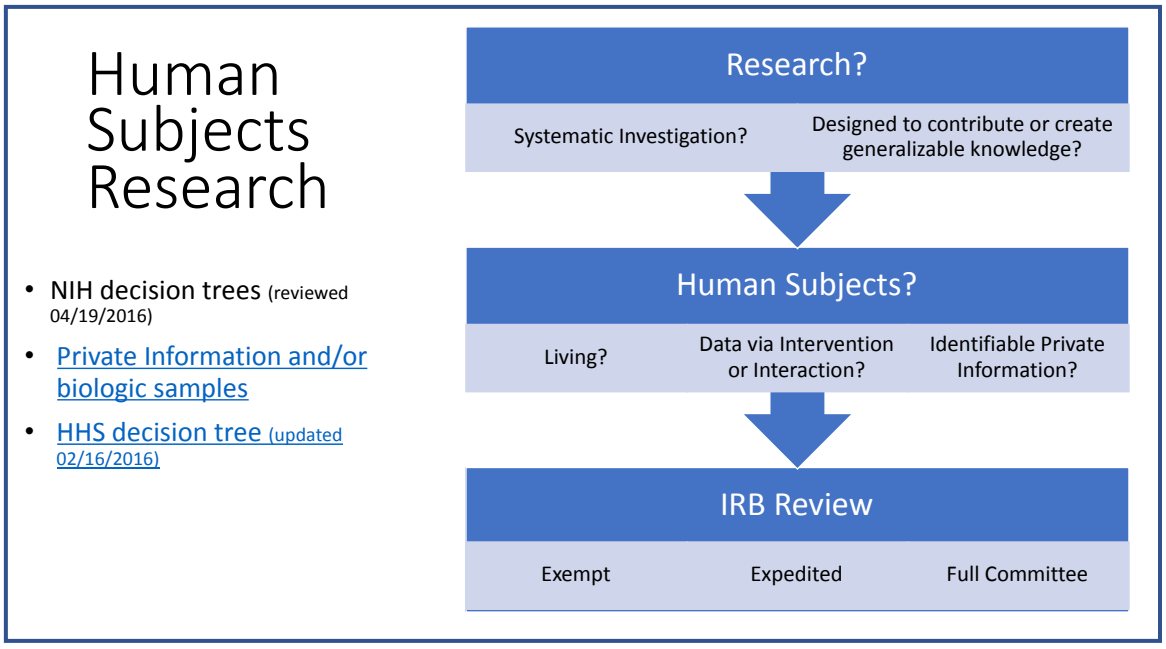
Cases for RCR/SOS (November 12, noon -2pm)

TRAINEE VERSION



Cases for discussion during noon -1pm seminar

1. A faculty member wishes to distribute and collect evaluations from undergraduate students attending their class/seminar.

   Evaluations are a component of the class/seminar, however the faculty member wishes to add 2 questions to the evaluation form to better assess student needs and interests in the topic. This information will help improve the class/seminar.

   No names or identifying information will be collected with the evaluations.

2. A faculty member wishes to send out a survey to colleagues (pharmacists & Infectious disease clinicians (NP, MD, DO)) to assess their level of knowledge, regarding pre-exposure prophylaxis (PrEP). PrEP is known reduce HIV incidence when taken regularly.

   This survey data will be used to design and inform additional interventions to increase PrEP competency among health care providers and to increase prescribing rates.

Cases for discussion during 1pm-2pm (or other designated) break out small group session

IRB CASES (30 minutes)

1. A lab proposes to investigate looking at various bacteria isolates & growth media & techniques to identify the best possible ways to culture the isolates for use in future projects

   The isolates will be obtained from a commercial source (ATCC) and the information will only be used by the lab for internal purposes.

2. An investigator has been contacted by a Sponsor to evaluate a new diagnostic assay tool using bacterial isolates.

   The isolates will be obtained from a commercial source (ATCC) and the information will only be used by the lab for internal purposes.

   The Sponsor will be submitting the information from this protocol to the FDA.

