CTSI Academy of Research Excellence (ARE)
The University of Florida

ARE Mission:

The University of Florida CTSI, Academy of Research Excellence (ARE), will help develop and recognize exemplary investigators, focusing on promoting high quality, innovative clinical research, and with the highest regard for research integrity, ethics, professionalism and regulatory requirements. The ARE is also dedicated to promoting an atmosphere of professional collegiality and openness, including active role-modeling and the mentoring of Junior Faculty and health science students, and enhancing and earning trust and support among the general public and potential research participants/subjects. This Academy represents the continuing commitment to excellence in research at the University of Florida Health Science Center and the UF-CTSI.

Course Overview and Syllabus:
Master Certification for Excellence in Human Subject Research and Protections

Overview:

The educational component of the ARE program consists of ten-2 hour course sessions. One hour of the session will be dedicated to lecture. Invited guest speakers from various departments such as IRB,RAC and CTSI will discuss their departmental training opportunities, assistance availability, review process, audits and other pertinent information. The seminar portions will consist of interactive and active participation of participants. Typically, this portion of each seminar will be used to, discuss particular issues in the context of the participants' own research enterprises and a topic oriented discussion. **Attendance is required for the seminars sessions.**

The ARE Program is primarily designed for clinical investigators at UF who are developing successful track records of grants and publications, and are committed to becoming outstanding and exemplary investigators, who wish to develop expertise in human subject research and protections.

Program Prerequisites:

The prerequisites for this Program will include: 1. Review of the Belmont Report, and FDA Regulation 45 CFR 46, 2. Successful completion of the CITI modules: Basic Ethics and Regulatory Issues, Historical perspectives and Informed Consent (myUFL > main menu . Training & Development > CITI training) **OR** the NIH Training http://phrp.nihtraining.com/users/login.php, and 3. the UF IRB Training. NOTE: Be sure to print out copies of the Citi or NIH certificate of

completion, and email to Cheri Knecht (cesk04@ufl.edu) in order to be credited with meeting the prerequisites prior to the first session.

Education/Training:

A. Seminar series. Every month for 5 months there will be bi-weekly 2- hour sessions. The 10 sessions will be interactive with a focus oriented to practical issues.

B. Mentoring. One of the major goals of the ARE program is to develop a cadre of experienced investigators who have the desire and skills to help promote excellence in clinical human subject research by serving in various capacities as role models and mentors. We expect that the interaction of ARE participants/investigators during this program, especially the seminar portion, will serve to foster open communication and the sharing of strategies and methodologies concerning issues in clinical human subject research between investigators who would not normally interact.

C. Establishing and enhancing practical skill in the development of informed consent forms, and in the process of asking/obtaining informed consent from participants. ARE course participants will practice and video record simulated informed consent process where they will explain and ask a simulated research subject for informed consent to participate in one of the participant's/investigator's research projects. Each participant will complete a self- assessment of their recording to discuss during session in order to identify strategies, strengths and areas for improvement.

D. Review of participants' research enterprises (site visit): Collegial and educational review of the participant's research enterprises will be conducted by the ARE working group. This will help focus the discussions and seminar topics to the needs of the participants. Seminar participants will lead discussion and analysis of various ways they organize their research enterprise.

ARE Master Certification Educational Program Evaluation:

Participants in the ARE Master Certification Program will be expected to attend **all** seminar sessions and to actively participate. Participants will receive feedback from both the ARE Program coordinators and their peers. IRB related ARE incentives for investigators must be approved by the IRB Executive Committee for individual investigators who successfully complete the Program.

There are two evaluation surveys given to all participants which assess; 1) the impact of the Program on participants, and 2) the impact on the education/training value on the Investigator's research enterprise:

- The Program: An evaluation and questionnaire will be administered at Program completion.
- A baseline and post questionnaire is given pre and post program.

The ARE Working Group has developed a five year evaluation strategy to assess the long term impact of the ARE activities on Program participants, as well as on the UF research enterprise and research culture.

Program Incentives:

A. Acquisition of expertise and skills:
Program participants will acquire experience and expertise concerning the ethical and federal and state regulatory aspects of human subject research that will meet and exceed all NIH Investigator training requirements.

