How to write an IRB

For this recipe you will need;

- *An idea for a research project*
- *Your institution's IRB application*
- *Patience, perseverance, and ideally an experienced mentor!*

Step 1: Clearly define the question(s) your research seeks to answer.

Step 2: Tell your colleagues about your project and solicit assistant investigators.

Step 3: Clearly identify roles, responsibilities, and timeline expectations with your co-investigators, including anticipated author order on the paper you will write to publish your findings. Put this in writing and make sure everyone has a copy.

Step 4: Complete this research outline (easiest to break it up into parts among your group):

Title: Be concise, don't capitalize every word

Subject Population: a brief description

Age of Subjects: Specify in particular the follow age ranges: newborns, 0-17, 18-65, over 65

Collection of Subject Demographics: What are you collecting? I.e., ages, gender and race

Population: Who are you studying?

Does the project involve active subject recruitment? If you'll recruit subjects, you'll need to describe in detail how you will do this.

Control / experimental / total subjects: Describe each group.

Abstract: This gives the IRB a good idea of what you are trying to study and how you plan to go about it. Put effort into this – with minimal modification this is the abstract to the article you'll publish about this project!

Research Plan: This is where you build a detailed outline of your project

1. Objectives / Specific Aims What clinical question are you trying to answer? What is your null hypothesis?

2. Background and Significance Why is this important? To whom is it important?

3. Research Design / Methods / Subject Justification Specify your research design. Is it retro- or prospective? How many arms? Cross over? Briefly describe your methods (you'll go into detail later). Will you pull data from an established database? Recruit subjects? Give a justification for your subject selection. This is particularly important if your subjects are considered vulnerable populations.

a. General Approach

i. Research Objective What clinical question are you trying to answer? What is your null hypothesis?

ii. Detail how many groups or Arms are in the Study and what each receives Be complete and concise.

iii. Randomization procedures How will you randomize? If you are not randomizing, why not?

b. Methods and materials Again, complete and concise. Be sure to include all actions the researchers will take, all anticipated interactions with subjects, and all tools/surveys/equipment you plan to use.

i. Experimental Procedure Step by step, what are you planning to do?

ii. If collaborative, what occurs at each institution Be explicit. Your IRB may require a formal data-sharing agreement or memorandum of understanding.

iii. Research material to be collected Be concise and complete. Anything not listed to the IRB cannot later be collected (unless you later submit and receive approval for a waiver before you collect it.) Here you can also specify PII vs non-PII data. Studies without PII may be eligible for an "expedited" review.

iv. Data collection tools Forms, surveys, databases, equipment etc.

v. Protection and security of data and identifying information Physically or electronically how will information be secured and who will have access to it?

vi. Disposition of data and identifying information at end of project Be specific – for how many years will information be retained. How will physical and electronic information be destroyed or archived?

vii. Gender and ethnicity Will this information be collected and if so, why?

c. Subject population

i. Subject inclusion and selection criteria How will you identify appropriate subjects for inclusion?

ii. Subject exclusion What, if any, are your exclusion criteria?

iii. Subject recruiting methods Be thorough – signs, mailers, booths, commercials, emails? Be explicit in subject compensation if any – money, time, promotional items. Your recruiting materials will be reviewed and should clearly address how the study might (or, better, will not) impact the subjects' access to care or quality of care.

iv. Informed consent procedures Be thorough, and be sure to address potential barriers like language, legal ability to consent, subjects' ability to revoke consent (your consent forms should include instructions on how to revoke consent), and again address how the study might (or, better, will not) impact the subjects' access to care or quality of care

v. Justification for use of this subject population The more vulnerable your subjects, the more potential harm of your intervention, the stronger your justification must be.

vi. Vulnerable populations Clearly identify all "vulnerable" subjects. Vulnerable populations explicitly include: children, minors, pregnant women, fetuses, human in vitro fertilization, prisoners, employees, military persons, students in hierarchical organizations, terminally ill, comatose, physically and/or intellectually challenged individuals, visual or hearing impaired, ethnic minorities, refuges, international research, economically and disabled and healthy volunteers. Vulnerable populations also include *any other* population that might be at risk for exploitation.

vii. Number of subjects and justification Justification comes from your statistical modeling – this allows the IRB to see that you are not subjecting an unnecessary number of subjects to your intervention.

i. List and document risks Be broad – if data you collect (including that the subject is involved in your study) were available to all persons, what might happen? Loss of insurance? Loss of job? Embarrassment? If the intervention or lack of intervention were to cause harm, what would that harm be? Side effects? Loss of function(s) permanently or temporarily? What are the chances of harm with your intervention – are there animal studies, previous human trials, theoretical models, analogous interventions that allow estimation? Don't forget every aspect of your intervention. For example, treatment with intramuscular agent X includes not only the effects of X, but the risk of injection alone.

ii. Justification of risks What might subjects in particular and the field of medicine in general gain?

iii. Minimization of risks Be thorough – address every risk listed above and clearly describe risk minimization process and procedures. This includes pre-screening subjects, intervention technique, and post-intervention monitoring.

e. Benefits What does the world gain from this study?

f. Cost to subjects Typically time and money, but also may be physical limitations (including driving, reading, sports) or mental limitations (fatigue, focus) depending on your interventions.

4. Adverse event management and reporting The next step to risk mitigation strategies above. If something goes wrong, what happens? Describe how an adverse event would be identified, to whom it would be reported, and what possible outcomes an event might trigger – risk amelioration, dropped from study, study on hold, study shut down, anything else. Also note that this must include how the researchers will notify the IRB.

5. Statistical analysis What analysis will you perform? Why? Make sure your model fits your anticipated data. Describe in detail power, confidence intervals, and sample sizes. Consider the impact of smaller sample sizes/drop-outs on your confidence intervals.

6. Significance to your institution Some institutions will explicitly ask this. It is a way for their IRB and internal leadership to make sure researchers are meeting the needs of their employers.

7. Patent disclosures/inventions Are you testing for your patent or invention? Disclose here.

8. Potential hazards to the research team Detail.

9. Anticipated enrollment time Include an estimate of how many subject per year over how many years your study will run.

10. Bibliography for background section/ research plan Some IRBs will direct you to cite in a specific style. You should have a great bibliography – See Chapter 3 for how to do a literature search. Be thorough – this will be the foundation for the References in the article you'll publish about this project.

Step 5: Cut and paste from the outline into your institution's IRB form.

Step 6: Submit your IRB!