

Navigating the Boundaries between Research and Clinical Care



Definitions

- Clinical care
 - Paid for doing it
 - Sued for not doing it
- Research
 - Not paid for doing it
 - Sued for doing it

Boundaries between what?

- Purpose
 - Research – focus is generalizable knowledge
 - Clinical – focus is the individual
- Type of information
 - Research: discovery, interesting, waiting to be accepted
 - Clinical: acceptance suggests relative ‘truth’
- Rules of engagement
 - Research: IRB, consent? Waiver?
 - Clinical: ‘clinical’ consent forms sometimes....or else just show up

Boundaries between what?

- The inhabitants on both sides of the boundary
 - ‘Extreme’ researchers
 - Do not realize that tissue sample come from a person
 - Primary clinical players: clinicians, payers, administrators, different IT people
 - Often with no training in research
 - *Luckily we have straddlers: researchers, clinicians, IRBs, funders, IT*

Boundaries between what?

MORE ON THE INHABITANTS

- Extreme Researchers
 - Gotta get moving – this is ready for launch
 - Systems had better be in place...because it is coming...

Look at all the great data we have...



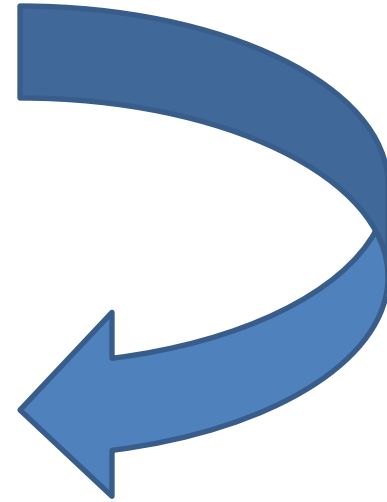
Boundaries between what?

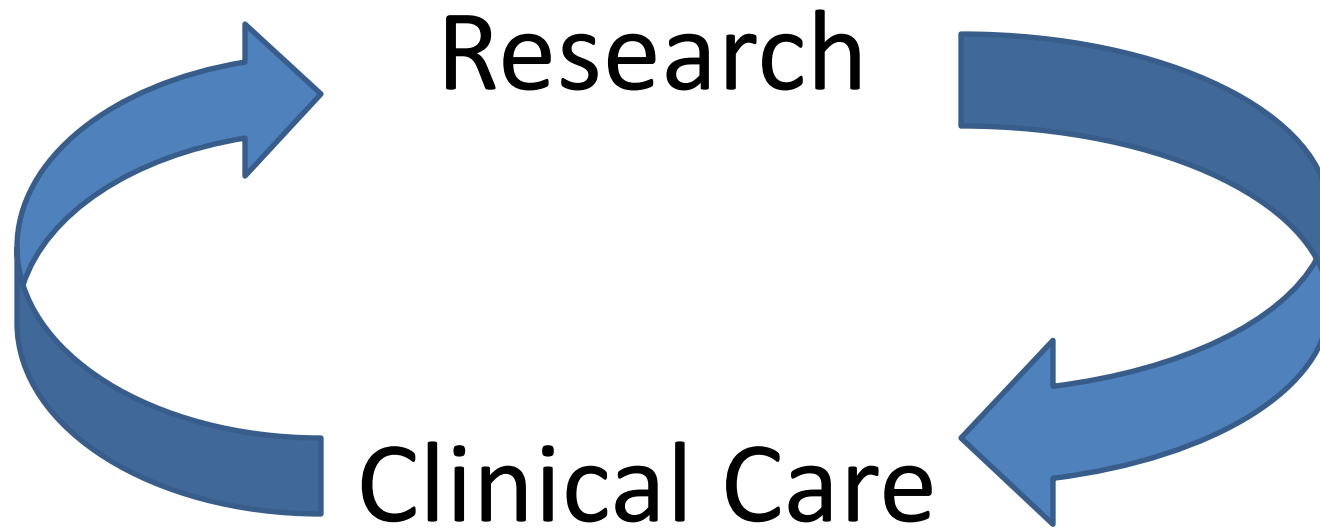
MORE ON THE INHABITANTS

- Clinicians
 - Another ‘over-promise’
 - Researcher errors of enthusiasm
 - Even my ‘genetics’ friends do not agree
 - Simply too fluid
 - There are too many other problems
 - When I have to do it I shall be told
- Public
 - Perhaps ahead of most clinicians?

Research

Clinical Care





We need more straddlers

- Researchers who understand and can interact with the clinical enterprise
 - Understand concepts of validity and utility
 - Clinicians are more than sources for tissue and data
- Clinicians who can interact with the research community
- Clinical systems with rational adoption strategies
- IT systems that can robustly capture and respect the differences between clinical and research needs
- Payers who endorse adoption of new ‘stuff’

We need more straddlers

- A public that understands the need for investment in research
 - Opposing interests
 - Citizen model:
 - “Fine, use my stuff – do not bother me with all these consents.”
 - More ego-centric model: (Havasupai, Henrietta Lacks, Neonatal Blood Spots)
 - Need to control uses and users of one’s materials
 - Expectation of return of research results
 - Payment

Comment on the regulatory environment

- Common Rule
 - 1970's oversight for 2011 research
 - ANPRM – stay tuned
 - Identifiability of tissue (DNA)
 - Requirement for consent for use of tissue and data
 - Possible loss of waiver capacity
- Lack of standardization
 - Common Rule, FDA Regs and HIPAA
- Lack of guidance on 'genetics'
 - Leads to inconsistencies between IRBs
- Keep your eye on HIPAA and HITech