**Guidance on the Research Summary (Key Information)**

The revised federal rule governing human subjects research (the “Common Rule”) requires changes to the format of informed consent documents. This includes the new element of “key information,” which must be presented at the beginning of the consent form.

The Common Rule defines key information as **a concise and focused presentation** that is **most likely** to assist a prospective subject or legally authorized representative in **understanding the reasons why one might or might not want to participate in the research**. Currently there is little federal guidance providing a more detailed description of what key information must include. This JHM IRB guidance has been developed to assist investigators with complying with this requirement pending further clarification from DHHS.

**It is important to note that:**

* The research summary/key information **should** include information about why an individual **may not** want to participate (e.g. significant time commitment or risks).
* Information in the research summary/key information **should not** be a direct cut and paste from information found in the main body of the consent form.
* If the study is first in human or first in a particular population (e.g. children or people with a specific diagnosis) this must be clearly stated in the summary/key information.
* The content of the research summary/key information will vary depending on the nature and complexity of the research.
* This research summary/key information section will introduce the study to participants as an **overview**. The sections of the consent form that follow will provide the complete details. Participants must read the entire document before making their final decision.

**Suggestions:**

* Consider what key facts and concise information you would present to a lay person if you had less than 10 minutes to explain the study (“what”, “who”, “where”, “when”, “how”) that can be conveyed in 2-3 paragraphs.
* Present the key information in the same order in which the information will be presented in the body of the consent form (e.g. the description of the research procedures is followed by a description of the risks of participation).

**Examples:**

***Example 1:***

This is a research study to determine the safest, most effective dose of the drug ABC-123 for people with XYZ disease.

Depending on when you enroll in this study, you will receive higher doses of ABC-123 until the safest and best tolerated dose is reached. ABC-123 is given via *i.v.* infusion in the clinic. You will have tests, exams and procedures that are part of your standard care and for study purposes. Each clinic visit will last 4-5 hours. Infusions of study drug will be given during week 1 of each 3-week cycle. After two cycles, you will be evaluated and you may be able to continue receiving ABC-123 if you have had no bad reactions to the study drug or disease progression.

There are risks to this study drug that are described later in this document. Some risks could be serious and not all of the side effects/risks are known.

***Example 2:***

The purpose of this research study is to determine the effectiveness of physical therapy in the treatment of people with ABC. Participants will undergo a 2-day screening that includes a blood draw, exercise testing, and completion of quality-of-life surveys. Once screening is complete, participants will complete a physical therapy program that will require visits 3 times each week for 16 weeks, for a total of 48 visits. Each visit will take about 2 hours. Participants will also be asked to complete a pain diary and have blood samples taken every 4 weeks throughout the study. Follow-up phone calls from the study team will occur at 4 weeks and 8 weeks after completion of the physical therapy program. Total study duration is about 6 and one-half months.

The greatest risks of this study include the possibility of injury during the physical therapy program and loss of confidentiality.

***Example 3:***

The purpose of this study is to compare the gastrointestinal (GI) tract in children with Inflammatory Bowel Disease (IBD) and children without IBD.  The information we learn by doing this study may help us to develop some target treatments for GI complications in children with IBD but participation in this study is not expected to benefit your child directly.

Participants in this study will have a blood sample collected and a small piece of tissue removed from their intestine during their clinically scheduled procedure. The comparison of tissue from both groups of children will be done in the laboratory after collection of the tissue. Parents of participating children will also be asked to complete a questionnaire. Your child’s participation is complete once the medical record and questionnaire have been reviewed, and the tissue and blood sample have been collected.

There are risks to having the tissue sample collected that are described later in this document.