Patient Advisory Council and IRB Meeting

- Feedback last year indicated that a meeting of engagement group and IRB (Institutional Review Board) group would be very valuable
- IRBs work under a framework of regulations, “common rule” which hasn’t been updated since 1991, but changes are coming as early as January
  - This will change quite a bit of processes and what is looked for
- In January 2017 revisions were issued and the majority are scheduled to go into effect on January 18, 2018, revisions include:
  - Continuing review: no longer required for some minimal risk research
  - Exemptions: updates to categories and new categories
  - Informed consent
  - IRB of record
- Informed consent process
  - Consent must begin with a concise and focused summary of the key information that is most likely to assist the subject, or legally authorized representatives in understanding the reasons why one might or might not want to participate in the research
  - Requirement applies to all informed consent processes
- Where did the need for the concise summary come from? Whose idea was this?
  - When the director of federal agency was asked, it was stated that there was no patient involvement in the decision. However, an involved institute did have some participation in engagement activities and feedback.
  - What is the key information that needs to be presented? Is what we consider to be key information going to be key for all individuals?
- Thoughts on current informed consent documents:
  - Smoking Cessation
    - Not written well and is discriminatory
    - Too long and detailed
      - How would you explain to a friend? It would be much shorter and only cover the things the participant may be interested in
      - A bulleted two paragraph summary would be much better
    - Who, what, why is missing
    - Readability needs improvement
    - There were many more negative aspects than positive – easy to find negatives, had to reach for positives
    - Need to emphasize that we care about the population being studied
    - Still include negatives, but need to start on a more positive note so people don’t decide they are not interested before reading the entire page – why is this beneficial to you? Here are the reasons why you may not be interested
  - Antibiotics Study
    - Headers in summary made it easy to read, but bullets would also be good to make it easier to read
• If this is supposed to be key information, but the summary did not provide enough information that would be valuable to potential participants
  • Says if you are not in the study you will receive surgery... is this true?
  • Doesn’t include risks of antibiotics vs. surgery
  • Provided a very good introduction into having patients ask more questions from the investigator – we like to see this kind of communication, but there still needs to be more included in concise study
  • Says people in Europe are more likely to get antibiotics than surgeries, but doesn’t state why
• People could not determine if they qualify for this study or why they should be interested from reading the concise summary
• Cons of study need to be included as well
• Overall, this did not g
  • AZet to as many questions as one would have
• Summaries need to be labeled as summaries
• Summary does not mention that this is research and possible benefits are not known at this point as the researchers really don’t know
  • Heart Study
   • What would we want to know if we would be in a study?
     • Why are we doing the study?
     • What is expected of me?
     • What are the risks and benefits?
     • What is the compensation?
   • Summary was confusing on where it started and where it ended and what was part of the summary vs. informed consent
   • Bulleted part of diagnoses assumes that if you have that diagnosis you will know what it is, but terminology is way out there
   • After reading, still not sure what is being studying
   • Wording needs to be more patient friendly so they know what is going on rather than being confused and more worried than necessary with routine procedures that are not described properly that they would be fine with if they had a clear understanding
• Hemodynamics Project
  • Should state costs of alternatives
  • How will patients know about results?
  • How long will it take to get the results?
  • Liked having the headings so they can focus on sections they are particularly concerned about
• Purpose of concise summary is supposed to enhance understanding of informed consent documents
  • This is at least a start, and could continue to be improved upon
- Some people think a page is too long, and others think longer would be better. Majority opinion is that shorter is better though (less than a page)
- Will concise summaries be the same format everywhere? No
  - Would be nice if everyone could follow the same template
- What is the study, why does it matter? What will the impact be? What is expected of patients and investigators? What is the obligation for transparency?
- Structure could be the headers, and they should be pretty standard across the board