**Template CHLA Document for Adding a CHLA Key Information Section for Consent Forms**

**Version Date: 03-01-2021**

|  |
| --- |
| The CHLA IRB requires a **key information summary section**. This section must come first and should include a concise summary of information that is relevant to why someone might or might not want to take part in the research. The entirety of this section should be no more than one full page in length. **Instructions:**Check in with the sponsor/CRO to determine if the sponsor’s consent template approved by the central IRB includes a key information section. 1. If the sponsor template includes a key information section, this **document is not required**.
2. If the sponsor template **does not include a concise summary or key information section**, complete this document and include it with your CHLA ceded review submission **and** your submission to the central IRB for the study.
 |

**KEY INFORMATION**

You are being asked to participate in a research study. This section describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide the details of the research.

**What should I know about this research?**

* Taking part in this research is voluntary. Whether you take part is up to you.
* If you don’t want to take part, it won’t be held against you.
* You can take part now and later drop out, and it won’t be held against you.
* If you don’t understand, ask the research team questions.
* Ask all the questions you want before you decide.

**How long will I be in this research?**

Participation will last up to \_\_\_\_. [indicate maximum time of participation, if a subject completes all procedures]

**Why is this research being done?**

This research is being done to find out \_\_\_\_. [keep to a single sentence, such as “… the best way to treat people with Cystic Fibrosis.” or “…how teens think about drug use in their social group.”]

**What happens to me if I agree to take part in this research?**

Study procedures for this research are: [Briefly in simple terms list the procedures that are key to the research and are most likely to affect someone’s decision about whether to take part in the research study. A bulleted list is acceptable.] Examples:

* Take a study drug every week by injection under your skin.
* CT scan(s). If you are not able to lie still during the scan, you will get some medicine to help you sleep.
* Complete questionnaires about your view on drug use in teens and young adults.
* Have blood drawn by inserting a needle into a vein or by using your port.
* Complete a diary every day to record your medication use and any side effects that you experience.
* Let the research team record information from your medical record related to your condition and the treatment you receive.

**Could being in the research hurt me?**

The most important risks or discomforts that you may expect from taking part in the research are: [Briefly list **up to 5** main study risks in lay terms most likely to affect someone’s decision about whether to take part in the research study – pick only the most common risks. A bulleted list is acceptable.] Examples:

* Trouble breathing
* Feeling uncomfortable answering personal questions about yourself
* Chemo side effects, such as feeling tired, losing hair, and nausea.
* Allergic reactions
* Irregular heart beat

Please see the risks section below for a complete list of expected risks.

**Will being in this research benefit me?**

The most important benefits that you may expect from taking part in this research are: [Briefly list the reasonably expected benefits to the subject most likely to affect someone’s decision about whether to take part in the research study. Keep it to **one** sentence. If there are no benefits, state: It is not expected that you will personally benefit from this research.]

**What other choices do I have besides taking part in this research?**

Instead of being in this study, your choices may include: [List the major approved alternative options that are available that may be advantageous to the subject. If this is a study in which there is no disease or condition being treated, you can eliminate this section from the summary, and include it only in the body of the consent. If there are no alternatives, this section can be omitted. Briefly list the alternatives: **2 maximum**.] Examples:

* Get routine care or treatment for your condition.
* Join another clinical research study.

**What else should I know about this research?**

Other information that may be important for you to consider so you can decide whether to take part in this research is: [Describe any additional information that may be important to know for this study, such as study requirements that may burden subjects, e.g., an extensive study visit schedule, time away from work, overnight stays, etc. If this does not apply, this section can be omitted.]