

Bertha deLanda

December 2011

Research Compliance Office



# 21 CFR 50.25

(c) “When seeking informed consent for applicable clinical trials...the following statement shall be provided to each clinical trial subject in [informed consent](#) documents and processes. This will notify the...subject (about the)... clinical trial registry databank”



# DEFINITIONS

## ○ Applicable Clinical Trial

Drug or Biologic Study (with or without an IND)



Exceptions:

1. Phase 1 study
2. Expanded access study (e.g., Compassionate Use)
3. Drug used as part of routine care and not under study

Device Study (with or without an IDE)



Exceptions:

1. Small feasibility study
2. Expanded access study (e.g., Compassionate Use)
3. Device used as part of routine care and not under study



# SUMMARY

- Effective date: March 7, 2012
- Does not apply retroactively
- Changes to eProtocol have been made

## APPLICATION

- Informed Consent Templates
- eProtocol Application
- Website
- Other docs (guidance docs, HRPP, etc.)

**Study registration requirement has been in effect since 2007, but inclusion in consent forms is new requirement**



# CHANGES: INFORMED CONSENT TEMPLATE

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

## Changes made to:

- Stanford Medical Consent Templates
- VA PAHCS Medical Consent Templates
- Short Form (all versions)





- Personnel Info
- Participant Population
- Study Location
- General Checklist
- Funding
- Resources
- Protocol Information
- Obligations
- Check for Completeness
- Print View
- Event History

Submit Protocol

### General Checklist

Yes	No	<b>Multi-site</b>
<input type="radio"/>	<input checked="" type="radio"/>	Is this a multi-site study? A multi-site study is generally a study that involves one or more medical or research institutions in which one site takes a lead role. (e.g., multi-site clinical trial)
<input type="radio"/>	<input type="radio"/>	Is Stanford the coordinating institution or are you the lead investigator for this multi-site study?
Yes	No	<b>Collaborating Institution(s)</b>
<input type="radio"/>	<input checked="" type="radio"/>	Are there any collaborating institution(s)? A collaborating institution is generally an institution that collaborates equally on a research endeavor with one or more institutions.
Yes	No	<b>Cancer Center</b>
<input type="radio"/>	<input checked="" type="radio"/>	Cancer Subjects (e.g., clinical trials, behavior/prevention) or Cancer Tissues (e.g., blood, cells, body fluids). <i>For Cancer Center Studies, you must submit electronic copies of the protocol, consent, eProtocol PDF, Protocol Registration Form and other pertinent study documents to the Cancer Clinical Trials Office. Email these documents to <a href="mailto:CCTO-Protocol@stanford.edu">CCTO-Protocol@stanford.edu</a>. The Protocol Statement of Support must be provided to the SRC prior to scientific review of the protocol. See</i>

If answered no, the section grays out

Yes	No
<input type="radio"/>	<input checked="" type="radio"/>
<input type="radio"/>	<input checked="" type="radio"/>
<input type="radio"/>	<input checked="" type="radio"/>
<input type="radio"/>	<input checked="" type="radio"/>

### Drug /Device

Investigational drugs, biologics, reagents, or chemicals?

Commercially available drugs, reagents, or other chemicals administered to subjects (even if they are not being studied)?

Investigational Device / Commercial Device used off-label?

IDE Exempt Device (Commercial Device used according to label)

For drug, device or biologic studies, [click here](#) for instructions regarding who must register a clinical trial at [clinicaltrials.gov](http://clinicaltrials.gov).

<input type="radio"/>	<input checked="" type="radio"/>	please see <a href="http://otl.stanford.edu">http://otl.stanford.edu</a>
Yes	No	<b>Biosafety (APB)</b>
<input type="radio"/>	<input checked="" type="radio"/>	Are you submitting a Human Gene Transfer investigation using biological agent or recombinant DNA vector? If yes, please complete and attach the <a href="#">Gene Transfer Protocol Application Supplemental Questions</a> to section 16 of the eProtocol application.
ADR #		



## Questions related to studies requiring registration should be referred to Spectrum



For drug, device or biologic studies, [click here](#) for instructions regarding who must register a clinical trial at [clinicaltrials.gov](#).



