Quick-start Research Navigator—Electronic version available on IRG intranet page, GME intranet page at GV and KMC and at www.ketteringhealth.org/research

Research Design

Research Preparation

Research Execution

Research Analysis

**Research Training (all key personnel need to complete)**
- IRBNet Account
- Electronic Signature Attestation
- CITI Human Protections Training
- Conflict of Interest (Financial Disclosure, CITI COI Training)

**Recruitment**
- Informed Consent

**Data Collection**
- Subject Enrollment

**Quality Control and Compliance**
- Protocol Deviations Reporting
- Severe Adverse Events

**Continuing Reviews (as needed)**

**Dissemination of Results**
- Publication
- Presentation
- Report Results to Clinicaltrials.gov

**Data Analysis**

**Study Closure**

**Design**

**Study**

**Decide on Research Team (Key Personnel)**

**Obtain Funding (if applicable)**

**Register with clinicaltrials.gov (if applicable)**

**Completion of Required Submission Documents**

**Amendment and Re-submissions**

**IRB Submission**

**IRB Approval**
To access guides and forms, you must first log in to IRBNet.org (see “creating an IRBNet account” under Research Preparation)  Rev. 11/2016

Research Design

☐ Design Study or Project

- Does my activity require IRB review?
- Need ideas? Browse past research at KHN

- Case series and case reports
  - Require IRB review—contact IRB for instructions on submission 937-395-8309
  - Grandview Residents—OU CORE is available to help with write-up. https://www ohio.edu/medicine/about/offices/core-research-office/research-opportunities.cfm
  - Non-Grandview Residents—see Departments and Contacts list for faculty mentors.
    - Writing a medical case report
    - Writing a clinical case report 15-minute course

- Prospective and retrospective studies
  - Grandview Residents—Ohio University CORE
    - Contact OU CORE for idea development https://www ohio.edu/medicine/about/offices/core-research-office/getting-started.cfm
    - Register project with CORE at http://research.ohiocore.org/index.do
    - Work with CORE to:

- Develop project proposal using CORE templates (available upon request). A well-developed proposal facilitates the IRB submission process.
- Power analysis
- Create a data collection template to capture data on all variables.
- Access editing services.

- OU CORE must approve project before continuing to research preparation.

- Non-Grandview Residents—Graduate Medical Education Research Committee
  - Dr. Colwick Wilson with Innovation, Research & Grants is available to assist with study design 937-395-8364
  - See Departments and Contacts for list of mentors within your program or specialty

☐ Decide on Research Team (Key Personnel)

- All residents must have an attending or faculty as PI
- All key personnel must create IRBNet account and complete required trainings (See Research Preparation for required forms and trainings and instructions for completion).
- Determine all contributors and co-authors. Co-authors must have significant intellectual contributions
To access guides and forms, you must first log in to IRBNet.org (see “creating an IRBNet account” under Research Preparation)

☐ Obtain Funding

☐ Contact Innovation, Research & Grants (IRG) if you are applying for external funding (contact IRG before submission for grant) 937-395-8390 or innovationcenter@ketteringhealth.org

☐ Contact Kettering Health Network’s IRB office before applying for funding. Additional KHN requirements exist for funded projects. 937-395-8309

• Dayton Area Graduate Medical Education Community (DAGMEC)—Resident and Fellow Research Support Grant program
  o Spring deadline is April 15th
  o Fall deadline is October 15th
  o See http://www.dagmec.org/researchgrant.html for details and how to apply

• Grandview Residents
  o Apply for seed funding at https://www.ohio.edu/medicine/about/offices/core-research-office/research-opportunities.cfm

• Funding opportunities for non-GV residents
  o Many national associations and organizations offer grants. You may want to any associations within your specialty or that you are a member with.
  o Agency for Healthcare Research and Quality
  o American Association of Colleges of Pharmacy (AACP)
  o American Medical Association (AMA)
  o DAGMEC

Resources:

• Protocol Development Guide—Located on www.irbnet.org under the Institutional Review Board library under the Forms and Templates tab
• Introduction to Human Research Protections—Online tutorials from Office for Human Research Protections (Click on the Browse button to continue)
• Human Research Protections Educational Videos
• Human Research Protections FAQs
• Kettering Health Network Policies

The research process

- Theoretical formulation of the research problem
- Empirical research questions
- Research design (operationalization)
- Data collection
- Research design (planning)
- Data analysis
- Answering the empirical research questions
- Theoretical interpretation of the results
- Literature review
- Conclusions
- Research idea
To access guides and forms, you must first log in to IRBNet.org (see “creating an IRBNet account” under Research Preparation)  

