Assignment: PARTICIPATE IN A MOCK IRB ON 1/12/2016

The materials for the mock IRB (Attachments 1 through 5) *should be read **before class***. For this class, we will function as an institutional review board (IRB). We will review one protocol (Attachment 1) and the accompanying consent document (Attachment 3) and vote on whether or not to approve them. Be prepared to discuss the protocol using the NIH IRB review standards (Attachment 4). ***Also, bring a copy of the protocol, the consent form, and the NIH IRB review standards to class with you.*** You will need to be looking at them during the class.

Before the mock IRB session, you should go through the PowerPoint of the computer-based training (CBT) program for IRB members, which is Attachment 5 (you should spend about an hour on that PowerPoint).

We may also discuss, depending on the availability of time, some of the cases provided in "Case Vignettes for Discussion" (Attachment 2).

Objectives of the mock IRB

a. Apply the ethical principles of The Belmont Report and the legal requirements of 45 CFR 46 to specific research protocols involving human subjects.

b. Understand and apply, to specific protocols, the criteria for IRB review and approval of research activities involving humans.

Objectives of the CBT on protecting human subjects

After reviewing the CBT (Attachment 5) you should be familiar with:

a. The ethical principles of The Belmont Report and the requirements of the Federal Regulations for the Protection of Human Subjects (see attached materials),

b. The roles and responsibilities of (1) researchers conducting research with human subjects, and (2) Institutional Review Boards (IRBs).