Washington University in St. Louis research toolkit for medical student researchers

Human Research Protection Office, Washington University School of Medicine in St. Louis

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Research Toolkit

For Medical Student Researchers
This Research Toolkit is a guide for conducting research as a Medical Student at the Washington University in St. Louis School of Medicine. It contains information about important points of federal and institutional policy related to research, as well as helpful resources available to the WU research community.

For a Medical Student Researcher that intends to develop a research protocol that involves human subjects, review and approval by the Institutional Review Board (IRB) is required. Students conducting independent research should complete CITI training and refer to the Human Research Protection Office (HRPO) for help in beginning the application process.

Medical Student Researchers may also become a study team member of an existing project. All student researchers participating in existing projects will need to complete Human Subjects Training (CITI) and be added to the approved study.
At any time during the research process, one of the most helpful resources available to you is the **HRPO SWAT!** (Staff With Answers Today!) service. There is a HRPO staff member **On Call** at all times during business hours. Just call 314-633-7400 to be connected.

In addition, there are **Office Hours** available throughout the week. Check the HRPO website for the current Office Hours schedule.
The DHHS regulatory definition of research is outlined at the beginning of the “Common Rule” (45 CFR 46.102). This definition applies to all research activities conducted at Washington University in St. Louis. In this section of the DHHS regulations, a basic distinction between research and human subjects research is defined as following:

Research is “A systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”

- It is systematic in that it involves: A predetermined method for answering specific questions or achieving specified outcomes that has taken into account various factors that could affect data collected during the study.

- It is generalizable because it involves: An intent to contribute to your field of study by producing results that can be applied beyond the initial participant population.

Human Subjects Research is research that involves “a living individual about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information.”

Let’s take a closer look at this:

- **About whom** = a living human subject about whom data are being collected.

- **Intervention or Interaction** = “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** = “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. Private information must be individually identifiable in order for obtaining the information to constitute research involving human subjects.”
The FDA regulatory definition of research is slightly different, given that the FDA has specific jurisdiction over research that involves drugs, biologics, devices, and related test articles (21 CFR 50.3). This definition also applies to all research activities involving FDA-regulated test articles conducted at Washington University in St. Louis. In this section of the FDA regulations, “research” is defined in terms of “clinical investigation”:

**A Clinical Investigation is:**

“Any experiment that involves a test article and one or more human subjects that is either subject to requirements for prior submission to the Food and Drug Administration under section 505(l), or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted to, or held for inspection by the Food and Drug Administration as part of an application for a research or marketing permit.” (21 CFR 50.3(c))

**A Human Subject is:**

“an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.” (21 CFR 50.3(g))

**A Test Article is:**

“any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act or under sections 351 and 354-360F of the Public Health Service Act (42 U.S.C. 262 and 263b-263n).” (21 CFR 50.3(jj))
Understanding the nuances of these definitions is important, because according to federal and institutional policy, human subjects research requires review and approval by an Institutional Review Board before implementation.

**How to determine if your research involves human subjects:**

At WU, investigators are expected to recognize when they are engaged in activities subject to IRB jurisdiction. Contact the Human Research Protection Office (314-633-7400) and a staff member will guide you through the process of making this determination. *But before making this decision yourself, it is helpful to consult with the IRB.* There are many ethical and regulatory factors that may make your proposed research subject to review.

**Examples of Non-Human Subjects Research:**

- Procedures performed for clinical purposes.
- Case histories or series (if a limited number of patients are included, typically five or less). There may be important HIPAA issues to consider even if the case series does not qualify as Human Subjects Research.
- Review and analysis of publically available data.
- Research that involves cadavers.

**Examples of Human Subjects Research:**

- Conducting a chart review of treatment outcomes.
- Surveying cancer survivors about perceptions of quality of care.
- Collecting tissue or blood for analysis.
- Comparative study of clinical interventions.
Given these regulatory definitions of research and human subjects, these are the **Basic Requirements for Research at WU:**

- Any research that involves human subjects conducted by a WU/BJH/SLCH employee, agent, student, fellow, or post-doctoral appointee must be reviewed and approved by the IRB before any proposed study procedures begin.

- In addition to the regulations for the protection of human subjects in research, investigators are required to follow all relevant federal, state, and institutional policy relevant to their research.

