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.