B. IRB related incentives:
• ARE Investigators will have their IRB full-board submissions reviewed in the initial "block" during IRB meetings. Investigators will know when their submissions will be reviewed and will have additional time (by virtue of being first on the IRB agenda) to make any needed corrections.
• ARE Investigators will have an assigned IRB staff person to assist in submission of corrections at full board meetings (if needed).
• A specific IRB staff person will be assigned to shepherd submissions
• Accelerated turnaround time (review by IRB chair or designee, 48-72 hours for Expedited), shorter deadlines and guaranteed IRB staff pre-review of full board submissions.
• Regulatory Compliance Assessment and research team education.

C. Review of research protocols/IRB submission by the CTSI Regulatory and Ethics

Core:
The CTSI Regulatory and Ethics Core will offer assistance and review of research protocols during protocol development and prior to IRB submission.

Membership in the Academy of Research Excellence:

A. ARE member designation is effective for 1 year and renewable (to be determined by future participation in ARE activities).
B. Those investigators who complete this Program and who become members of the ARE will be expected, when feasible, to continue to participate as leaders in the training program, participate in update sessions, and to serve as mentors.
C. ARE members will be expected to attend annual speaker programs.

Program Faculty and Group Coordinators:

Ray Moseley, Ph.D. ARE Director
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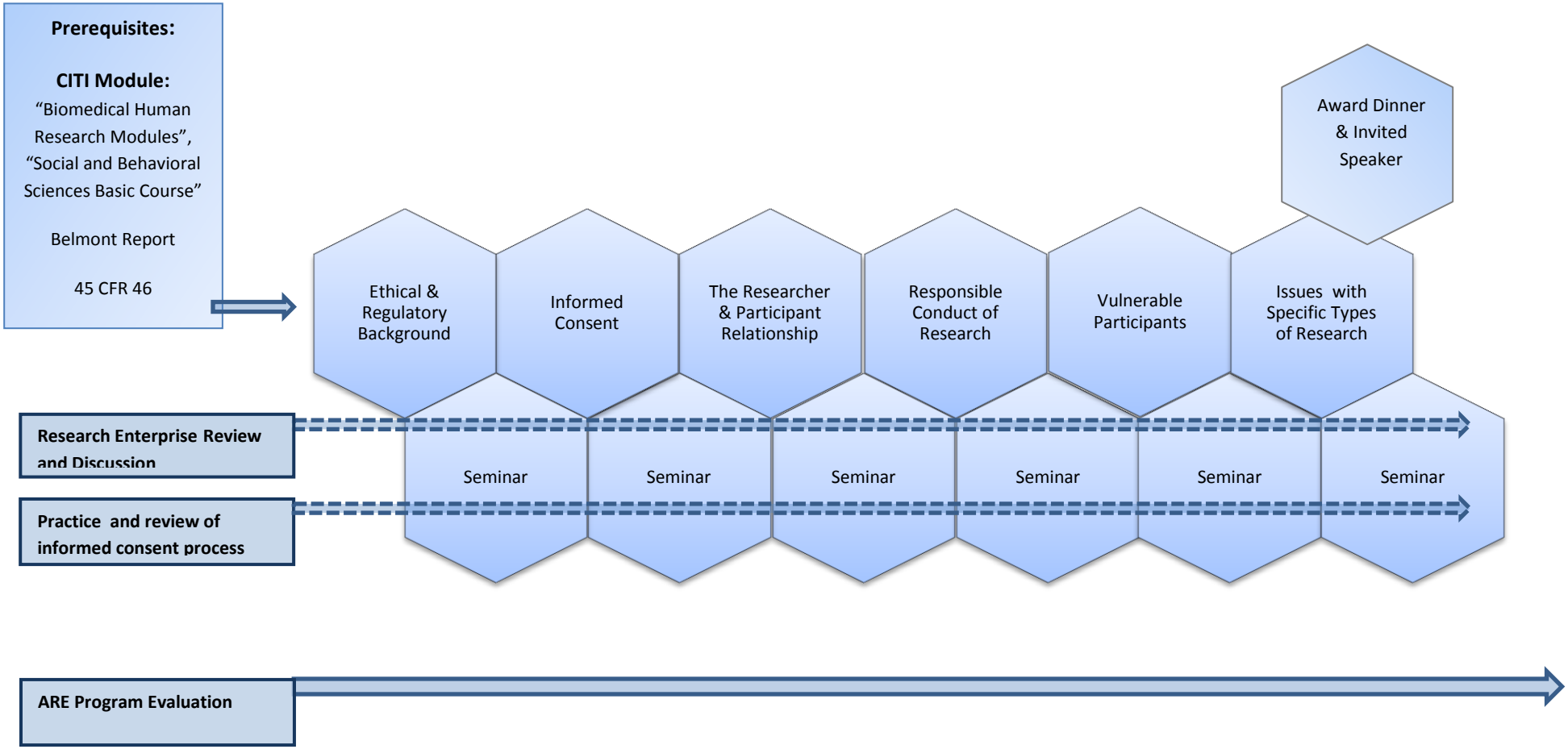
ARE Master Certification for Excellence in Human Subject Research and Protections Schema