- Any changes to approved research must be reviewed and approved by the IRB before proposed changes to research is implemented.

- Any adverse events or unanticipated problems must be reported appropriately to the IRB, according to federal and institutional policy.

- Any deviations from the study procedures approved by the IRB must be reported appropriately to the IRB, according to federal and institutional policy.

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**Research Misconduct:**

*Washington University defines research misconduct as:*

1. Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results; or

2. Knowing violations of federal and institutional rules and regulations governing the conduct of research involving human research participants that are serious or continuing; or

3. Violations of the University's *Policy for Authorship on Scientific and Scholarly Publications.*

Research misconduct does not include honest error or differences of opinion or differences in interpretations of data. A finding of research misconduct requires that: There be a significant departure from the accepted practices of the relevant research community; and the research misconduct be committed intentionally, knowingly, or recklessly; and the allegation be proven by a preponderance of evidence.
In 1972, several journalists broke the story that scientists conducting a federally funded study in Tuskegee, Alabama had been withholding penicillin from hundreds of male subjects with syphilis since the late 1940s in order to observe the natural history of the disease. After being told they were simply being treated for “bad blood,” subjects also received spinal taps for research purposes that were described as a “special free treatment.” 28 participants died from lack of treatment. Whistleblower accounts of the infamous Tuskegee Experiment generated enough public outrage that Congress was moved to pass the National Research Act in 1974.

Now mandated by the 1974 Act, any federally funded research that involves human participants requires review by committees we call Institutional Review Boards (IRBs), which apply a specific set of regulations designed to protect the safety and welfare of human research participants. IRBs use these regulations to evaluate the risks and benefits of proposed research, ensure the equitable selection of subjects, ensure that participants will be adequately informed about the nature of the research, and address related concerns.

In 1974, an initial set of regulations for the protection of human subjects were registered (45 CFR 46). Several years later, the Belmont Report was produced by a commissioned panel of experts and established respect for persons, beneficence, and justice as the cornerstone principles of human research ethics (see the follow page for a summary of this document). 45 CFR 46 was subsequently revised, and regulations specific to pregnant women and neonates, prisoners, and children were added.

In a watershed 1966 NEJM article surveying the conduct of 50 published studies, Henry K. Beecher noted many research ethical failures:

“Evidence is at hand that many of the patients in the examples to follow never had the risks satisfactorily explained to them, and it seems obvious that hundreds have not known that they were the subjects of an experiment although grave consequences have been suffered as a direct result of experiments described here.” (Ethics and clinical research. NEJM, 1966, 274: 1354–1360.)
From The Belmont Report (1979)

“The distinction between research and practice is blurred partly because both often occur together (as in research designed to evaluate a therapy) and partly because notable departures from standard practice are often called “experimental” when the terms “experimental” and “research” are not carefully defined.”

“For the most part, the term “practice” refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success... By contrast, the term “research” designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships).”

Belmont’s Basic Ethical Principles:

- **Respect for Persons.** Respect for persons incorporates at least two ethical convictions:
  - Individuals should be treated as autonomous agents. There is an ethical requirement to acknowledge autonomy.
  - Persons with diminished autonomy are entitled to protection. There is an ethical requirement to protect those with diminished autonomy.

- **Beneficence.** Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Two general rules have been formulated as complementary expressions of beneficent actions in this sense:
  - Do not harm.
  - The research process must maximize possible benefits and minimize possible harms.

- **Justice.** Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of “fairness in distribution” or “what is deserved.” An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly.
What is an IRB?

An IRB is a committee of at least five members with diverse backgrounds that have expertise to review the type of research being proposed. These committees require:

- At least one member whose primary background is related to science/medicine.
- At least one member whose primary background is not related to science/medicine.
- At least one member not affiliated with the institution conducting the research.

What does an IRB do?

The IRB meets on a regular basis to review proposed human subjects research based on the criteria for approvability found in the federal regulations (see below for these criteria). The IRB approves research, recommends changes to the research that will better protect the rights and welfare of human subjects, or disapproves research.

IRB review is required:

- Prior to the conduct of research.
- Any time there is a change to the research.
- Any time there has been an event that may increase risk to participants or others.
- At least every 12 months on a continuing cycle.

