRB review is warranted.

When the expedited review procedure is used, the IRB chairperson or member(s) conducting the review shall inform IRB members of research protocols which have been approved under the procedure.

At a convened IRB meeting, any member may request that an activity which has been approved under the expedited procedure be reviewed by the IRB in accordance with non-expedited procedures. A vote of the members shall be taken concerning the request and the majority shall decide the issue.

Eligibility for Expedited Review

Expedited review is applicable for research activities that involve no more than minimal risk to the human participants and that can be placed in one or more of the [nine categories](#). See the website below for the categories and further information.

[http://ors.umkc.edu/research-compliance-\(iacuc-ibc-irb-rsc\)/institutional-review-board-\(irb\)/expedited-review](http://ors.umkc.edu/research-compliance-(iacuc-ibc-irb-rsc)/institutional-review-board-(irb)/expedited-review)

Appendix 9: How to submit an application for Determination of Human Subjects Research

- 1) Log in to <https://umkc.keyusa.net>
 - i) If you are not currently registered in the system click on “Register “
 - (a) A username and password will be emailed to you.
- 2) Once logged in you are at your home page (Research Staff). From there you are able to create a protocol. Select “**Create Protocol**” located at the top of the page.
 - i) Enter study title, investigator and coordinator information if applicable. Select “**Create**”
- 3) Follow page prompts and enter relevant information in the following tabs: Personnel Information, Subject Checklist, Study Location, General Checklist, Funding, and Protocol Information.
- 4) In the Protocol Information section, tabs will populate at the top of the page. For DHR applications you will only need to complete the first three tabs: Summary Application Type, and Not Human Subjects Research tab.
 - i) For Application type, select “**Not Human Subjects Research**”
 - ii) For NHR tab, answer each question.
 - iii) The remaining tabs will be grayed out. If applicable, you may attach study related documents on the last tab called **Attachments**.
- 5) Once you believe you have completed the application click **Check for Completion** on the menu panel.
 - i) The system will check for completeness and notify you of sections you must complete to submit, if applicable.
- 6) The identified PI must be logged in to “check” the obligations section.
- 7) Click Submit Form on the menu panel.
 - i) In the pop-up box, click “Yes” to submit the IRB Protocol.
- 8) You will receive an email confirming submission of the application.
 - Once the application is submitted, a designated representative of the UMKC IRB will review the information and determine whether the project requires IRB review. If the project is deemed “not human subject research”, investigators will receive a letter indicating such. If the project does qualify as Human Subject Research under OHRP and FDA regulations, the investigator will receive correspondence from the IRB stating that a full application for IRB review and approval must be completed in order for the project to proceed.

Appendix 10: What is QA/QI?

There is no regulatory definition but often QA/QI is described as “systematic, data-guided activities designed to bring about immediate (or nearly immediate) improvements in health care delivery”, and the combined efforts of everyone to make changes that will potentially lead to better patient outcomes, better system performance, and better professional development. In medical institutions, QA/QI is a necessary, integral part of hospital operations and is not subject to review as research, as defined under federal regulation. Rather, it is governed by Joint Commission and hospital standards. Human Subject Research (HSR) is governed by federal regulation, under IRB oversight.

What are some differences between QA/QI and Research?

Points to consider	Research	QA/QI
Purpose	To test a hypothesis OR establish clinical practice standards where none are accepted	To assess or promptly improve a process program or system; OR improve performance as judged by accepted/established standards
Starting Point	To answer a question or test a hypothesis	To improve performance
Benefits	Designed to contribute to generalizable knowledge and may or may not benefit subjects	Designed to promptly benefit a process, program, or system and may or may not benefit patients
Risks/ Burdens	May place subjects at risk and stated as such	By design, does not increase patient’s risk, with exception of possible privacy/confidentiality concerns
Data Collection	Systematic data collection	Systematic data collection
End Point	Answer a research question	Promptly improve a program/process/system
Testing/ Analysis	Statistically prove or disprove a hypothesis	Compare a program/process/system to an established set of standards.

Appendix 11: What is Human Subjects Research (HSR)?

The Office of Human Research Protections (OHRP) defines **research** as *a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge* and **human subject** as *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* (45 CFR 46.102(d)). For example, if a project using human subjects is designed to test a novel hypothesis, replicate another researcher's original study, or withhold any aspect of conventional care shown to be beneficial in prior studies, OHRP's definition of human subject research would apply.

