

Research Protocol Template

(original source of this template is

<https://resident360.nejm.org/expert-consult/introduction-to-research-in-residency> ;

modified in part by the UTHSC IRB)

Helpful hints:

- If you are new to research here, consult the UTHSC IRB's webpage Getting Started (<http://www.uthsc.edu/research/compliance/irb/researchers/getting-started.php>) to find out the steps to take to obtain IRB approval.
- Consult the UTHSC IRB's SOP page to learn about policies related to your research, such as Informed Consent; Additional Protections for Children, Pregnant Women & Fetuses, & Prisoners; etc.: (<http://www.uthsc.edu/research/compliance/irb/researchers/standard-operating-procedures.php>)
- UTHSC defines Key Study Personnel (KSP), who should be included in your IRB application, as the following - from the Conflicts of Interest policy (<http://www.uthsc.edu/research/compliance/irb/researchers/documents/conflicts-of-interest.pdf>):
 1. Principal investigators and Co-/Sub-Investigators;
 2. Individuals listed on the grant or contract application;
 3. Individuals listed on an FDA form 1572;
 4. Individuals who are named as contact persons in the informed consent or recruitment materials;
 5. Individuals who provide supervision of the people obtaining informed consent;
 6. Individuals who obtain informed consent;
 7. Individuals who perform study interventions, interactions, or observations of non-public behavior, or who review private, individually identifiable information or specimens from subjects, as defined at 45 CFR 46.102(f);
 8. Individuals who are responsible for the overall conduct of the study; who play an essential role in study design, implementation, etc.; or who coordinate execution of study activities; and
 9. Individuals who perform services that merit professional recognition or publication services.
- Consult the UTHSC IRB consent form templates here: <http://www.uthsc.edu/research/compliance/irb/researchers/consent-forms.php> .
- Call the UTHSC IRB at (901) 448-4824 to set up IRB training if you are not familiar with the IRB application process, iMedRIS (UTHSC's electronic research application system), and/or UTHSC IRB policies.

Title:

Principal Investigator:

Other Investigators:

Institutional affiliations:

- **Abstract**

Provide a summary of the study background, aims, and design

I. BACKGROUND AND SIGNIFICANCE

A. Background information on condition or problem to be studied: Include incidence, typical characterization of the condition, etc.

B. Previous studies looking at the same condition/problem: Include what has been looked at to this point, gaps in the literature, inconsistencies, and variations from what you will be proposing.

Describe the current environment that is the basis for the proposed research, including a presentation of the problem (with references) and a review of current literature. Include a critical evaluation of current knowledge and preliminary studies related to the proposed research and describe how this proposal will enhance this knowledge.

If a drug, biologic, or device study, indicate whether the agent is approved by the FDA, currently marketed, and being used in accordance with its approved indication(s).

II. STUDY OBJECTIVE(S); INCLUDING SPECIFIC AIMS AND/OR HYPOTHESES

- A. List the broad, long-term objectives and describe concisely and realistically what the research is intended to accomplish and the hypotheses to be tested.

Describe the purpose of the study, including identification of specific primary objectives/hypotheses. Secondary objectives/hypotheses should be described as necessary.

- **Administrative Organization**

Describe the participating units, including other participating study sites, laboratories, data management center, and coordinating center as applicable.

III. METHODS

A. Study Design

1. Definitions
2. Prospective/retrospective?,
3. # of centers, Randomized?,
4. Blinded?, Placebo?, etc.
5. Period of enrollment or chart review covers? Informed consent?
6. Study Drugs, Device, or Intervention
7. Randomization/Sampling (If appropriate)
8. Instruments: Standardized Surveys, etc.
9. Endpoints: the main thing that you are looking at

B. Study Population

1. Who? Age, Sex, Race, Diagnoses, Ability to Consent/Assent, Ability to speak English, Pregnant Women/fetuses, Prisoners, Students/Employees, etc.
Be sure to mention if you may *incidentally* include any vulnerable populations.
2. Inclusion/Exclusion criteria
3. Experimental group vs. Control group