“The mission of the IRB is to protect the rights and welfare of participants in ‘human research’ as defined in 45 CFR 46.102(d) and (f) and ‘clinical investigations’ as defined in 21 CFR 50.3(c).”
Criteria for the Approvability of Research (45 CFR 46.111/21 CFR 56.111)

In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized:
   
   (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
   
   (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

   In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research).

   The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable.

   In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116 (See Consent Elements).

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.
(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

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This last point addresses what IRBs refer to as “vulnerable populations.” The regulations contain specific policy for the following three:

· **Pregnant Women, Human Fetuses and Neonates**

Research involving pregnant women and fetuses may only be approvable if it meets a lengthy list of conditions described in the regulations. For research that holds out the prospect of direct benefit solely to the fetus, the consent of the pregnant woman and the father is required. For other types of research, the consent of the pregnant woman is often sufficient.

· **Prisoners**

Prisoners are considered vulnerable due to being in an environment that can inhibit free choice. Research involving prisoners may only be allowed in four categories described in the regulations. An IRB prisoner representative is required for the review of these studies.

· **Children (Minors)**

The regulations define children as participants that have not reached the legal age to consent to treatments or procedures involved in the research. The regulations define four categories of research for children, generally distinguished by the risks and benefits of proposed research. Each category has specific assent and consent requirements that are evaluated during IRB review.
Types of IRB Review

DHHS regulations describe several different ways proposed Human Subjects Research is reviewed by the IRB (FDA regulations contain additional guidance for the review of clinical investigations that involve test articles. The IRB first makes a basic determination about whether a study qualifies as human subjects research or non-human subjects research. If a proposed study crosses the threshold defined by both “research” and “human subject,” the following required review can go several directions:

- **Exempt**: There are a number of categories of research described in the regulations that are considered exempt from continuing IRB review.

  Some chart reviews or surveys, for example, can fall into an exempt category. These applications are not as intensive as other types of review.

- **Expedited Review**: If a study does not meet the conditions of an exempt category, it may fall under one of the categories that qualify research for expedited review. This means that a study will be reviewed by one IRB reviewer rather than being submitted for review at a fully convened IRB meeting. Such studies must pose no more than minimal risks to subjects, which according to the regulations means that 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 examinations or tests.”

  Identifiable surveys and some collections of blood are examples of research that require expedited review.

- **Full Board Review**: Studies that do not meet either exempt or expedited conditions require review at a fully convened IRB meeting. Typically, this applies to studies that involve greater than minimal risk to subjects.

  Clinical trials and are examples of research that requires full board review.
Submitting to the IRB

To submit an application to the WU IRB, you will need to pick the right application in myIRB. One of the very first questions in a new application form asks if you want “Regular” or “Exempt Status” review. If you think your study qualifies for exempt status, selecting that option will open up an abbreviated application. If your study may be either expedited or full board, selecting “regular” here will open up the full application.

Other application types include:

- **Modification/Update Form**: This application allows you to submit modifications or changes to research to the IRB for review.

- **Continuing Review Form**: An approved study must submit a continuing review application at least every 12 months. There are rare occasions in which the IRB may require a shorter continuing review cycle.

- **Reportable Event Form**: This application allows you to submit reports of unanticipated problems and issues related to non-compliance to the IRB for review.

- **Exception Request Form**: This application allows you to submit a request for an exception from an approved protocol for one research subject to the IRB for review.

- **Project Close Form**: This application allows you to notify the IRB that a study has been concluded.

If you intend to manage the myIRB application for your own study, you can save yourself a lot of time by attending the myIRB training sessions. One two-hour session covers the basics of the myIRB system and New Project applications. Additional sessions cover other training topics. You can sign up for these training sessions at: hrpohome.wustl.edu.
During the initial stages of any research project, there are a number of basic questions that need to be addressed. Fortunately, the regulations are helpful in that they help narrow the focus of these questions in such a way that thinking from the perspective of IRB review can make your protocol development and review timelines more efficient. In addition, thinking about some of these questions during the planning stages can lead to more robust and ethical research practices.

Some important questions to consider:

- **What is your research question?**
  
  The ethical conduct of research is something that begins with the design of your study. Are all of your proposed procedures relevant to the research? If not, then putting participants at any additional risk related to study procedures is ethically problematic. Is your population size large enough to produce the necessary data to fulfill intended outcomes? If not, then you should consider a different study design or consider alternative data collection and analyses strategies. These kinds of design-oriented questions should be considered even while the ideas for your research are still developing.