The FDA does not use the term research, but considers it to be synonymous with clinical investigations, meaning any experiment that involves a test article and one or more persons (21 CFR 56.102(23)(c)). For example, if you are comparing the safety and/or effectiveness of a drug, or comparing a regulated device to another, you are engaged in a clinical investigation and must follow FDA regulations.

Is it research if I intend to publish?

The intent to publish is an 'insufficient criterion' for determining whether a quality improvement activity involves research, according to OHRP.

When QA/QI is published or presented, the intent is usually to discuss potentially effective models, strategies, assessment tools or to provide benchmarks, rather than to develop or contribute to 'generalizable' knowledge.

What if I am getting funding for my project?

Outside external funding may make a difference in distinguishing between QA/QI and research. An NIH research grant to support a project would often be considered research. Internal funding to improve a program may not.

What if I need to access PHI?

HIPAA makes an exception for QA/QI activities, including outcomes evaluation and development of clinical guidelines or protocols. These activities fall under the category of 'health care operations' for which no HIPAA Authorization or Waiver of Authorization needs to be sought. The hospital's Privacy Office can authorize the use of PHI for QA/QI projects.

Appendix 12: Eprotocol (IRB) entry directions

Initial submission

1. Log in to <https://umkc.keyusa.net>
2. If you are not currently registered in the system click on “Register”
 - a. Username format – last name first initial or last name first and middle initial i. A username and password will be emailed to you
3. Once logged in you are at your home page (Research Staff). From there you are able to create a protocol
 - a. If you are entered into eProtocol with more than one role, place your cursor over the eProtocol tab in the upper left corner, then over Investigator.
4. Follow page prompts and enter relevant information as one would on the paper application.
 - a. Moving your cursor over the tabs at the top of the page will display the relevant sections of the application. You may also navigate through the application by clicking next.
5. Once you believe you have completed the application click Check for Completion on the menu panel.
 - a. The system will check for completeness and notify you of sections you must complete to submit, if applicable.
6. The identified PI must be logged in to “check” the obligations section.
7. Click Submit Form on the menu panel.
 - a. In the pop-up box, click “Yes” to submit the IRB Protocol.
8. You will receive an email confirming submission of the application.

Making requested revisions for Cycle Comments

1. You will receive an email notification from eProtocol identifying that there have been comments received back from the IRB.
2. Log in to <https://umkc.keyusa.net>.
3. Select the “Comments Received (Cycle 1)” link for the protocol number referenced.
4. Respond to each individual comment in the response box. As applicable you must modify the application accordingly.
5. To change the application, click the “Get Protocol” button.
 - a. Select “Edit”
 - b. Go to the relevant section of the application to make the requested revisions.
 - c. Save the application.
 - d. Close out of the application screen.
6. At the Investigator Comments screen, select “Submit to IRB”
 - e. Select “OK” in the pop-up box.

Instructions on how to obtain the approval letter

1. You will receive an email stating the protocol has been approved.
2. Log in to <https://umkc.keyusa.net>
3. Scroll down to the Approved Protocols section.
4. Click on the Protocol ID link of the application in question.
5. In the pop-up box, click “Open in View Mode”, click the OK button.

- a. Click the “Event History” option on the menu panel
- b. Select Approval Letter.

Amendment

1. Log in to <https://umkc.keyusa.net>.
2. Select the Protocol ID number that needs to be amended.
3. Select Start Amendment
 - a. Amendment application screen will be launched. Complete the amendment application screen and click “Next”
 - b. Select the relevant section(s) that will be changed.
 - c. Make the change within the application.
 - d. Click on the Obligations tab on the menu panel and check the box at the bottom to confirm.
 - e. Click Submit form.
 - f. Click “Yes” in the Confirmation pop-up box to submit the amendment.
4. Possible email notifications:
 - a. If the IRB has questions/comments you will receive an email that you have received comments from the IRB.
 - b. If your application is approved without required revisions you will receive a notification your amendment has been approved.
5. If application revisions are necessary, log into the system and select the application in question.
 - a. Respond to any comments made by the IRB.
 - b. Go to the relevant section of the application to make the requested revisions.
 - c. Click on “Submit to IRB”.
 - d. Click “OK” in the pop-up box.