C. Assessment of Resources

Indicate how investigator will ensure that the study:

1. Has sufficient access to the study population

2. Has sufficient time to conduct and complete the study
3. Has adequate qualified staff members to conduct the study
4. Facility is adequate to conduct the study
5. Staff has been adequately trained on the protocol and their specific research-related duties
6. Has sufficient funding: If the study is not funded by a federal agency, industry sponsor, etc., clearly explain who, what department, or which clinic or hospital has agreed to pay for all research procedures (meaning those that are performed solely for research purposes, such as research blood draws, associated labwork costs, any extra anesthesia or extra amount of contrast agent that is required for research purposes, extra OR time required, extra X-rays/MRIs/CTs, cost for research specimen storage, hospital staff time if nurses will be conducting many repetitive research procedures within a small timeframe, etc.) and for the drug/biologic/device that will be administered and evaluated for research purposes. Remember that some insurance companies will *not* pay for research procedures/drugs/devices.

D. Detailed Study Procedures

Include a description of the study procedures.

IMPORTANT: Be sure to specify which procedures would occur anyway if the patient/subject were not participating in the study (i.e. are standard of care procedures at your clinic/hospital), AND which procedures will be performed solely for research purposes (i.e., would not be performed outside of the study).

For example, how many more visits to the clinic are required; how many more surveys/questionnaires; how many more separate research blood draws; or how many more cc's of blood will be drawn back solely for research purposes? Don't forget to include randomization as a research procedure.

Note that if you are randomizing between two standard of care procedures, both procedures then become "research procedures" or "procedures being performed for research purposes" because the physician and patient's preference/choice for a certain standard of care procedure is then removed. Further, risks associated with those typical standard of care procedures then become (due to the randomization) research risks that must also be discussed in the consent form.

If all procedures will be performed solely for research procedures (i.e., none would occur if the patient/subject were not participating in the study), state this.

Be sure to include (as applicable):

1. Plans for Recruitment- advertising fliers/posters/emails/social media, receive referrals from non-investigator physicians, identifying from own patient base, etc.
2. Screening– medical record review? telephone or in person? screening questions or procedures such as blood draws?
3. The number of visits and estimated length of each study visit
4. Randomization- how you will randomize (e.g., using a random computer-generated number), and to how many different arms/treatment groups
5. Procedures and/or interventions that will be performed for each visit (a chart may be helpful)- provide as many details as possible!
6. For medical record abstraction, indicate whether or not the data will be obtained prospectively (i.e., after the date that you submit your IRB application), or if all data you wish to review are already in existence. If you are reviewing/using previously existing specimens, records, or data, indicate whether all the specimens, records, or data were obtained for clinical care purposes, or whether they were obtained in other research studies (if so, and if the other study was approved here, provide the UTHSC IRB#). Explain what information will be used to identify potential human subjects for inclusion in your study, and all the ways in which you will identify them.
7. Clearly indicate which research procedures will occur at each site (recruitment, screening, obtaining consent, medical record abstraction, conducting surveys, study visits, implantation of device, etc.).
8. For a drug study, include instructions for administering drugs, handling drugs, and storage and disposal, including who will dispense the drugs (including their qualifications) and where they will be dispensed. Indicate whether and how you will track compliance if the drug will be taken by subjects at home.
9. For a device study, include instructions for administering, training subjects on the use of, and/or implanting device; storage of the device; if applicable, who will implant the device (including their qualifications) and in what clinic/hospital; and whether subjects will be allowed to keep a device after the study if they are using it at home, such as a pedometer.
10. For biological samples, explain how the samples will be collected, as well as storage, testing, and disposal methods
11. For behavioral studies, identify the instruments being used and who will be administering the instrument (including their qualifications)
12. For a survey study, include who created the survey, whether survey has been standardized, how survey will be distributed and returned, and how confidentiality will be maintained
Remember that you are not *conducting a research survey* if you are copying (from a medical record, for instance) the results of a survey that was administered as part of standard care; you are conducting a record/chart review.