Schedule and Topics:

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Session 1:
Introduction:

Wednesday, *January* 21, 2015 3:00-5:00pm, CTSB, rm:

- Course Overview: Objectives
- Course Structure: sessions building activities
- Prerequisites
- If you have to miss a session
- Topic options for PI's to facilitate in session

Ethical and Regulatory Background

How IRB members review submissions.
What the IRB staff looks for when reviewing submissions.
What are the common mistakes when submitting?
Understanding the psychology/motivation of IRB Boards and Staff.
Effective IQ question "descriptions".
Strategies for making the IRB review process go a lot smoother and faster.
Responding to questions from the IRB staff and Board.

Session 2: Ethical and Regulatory Background

Wednesday, February 4, 2015 3:00-5pm, CTSB, rm:

When an IND/IDE is required and Process to obtain IND/IDE
Why a study should be registered with ClinicalTrials.gov
How PubMed Central Compliance requirements affect Federal Grants

Session 3: Informed Consent

Wednesday, February 18, 2015 3:00-5pm, CTSB, rm:

Developing the informed consent form.
Explaining risks and benefits in the consent form.
Assessing participant/subject understanding.
What is the 8th grade language deal?

Session 4: Informed Consent

Wednesday, March 4, 2015 3:00-5pm, CTSB, rm:

Practical aspects in identifying and screening participant/subjects
"Asking" for consent: Why language matters in research and other slippery slope issues.
The ICF is a tool for use in asking for IC.
Because a participant/subject "agrees to participate in research" does not mean you have IC!
Why spelling errors in the ICF matter.

Session 5: The Researcher-Participant Relationship

Wednesday, March 18, 2015 3:00-5pm, CTSB, rm:

Recruitment of participants/subjects
Understanding and building bonds with your research subject community.
High drop-out rate may reflect a poor screening and recruiting process.
How to design effective and appropriate advertising for participants/subjects
What is the payment process @ UF
Available Resources at UF for recruitment

Session 6: The Researcher-Participant Relationship

Wednesday, April 1, 2015 3:00-5pm, CTSB, rm:

Should you pay participants? What is reasonable?
What is the payment process @ UF
Influences of Researcher–Participant Relationships
Available Resources at UF for recruitment
Follow up after the study-results

Session 7: Responsible Conduct of Research

Wednesday, April 15, 2015 3:00-5pm, CTSB, rm:

Research Misconduct: how to avoid it, how to recognize it.
Participant complaints: Would you know if the Participant was unhappy with your research?
Inclusion/exclusion criteria: The IRB holds you to what you tell them you're going to do!
When should you ask for a Certificate of Confidentiality?

Session 8: Responsible Conduct of Research

Wednesday, April 29, 2015 3:00-5pm, CTSB, rm:

Conflicts of interests
The responsibilities of the PI
Hiring, supervising and firing a research coordinator.
Keeping research records and the finances clear
Retrospective studies…mean retrospective. Common issues with retrospective studies.

Session 9: Vulnerable Participants

Wednesday, May 6, 2015 3:00-5pm, CTSB, rm:

Emergency and Intensive Care Research-
The protections for Children, Prisoners, Impaired subjects
You don't have to be in prison to be a prisoner!!
When should you consider including and enrolling vulnerable subjects?
Do prisoners have a choice?
"Accidentally" enrolling a vulnerable subject: What do you do now?

Session 10: Vulnerable Participants

Wednesday, May 20, 2015 3:00-5pm, CTSB, rm:

Assent Issues
"Re"-consenting when one of your participants turn 18
Conversations with your minor participants/parents
Age & level of maturity of minor participants matter
Assess whether participants understand what will be done to them

Special Speaker and Awards Dinner, TBD