Continuing Reviews

1. Log in to <https://umkc.keyusa.net>.
2. Select the protocol due for a Continuing Review.
3. In the pop-up box select “Start Continuing review”.
4. Complete the Continuing Review application.
 - a. Click “Next”.
 - b. Revise the relevant section(s) of the application that need to be modified.
 - c. Click on the Obligations tab on the menu panel and check the box at the bottom to confirm.
 - d. Click Submit form.
 - e. Click “Yes” in the Confirmation pop-up box to submit the amendment.
5. Possible email notifications:
 - a. If the IRB has questions/comments you will receive an email that you have received comments from the IRB.
 - i. If application revisions are necessary, log into the system and select the application in question.
 1. Respond to any comments made by the IRB.

2. Go to the relevant section of the application to make the requested revisions.
 3. Click on “Submit to IRB”.
 4. Click “OK” in the pop-up box.
- b. If your application is approved without required revisions you will receive a notification your amendment has been approved.
- i. Obtain the approval letter through the event history, or respond accordingly to the IRB’s comments.

Final Report

1. Log in to <https://umkc.keyusa.net>.
 2. Select the Protocol ID in question.
 3. Select “Start Final Report Form” and click “OK”.
 4. Complete the Final Report Form and click “Continue”.
- a. You must be able to click “Yes” to all of the questions in order to complete the

Appendix 13: Spanish Informed Consent translation

Please submit your Consent Form to the Language Access Services on TMC Center point (intranet) - Click on “Services”, and then click on Interpreting Services Hospital Hill, click on “translation request form”.



Appendix 14: Other Helpful website links

- Authorship ICMJE (International Committee of Medical Journal Editors) recommendations
<http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>
- UMKC IRB phone numbers
<http://ors.umkc.edu/contact>
- UMKC IRB policies
[http://www.ors.umkc.edu/research-compliance-\(iacuc-ibc-irb-rsc\)/institutional-review-board-\(irb\)/standard-operating-procedures](http://www.ors.umkc.edu/research-compliance-(iacuc-ibc-irb-rsc)/institutional-review-board-(irb)/standard-operating-procedures)
- How to make a TMC request for data from TMC Millenium:
http://centerpoint/sites/research/Forms/TMC-data_request.pdf
- UMKC Research Administration phone numbers
<http://med.umkc.edu/ora/contacts/>
- UMKC Research Overview <http://med.umkc.edu/research/>
See links for particular areas at the bottom.
- There are IRB reciprocity agreements for certain types of research conducted at more than one institution. See – [http://ors.umkc.edu/research-compliance-\(iacuc-ibc-irb-rsc\)/institutional-review-board-\(irb\)/collaborations-with-other-institutions](http://ors.umkc.edu/research-compliance-(iacuc-ibc-irb-rsc)/institutional-review-board-(irb)/collaborations-with-other-institutions)
- Some projects such as single-patient case reports or [quality improvement](#) initiatives may not meet the federal definition of research. These activities may not require IRB committee review. The UMKC Research Protections office has a determination process to assist individuals to determine if the project must be reviewed by the IRB. See - [http://ors.umkc.edu/research-compliance-\(iacuc-ibc-irb-rsc\)/institutional-review-board-\(irb\)/not-human-subjects-research](http://ors.umkc.edu/research-compliance-(iacuc-ibc-irb-rsc)/institutional-review-board-(irb)/not-human-subjects-research)

Appendix 15: Self checklist for researchers

This checklist can be used as a tool to track research progress.

Development

- Literature review
- About 5-15 articles reviewed
- This is an original study and has justified cause
- Study question is clear and concise
- CITI Training completed
- School forms and Research Administration Forms, as applicable
- Prepare initial study protocol
- Follow any department guidelines
- Medical students: complete Research information form?
- Medical students: have you received approval to participate in research?

Protocol is finalized

- Fill out IRB protocol submission
- Submit to IRB

AFTER IRB APPROVAL (make sure everyone working on study is IRB approved)

- Request Data from EMR, if applicable
- Data collection
- Data acquisition and organization

AFTER DATA COLLECTION

- Data analysis
- Writing

- Submit for major meeting and peer review in a journal