Tips to Increase Screening / Enrollment in Clinical Trials

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Screen *Better*, Enroll More!

- We all have many daily goals
- Our highest goal = *more efficiency*
  - Eliminates wasted time
  - Allows us to do more!

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Why Research is Difficult

- Physicians are busy being physicians, and allocating to research costs time and money
- Paperwork.. greatly increased
- Hard to find good help
- Managing personnel
- Regulatory Concerns: Unfriendly Review boards, Audits and Warning Letters
- Still have to find patients!

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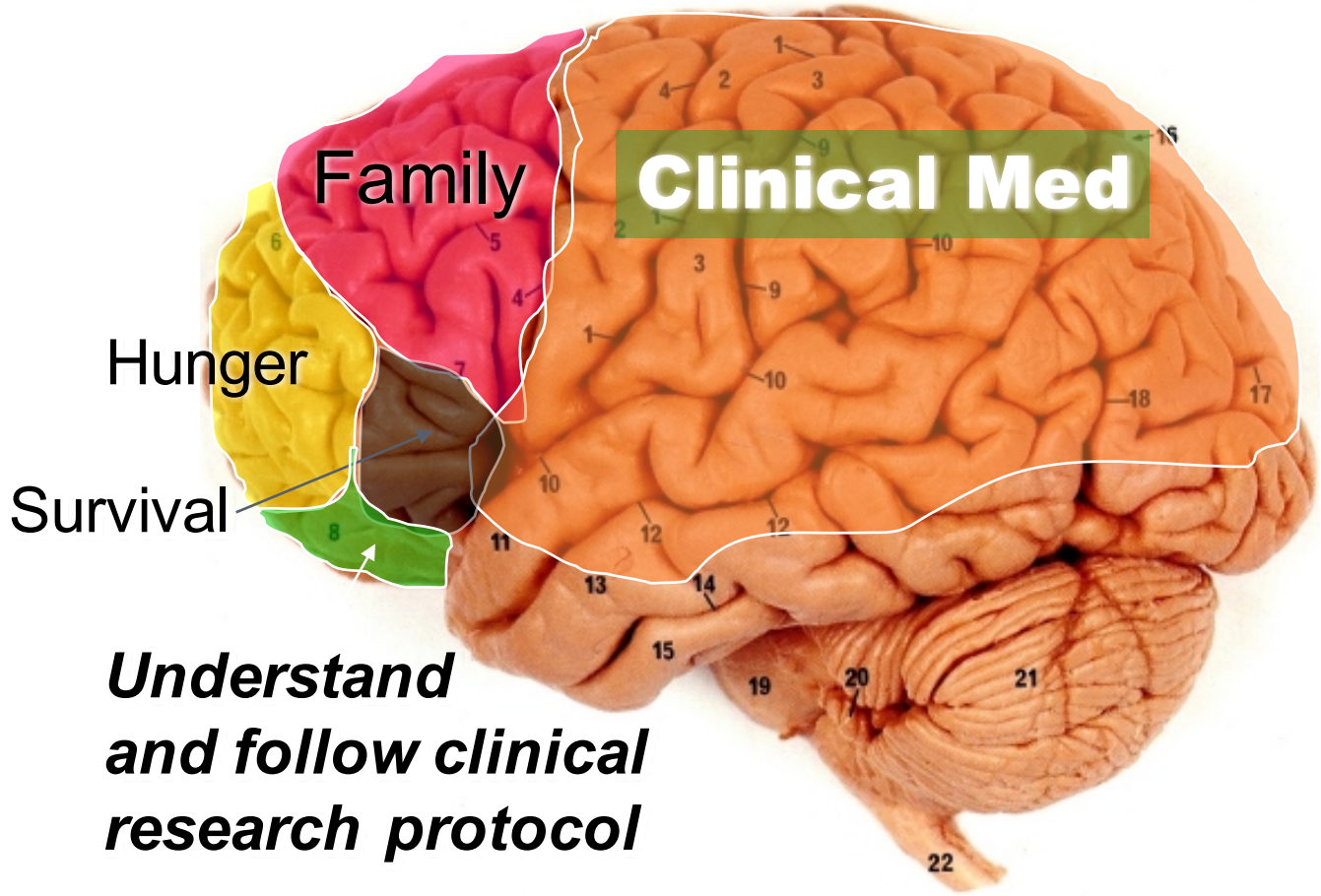
A Hypothetical Clinical Investigator's Brain



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So why do it?

- Evidence-based medicine = pride of Cardiology
- Accessibility to new devices and therapies
- YOU can add credibility to data
- It can be fun and rewarding!
  - Establishment of a team/center of excellence
- Goes beyond routine clinical care

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Screening Starts with the Protocol!

