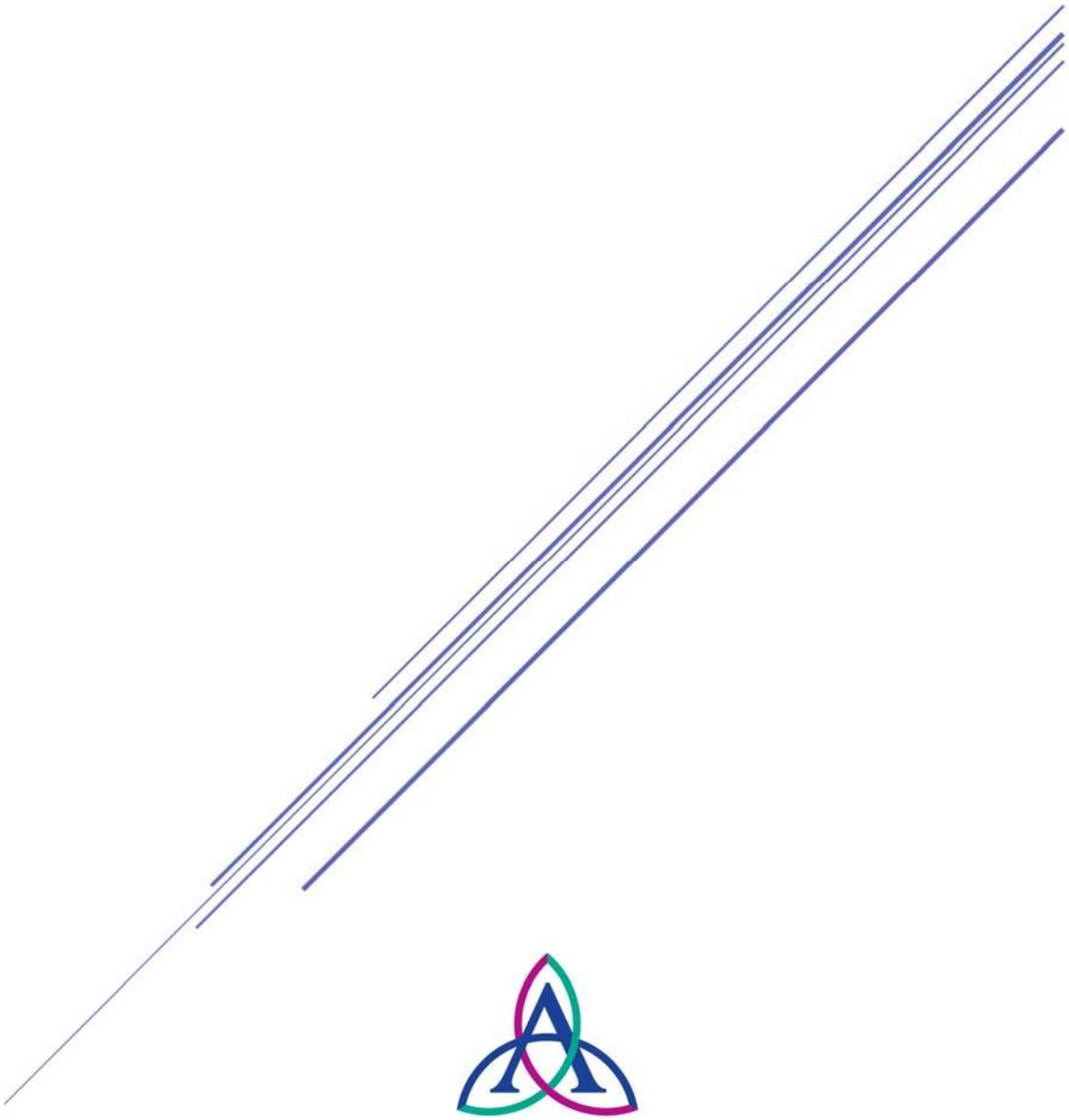
Conducting Research at Ascension St. John Hospital:

A Guide for Residents and Fellows



Ascension
St. John Hospital

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Introduction

This brief guide will help you to get started with the research process and will provide answers to some of the most frequently asked questions. This guide is not meant to replace the assistance you will receive from GME Research and your faculty mentors. It is just a starting point!

