

Research with Human Subjects

False Hopes and Best Data

Appelbaum

- *Therapeutic misconception* – People just don't believe that they will be randomized
 - o Study found that around 60-70% of people did not understand they were being randomized
 - o Concept of “personal care”- which is that a doctor tailors therapy to the individual is socialized in our society – people still believe that care is being personalized
 - o Personal care – Term coined by Charles Fried: physician's obligation is first to the patient's well being and is to maximize benefit
- Medical research has properties that interfere with personal care
 - o Randomization
 - o Rigid protocols: i.e., can't adjust dose to minimize side effects, must discontinue from study
 - o Need for wash out period, which may make patient feel ill, or risk relapse
 - o Lack of adjunctive medications may make patient feel worse
- Arguments- what should we do about therapeutic misconception?
- Is IRB approval adequate?
- Patients can be taught if time is taken – but who should teach them? The researcher? A neutral explainer- who may be responsible to the IRB?....
- Consider that it may be unethical to continue present therapy without being certain that it is the best available – i.e., need blind RCT to verify the truth – and need patients to enter study to do that
- Neutral explainer may help circumvent anger/dissatisfaction in patients when if after the study they realize that their care was not personalized