13. For quality improvement studies, call the IRB to discuss how this should be designed and/or written because it sometimes difficult for the researcher to fetter out what parts are being performed by an institution for quality improvement and what parts are being performed solely for research purposes (i.e., would not occur outside of the research study).
14. For studies where you would also like to create a data or specimen repository *in addition to the main study*, each section of your protocol must separately address the repository [e.g., what is the purpose of the repository (apart from the main study); what are the risks and benefits of participating in the repository (apart from the main study); etc.]. Further, a separate repository consent form is required. (Note that a repository is being established when private information and/or biospecimens (that will be or already have been collected) will be stored for future research studies in addition to, or separate from, any current objectives.)
15. For studies where some research procedures will occur at sites *other than local Methodist Healthcare and Regional One Health sites*, a letter from administration at that institution stating that you have permission to conduct the study there (include the name of the study), will be needed before the IRB can grant approval for you to conduct the study at that institution. Le Bonheur Children's Hospital provides this initial permission to conduct research there via an email correspondence in iMedRIS, UTHSC's electronic research application system.
16. For studies involving other investigators at other sites, clearly indicate how each site will be involved (what research procedures will be performed at each site), including whether you will send or receive data/specimens, how, and in what form [identifiable, void of all 18 HIPAA identifiers, void of the 16 direct HIPAA identifiers, coded and who maintains the key to the code (and where) linking back to identifiers, etc.].
Please note that if your study involves sending/receiving data from other sites/investigators, you will need to contact the UTHSC IRB to discuss issues such as required IRB approval documents from the other site and/or adding a non-UTHSC investigator to your application. In addition, you may need to consult UTHSC Sponsored Programs about whether you will need a data transfer agreement with another institution. Lastly, if another institution requests an IRB reliance agreement with our institution, this will need to be discussed with the UTHSC IRB as it may not be allowed or it may not be necessary.

IV. DATA COLLECTION

- A. How data will be collected (querying a database, medical record review and abstraction, only received from someone else/another institution, etc.)

B. What data will be viewed versus collected (recorded); e.g., MRN, FIN, name, full address or just zip code, demographics, comorbidities, medications, scores on standardized tools, etc.

Specify whether the data is identifiable, void of all 18 HIPAA identifiers, void of the 16 direct HIPAA identifiers, coded and who maintains the key to the code (and where) linking back to identifiers, etc.

Explain whether key study personnel will be de-identifying data, coding data, etc.

V. DATA ANALYSIS

A. Sample Size Considerations

1. Power analysis based on previous studies or exploratory study?
2. Justifying the sampling procedure

B. Statistical Methodology

1. Comparisons to be made and statistical tests to be used for the comparisons.

You must indicate the specific statistical method/test that will be used; a statistician may need to be consulted before submitting to the IRB.

VI. DATA AND SAFETY MONITORING PLAN (if applicable)

A. Describe any provisions for monitoring the data and subjects for safety.

VII. STUDY LIMITATIONS

A. Potential limitations of procedures & any potential logistics issues

VIII. ETHICAL CONSIDERATIONS

A. Informed Consent

1. Provide a description of the Informed Consent Process, including:
 - a) Circumstances under which consent will be obtained (place & timing)
 - b) How consent will be documented in the research record [this is not just having the required signatures on the consent form; consult the Informed Consent policy (<http://www.uthsc.edu/research/compliance/irb/researchers/documents/informed-consent.pdf>) about documenting the consent discussion]
 - c) Special provisions for vulnerable populations (legally authorized representatives for adults who are not competent to consent; obtaining permission from parents/legal guardians; obtaining assent from children of 8 years and older; etc.)
 - d) Steps taken to minimize coercion
 - e) Who will be involved in obtaining consent (these persons must be named in your IRB application)
 - f) When will subject be approached
 - g) Method used to ensure that subject fully understands study procedures

2. If requesting waiver or alteration of consent, the research procedure(s) may be no more than minimal risk, and explain why the study cannot be practicably carried out without the waiver or alteration