At Ascension St. John Hospital, residents are required to complete a research project before they graduate. The project(s) can be done at any time during your residency or fellowship. If you are a resident and you hope to apply for fellowship, it is to your advantage to get started on a project (or projects) early.

The types of projects that can be done include:

- Standard research projects (prospective, retrospective etc.)
- Quality Improvement projects
- Secondary analysis of existing databases
- Cost-effectiveness analyses
- Collaborative research
- Meta-analyses

There is a lot of assistance available to you from start to finish in working on your project. But sometimes, getting started and understanding the steps can be a bit confusing. Hopefully, this guide will be of help.

Define a Research Idea

The first step in designing your research project is to develop a research question that can be investigated using the resources you have available to you here, including the type of patients that we serve, the prevalence of various diseases, the time you have available and costs. For many trainees, the most difficult part of the research project is finding an idea. So, where can you look for ideas?

1. Staying current in the medical literature in your areas of interest often sparks ideas

2. Your daily work—seeing patients— is also a good place to find an idea
3. Talk to your faculty
4. If all else fails, come to the Research Department and we can let you know about studies that could be continued or could have a "Part II".

Once you have a couple of ideas that interest you, your next step is to speak to a faculty mentor or subject matter expert in your topic area to get their advice. Often, talking over the idea with a more experienced person will help you to refine the idea or find new and interesting angles to include in your study. It is also important to make sure that you are not repeating a project that has already been done many times. Ideally, each project should make some contribution (however small) to the medical literature. If you are doing a quality improvement project, it should help to close a practice gap or improve the care that patients receive.

Review the Literature

Once you have a good idea and the support of a faculty mentor, your next step is to review the literature to see what has already been done in the project area. This is essential for crafting your research question and for making sure that your question is both relevant and unique. The librarians can help you to do a literature search or you can do one on your own, using library resources such as Ovid or PubMed. Both are available on the library website. If you need help in learning how to do a literature search, the Research Department will give you a hand.

Meet with your Medical Researcher

Every trainee has the benefit of working with an experienced medical researcher who will help you with your protocol, sample size calculations, statistical analysis, IRB submission and abstract and manuscript preparation. You should meet with your medical researcher early on, so the medical researcher can be your partner in developing a worthy project. The sooner you meet with the medical researcher, the easier the process will be.

Develop your Protocol

Using the protocol outline (Appendix 1), you need to develop your research protocol. The protocol is the formal plan of how you will do your research. It must be written very specifically, with substantial detail. Once you have a first draft of the protocol, you should send it to your medical researcher. At this point, you will work collaboratively with the medical researcher until your protocol has all the necessary components and is in good shape to submit to the IRB. Working on the protocol is an iterative process between you and the medical researcher. You may work through several drafts of the protocol until it is complete. You will also have to work on ancillary forms, such as a data collection sheet, consent forms and other documents.

For meta-analyses and projects that involve secondary analysis of existing data, there is a different protocol outline. Please contact Dr. Szpunar for the outline.

GME Research Committee

If your project is a prospective interventional project and/or it has a budget more than $2000.00, the project will first be reviewed by the GME Research Committee before you can seek IRB approval. The GME Research Committee meets monthly, when there is a protocol to consider. You and your faculty mentor will be asked to attend the meeting and give a brief description of your project. Then, committee members may ask you questions or make suggestions. Once the committee approves your project, you can proceed to IRB submission.

Sometimes, the GME Research Committee cannot approve the project the first time it is presented. If substantial revisions are required, you will need to attend another committee meeting when you have completed the revisions. This will add at least one additional month to the protocol development process.