**Research Preparation**

☐ **Register IRBNet account**

1. Go to www.irbnet.org
2. Click on “New User Registration” located in the upper right-hand corner
3. Follow the prompts to complete the required information - make sure you **affiliate with Kettering Health Network**
4. IRBNet will send an email to the email address you provided
5. Go to your email and click on the link IRBNet emailed you to confirm registration (this is an important step often missed)

☐ **Print off and complete electronic signature attestation document and mail to the Conflict of Interest Committee:** *(See form 1)*

  *Conflict of Interest Administrator*
  *Kettering Medical Center—1E*
  *3535 Southern Blvd.*
  *Kettering, OH 45429*

☐ **Complete CITI program human protections training and upload to IRBNet** *(See guide 1)*

1. Go to [www.citiprogram.org](http://www.citiprogram.org)
2. When registering, be sure to select Kettering Health Network as the affiliated institution. You choose Kettering Health Network under the **Participating Institutions** drop down box and complete all requested demographic information, including the creation of a username and password.
3. Go to “**Add a course or update your learner groups**”
4. Select “**Yes**” to take the **Conflict of Interest Course** and scroll down. **This is only required if project is funded.**
5. Select **Group 1 for Biomedical** projects and scroll down and click “Submit”
6. You will see the courses added to your account. Click on the link to enter and complete each of the training modules. The modules could take 1-4 hours depending on your research experience. They can be taken all at once or taken a few at a time depending on the time you have to complete the training.
7. Once you’ve complete the CITI courses, save the completion reports to your documents (Note: You will need to click on “Print Report” at the Main Menu and the option to save will appear).
8. Upload completion transcript(s) to IRBNet.

☐ **Update CV/resume and upload to IRBNet** *(See guide 1)*
To access guides and forms, you must first log in to IRBNet.org (see “creating an IRBNet account” under Research Preparation)

☐ Complete IRB project submission in IRBNet
(See required forms in table below and guides 2 and 3 for submission assistance) Obtain the current version of documents at the IRBNet website under “Forms and Templates.” These forms are located in both the Conflict of Interest and Institutional Review Board libraries. After all documents are uploaded, sign and submit project package. You may also contact the IRB office for help with submission. 937-395-8309

☐ Complete CITI program COI training and upload to IRBNet (See steps for CITI program training and guide 1)

Guides:
Guides 1-3 are located under Forms and Templates within the Institutional Review Board library on IRBNet.org. Guide 4 can be found under the Conflict of Interest library.

1. Guide to Submitting CVs and Educational Certificates in IRBNet
2. Guide to IRBNet for Researchers (Initial Submission)
3. Guide to IRBNet for Researchers (Post Submission)— For amendments and revisions
4. Submitting Annual Financial Disclosures in IRBNet

Forms: *= if applicable
All forms are located under Forms and Templates, within the Conflict of Interest Library on IRBNet.org

1. Electronic Signature Attestation
2. Financial Disclosure Form

☐ Share project on IRBNet with investigators and all key personnel (See guide 2)

☐ Register study on www.ClinicalTrials.gov – See FDAAA 801 for which trials must be registered and have results submitted to ClinicalTrials.gov. Registration is required for journal publication.

1. Apply for account—Please contact Innovation, Research and Grants for assistance at 937-395-8390
2. Register study
3. Edit study record (if needed)

If study is funded:

☐ Complete Financial Disclosure Form and upload to IRBNet (See guides 2&3 and form 2&3)
To access guides and forms, you must first log in to IRBNet.org (see “creating an IRBNet account” under Research Preparation)

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To access guides and forms, you must first log in to IRBNet.org (see “creating an IRBNet account” under Research Preparation)

Research Execution *You many not begin until you obtain approval from IRB*

☐ Recruitment and Screening

☐ If EPIC is used to prescreen for subjects for recruitment **before** the patient is consented, complete HIPAA Request to Conduct Activities Preparatory to Research form (See form 4 and guide 5).

☐ Keep track of all subjects approached and consented in a screening and enrollment log

☐ Informed Consent and Subject Enrollment

- Only use the most current, stamped, IRB approved versions of the consents
- Do NOT start any study-related procedures without first obtaining written informed consent.
- Only team members listed on the Delegation of Responsibilities (DOR) log can obtain consent.
- Do not leave **any** required fields blank.
- Only sign where required on the consent document.
- Consent must be signed in the presence of the person obtaining consent.
- Do NOT complete any areas for the subject.
- Maintain the original consent form and give a copy to the subject.

