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Institutional Review Board

**Instructions for the Informed Consent and HIPAA Authorization for Research Template**

1. This template, developed by Weill Cornell Medicine’s Institutional Review Board (IRB), has been created to assist the Principal Investigator (PI) in the design of their informed consent form (ICF). It is important that PIs adapt their own ICFs to the outline and requirements of their particular study. Ensure descriptions and added details are written in plain language that is clear, easy to understand, and in a way that facilitates comprehension.
2. Do not be concerned by the length of this template. It is long because it contains guidance and explanations which are for you and which you will not include in the informed consent forms that you develop and provide to participants in your research.
3. Consider the method or mode of communication and informed consent process with potential participants. For example, when using email communication consider informing participants that email is not secure way to communicate about your health or to share private information given there are many ways for unauthorized users to access email.
4. In this template:
   1. Square brackets ***[containing red bold and italicized text]*** are instructional to you.
      1. Once the instructions are followed, the ***[bold and italicized text]*** should be deleted from the template before proceeding.
   2. Square brackets containing [red text] are intended as template language to include, if applicable to your study, or to remove, if not applicable to your study.
      1. If the template language is applicable to your study, remove the square brackets and make the font color black.
   3. When you’ve completed the creation of the ICF, there should be no red text remaining.
   4. Please ensure that you update the header and footer.
   5. Prior to submitting to the IRB, convert to PDF first, then delete this instructional page.

TEMPLATE ON THE FOLLOWING PAGE

|  |  |
| --- | --- |
| **Project Title:** |  |
|  |  |
| **Research Project/Protocol #:** |  |
| **Principal Investigator:** |  |
| [Arm/Group] | ***[If there is more than one consent for the study, please indicate the type of consent here (E.g., Screening Consent; Group B Consent). Otherwise, delete this row.]*** |
| **Subject Name or number:** |  |
| [MRN] | ***[If you will not be obtaining the MRN, please delete this row.]*** |

***[If this study involves minors, and this is a parent consent, or if it involves an LAR signing on behalf of the subject, please include one of the following introductory statements as it applies to your study:]***

***[If for Parental/Guardian Permission]:***

Please note that references to “You” or “your” refer to your child [the child] who will be participating in the study for whom you are providing consent.

***[If use of an LAR]:***

This consent form is written to address a research subject. If you will be providing permission as the legally authorized representative of a subject, the words ‘you’ and ‘your’ should be read as ‘the subject’ and ‘subject’s’.]

**Please note, are you currently or have been (within the last 6 months) a participant in any other research study at Weill Cornell Medicine, New York Presbyterian Hospital or elsewhere? If so, please inform the research team.**

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**INSTITUTION: Weill Cornell Medicine *[If applicable, include other institutions participating in this research under the Weill Cornell Medicine IRB’s approval, including institutions that will be receiving data about the subject and/or locations to which subjects will have to travel for research.]***

**STUDY SPONSOR/FUNDING AGENCY: *[specify sponsor and/or funding source; if internal, state ‘Weill Cornell Medicine’]***

|  |  |
| --- | --- |
| **KEY INFORMATION ABOUT THIS RESEARCH STUDY**  ***[Full Board and Expedited studies approved after 1/20/2019 are required to include a Key Information Section (unless your expedited consent form is six pages or shorter, including the Signature blocks). The Key Information Section is required for all studies (Full Board and Expedited) submitted after 4/3/2022. Include the most crucial information from the potential participant’s perspective. The Key Information Section should be concise, no more than 1-2 pages in length.]***  We are asking you to choose whether to volunteer for a research study about [***insert general description of study*]**. This page is designed to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below. | |
| Purpose: What is the study about and how long will it last? | ***[Briefly describe the purpose of the study and the procedures to be followed in lay terms. Specify if the treatment/intervention administered in this study is similar to, or different from the standard of care the participant would receive if not in the study. For detailed descriptions, use the Consent Document.]***  By doing this study, we hope to learn \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. Your participation in this research will last about **[*state in hours, days, months, years*]**.  ***[If testing Food and Drug Administration (FDA)-regulated products for safety or effectiveness, include the following]****:* The purpose of this research is to gather information on the safety and effectiveness of \_\_\_\_\_\_\_\_\_\_\_\_ ***[state name of drug, device, etc. Indicate if the drug, device, or biologic is FDA-approved and whether it is being used in the study for an alternate use or consistent with labeling indications]****.* |
| Benefits: Key reasons you might choose to volunteer | **[State the most important reason(s) {i.e., potential benefit(s)} of volunteering to participate in this study. For studies with no direct benefit, we suggest:** [The study will not include a direct benefit to you. However, some participants appreciate knowing they have contributed to research that may benefit others in the future.] For a complete description of benefits, refer to the Consent Document below. |
| Risks: Key reasons you might choose NOT to volunteer | ***[State the most important reason(s)/risk(s) why a participant may NOT want to volunteer for this study considering the participant’s perspective. Items to highlight for the participant could include large out of pocket expenses, participant responsibilities that many people might consider burdensome (e.g., abstinence from sexual relations, cigarettes or alcohol, inability to drive a car while taking study medication, need for overnight stays or admittance to a secure facility), potential impact on non-participants (e.g., caregivers, family members, children, partners), or serious implications for future treatment (e.g., use of an experimental intervention may make a standard clinical intervention ineffective or unavailable after the study, or lack of post-trial access to the experimental intervention).]*** *For a complete description of risks, refer to the Consent Document below.*  *[****If******alternative treatments/procedures are key to the participant’s choice, discuss those that might be advantageous to the subject or indicate if no known alternative exists.]***For a complete description of alternate treatment/procedures, refer to the Consent Document below. |
| Voluntary Participation: Do you have to take part in the study? | If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights or access to care ***[delete ‘or access to care’ if not applicable]*** you would normally have if you choose not to volunteer.  ***[Add the following for student volunteers:]***As a student, if you decide not to take part in this study, your choice will have no effect on your academic status or class grade(s).  ***[Add the following for employees of WCM/NYP]***As an employee of WCM/NYP, if you decide not to take part in this study, your choice will have no effect on your employability or performance review. |
| What if you have questions, suggestions, or concerns? | The person in charge of the study is ***[Principal Investigator]*,** [PI]. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is**: [*PI contact information]***.  If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the Weill Cornell Medicine Institutional Review Board (IRB) between the business hours of 9am and 5pm EST, Monday-Friday at 646-962-8200 or send an e-mail to [irb@med.cornell.edu](mailto:irb@med.cornell.edu). |
| **This overview does not include all the information you need to know before deciding whether to take part in the study. Much additional detail is given in the full consent document, which can be found on the pages that follow. Be sure to review the rest of this consent form before deciding about participation.** | |