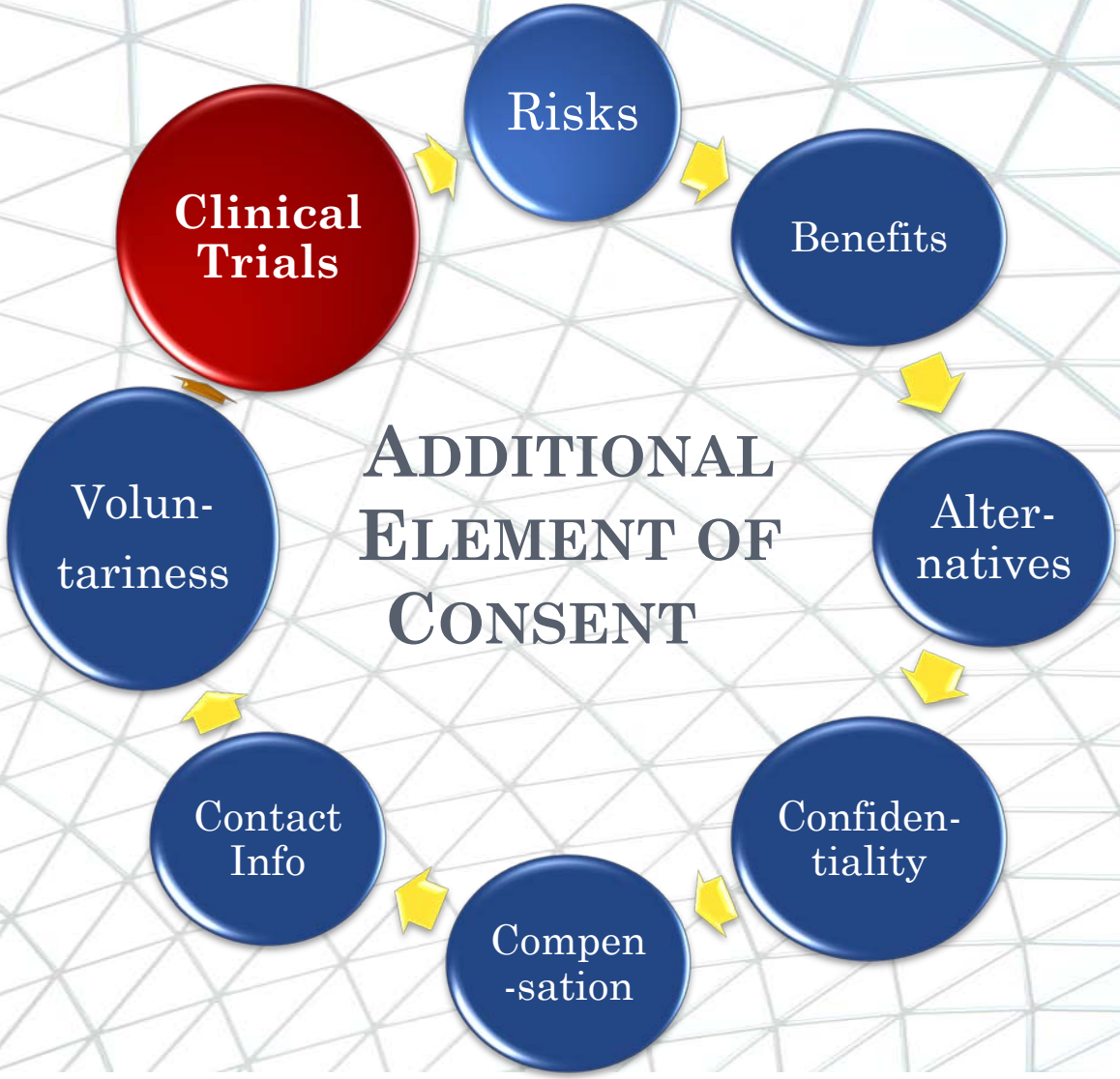


Bertha deLanda

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.)

