Informed Consent Template Guide

Always refer to the text in blue on the consent form templates for guidance with each section. This document should be used in conjunction with the consent template to provide additional information or to highlight specifics that may not be explained in detail on the form.

*New template additions or changes are highlighted in yellow

GENERAL:

- *The Informed Consent process is not complete without participant signatures on both Informed Consent Parts I and II. Part I is the consent form and Part II is the HIPAA form.*
- *Every consent form must have a separate HIPAA form.*
- *The minimum font size that should be used in the consent form is 12pt.*
- *Consent forms must be written in a manner comprehensible to someone with an 8th grade reading level and layman's terms shall be used in the description of the research. No scientific or technical symbols should be used without explanation.*

SECTION HELP:

Header

- The Header should only consist of the PBRC IRB# in the top left. The right side should remain blank for the IRB approval stamp.

Footer

- The Footer must contain the version date and page numbers. Other language (such as the Protocol version) may be included if requested by the PI or the sponsor.
- The version date in the footer should match the version date in the footer of the corresponding HIPAA form.

1st Page

- "Study Sponsor" has now been added under the "Title of Study"

Section 4

- Approved language regarding food allergies has been added to the template

Section 5

- Table of Procedures (Train Schedule) needs to fit on 1 page and not flow over to the next page. You may have multiple tables if needed.
- Visit Subheadings & Descriptions
    - Include a description of the procedure if it is the first time it is mentioned. Please check the "Study Procedures with Associated Risks" document on our website for approved study procedures description language. http://www.pbrc.edu/hrpp/forms/
    - If each visit or group of visits is separated into sub-headings, include the following to each sub-heading if applicable: approximately how long the visits will be and any fasting details (fasting visit; how long to fast). Formatting example below for a "Visit 1" that includes a physical exam, blood draw, ECG, and questionnaires.

      Visit 1 – Approximately 1.5-2 hours – Fasting Visit (nothing to drink for 10 hours prior to visit)

        - **Physical Exam** (Include a description of what the physical exam entails)
        - **Blood Work** (IV Procedure) – An IV line will be placed in your arm vein for blood draw purposes and will remain there throughout the testing. Blood will be drawn at specific times. During your IV procedure, a small amount of your own blood (less than 1 teaspoon) will immediately be returned into your vein through the IV after each specimen is collected.
        - **Echocardiogram (ECG)** – An echocardiogram is a procedure that uses sound waves to create a moving picture of your heart. For this procedure, you will be asked to disrobe from the waist up or change into a hospital gown and lie on an examination table on your left side. A gel will be spread on the skin of your chest, and the ultrasound probe will be applied to your chest and directed toward your heart to record the activity of your heart. You will feel slight pressure on the skin of your chest from the probe. You also may be asked to breathe in a certain way or to roll over. Electrodes will be also placed onto your chest to allow an electrocardiogram (ECG) to be performed during this procedure. The entire procedure will take approximately 45 minutes. This scan is for research purposes only and not for diagnostic treatment.
        - **Questionnaires** – (Describe the questionnaire and/or types of questions that will be asked).

Section 6

- Include the risk language for each procedure or drug. Please check the "Study Procedures with Associated Risks" document on our website for approved study procedures risk language. http://www.pbrc.edu/hrpp/forms/

Section 10

- Approved language has been added to the template if the sponsor requires MMSEA information.
- Approved language has been added to the template if the consent form is for a caregiver of an elderly subject.

Section 14

- Please make it clear if the subject will or will not be compensated for screening visits, if applicable.
- Additional approved language has been added regarding payment to U.S. Citizens, taxable income, and payment to Non-US citizens.

Section 17

- "What you need to know about future research with your biospecimens and/or imaging" – This is the new Biospecimens for Future Research Section that has been revamped and also includes language for keeping MRI scans (Imaging) if applicable.
    - This section has been moved after the signature section.
    - If this section is not applicable to your study, remove it. If you are storing biospecimens and/or imaging for future research, select which part applies and delete the rest.
    - It is broken up into 4 parts:
        - Part A: If biospecimens for future research is optional
        - Part B: If biospecimens for future research is not optional
        - Part C: If Imaging for future research is optional
        - Part D: If Imaging for future research is not optional