(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)
  - Device Study (with or without an IDE)

**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

**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

http://researchcompliance.stanford.edu
Study registration requirement has been in effect since 2007, but inclusion in consent forms is new requirement

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.)
“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)
If answered no, the section grays out.

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.

Biosafety (ARE): Are you submitting a Human Gene Transfer investigation using biological agent or recombinant DNA vector? If yes, please complete and attach the Gene Transfer Protocol Application.

Supplemental Questions to section 16 of the eProtocol application
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.
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 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.

http://researchcompliance.stanford.edu
# IRB Reviewer Concerns

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

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<td>Click &quot;yes&quot; to confirm that you have accessed the website and read the clinicaltrials.gov reporting requirements provided.</td>
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<td>This study will be registered on <a href="http://clinicaltrials.gov">clinicaltrials.gov</a>?</td>
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IRB REVIEWER CONCERNS

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

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

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<tr>
<th>Informed Consent</th>
<th>May inquire if the study will be registered, but otherwise take no action.</th>
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<td>Your study will be registered in clinicaltrials.gov...</td>
<td>SPECTRUM website: <a href="http://spctrm.stanford.edu">http://spctrm.stanford.edu</a></td>
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