

How to plan a study

Xiaolin Zi, Ph.D.
Department of Urology



UC Irvine Urology

Steps for planning a study

1. Formulating and documenting a research question
2. Literature review, background and rationale
3. Meet regulation requirements
4. Research materials and instruments
5. Collaboration and research team build-up
6. Study population and sample size calculation
7. Budget
8. Timelines
9. Research method establishment and validation, quality control
10. Data collection and documentation
11. Outcome measurements and statistical analysis
12. Potential pitfalls and alternative plans
13. Summary of results and discussions

1. Formulating research question

- **What types of research questions: descriptive, exploratory, explanatory, predictive or hypothesis-driven ?**
- **Should be concise and accurate**
- **Brainstorming, group discussion and refining the question**
- **Whether your question is within addressable range, not too broad and not too narrow**

2. Literature review, background and rationale

- **Writing down keywords and searching for related literatures in PUBMED and NIH RePORTER**
- **Defining the gaps between the research question to be asked and currently reported studies: what has been done and what need to be done?**
- **What are the significance and impact of your research question?**
- **Whether your study will generate a paradigm shift concept, fill up the gap of the knowledge or bring in incremental changes in knowledge or methodology?**
- **Whether your research question is logic and supported by published data?**
- **Potential implications of your study, such as impact on current patients' care, new treatments, policy change, etc.**

3. Meet regulation requirements

- **Must pass the EH&S for Laboratory & Research Safety training requirements**
- **Attend Citi, HIPPA, radiation safety training courses, depending on types of research**
- **Securing Institutional Biosafety Committee approval for biosafety issues (e.g., blood draws, cell culture, specimens transferred , etc.)**
- **Securing Institutional Animal Care and Use Committee (IACUC) approval for animal related research**
- **Securing the Human Stem Cell Research Oversight (hSCRO) Committee approval for stem cell related research**
- **Securing institutional review board (IRB) approval for human related research**
- **Securing controlled substance approval.**

4. Research materials and equipment

- **Finding your research materials (reagents, biospecimens, consumable supplies, kits, animals...)**
- **Listing needed equipment**
- **Finding available core facilities for services of specialized experiments and shared equipment**
- **Contacting other principle investigators for obtaining some specialized reagents and equipment**

5. Collaboration and research team build-up

- **Finding opportunity to collaborate with people from different disciplines by attending conferences and seminars and sharing your ideas with different researchers.**
- **Be clear about what skills you're bringing to the collaboration and what skills you think the other people are going to be able to bring**
- **Be reliable in your collaboration**
- **Be realistic about what he or she can deliver**
- **Communicate regularly and resolving disagreements respectfully.**
- **Finding who belong to your research team**
- **Defining the role and responsibilities of each team member**
- **Setting up regular team meetings and creating agendas for the meetings**
- **Making sure that each person's contribution to the team is recognized and valued**

6. Study population and sample size calculation

- **Determining appropriate and representative study population by inclusion and exclusion criteria**
- **Identifying potential confounding factors**
- **Avoiding selection bias**
- **Determining acceptable power**
- **Calculating sample size**
- **Can we recruit sufficient subjects into the study within proposed time frame?**

7. Budget

- **Personnel cost: salary based on percentage of effort and fringe benefits**
- **Supplies**
- **Research materials**
- **Communication and publication costs**
- **Travel to conferences**
- **Access to equipment**

8. Timelines

- **Creating a timeline table with your statement of work**
- **Be realistic about what you will do and when you will do**
- **Consulting with a more experienced researcher**
- **Setting-up milestones to be achieved at each research stage**
- **Setting up the timeline with google calendar and sharing with your team members**

9. Research method establishment and validation, quality control

- **Optimizing and streamlining research methodology**
- **Always including positive and negative controls**
- **Determining inter variability and intra variability**
- **Equipment calibration**
- **Establishing standard operating protocols (SOPs)**
- **If possible, conducting a pilot study**

10. Data documentation and collection

- **Understanding methodology**
- **To be accurate, clear and complete**
- **Double check to avoid mistakes in data collection and avoid mismatch and missing data**
- **De-identifying confidential information**

11. Outcome measurements and statistical analysis

- **Determining what need to be measured and how can it be measured for the study question?**
- **Describing general characteristics of outcomes, such as means, rates, proportion, data distribution, variance equivalence among groups.**
- **Decide the best way to represent the data and select comparison groups**
- **Determining primary and secondary outcomes**
- **Consulting with statistician for performing appropriate statistical tests**

12. Potential pitfalls and alternative plans

- **Are the results expected ? Is there a plausible interpretation.**
- **What are potential problems for the methodology**
- **Are the results repeatable?**
- **Identifying potential biases**
- **Developing alternative strategies for potential problems**

13. Summary of results and discussions

- **Writing up conclusions in relation with the aims of your study and making sure that your conclusions are supported by your results**
- **Discussing your findings in comparison with published studies.**
- **Explain inconsistent or unexpected results.**
- **Discussing limitations of your study**
- **Discussing significance, importance and implications of your results**
- **Pointing out future direction**
- **Acknowledgements to collaborators and funding resources**