How to Start a Research Program in a Private Practice

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Why Do Research?

- Adds value to your practice
- Gives other treatment options for patients
- Allows patients to be more involved in their care
- Covers study-related patient treatment (scans, study drug, etc.)
- Patients get more attention/support due to constant contact from the study coordinator/study nurse to monitor patient care

What You Need to Get Started

- Staff
  - MD to be Principal Investigator (PI) who is interested in conducting research
  - Research Coordinator
- Storage
- Supplies
- Time/Dedication from all parties involved

Principal Investigator (PI)

- According to the Code of Federal Regulations (21 CFR 312.60), the PI's role is to:
  - Assume overall responsibility for the management of the study
  - Assign responsibilities for other members of the team
  - Ensure informed consent is properly obtained from study subjects
  - Be the liaison for major patient care issues with the sponsor and institutional review board (IRB), an oversight committee, and ensure that the IRB is informed of all safety issues
  - Make medical assessments, evaluating the efficacy of the study medication and whether adverse events are study related or not
  - Ensure the accuracy of the data that are submitted
- Every study requires time commitment from the PI, including reading the protocol to determine interest/clinical need and training from the Sponsor on the protocol requirements, study drug/drugs involved, and potential adverse events from the study drug

Study Coordinator (SC)

- Person in charge of managing the individual study site
- Helps assess feasibility
- Handles, prepares, and tracks document submission
- Manages the day-to-day logistics of the research program
- Can be a nurse or other administrative staff that are detail oriented and highly organized
- Depending on how your practice is setup, the SC can also be in charge of study drug or any drug received from the Sponsor to be used in the specified clinical trial (receipt of drug and its accountability/dispensing)

Study Nurse (SN)

- This is a position that can be added in once you've built up your interventional study program
- Helpful to the research program because the nurse has the clinical experience necessary to educate patients throughout the trial (i.e., an extension of the PI)
- Shows Sponsors that you're serious about research and have dedicated resources to conduct research effectively
- Can enhance your worth to others in the community as being a serious research program

Storage & Supplies

- Space to store study supplies received from Sponsor
  - Once you are initiated to participate in a study, you will receive study binders, shipping boxes for blood samples, laboratory kits for blood collection, and possibly equipment (EKG, etc.)
  - If you're not sure if you have the space, make sure to ask the Sponsor what you will/will not receive for the study so you can plan accordingly
- Space for the study monitor (CRA) to monitor data being collected for the study and study binders (typically a room that can be made available with a computer that has access to your EMR)
- Refrigerator / -20 ℃ Freezer
  - Refrigerator (to hold study drug) and -20 freezer (frozen blood samples) is a must to conduct most interventional trials
  - Thermometers to measure freezer, refrigerator, and ambient temps
    - You must keep a log of all recorded temperatures and ensure the space used is cool enough to store ambient lab supplies (max 77 ℉)
    - Refrigerator and freezer temperature need to be in the appropriate range (according to the protocol) at all times to ensure proper storage of study drug and blood samples
    - Refrigerator and freezer must lock. Locks can be purchased and added to the equipment (e.g. Marinelock), can be purchased already built-in, or should be in a locked box inside the equipment.

Research Training

- Good Clinical Practice (GCP) training (free)
  - **Required** by every Sponsor to ensure proper training of research staff
  - https://gcp.nidatraining.org/
  - Completed every 3 years
- Collaborative Institutional Training Initiative (CITI) training
  - Offers several training modules
  - More in depth training
  - Costs money
- Familiarization with International Conference of Harmonisation (ICH) and FDA Guidelines
  - Declaration of Helsinki / Belmont Report
  - ICH E2A, ICH E6(R2), ICH E8, ICH E9, ICH E11
  - Title 21 Part 312

How Do I Become a Site for a Trial?

- ClinicalTrials.gov
  - Allows you to search by disease type and phase, region, etc.
  - Email/call the contact given for the study and ask if they are looking for new sites
    - If they aren't, ask them to get on a potential site list to be considered for future studies
- Medical Science Liaison (MSL)
  - Work on the Research & Development side of pharma (usually MD, PharmD, or MSN)
    - If you don't know who this person is, contact your pharma sales rep to see if they can obtain this info
  - They can also recommend you as a site for upcoming trials that fit your site's needs
  - You must demonstrate to them an interest in research and show you have enough resources to conduct research
- SMO (Site Management Organization)
  - Entity that contracts with Sponsor and allows everyone participating in their network access to those studies
  - Helpful when you're first starting out
- CRO (Contract Research Organization)
  - Works directly for the Sponsor and is charge of conducting the study at multiple sites
  - If the CRO has worked with you in the past, they can recommend you as a site

Develop Standard Operating Procedures (SOPs)

- Informed Consent Process
- Temperature Monitoring
- Temperature Excursion
- Investigational Product (IP) Destruction
- Documenting Adverse Events / Serious Adverse Events

- You can search for a standard template online and modify according to your site's guidelines as long as they meet FDA guidelines