Informed Consent/Assent Form requirements

The Informed Consent/Assent Form must encompass all requisite consent elements as outlined below. It is strongly advised to utilize NYCHP IRB Consent Templates as they already integrate all these mandatory components of consent.

1. Access and use the NYCHP IRB template available on the "IRB Templates" section of our official website.
2. For CEME, the NYCHP IRB template should be adopted unless a specific consent template is demanded by your institution.
3. All forms must provide a top margin of 1.25" or more on each page to accommodate the electronic approval stamp.
4. The inaugural page of every consent form should be based on the official letterhead of your academic unit or College. Contact your Research Director to procure a copy.
5. For CEME, unless your institution mandates its own letterhead, use the NYCHP IRB letterhead.

If your Informed Consent Form does not fulfill these requirements, it will be returned for necessary amendments.

Mandatory Consent Elements: The consent form must incorporate the ensuing eight elements to demonstrate that the consent process encompassed these crucial principles of Informed Consent:

1. Outline of the research, including the study's purpose, the associated procedures' duration and nature, the experimental procedures, if any.
2. Potential risks that participants might foreseeably encounter.
3. Benefits for participants resulting from the research.
4. Suitable alternative treatments or procedures that might be beneficial to the participant, as applicable.
5. Statement describing confidentiality levels for records identifying the participant.
6. For studies with more than minimal risk, explanation regarding potential compensation, available medical treatments and how to acquire such treatments.
7. Contact details for inquiries regarding research, participant's rights, and research-related injuries.
8. Statement emphasizing voluntary participation, no penalty for refusing to participate, and freedom to withdraw at any time without penalty or loss of entitled benefits.

Additional Consent Elements: The following six elements should be included where relevant, although not federally mandated. The IRB may deem some or all of these additional elements necessary during the review process:

1. Statement about unforeseeable risks to the participant (including embryos or fetuses) due to a specific treatment or procedure.
2. Conditions where the researcher may end participation without participant’s consent.
3. Any extra costs to the participant resulting from research participation.
4. Process and potential consequences of participant's early withdrawal from the study.
5. Statement on how significant new findings discovered during the research will be communicated to participants.
6. Approximate number of participants involved in the study.

Requirements by Other States or Federal Agencies:

1. For FDA-regulated drug or device clinical trials, the statement below is required: “This clinical trial's description will be available on **http://www.ClinicalTrials.gov**, as per U.S. Law. This website will not contain identifiable information about you. It will typically include a results summary. You can search this website at any point.”
2. Statements required by state law and regulations, depending on the study location.
3. Statements required by non-NYCHP Institutional Review Boards reviewing and approving the study.
4. Statements required by sponsored, funding agencies, or other entities with authority over the study