Institutional Review Board (IRB)

All research and quality improvement projects, even if they appear to be exempt, need to be reviewed by the IRB. The IRB examines the human rights aspects of the project and seeks to

ensure that the federal regulations, state law and local policies regarding human rights protections are being followed. IRB review can take from as little as two weeks to two months or more, depending upon the type of project you are doing, the type of IRB review required and whether revisions are required.

Types of IRB Review

In general, there are three types of IRB review: exempt, expedited and full board. For a project that is more than minimal risk or involves vulnerable populations, full board review is likely required. The IRB meets once per month and your project must be submitted by the posted IRB meeting deadline (available on IRBNet) to be on the agenda for that month.

For projects that are minimal risk and do not involve vulnerable populations, expedited review is the likely type of review (although there may be some exceptions). For expedited review, the project does not have to be reviewed by the full board. Expedited review does not mean instantaneous review! You should budget at least two weeks for an expedited IRB review. This process could take longer if changes are requested.

IRB Training Requirements and IRBNet

To conduct research at Ascension St. John Hospital, all investigators and members of the study team must have completed training on the protection of human subjects in research. We use the CITI program. Training certificates are valid for three years. Your medical researcher or the IRB staff will give you instructions on how to enroll in CITI and choose the correct training courses.

IRBNet is an electronic submission system for the IRB. For your project submission, you must first register in IRBNet. When you register, you should also upload your CITI training certificates. You can register in IRBNet at www.irbnet.org. Make sure to choose Ascension St. John Hospital, Detroit, MI as your affiliation.

IRB Forms and Documents

There are various forms and documents that must be submitted to the IRB in addition to your protocol. These may include:

- The Research Application
- The Team List (or delegation log)
- Data collection sheets
- Consent and assent forms
- Letters of agreement
- Telephone Scripts
- Questionnaires and other measurement tools
- HIPAA waiver forms

Your medical researcher will help you to initially fill out the forms and will help you to create the other forms that are needed for your project.

IRB Initial Submission

Once the medical researcher has approved your protocol, you have received approval from the GME Research Committee and all forms and documents are ready, the medical researcher will upload your project to IRBNet. The project will then be shared with you and your Department Chair. You will be asked to electronically sign the "package" (the set of documents in a submission) and your Department Chair will also be asked to sign the package. The medical researcher must sign the package as well.

Once all documents are uploaded and all signatures are in place, the medical researcher will submit the project to the IRB for you.

IRB Continuing Review

After your study is approved, it may require a continuing review, usually on an annual basis. IRBNet electronically generates three reminders that the continuing review date is approaching:

at 60 days, 30 days and 15 days. Your medical researcher will forward these reminders to you, your faculty mentor and your Program Director, along with the appropriate forms. Given that an expedited review can take up to two weeks, once you get the 15-day reminder, you are close to running out of time. If your project expires because of lack of continuing review, all study activities must stop. The study will need to be re-opened as a new study.

IRB Closure

When you have completed your study—including the publication of a manuscript (if applicable), you must formally close the study with the IRB.

Conducting your Study

Once your study has IRB approval and you have all the materials that you need, you can begin to work on your study. Your medical researcher will meet with you to review some essential things to remember about changes to the project and about data safety. The medical researcher will also speak with you about how to maintain your study records, consent forms etc. It is important to note that when the IRB approves your study, they are approving exactly what is stated in the documents that you have submitted. This means that if you need to make a change to your study, for example to add a team member, add additional data elements, extend the study time line or other actions, you need to file an **amendment** with the IRB. Only when the amendment is approved, you can implement those changes. Your medical researcher will help you with this process.