- **What risks are there?**
  
  When evaluating the risks related to your study, the IRB considers all procedures defined in the protocol, subject vulnerabilities, privacy and confidentiality issues, and a range of reasonably potential risks that the investigator needs to address. What can you do to minimize any risk related to your study?

- **Do benefits outweigh risks?**
  
  Many ethical problems inherent to research-related risk are evaluated relative to the possibility that a study poses direct benefit to subjects or more general benefit to society and the advancement of knowledge in a particular area. When considering the participation of vulnerable populations such as children or pregnant women, the regulations contain specific requirements for evaluating the risks versus potential benefit. This evaluation also guides what type of consent process will need to take place while recruiting participants.
• **How are you going to recruit subjects?**

The selection of subjects for research is an important issue from the perspective of research design, but it is also an important element of the ethical and regulatory implications of your study. If your plan is only based on convenience, it may not be approved by the IRB. Recruiting subjects that may best benefit from research may be more difficult in terms of recruitment and retention, but both the risks and benefits of research should be fairly distributed across your potential pool of subjects.

• **How will you obtain and document informed consent?**

You should begin developing your plan to obtain and document informed consent in the earliest stages of project development. If you think a waiver of informed consent may be necessary for your research, consult as early as possible with HRPO about the regulatory considerations involved. If you are working with vulnerable populations, there may be additional consent and consent documentation concerns that are also best negotiated in consultation with HRPO. While drafting your consent form, be sure to think about scientific language and concepts from the perspective of your potential subjects, and write in such a way that will be easily understood by a layperson.

• **What data and safety monitoring will be necessary for your study?**

Studies that pose risk to subjects often require an additional plan to regularly monitor data produced by the study and the overall safety of subjects during the study. Many data and safety monitoring plans include physicians or scientists that are not engaged in the research to lend a measure of independent review to the oversight process.

• **What privacy and confidentiality protections need to be in place?**

Privacy refers to an individual’s control over the timing and context of sharing personal information. Confidentiality refers to an investigator’s control over the sharing or release of private information about a research subject. Many studies collect information about participants that may cause harm if released. In such cases, protecting the privacy and confidentiality of participants is a significant concern. Private information should not be collected unless it is needed to answer your study question.
But even in studies collecting more general information, the collection of information about subjects for research purposes requires detailed attention to the physical or electronic protections in place during the collection and storage process.

- **Are your recruiting any vulnerable populations?**

There may be cases when a study requires the participation of vulnerable populations to answer the research question. In other cases, a large sample size may naturally contain potential subjects that have vulnerabilities. Either way, the recruitment of vulnerable populations can require additional ethical, regulatory, and administrative scrutiny. When considering potential subjects, keep in mind that the regulatory categories of pregnant women and neonates, prisoners, and children represent important forms of vulnerability. But many more hidden vulnerabilities include: terminal illness, economic disadvantage, non-English speaking, decisional impairment, etc...

There are two ways to enhance your recruitment strategies at WU:

- *Volunteers For Health* is a Research Participant Registry that can help researchers find qualified study participants.

- The Center for Community-Engaged Research (CCER) in the ICTS can connect researchers with HealthStreet, which aids in the recruitment of local community members.
What Should I Keep In Mind While Getting Started?

- Before you begin developing a protocol and filling out a myIRB application, it is often helpful to talk to someone in the Human Research Protection Office to see if there are and specific regulatory or ethical issues you should consider along the way. This can save you a lot of time during the review process.

- The earlier you get started with putting together a protocol and myIRB application, the better. The initial and ongoing administration of your study can often require more time than you anticipate, and this additional time should be factored into your schedule.

- In addition to the time it takes to submit your study to the IRB, your study may also be subject to review by additional review committees at WU. If your study is subject to additional review, this may increase your anticipated time to approval. (See below for a description of other review committees at WU.)

- Be aware of your resources. The Human Research Protection Office is a good place to turn if you are not sure who to talk to about an issue with your study or are looking for additional local or national resources.