B. Risks and Side Effects

1. Potential Risks (include medical, psychological, legal, financial, social)
 - a) Assess for severity and likelihood (loss of confidentiality is almost always a risk)
 - b) Procedures for protecting against or minimizing risks
 - i. Safety procedures/checks
 - ii. Procedures for maintaining confidentiality
 - c) Unforeseen risks

2. Adverse events (define; consult the UTHSC IRB policy at <http://www.uthsc.edu/research/compliance/irb/researchers/documents/adverse-event-reporting.pdf> for more information)
 - a) Provisions for medical and professional intervention
 - b) Reporting adverse events

3. Compensation for Injuries
 - a) Where and from whom medical therapy may be obtained
 - b) Who will pay for the therapy
 - c) Whom to contact in case of injury

C. Benefits

1. Explain the expected direct benefits in relation to the subjects. If there are none, then state this explicitly.
2. Explain the benefit to general science or others.

D. Alternatives to Participation

1. If the prospective subject did not participate in this study, list the procedures that would not occur (i.e., list the procedures that are being performed solely for research purposes).
2. If this study involves providing treatment(s) for a condition, is each type of treatment available outside the study, in standard care? Will the prospective subject have to go outside of your clinic/hospital to receive any of the aforementioned treatments without participating in the study?

E. Costs to Subject

1. Clearly describe the financial costs that the subject (and his/her insurance company) may incur for any procedures that will be performed solely for research purposes, and for any drugs/biologics/devices that will be administered and evaluated for research purposes (if there are no costs, state this).
 - a) Justify any costs that the subject will incur as a result of participating in the study.

F. Compensation to Subject

1. Describe any reimbursement to the subject for expenses related to their study participation such as gas, hotel, daycare costs, lunch, etc. Indicate whether submitting receipts for these costs is required for reimbursement.
2. Describe any payment that is received by the subjects, whether monetary or otherwise. When determining payment, keep in mind what is reasonable based on the time and effort required of the subject, and what amount may be high enough, dependent on the risk involved, to be considered undue inducement for populations of low socioeconomic status. The use of payment to offset the burden due to participation in the research should be incremental and not based on study completion.
 - a) Discuss schedule of payments, types of payment, amounts (per visit, etc.), total possible amount,

G. Provisions for vulnerable subjects

1. Indicate whether there will be vulnerable subjects in the study
2. Describe additional protections provided to these subjects to protect their rights and welfare

H. Subject Privacy and Data Confidentiality

1. Privacy of Participants
 - a) Describe appropriate provisions to protect the privacy of the subjects.
2. Confidentiality of Data
 - a) Provide a clear description of how the data will be disseminated. Outline the sharing of data with others outside of the institution, and include provisions for maintaining confidentiality. Additionally, describe how the results of the data will be used (i.e. presentations at professional organizations, submission to professional journals).
 - i. Will data be identified?
 - ii. How will data be kept secure (where will data be stored)
 - iii. Who will have access to the data?

3. Plan for Record Retention and Disposal (consult UTHSC IRB policy at <http://www.uthsc.edu/research/compliance/irb/researchers/documents/study-closure-and-record-retention.pdf>)

4. Limits to Confidentiality

IX. CONFLICTS OF INTEREST

A. Divulge any conflicts of interest you may have (such as a significant financial interest in the drug/device company)

X. PLANS FOR DISSEMINATION OF FINDINGS

XI. REFERENCES

A. These must be cited in the Background section.

XII. APPENDICES

A. Data collection instruments/spreadsheets, case report forms, rating scales, surveys, diaries, package inserts for drugs/biologics or Investigator's Brochures, device manuals, 510(k) clearance letters, IND/IDE letters/documents, FDA communication, recruitment materials, telephone screening scripts, consent forms, Data Safety & Monitoring Board (DSMB) reports, IRB approval documents and letters from other institutions with which you will work (e.g., send or receive data/specimens whether they are completely de-identified or not), etc.

Remember that any documents you will use for your study, whether you will give them to subjects or not, must be submitted to the IRB for review and approval/acknowledgement before they are used.