Data Security

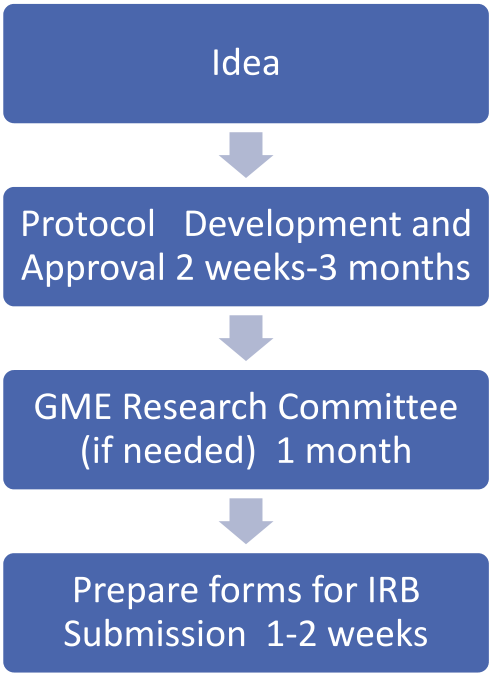
This set of guidelines should always be followed:

1. All data collection must occur on Ascension St. John premises
2. Only the study investigators and data analyst should have access to the research data
3. All paper data collection forms must be stored in a secure, locked area when not in use

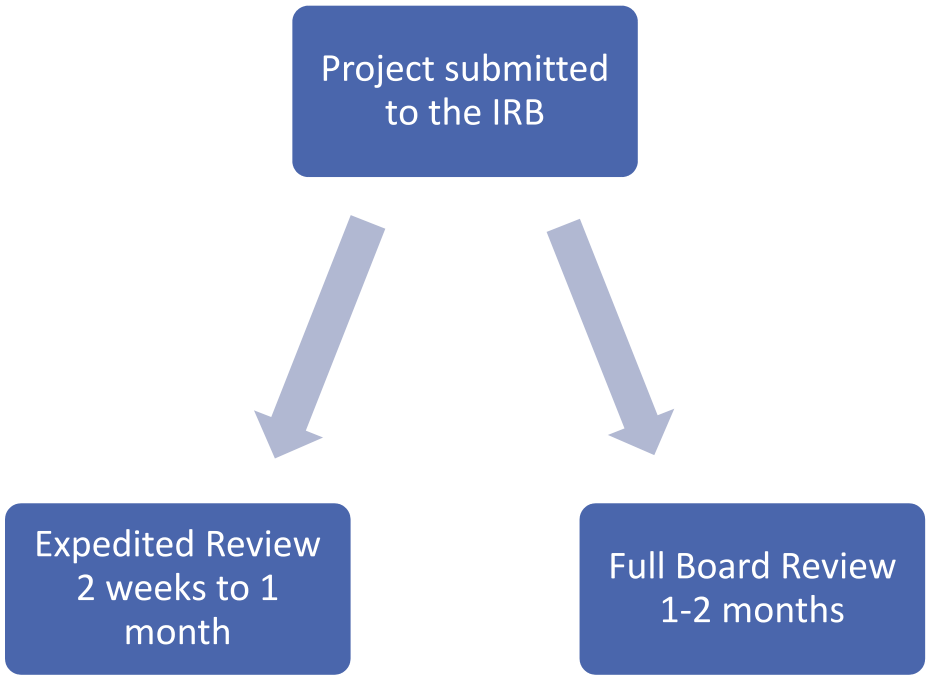
4. All electronic data must be stored on an Ascension St. John, network, password-protected computer drive, i.e. your H: drive or the One Drive.

No patient data should ever be stored on a personal device of any type!

Study Timeline—Research Development



Study Timeline—IRB Approval



How Long Does It Take to Get a Project Approved?

The time from the conception of your idea to final approval can vary greatly depending upon the following items:

- How long it takes to develop your protocol so that it is ready to go to the Research Committee or IRB. This depends upon the type of project, writing skills and the workload of both you and the medical researcher. Remember, this is an iterative process and it takes a few drafts until the protocol is ready. The sooner you respond to requests or questions, the sooner the project will advance. So, the length of the protocol development phase greatly depends upon you. The Research Department also has some busy times during the year, when the volume of projects is high. The volume of projects will affect response time.
- GME Research Committee: If your project needs to be reviewed by the Committee, you should add one to two months to the pre-IRB development process.