3. A department has been approached to participate in a national database regarding palliative care in the US and will be used for accreditation of the program.

   The purpose of the database is to provide quarterly quality assurance reports along with national benchmarks/trends to each participating institution.

   Twist! The database will also make the data collected available for researchers to use and researchers will need to sign a data use agreement prior to receiving the data.

4. All M1 students will be asked to complete a survey to collect information regarding their history of playing videogames. This survey will be administered at the same time as a standard assessment of spatial awareness.

   This information (gaming history, spatial awareness assessment, grades) will be analyzed to see if there is a relationship between the type of videogames, a student's spatial awareness and overall success in the course.

   The team plans to collect this information systematically over the next 4 years with the possibility of expanding to other medical schools.

5. Medical students for their scholarly project wish to develop and implement a screening tool to screen, identify and treat latent TB among patients being seen at the local free clinic.

The project will evaluate the number of screenings completed and outcomes of those patients.

This information will be presented as a poster at MCW.

6. An Investigator wishes to obtain 200 colon cancer tumor samples from the NCI specimen bank to examine for a certain biomarker expression.

   All the specimens will be coded and the MCW investigator will not receive any identifying information except date of diagnosis, date of specimen collection.

7. A clinician has identified a patient that they would like to write up and publish as a case report. No identifiers will be included with this report.

   The treating physician has obtained HIPAA authorization from the patient for this case report.

8. You have been approached by a colleague at another institution to collaborate on a research project with them. They would like for you to analyze data which will be collected for their NIH research project looking at a new intervention to be used in life-threatening traumas.

   The research is proposed to be carried out in a number of major metropolitan areas and their Level 1 trauma centers.

   The data will be provided to you coded, and MCW will not be a participating site (i.e. recruitment & enrollment of subjects).

9. A research team would like to conduct a prospective observational investigation of Olanzapine vs Haloperidol vs Ziprasidone vs Midazolam for the treatment of acute undifferentiated agitation in the ED.

   All 4 drugs are currently used in this setting and the team is looking to evaluate the safety and effectiveness of each of these compounds and will collect the information from the medical record.

   The team has identified a set time period each drug will be used in the ED setting and this will not decided by the treating clinician.

10. An MCW Investigator is partnering with community clinics to begin to look at the components which go into the patient decision-making process when opting for colorectal cancer screening.

The team will be assessing and providing patients knowledge about colon cancer, risk factors and available options for screening. Patients will be randomized to 1 of 3 arms:

- Individual risk assessment & shared decision making
- Non-invasive screening & no financial barrier
- Invasive screening and limited financial barriers

Follow up will occur 2 weeks (via telephone call) and again 12 months later.

TISSUE BANK CASE (20 Minutes)

Aortic tissue samples from patients undergoing cardiac transplantation have been collected and stored for many years. Permission for the sampling was granted under the blanket research approval in the surgical consent form. Previously, investigations were permitted under waiver of IRB review because the samples were used completely without identifiers. The samples (n=2000) were dated and stored untouched in liquid nitrogen.

The medical team gave permission to Dr. Gomez, a geneticist, to sample all 2000 specimens to study the prevalence of a number of gene polymorphisms proposed to relate to development of dilational cardiomyopathy. The genetic findings were to be related to a specific patient by identifying the tissue donor by correlating the sample date to the operative schedule. Dr. Gomez claims that no IRB approval or new consent forms were required for this study because the study did not utilize individuals, only stored tissue.

Questions and answers:

1. Is IRB approval required?

2. Are there any limitations on Dr. Gomez' access to the tissues?

3. To perform a complete genetic search, Dr. Gomez would like to provide some of the material to other labs including some commercial labs. Are there any limitations to that?

4. There may be several forms of dilational cardiomyopathy. Dr. Gomez plans to arrange for a cardiology fellow to collaborate and to review all the charts to distinguish between the clinical forms of the condition to further define the genetics. Is there a problem with this?

5. If there are problems how should they be handled?