**Tips for Drafting the Key Information Section of the Informed Consent Document**

**Things you should know about the Key Information Section:**
- KUMC will require a Key Information section for consent forms that are longer than 8 pages.
- The purpose of the Key Information Section is to provide subjects with the key points that will help start their decision-making process about whether or not they want to join this study.
- The federal government advises us to think of this section as a decision aid.
- Key Information does not replace the consenting process.
- Study personnel must still review the entire consent document with potential subjects.

**Formatting:**
- The Key Information section will likely be 1 – 2 pages in length
- Paragraphs should be 1 – 3 sentences
- Write short, simple sentences
- Aim 6th – 7th grade reading level
- Consult the templates on our website as a starting point; however, investigators are free to consider other formats that meet the goals of the section
- Study teams are encouraged to include a flow chart or diagram to improve comprehension

**Questions and examples that may help determine the content for your particular study**

Why are people interested in joining your study?
- Reason for the research
- Subject population
- Nature of the test article
- Willingness to contribute to discoveries that benefit future patients

How does this study differ from their other options?
- Access to a new drug
- Free medications or frequent monitoring
- Improved quality of life

What extra procedures will occur solely because of the research?
- Highlight research vs standard care
- Explain what will be different or extra if they decide to join

What must they be willing to do if they decide to join?
- Attend frequent study visits
- Forego standard meds
- Postpone standard care
- Be willing to be randomized
- Be willing to be assigned to an early dose in dose escalation that might not be effective
- Self-inject
- Share their genetic data
- Accept impact on future care options
In your prior studies, why did some people decide not to join? *These concerns may indicate issues that should be addressed up front.*

- Time commitment (duration or number of study visits)
- Not wanting to be randomized
- First-in-human study or little data about drug effectiveness
- Lengthy screening period
- Ineligibility for future studies because of receiving the study therapy
- Concerns about the use of genetic information
- Concerns about impact on insurability

In your current studies, what are some of the typical complaints from subjects? *These also may indicate issues to address up front.*

- Certain burdensome side effects
- Inconveniences such as the daily diary, dietary restrictions, etc.
- Lifestyle changes such as double-barrier contraception

What are the top 2 – 5 side effects you are anticipating?

Are there rare but serious side effects you will be closely watching for? (include 1 – 2 if applicable)

Will participants get individual results?

Is there any way you could condense the study plan into a diagram or flowchart? (Extra credit points here!)

*It may help to think in terms of The Top Ten Things You Should Know About This Study.*

It may also help to think of the concise summary as the teaser or trailer for a movie.