Origin of the Informed Consent Items:
The template for the IRB-01 Informed Consent is derived from the need to meet the mandatory elements of consent as stated in 45 CFR 46. There are eight mandatory elements of consent. Here are the mandatory elements and the associated Items in the Informed Consent template:

♦ A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any products which are experimental (Items 5, 7, and 8).

♦ A description of the reasonably foreseeable risks or discomforts to the subject (Item 10).

♦ A description of any benefits to the subject or to the others which may reasonably be expected from the research (Items 11a, 11b, and 11c.)

♦ A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject (Item 12).

♦ A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that external regulatory agencies, such as the FDA, may inspect records (Items 17, 18, 19, and 20).

♦ For research involving minimal risk, an explanation as to whether any compensation and/or medical treatments are available if injury occurs (Items 15 and 16).

♦ An explanation of whom to contact for answers to pertinent questions about the research and subjects’ rights, and in the event of injury (Items 2, 13a, and 16).

♦ A statement that participation is voluntary (Items 5, 12, and 13a).

Frequently Asked Question:

**Question:** What is the difference between a Retrospective Data/Chart Review and a Retrospective Record Review Arm in myIRB?

**Answer:** A Retrospective Data/Chart Review is a study where all of the data and/or samples being studied exist at the time the proposed new study is submitted to the IRB.

A study may involve a retrospective component which is when Retrospective Record Review Arm should be chosen if the proposed new study includes a population that is only a record review with a waiver of consent.

Announcement:

Note that effective March 2015, CITI Program's website will block use of Internet Explorer version 7, which is now more than 8 years old, as it does earlier versions of IE. Site users will need to have IE 8 or later, or use a current version of Chrome, Firefox, or Safari.

Upcoming Education:

The December Brown Bag will be held on December 10, 2014 and the speaker is Dr. Sue McGorrery, vice-Chair, IRB-01. Additional details will be sent out on the list serve.

The next Boot Camp will be held December 9, 2014. Mark your calendars now!