The Clinical Trial Informed Consent Form

Public Posting and Ensuring the ClinicalTrials.gov Statement is Included

Revised Common Rule requirement to post the ICF applies if:

<table>
<thead>
<tr>
<th>Clinical Trial</th>
<th>Funded by a Common Rule Agency</th>
<th>ICF Posting Basics</th>
</tr>
</thead>
<tbody>
<tr>
<td>A research study in which one or more human subjects are <strong>prospectively</strong> assigned to one or more interventions (which may include placebo or other control) to <strong>evaluate the effects</strong> of the interventions on biomedical or behavioral health-related outcomes.</td>
<td><strong>AHQR; DoD; DoE; DoJ; NIH</strong></td>
<td>• Awardee must publicly post (on ClinicalTrials.gov or Regulations.gov) one blank IRB-approved ICF used to consent participants</td>
</tr>
<tr>
<td></td>
<td><strong>IRB-Approved on or after 01/21/2019</strong></td>
<td>• This makes a subset of IRB-approved ICFs public facing documents</td>
</tr>
<tr>
<td></td>
<td><strong>Will apply to clinical trials approved prior to this date when the (still active) trials are transitioned to comply with the Revised Common Rule</strong></td>
<td>• <strong>Process:</strong> JCTO provides monthly OnCore report to LO, who contacts study teams about posting at the appropriate time</td>
</tr>
</tbody>
</table>

Confirmation of this requirement is conducted at the time of pre-review by IRB Analysts, with any questions about its applicability resolved in consultation with the IRB Manager, QA Manager, and/or the CT.gov Administrator.

**It’s important not to rely on SASP to determine whether a study is an NIH-funded clinical trial and/or an ACT!**

<table>
<thead>
<tr>
<th>A study is an <strong>NIH-funded Clinical Trial</strong> if you answer yes to ALL of the following questions</th>
<th>A study is an <strong>FDA Applicable Clinical Trial (ACT)</strong> if you answer yes to ALL of the following questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the study...</td>
<td></td>
</tr>
<tr>
<td>✓ Involve one or more human subjects?</td>
<td>Is the study...</td>
</tr>
<tr>
<td>✓ <strong>Prospectively assign</strong> human subject(s) to intervention(s)?</td>
<td>✓ Interventional?</td>
</tr>
<tr>
<td>✓ Evaluate the effect of <strong>intervention(s)</strong> on the human subject(s)?</td>
<td>✓ With at least one facility in the U.S. or U.S. territory? OR With FDA-regulated product manufactured in U.S. or U.S. territory and exported for study in another country? OR Conducted under an IND or IDE?</td>
</tr>
<tr>
<td>✓ Have a <strong>health-related biomedical or behavioral outcome</strong>?</td>
<td>✓ Evaluating one drug, device, or biological product regulated by the FDA?</td>
</tr>
<tr>
<td></td>
<td>✓ NOT phase 0, NOT phase 1, NOT device feasibility study</td>
</tr>
</tbody>
</table>

**Whereas the definition of ACT excludes phase 0 and phase 1 studies, the NIH definition of clinical trial does not**

If the study you’re reviewing is an NIH-funded clinical trial that is phase 0 or phase 1, the ClinicalTrials.gov statement is still required in the ICF.

**The ClinicalTrials.gov Statement**

Certain clinical trials require an exact, unaltered statement in the ICF, which IRB Analysts will check for during pre-review

- NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information available [here](https://grants.nih.gov/policy/clinical-trials/definition.htm)
- Final Rule for Clinical Trials Registration and Results Information Submission (42 CFR Part 11) available [here](https://grants.nih.gov/policy/clinical-trials/definition.htm)

While a statement is already included in the WCM ICF template in the “Confidentiality” section, Investigators must edit the statement appropriately depending on the following guidelines provided below.

**If the study is interventional and evaluating an FDA-regulated product (regardless of funding source):**

“A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.”

**If the study is an NIH funded clinical trial that is not evaluating an FDA-regulated product:**

“A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.”

**Note:** If the study is NIH funded AND interventional AND evaluating an FDA-regulated product, use the FDA-regulated product language above instead.

**If the clinical trial (per ICMJE) is to be published in an ICMJE Journal but is not an intervention of an FDA-regulated product, nor a clinical trial funded by NIH:**

“A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This website will not include information that can identify you. You can search this website at any time.”

**If the clinical trial is funded by a Common Rule agency other than the NIH:**

“A blank informed consent form will be made available on [ClinicalTrials.gov or Regulations.gov]. This website will not include information that can identify you. You can search this website at any time.”

**If the study (whether observational or interventional) is funded by PCORI:**

“A description of this study will be available on http://www.ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the study results. You can search this website at any time.”
A study evaluating a device would only qualify as an ACT if the device must receive any of the following:

1. A finding of substantial equivalence under section 510(k) of the FD&C Act; or
2. An order under section 515 of the FD&C Act approving a pre-market approval (PMA) application for the device product; or
3. A Humanitarian Device Exemption under section 520(m) of the FD&C Act

- Most Class I devices and some Class II devices are exempt from the requirements for a finding of substantial equivalence under section 510(k) of the FD&C Act and do not require a premarket approval order.
- By contrast, most Class II and all Class III devices require either clearance under section 510(k) of the FD&C Act or premarket approval under section 515 of the FD&C Act.

### Considerations for Trials Evaluating Devices

#### ACT Clarifications

ACTs are interventional studies that evaluate FDA-regulated drugs, devices and biologics (approved or not; with or without an IND or IDE)

- **Does not include Phase 0 or Phase 1 studies**
  Although the term “phase 0” is used in practice (e.g., to refer to clinical trials that are exploratory in nature and are not designed to evaluate therapeutic or diagnostic intent), any trial that would be referred to as “phase 0” meets the definition of a phase 1 trial under FDA regulations (21 CFR 312.21).
  View the Phase 1 definition at [here](#)

- **Does not include device feasibility studies, which constitute:**
  - Evaluation of a device product in a small study (generally fewer than 10 participants) to determine the feasibility of the product; or
  - A study to test a prototype device for feasibility and not health outcomes.
  *Such studies are conducted to confirm the design and operating specifications of a device before beginning a full clinical trial.*

### NIH Definitions

#### Health-related biomedical or behavioral outcome
The pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects’ biomedical or behavioral status or quality of life
- positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression)
- positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers, reading comprehension and/or information retention)
- positive or negative changes to disease processes
- positive or negative changes to health-related behaviors
- positive or negative changes to quality of life

#### Prospectively assigned
A pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial

*Note: Single arm trials still qualify as prospective assignment if assignment is pre-defined in the protocol*

#### Intervention
A manipulation of the subject or subject’s environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints
- drugs/small molecules/compounds, biologics, devices
- procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews)
- strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits)
- treatment strategies, prevention strategies, and diagnostic strategies