- IRB Approval: as noted above, depending upon type of project, type of review and your response time to IRB questions or revisions, this can take from two weeks to two months (for full board projects that need revision).
- At minimum, you should start to develop your project at least three months before you want to start collecting data.

Frequently Asked Questions

Q: Do I need to get IRB approval for a Case Report?

A: For a case report, you first need to get consent from the patients or the patient's family if the patient is deceased. The policy and the forms can be found on-line in PolicyStat, in Canvas in the Research course and on the Ascension St. John GME Research internet site (https://medicaleducationsjp.com/medical-education/test-research).

After you have consent and have written the case report, it is submitted to the IRB to obtain a "Not Human Subjects Research Letter". You will need this letter when you submit a travel request. Some journals also require this letter. Work with your medical researcher or Alice Mar to submit the case report to the IRB.

Q: Is there a difference between a Case Report and a Case Series?

A: A case series may be considered research in many cases. Before you start a case series, please contact Dr. Szpunar to discuss.

Q: Where can I find the instructions for CITI training?

A: The instructions can be found on the Ascension St. John GME Research internet site, the IRB internet website, on IRBNet and on the Canvas Research site. You can also email the IRB staff, Dr. Szpunar or your medical researcher to get the instructions.

Q: How long is CITI training good for?

A: Your CITI training must be renewed every three years.

Q: Can I ask a medical student to help me on my project?

A: Medical students who are on rotation at Ascension St. John Hospital from SGU, WSU, CMU and KSU can be included on resident and fellow projects or added after the project has started. They must complete CITI Training. If being added after the project has already started, an amendment must be submitted to the IRB.

Q: **What happens if I fail to do a continuing review for the IRB even though I want to keep working on my study?**

A: If a continuing review is not completed, the study is terminated. You will then need to re-open the study as a new project.

Q: I just realized that I need to change something about my study design or data collection sheet, what should I do?

A: Speak with your medical researcher who will help you to complete an amendment form. Do not make any changes to what you are currently doing until the amendment is approved by the IRB.

Q: Can I keep research data on my personal computer?

A: NO! All electronic patient data must be stored on an Ascension St. John, network, password-protected, encrypted computer—i.e. either your H: drive or the One Drive.

Q: I need some help with a poster, whom should I contact?

A: For help with the content of the poster, work with the medical researcher who helped you with the project. For help with poster design, layout and printing, contact Alice Mar.

Q: I am ready to graduate, what do I need to do?

A: To fulfill your graduation requirements, you must have written a manuscript that is based on your research project. The manuscript must be approved by the Research Department. For the IRB, you must also close your study or transfer your study to another resident, fellow or faculty member. Depending upon what you wish to do, you will need to fill out a Closure/Final Report from or an Amendment form.

If you have paper data collection sheets from your study, please bring them to the GME Research Office so that we can send them to storage.

Useful Contacts

Name	Role	Contact about	Contact Information
Dr. Susan M. Szpunar	Director, Biomedical Investigations and Research	Any research/IRB related issue	313-343-7838 Susan.szpunar@ascension.org
Deb LaBuda	Admin Asst. II, Research	Research travel, budgets, Dr. Szpunar's schedule	313-343-3802 Deborah.spampinato@ascension.org
Karen Hagglund	Clinical Scholar	Resident research	313-343-7384 Karen.hagglund@ascension.org
Shelby Miller	Clinical Scholar	Resident research	313-343-7469 Shelby.miller@ascension.org
Alice Mar	Clinical Scholar	Posters, Case Reports, Turning Point Audience Response System	313-347-0599 Alice.mar@ascension.org
Kathy Riederer	Research Scientist	Infectious Disease Research Lab	313-343-3746 Kathleen.riederer@ascension.org
Institutional Review Board (IRB)			
Lee Bowen	IRB Coordinator	IRB issues	313-343-3863 Lee.booze-battle@ascension.org
Othuke Abada	Research Assistant-IRB	IRB Issues	313-343-7224 Othuke.abada@ascension.org

The Mission of GME Research is to educate and assist individuals with all aspects of scholarly activity and research. We are here to help you.