- Research seldom goes as planned. Become familiar with what kinds of events need to be reported and how to get approval for modifications to your research. If you are unsure about an event or change in question, a consult with HRPO can quickly clarify what you need to do next when encountering unanticipated problems.
And Also... Avoid The Common Mistakes:

- Take CITI training and set up a myIRB profile as soon as possible: myIRB.wusm.wustl.edu. Also complete your compliance profile to see what additional training requirements may be necessary for your proposed research. This profile can be accessed at: complianceprofile.wustl.edu/

- Be aware of IRB review timelines and related institutional review scheduling issues. Given the set of deadlines associated with Medical Student research at WU, this is an important consideration.

- Consult with HRPO to see if your study involves an investigational drug or device, and is therefore also subject to FDA regulations. This would include, for example, the use of assays or in vitro devices in studies involving collected tissue or the testing of new software algorithms in hearing devices.

- Recognize subject vulnerabilities. While the IRB is charged with evaluating regulation-defined vulnerabilities, additional hidden vulnerabilities are also often discovered during the review process.

- Write consent/assent documents that are not too technical for potential subjects.

- Include all relevant parts of the myIRB consent form template while drafting your consent and/or assent documents.

- Be sure to include language in your consent/assent documents that adequately describes genetic and genomic research to potential subjects, which includes a description of privacy risks.

- Know the difference between “coded” with “anonymized.” Coded data are data that are collected with identifiers, but the data have been coded or keyed in such a way that only the person storing the code can re-identify data sets or entries. Anonymized data are data that have been permanently stripped of identifiers such that no one can relink to identifiers. The regulatory difference between these two methods of collecting and storing data can be significant.

- Talk with HRPO about additional concerns related to research that involves international subjects or research sites.
Other WU Review Committees:

There are a number of committees at Washington University that review human subjects research prior to or during review by the IRB. Several of these committees must give their approval before the IRB can begin to review the research. Consult with HRPO if you think one or more of these committees may be relevant to your research:

- ICOI (Institutional Conflict of Interest Review Committee)
- CIRC (Conflict of Interest Review Committee)
- ESCRO (Embryonic Stem Cell Research Oversight Committee)
- IBC (Institutional Biosafety Committee)
- P&T (Pharmacy and Therapeutics Committee)
- PRMC (Protocol Review and Monitoring Committee)
- RDRC (Radioactive Drug Research Committee)
- RSC (Radiation Safety Committee)
One of the most difficult aspects of navigating your first few research projects is knowing where to go to complete required training or get advice about an aspect of your research. Washington University in St. Louis has a very active culture of resources for investigators. Your capacity for completing a valuable study can expand greatly by taking advantage of these resources. Some of these resources lead to places where you can receive required training.

**Required**

- **Human Subjects Training (CITI):** CITI is a web based human research protections training program created by the Collaborative Institutional Training Initiative. Individuals affiliated with Washington University can access the program through RAS (Research Administration System) to complete their Human Subjects training. You will not be able to submit a myIRB application or become a study team member on an existing study until this training is completed. Call the HRPO office for more details (314-633-7400). CITI training is accessed through the HRPO website: hrpohome.wustl.edu

- **HIPAA Training:** HIPAA training is required for anyone that has access to Protected Health Information (PHI) at WU. Contact the WU HIPAA Office for more details (314-747-4975).

- **Research-Specific Training:** Working in the laboratory setting, with lasers, magnetic fields, patient care, radioactive materials, recombinant DNA, or some biological toxins requires specific training that can be accessed here: complianceguide.wustl.edu

At any time during the research process, one of the most helpful resources available to you is the **HRPO SWAT!** (Staff With Answers Today!) service. There is a HRPO staff member **On Call** at all times during business hours. Just call 314-633-7400 to be connected.

In addition, there are **Office Hours** available Tues. 1-4 and Fri. 8-11 in a convenient location. HRPO staff can work on applications with you in real time, work through pre-submission questions with you on the spot, and provide a range of services. Visit the HRPO website or call 314-633-7400 for location information.
Helpful Administrative Resources