Click "yes" to confirm that you have accessed the website and read the [clinicaltrials.gov](#) reporting requirements provided.



This study will be registered on [clinicaltrials.gov](#)?



## Government website on clinical trials



# CHANGES: WEBSITE



## Website home page:

### **ClinicalTrials.gov registration, and consent requirements:**

Consent templates (including short form process) now have the language required for applicable clinical trials registered on [ClinicalTrials.gov](http://ClinicalTrials.gov).

See [Medical Research](#) and HRPP Policy [Ch 5](#) for more information about requirements.





# IRB REVIEWER CONCERNS



IF...PD has stated they will be registering their study in [clinicaltrials.gov](http://clinicaltrials.gov) website...

...then additional language should be in informed consent section

IF...area in eProtocol is grayed out but additional language is in informed consent...

...take no action. There are other reasons why they may register for clinicaltrials.gov outside of drug/device FDA regulated studies.



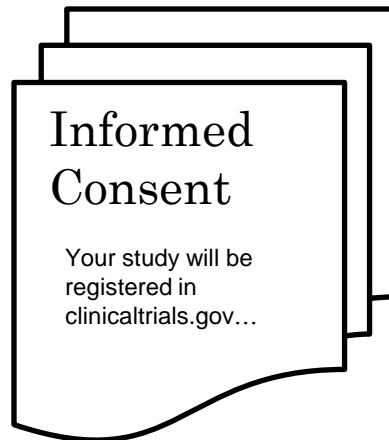
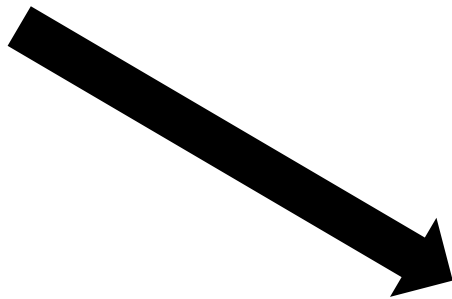
# IRB REVIEWER CONCERNS



For drug, device or biologic studies, [click here](#) for instructions regarding who must register a clinical trial at [clinicaltrials.gov](http://clinicaltrials.gov).

Click "yes" to confirm that you have accessed the website and read the [clinicaltrials.gov](http://clinicaltrials.gov) reporting requirements provided.

This study will be registered on [clinicaltrials.gov](http://clinicaltrials.gov)?



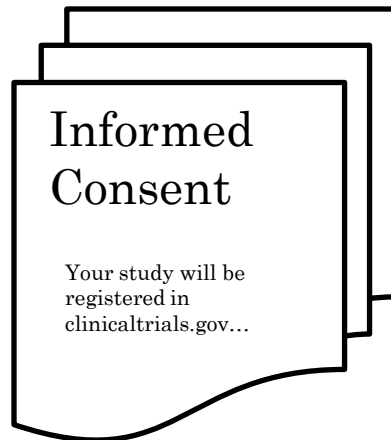
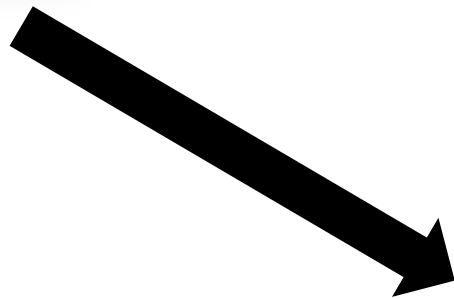
# IRB REVIEWER CONCERNS



For drug, device or biologic studies, [click here](#) for instructions regarding who must register a clinical trial at [clinicaltrials.gov](http://clinicaltrials.gov).

Click "yes" to confirm that you have accessed the website and read the [clinicaltrials.gov](http://clinicaltrials.gov) reporting requirements provided.

This study will be registered on [clinicaltrials.gov](http://clinicaltrials.gov)?



May inquire if the study will be registered, but otherwise take no action.

**SPECTRUM website:**  
<http://spctrm.stanford.edu>