Remember, when in doubt, ask a question!

Good luck on all your research endeavors!

Appendix 1: Outline of a Study Protocol

Outline of a Study Protocol

(Note. Questions are included to guide you in what goes where, not to be repeated in the actual protocol!)

Title

Investigator(s) and Residency Program

Introduction (Background and Rationale)

Based on the relevant scientific literature, write the background for your study. What do we know about your question? What do we not know? This sets the stage for your research question and/or hypothesis. Make sure to cite the relevant literature from your literature search.

Include citations as appropriate (North, West, and South 2002) and add to Reference list

Research Question:

What question will the study address? The question(s) should be specific, not vague.

Say this: Does enrollment in a tobacco quit line increase smoking quit rates in new Moms during the first three months after delivery?

***Not** this:* What is our experience with tobacco quit lines?

Hypothesis Statement:

A hypothesis is an educated guess. If your study is exploratory or descriptive, you may have only a research question and no hypotheses. If you are making comparisons, you likely will have hypotheses. The hypotheses are simply the research questions rephrased in a format that can be tested using statistics.

The hypothesis is always stated as a NULL hypothesis and is always accompanied by an alternate hypothesis. This format is used because, using statistics, we cannot prove something to be true, we can only disprove it. Our goal is to disprove the null hypothesis.

Example:

H_0: There is no association between carotid plaque as measured by ultrasound and coronary plaque as measured by CTA.

H_A: There is an association between carotid plaque as measured by ultrasound and coronary plaque as measured by CTA.

Try to write your hypotheses so that two-sided statistical tests can be done—so use the words "no difference" vs. "a difference" instead of "no difference" vs. "better" or "worse" (one-sided statistical tests).

Methods & Materials

Study Design (How will the question be approached?)

Who are the patients who will participate (inclusion and exclusion criteria)

What is the time frame?

What information are you collecting? How you will get it? (interview, records review, etc)

Any other pertinent info you are collecting (Patient #, date of surgery)

If a prospective study, how will the patients be assigned? (Randomly)

If it is a treatment study, how will you insure blinding of subjects and medical personnel?

How will you insure patient anonymity and confidentiality of records?

Draft of data collection form is included

Data quality:

How will you assure the quality of the data? Data abstraction and entry errors are common.

If there is one person collecting data, then a random sample of about 10% of the cases should be re-abstracted. The re-abstracted data should be compared to the original data to determine the number of errors, type of errors and to create a plan for error reduction.

If there are multiple people collecting data, you should:

1. Clearly define what each data element means (create a data dictionary);
2. Define where the data should be collected from (for example, collect blood pressure data from the "flowsheet" tab in eCare);
3. Conduct a training session with the other investigators or individuals collecting data;
4. Prior to the start of the study, have all individuals who are collecting data abstract several of the same charts and compare results. Determine where the mistakes are occurring and how to avoid them;
5. Develop an audit plan, for example, where 10% of the data are re-abstracted by the principal investigator to look for routine errors.

Talk with your medical researcher to help design the data quality process that is suitable for your project.

Power analysis

How many subjects will you need to include to find a statistically significant difference if it truly exists? A sample size analysis with the alpha error rate set at 0.05 and beta error rate

of 0.1-0.2 (corresponding to 80-90% power) is required. **Your medical researcher will help you with the sample size calculation—you are not expected to know how to do this step.**

Statistical Analysis

Describe how you will analyze the data to answer your research questions or hypotheses. Explain what descriptive statistics you will use and what inferential analyses you will do. **Your medical researcher will help you to write this section—you are not expected to know how to do this step. Your medical researcher will also perform the statistical analysis when your data are collected.**

HIPAA/Patient Confidentiality

Describe what measures you will take to protect patient data and confidentiality.