- **RCR Resources**: Resources for completing Responsible Conduct of Research requirements can be accessed here: research.wustl.edu/ComplianceAreas/rcr/Pages/default.aspx
- **Proposal/Grant Development**: A very helpful resource for grant-writing can be found in the Proposal Development Toolkit, accessible at: proposalhelp.wustl.edu
- **WUSTL Research Policy/Guidelines**: A comprehensive list of research guidelines and policies can be found at: research.wustl.edu. You can complete a helpful Compliance Profile at: complianceprofile.wustl.edu
- **Allscripts Training**: Ask your department for Allscripts View Only access. Allscripts help-desk can be contacted at 314-935-0909.
- **ClinDesk Training**: For access to ClinDesk contact the Office for Medical Student Research (314-362-6857) or email Roz Robinson with your phone number and research department (robinsonr@wusm.wustl.edu). ClinDesk support can be contacted at 314-362-4700.
- **myIRB Training and Profile**: myIRB training is a very helpful way to get your feet wet in the IRB application process. You can sign up for sessions and a profile at: hrpohome.wustl.edu

Helpful Research Resources

- **Becker Medical Library - Research and Publishing Support**: Staff at Becker can conduct literature searches and provide support for a wide range of research and publication issues. All Becker resources are accessible at: becker.wustl.edu
- **PubMed and Endnote Training**: Staff at Becker frequently hold training sessions on using PubMed and Endnote during your research. All Becker resources are accessible at: becker.wustl.edu
- **Becker Medical Library - Bioinformatics**: Staff at Becker can assist with database queries and help you find the right tools for your research. All Becker resources are accessible at: becker.wustl.edu
- **ICTS Resources**: The ICTS has a number of cores that provide valuable support during the research process. These resources range from regulatory support to research design. All ICTS resources are accessible at: icts.wustl.edu/cores
• **ICTS Tissue Banking**: The ICTS Translational Pathology & Molecular Phenotyping Core provides assistance for investigators with tissue banking needs. All ICTS resources are accessible at: icts.wustl.edu/cores

• **IT Security**: Many types research require compliance with WU IT security and encryption policy. The Security and Privacy Office can help you navigate that process at: secpriv.wusm.wustl.edu

• **Clinical Research Forms Library**: The Office for the Vice Chancellor of Research website maintains a Library of case report forms, data collection forms, delegation logs, and a variety of administrative tools helpful during the research process.

• **Community-Based Participatory Research**: HRPO has produced a number of helpful materials on developing research that is Community-Based or Community-Engaged. These materials can be accessed at: digitalcommons.wustl.edu/hrpo

• **Volunteers For Health**: Volunteers for Health is a Research Participant Registry that can help connect researchers with potential subjects: vfh.wustl.edu

• **Center for Community-Engaged Research / HealthStreet**: The CCER helps researchers develop community-engaged research. HealthStreet serves as the local community participant recruitment component of this process. http://icts.wustl.edu/cores/community.aspx

**Helpful Federal Resources**

• **45 CFR 46 (Common Rule)**: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

• **Presidential Bioethics Commissions**: bioethics.gov

• **Office of Human Research Protections**: http://www.hhs.gov/ohrp/

• **Food and Drug Administration - Clinical Trials Guidance / Good Clinical Practice**: http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm

• **HIPAA**: http://www.hhs.gov/ocr/privacy/index.html

• **Genetic/Genomic Research**: http://www.genome.gov/

• **Transnational Research Regulations**: http://www.hhs.gov/ohrp/international/
Medical Student Research Checklist

*Page Numbers Correspond to Medical Student Researcher Toolkit. The below may not be comprehensive in all cases, and is only intended as general guidance.*

If Participating in a Current Study
Consult with Research Faculty Mentor

**Required:**
- Complete HIPAA Training (21)
- Complete CITI Training (21)
- Create myIRB Profile (22)
- Be added to Study as a “Research Team Member” through a Modification.

**Very Helpful:**
- Complete myIRB Training (22)
- Create Compliance Profile (22)

**Additional Training as Needed:**
- Allscripts Training (22)
- ClinDesk Training (22)
- Research-Specific Training (21)
- CITRIX / VPN Training

If Conducting Independent Study
Consult with Research Faculty Mentor
Begin Developing Research Plan (18-19)

**Required:**
- Complete HIPAA Training (21)
- Complete CITI Training (21)
- Create myIRB Profile (22)
- Complete myIRB Application

**Very Helpful:**
- Complete myIRB Training (22)
- Create Compliance Profile (22)
- Consult with HRPO via Office Hours prior to myIRB application (21)

**Additional Training as Needed:**
- Allscripts Training (22)
- ClinDesk Training (22)
- Research-Specific Training (21)
- CITRIX / VPN Training