- The protocol has to fit your site's interest and practice patterns or otherwise you are wasting everyone's time.. *AND YOU MUST FOLLOW IT !!!!!!!!!*
- Know the strengths of your site—if you aren't a big primary PCI center, don't do primary PCI protocols.
  - Enthusiasm can be great, but if you fail to deliver, there can be lasting consequences

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Protocol-Specific Issues

- Some protocols lend themselves to enrollment---easy randomization, familiar devices/drugs
- *Success in research is more dependent upon enthusiasm and drive of site PI than how many co-PI's participate*
- Some co-PI's best not involved with complex devices
- We need to do a better job listening to our research nurses and staff (especially when enrollment is poor)

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Budgetary / Process Issues

- This is becoming more and more of an issue in increasingly cost-conscious times
- Does the study allow you to work *within* your current system?
  - Does it budget for *creation of a new system?*
- *What exactly is paid for??*
- Be careful of overcommittment
  - Data shows that Ponzi schemes fail

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Nurses/Staff: Keystones of Research

- *A intelligent, patient-oriented research nurse who takes ownership of protocols and good research practices is essential*
- Identify and hire nurses interested in clinical research
- Experience can be taught…enthusiasm cannot be!
- Visit a site doing research in a setting similar to yours…do it again and compare notes later.

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Growing the Research Nurses

- Goal: Make involvement in research what every nurse wants
- Team-based mentality with ownership of the study are very attractive propositions
- Great hours, nice investigator meetings, pride in enrollment status
  - Remember to treat them well!
  - Turn-over is going to happen, so growing the culture to attract others is important

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Better Screening: Research Nurse Responsibilities

- Identify patients / cast a very broad net (miss no one)
- Consent Patients / Gets PI for any pt queries
  - PI aid is critical….you set the tone!
  - Know protocol so if PI absent, sub PI follows
- Streamline in-house processes, report MACE events, post-enrollment concerns
- Late follow-up can be split with other nurses

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Screening Logs: Not Just for the Sponsor

- Intelligently designed screening logs can help you identify the source of the problem
  - Not just name, date, MRN
- Don't view this just as a checkbox responsibility
- Look over these from time to time (or get them sent to you)… not all "failures" may be failures in the long-term

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How to Enroll

- ALL patients are potential research candidates
- Early rounds: research nurses and doc meet to identify possible patients to consent (e.g. in cath lab for a lab study)
- Consenting by research nurses with back-up
- Research nurses in lab with patient as cath done to help with protocol question
- PI availability is CRITICAL

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FDA issues

- FDA audits increasingly ferocious
- **Site PI** not co-PI's or research nurses is held responsible
- Your oversight is critical
- A bulldog research nurse saves the day
- Documentation must be consistent

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Your job as study PI

- Know the protocol
- All events in the protocol at your site belong to you
- Report any issues/events of significance to national PI STAT
- Coordinators/Co-PI's are willing but nervous about 'doing wrong'
- The kiss of death—co-PI's unwilling to enroll because of confusion over protocol or harsh criticism by site PI

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Subinvestigator(s)

- Other members of the team
- Should be directly involved with subjects in the study
- *It is the investigator (and not the subinvestigator[s]) who is held responsible for the study site and subject to enforcement action for violations of FDA regulations*

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Don’t be this PI

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Problems in Paradise

- IRB issues
- Referral practice patterns
- Consent nightmares
- Patient post-enrollment queries—

  de-enrollment
- Co-PI fatigue…”not another protocol!”
- Research nurse turnover

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Persistence is Critical

- Finding patients is like finding/establishing new referrals
  - Takes time, and don't get discouraged
- Use EMRs to your advantage
  - Screening labs, meds, clinical characteristics
- Think like a marketing person: find and exploit "nodes" of influence

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Research Nurse Concerns

- “I’ve screened lots of patients for this protocol,….none seem to fit!”
- “I’ve been scanning the labs to see if patients qualify…none do”
- “Mrs. Jones qualifies, but I couldn’t get her to sign the consent”
- “I asked Dr B to talk with Mr White about the protocol…he wouldn’t”

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Managing Co-PI's and Research Docs

- "Why are we screening so many patients but enrolling no one?"
- "I really don't have time to explain the protocol to anyone"
- "Its not my job to get the protocol signed"
- "I don't really need to follow that part of the protocol"

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Some Specific Suggestions…

- "We need to sit down and better define how to get patients screened for a specific protocol"
  - It may take a focused intervention (e.g. for the next 3 weeks, bug docs to help with screening and identifying patients)
- The 'White Coat' effect…docs should be involved in explaining protocol, research
- We all can learn from each other!!
- Once it clicks, should be self-sustaining

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