References

Note: If you are using EndNote or other reference management software, choose the **Vancouver** style.

In the text, references should be cited as they are mentioned, usually at the end of the sentence. The first authors' last names should be followed by the year, as follows:

single author - (Franklin, 1776)
dual authors - (Franklin and Washington, 1776)
three authors - (Jefferson, Franklin and Washington, 1776)
four or more authors - (Hamilton et al., 1777)

Mentioning the first author by name to attribute an aspect directly should be handled as:

Franklin (1776) was the first to report the electrifying properties of lightening.

At the end of the article, a list of references should be included that is alphabetized by the first author's last name. Complete guidelines for reference types are available from the National Library of Medicine NLM via the library's Web site (http://www.nlm.nih.gov/). Below is the citation format that the Research Director recommends for protocols.

Standard journal article:

Vega KJ, Pina I, Krevsky B. Heart transplantation is associated with an increased risk for pancreatobiliary disease. Ann Intern Med 1996;124:980-3.

For more than six authors, list the first 6 followed by et al.:

Parkin DM, Clayton D, Black RJ, Masuyer E, Friedl HP, Ivanov E, et al. Childhood--leukaemia in Europe after Chernobyl: 5-year follow-up. Br J Cancer 1996;73:1006-12.

(From Uniform Requirements for Manuscripts Submitted to Biomedical Journals. International Committee of Medical Journal Editors, March 19, 1997.)

Budget

A list of the items/paid assistance to be used to acquire or enter data, and their costs.
(What will you need to do the study properly? What will it cost for those items?)

Example: A study comparing BMI and Body Fat in a study group and a control group

Item	Unit Cost	Number	Total Cost
Hand-held body habitus measurement devices	$200	4	$800.00
Diet and exercise handouts for study group	$3.00	200	$600.00
General dietary information handouts for control group	$0.50	200	$100.00
Study Incentive $5 Target gift card	$5.00	400	$2000.00
Total			$3500.00

Budget Justification

One or two sentences per line item in budget to explain why you need that item. If cost is unusual, explain how you reached that price.

Appendix 2: Research and IRB Pitfalls

COMMON Research and IRB Pitfalls

The items below require an amendment, approved by the IRB, prior to any changes to the study

- ❑ Increasing the sample size (i.e. reviewing more charts or including more patients than stated in the approved protocol)
- ❑ Changing/Increasing the data elements being collected
- ❑ Changing the time frame for data collection or location of data collection
- ❑ Changing the time frame for follow-up visits
- ❑ Adding additional study team members (i.e. having a medical student collect/enter data)
- ❑ Changing study inclusion/exclusion criteria (example: including older or younger subjects)
- ❑ Changing the approved study design or study procedures, i.e. adding or removing parts of the protocol (protocol deviation)
- ❑ Changing the sequence of study procedures
- ❑ Changing subject eligibility criteria
- ❑ Changing the informed consent form

DO NOT:

- ❑ Use an informed consent form that does not have a current IRB stamp
- ❑ Have your data analyzed by someone other than your designated data analyst

HIPAA Compliance and Data Protection Requirements

- ❑ All data collection must occur on St. John premises; data should not be removed from St. John premises
- ❑ Paper data collection forms must be stored in a locked file cabinet when not in use
- ❑ Electronic data must be stored on a St. John network, password-protected, encrypted computer drive
- ❑ Do not store data in a non-HIPAA compliant cloud drive, such as Dropbox or iCloud
- ❑ Any data that are shared by email must be encrypted. If sending data to a non-Ascension email address, put -secure- or -phi- in the subject line to encrypt the data
- ❑ Data must be stored for the duration of time specified in the research application; do not destroy data once the project is completed

There may be other "unanticipated problems" than those listed here.

Date discussed with resident ___/___/___

Medical Researcher signature: _____

Resident Physician signature: _____