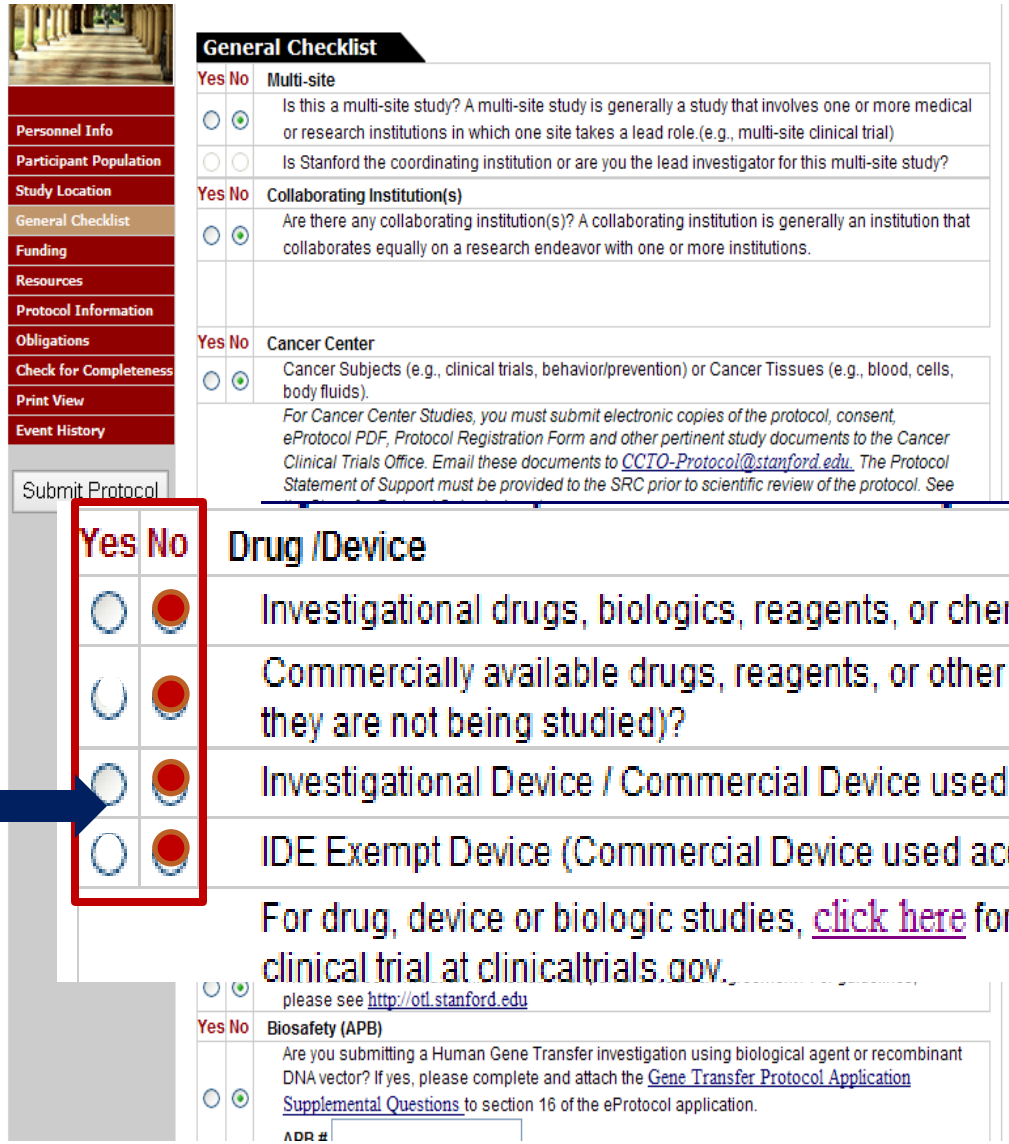
Study registration requirement has been in effect since 2007, but inclusion in consent forms is new requirement

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)



If answered no, the section grays out

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:

ClincalTrials.gov registration, and consent requirements: Consent templates (including short form process) now have the language required for applicable clinical trials registered on ClincalTrials.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…

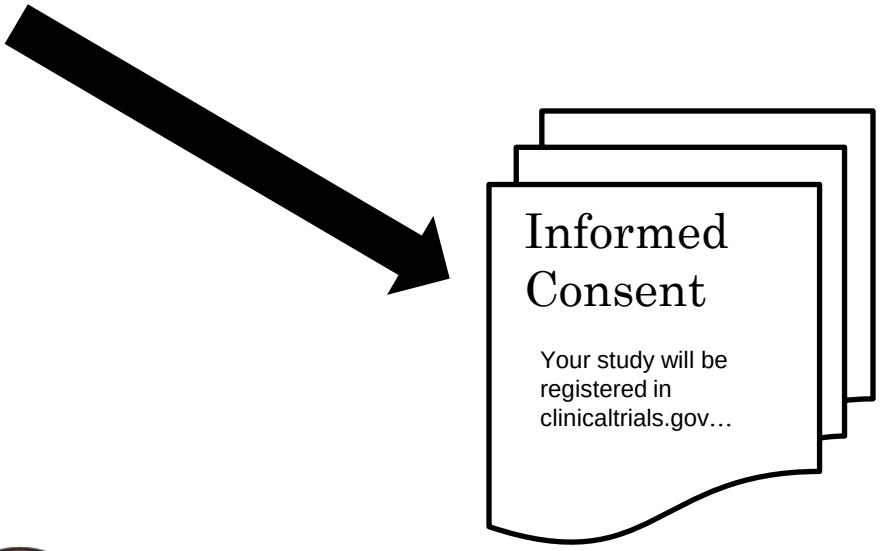
…then additional language should be in informed consent section

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.

IRB Reviewer Concerns

		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?

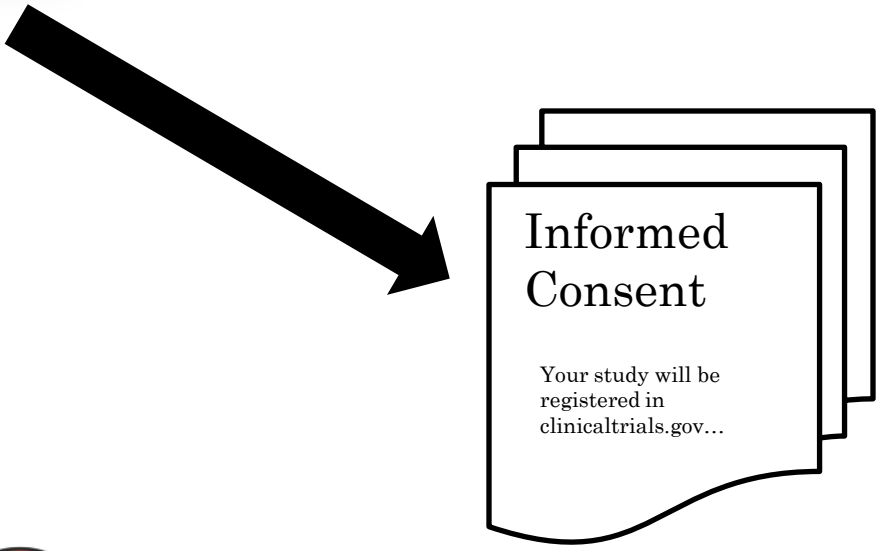


IRB Reviewer Concerns

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?



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

SPECTRUM website:
http://spctrm.stanford.edu