Checklist – How to Conduct Clinical Research

Steps for Conducting Clinical Research

	Step 1 – Identify a clinical problem or area of interest that you believe has research potential.
	Step 2 - Partner with an experienced clinical researcher (this researcher may act as a consultant / mentor or may be a part of your research team) and a statistician. • Discuss with experienced researcher the options for partnering with a statistician. • Discuss options for which IRB will be used.

	Step 3 – Plan out the design of your study.
	• Formulate your hypothesis.
	• Plan out your methodology (consult with the statistician during this stage). This includes:
	  ○ Who will you include in your study and how they will be recruited?
	  ○ Where will you conduct your study?
	  ○ What are the main outcomes of your study?
	  ○ How will you test for those outcomes?
	  ○ How will you analyze your data?
	  ○ How will you protect the rights of your research subjects (see step 6)?
	• Create a timeline for your study.
	• Plan how data will be organized. Create data forms that are separate from clinical records.

	Step 4 – Determine staffing requirements. • Decide if you can use one of your existing staff members on a part time or full-time status and what role they will play (administrative or clinical). • Determine if you will need additional employee(s) to assist in the study.

	Step 5 – Seek funding for the study.
	• You will need to be able to articulate the importance of your study and your research methodology.
	• Plan out a budget for the study. Consider costs such as:
	  ○ IRB approval (see step 6)-obtain fee structure for initial and annual fees.
	  ○ Recruiting research subjects.
	  ○ Purchasing study-related equipment and software.
	  ○ Compensating research staff.

	Step 6 – Apply for Institutional Review Board (IRB) approval • This is required for all research studies with human subjects. • No research can be done until IRB approval has been secured and changes to the research plan cannot be made without IRB approval. • Plan time for IRB approval – depending on the study, this can take several months and many times, revisions to the application are required. • Keep in mind that you may need to take research ethics training through your IRB in order to apply for IRB study approval.
	Step 7 – Recruit subjects.
	Step 8 – Conduct the study.
	Step 9 – Analyze data (see step 2 – partner with a statistician).

	Step 10 – Publish data.
	• Data can be presented:
	  ○ In peer-reviewed journals.
	  ○ At conferences.
	  ○ In trade journals.

Frequently Asked Questions

Why should I partner with an experienced clinical researcher to conduct my study?

An experienced researcher can help you plan out your study.[1] This can include helping you ensure that your methods are scientifically rigorous, that you are complying with rules regarding human subjects research and properly analyzing your data. Additionally, an experienced statistician can assist in proper study planning and data analysis, Options include partnering with a statistician who is based at a university or hiring an independent consultant. There are many pitfalls for novice clinical researchers – partnering with an experienced clinical researcher can improve your research study. See "A basic introduction to research: how not to do research" for more information on this issue.[1]

Where can I look for research funding?

- The AADSM
- Graduate dental programs at dental schools (if you are amenable to working with a dental resident)
- Partner with a researcher who has obtained (or is applying for) a grant from the National Institute of Dental and Craniofacial Research – it may be possible to conduct a sub-study under the Principal Investigator's (lead researcher's) main study

What is an IRB? Must I always apply for IRB approval?

An institutional review board (IRB) is an entity that reviews research studies before they are conducted to determine if they are ethically sound. The main role of an IRB is to make sure that the rights of research participants are protected.

If you are conducting a study that will lead to generalizable scientific knowledge, you must apply for IRB approval. If are going to use or access private patient information (including health information), IRB approval is required.[2] IRB approval is not always required for case studies, but you must still follow HIPAA regulations when collecting and reporting data.[3] Start by consulting your IRB to see if IRB approval is required for your study.

What if I do not have access to an IRB?

You can partner with a local university to have their IRB review your study (especially if you partner with a researcher from that university). You may also use a commercial IRB service. To note, if you do not work for an institution with an IRB, be sure to research costs associated with commercial IRB review. You can find many such services on Google. Note that the turn-around time and fees vary among services. Also, clarify if the fee is a one-time fee or requires annual renewal.

What are some important things to consider when planning out my research design?

- Will my study have a control group (a group that does not get the treatment)? How can I make sure that the two groups are similar?
- Does my study sample come from a very specific group (e.g. pediatric patients, patients with craniofacial anomalies, patients with specific dental findings, or is my sample typical of the practice of a general dentist)?
- How large will my study sample be? A statistician is invaluable at this stage of designing your study to assist with determining sample size.
- Do my outcome variables (i.e. the results I am measuring) have clinical relevance? How large of a difference in my groups will be meaningful to me? A statistician can also help answer this question.
- How reproducible are my measurements? Will I get nearly the same value for a measurement if I repeat it, or if someone else measures it?
- How will I record my research findings? It is advisable to create a data collection form separate from the clinical record to ensure that all data are recorded for each subject contemporaneously with its measurement. Otherwise, important information may be missing from the record, and data analysis will be hampered.
- What problems might I encounter during my study? How will I manage them?

Resources for Further Reading:

1. Vickers, AJ. A basic introduction to research: how not to do research. *J Soc Integ Oncol.* 2008; 6(2): 82-85. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2590769/

2. Boston University. Determining if IRB approval is needed. https://www.bu.edu/researchsupport/compliance/human-subjects/determining-if-irb-approval-is-needed/. Accessed May 3, 2019

3. Tufts University. Case repots. https://viceprovost.tufts.edu/HSIRB/policies/case-reports/. Accessed May 3, 2019