- Never use white out or scribble out an error. To make a correction, draw a single line through, date and initial.
- It is required for documentation of the consent process to be recorded in the patient’s medical record. **Complete the consent confirmation form.** (See form 5)

- **Place a copy of the ICF and consent confirmation form in the medical record (EPIC or paper chart).**

☐ Data Collection—only data specified in the protocol and included on the data collection form submitted to the IRB can be collected. If you require other information, an amendment to the protocol must be submitted.

- Data Security
  - Passwords are not to be shared
  - Laptops and computers being used to store data must be password protected
  - Flash drives used must be encrypted for transfer/storage of data
  - Any PHI sent via email must be encrypted
  - Limited access to the data
  - Paper copies of data must be stored in a locked cabinet

☐ Continuing Review: Completed at least annually, contact Innovation, Research and Grants for assistance with completion 937-395-8390 or innovationcenter@ketteringhealth.org
To access guides and forms, you must first log in to IRBNet.org (see “creating an IRBNet account” under Research Preparation) Rev. 11/2016

☐ Submission date is due before expiration date (See form 6 and guide 5).
☐ Submit Closed to Enrollment Form for prospective studies (See form 7 and guide 5).

Guides: All guides are located under Forms and Templates within the Institutional Review Board library on IRBNet.org.
5. Guide to Submitting New or Revised Materials-IRBNet

Forms: All forms are located under Forms and Templates within the Institutional Review Board library on IRBNet.org.
4. HIPAA Request to Conduct Activities Preparatory to research form
5. Consent Confirmation Form
6. Application: Continuing Review-Final Report Form
7. Closed to Enrollment Reporting Form

Resources:
1. 45 CFR 164—Code of Federal Regulations: HIPAA
3. Belmont Report—Respect for Persons, Beneficence, and Justice
4. HIPAA and Research—NIH

Data Consolidation
☐ All data entered into database (Excel spreadsheet or REDCap)

Data Analysis
☐ Statisticians:
  o Kettering Residents—For list of available statisticians, please contact Medical Education at 937-395-8609 or Dr. Colwick Wilson 937-395-8364
  o Grandview Residents—send data to OU CORE statistician (be sure to encrypt if protected health information is included)

Study Closure: After site analysis is complete
☐ Submit Final Report Form to IRBNet—form is located under Forms and Templates in the Institutional Review Board library on www.IRBNet.org (See guide 7 for submission)
☐ Retain research records for at least 6 years after completion of study, if HIPAA authorization was obtained—Contact Innovation, Research, and Grants for long term storage 937-395-8390 or innovationcenter@ketteringhealth.org
To access guides and forms, you must first log in to IRBNet.org (see “creating an IRBNet account” under Research Preparation)  

☐ **Dissemination of Results**

- **Presentation**
  - Poster design tips
  - DAGMEC holds the Virginia C. Wood Resident Research Forum—poster presentation
  - Helen L. Popoway Research competition through Kettering Health Network
  - Grandview Residents- OU CORE is available to help with poster and manuscript editing.
    - Application for travel funding to present at a conference available at https://www.ohio.edu/medicine/about/offices/core-research-office/research-opportunities.cfm
- **Journal publication**
  - Strategies to publish your research
  - Top journals that accept research from physicians in training
  - How to get your research published
  - Expert tips
- **Report results to ClinicalTrials.gov** (Click here for instructions)

☐ **Quality Control and Compliance**

☐ **Protocol Deviations**

☐ Report all protocol deviations to the IRB by submitting the Protocol Deviation/Exception/Violation Reporting Form to IRBNet. (See guide 7 for submission)

☐ **Serious Adverse Events (SAE):** Must be reported to IRB, sponsor, and FDA (if a drug study) within 5 working days.

☐ A SAE is an adverse event resulting in:
  - Death
  - Hospitalization
  - Life-threatening
  - Congenital/birth defect
  - Prolonged hospitalization
  - Severe/permanent disability

☐ Complete the Unanticipated Problem Reporting Form and submit to IRBNet. (See guide 7 for submission)

**Guides:** All guides are located under Forms and Templates within the Institutional Review Board library on IRBNet.org.

6. Unanticipated Events Flowchart
7. Guide to Submitting New or Revised Materials in IRBNet