Academic Honors – UF Requirements

Bill Millard, Ph.D.
College of Pharmacy
University of Florida
What is Academic Honors

- Students graduating with a Cumulative GPA in required courses of 3.5 or above receive academic honors through UF.
  - 3.5 = cum laude (with honors)
  - 3.6 to 3.79 = magna cum laude (high honors)
  - 3.8 and above = summa cum laude (highest honors)

- In 2004 - the SUS placed a “wrinkle in the magna and summa cum laude status” such that these folks must also complete a required honors project while at UF.
  - if you don’t you still graduate cum laude!
Resources on UF COP Web Site

- Academic Honors
- Research Opportunities Website
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<th># eligible</th>
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Academic Honors

• Why only 19-44%:

1. Students… like all of us: **Procrastinate!**

2. Students, like most of us, do not: **Plan!**
This is where we need your help!

• For most students… you are the last folks that they see or at least near the end of their tenure in the college… so it is **panic** time!

• At some point most students align themselves with an interesting APPE rotation that just gets them excited…

• So they will come to you for guidance associated with an academic honors research project.
Examples of academic honors projects may include, but are not limited to:

- Discovery of or resolution of a problem in a basic or clinical research laboratory.

- **Implementation and evaluation of a clinical service (e.g. DUR, MUE).**

- Compilation and interpretation of clinical or scientific data from the literature that resolves a significant problem or dilemma.

- **Implementation and evaluation of a survey that addresses a specific problem or dilemma.**
Titles of Projects for Academic Honors:

- Changes in Coenzyme Q10 (CoQ10) Following High-dose Atorvastatin Therapy.
- Recommendations for Vitamin D Supplementation in Patients with liver Disease.
- Managing the Complications of the “Aging” HIV Population
Academic Honors

Three components:

1. a paper… 3000 words… reviewed by you the mentor!
2. an oral presentation… to peers
3. a completed approval form.

• April 1, year of graduation is the deadline
But...

• The honors project should be the result of or in addition to a given APPE rotation/experience...

• It should not be an integral or major part of an APPE rotation...

• Projects with multiple students are acceptable as long as the students can each show ownership of an aspect of the project... so these projects should be a little more extensive with perhaps multiple arms... I leave this to your discretion.
Besides student procrastination and planning... the biggest issue we face is:

➢ The IRB!!!!
Why Do You Need to Know about the IRB??

• UF students are required to complete an “honors” project - note it does not have to be a “research” project.

• But if research is involved… as a UF student, they must comply with UF and Federal Research regulations… so IRB will be required.
Why Do You Need to Know about the IRB??

• A student must have a faculty advisor
  – Local (i.e.: at the facility)
  – UF employee… and paid by UF!

• As a preceptor, and you are paid by UF but have your practice site elsewhere you likely will have local IRB requirements…

This should be done and completed first… please!
Why Do You Need to Know about the IRB??

• If you are a preceptor, and you are **NOT** paid by UF then things get more dicey…

• As of 2103 UF students can no longer serve as PI’s on IRB proposals… **only faculty/preceptors paid by UF or approved through the UF-IRB can be PI’s.**

• The best suggestion would be to work with a student on a project that involves continuous quality improvement (CQI) or a literature review…
Why Do You Need to Know about the IRB??

• Leave PHI and HIPAA out of the mix if you can!
What is a “Human” Subject?

• “Human” subject is a living individual about whom an investigator obtains either
  – data through intervention or interaction with the individual; or
  – identifiable private information (ie: anything in a patient’s medical record).
What is Research, and thus requires IRB approval?

- Research:
  As defined by 45 CFR 46, “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge”

- Will it be presented or published?
CQI vs Research
How can you tell if it’s CQI?

• When the purpose of an activity is to assess the success of an established program in achieving its objectives
  – The information gained from the evaluation will be used to provide feedback to improve that program
  – The information will **not be presented or published to contribute to generalizable knowledge**

• The evaluation is a management tool for monitoring and improving the program.

• Information learned has immediate benefit for the program and/or clients receiving the program or services.

• **Note:** something can be a CQI project, but also meets the definition of research… so be careful here!
The website below clarifies the relationship between Continuous Quality Improvement (CQI) projects and research projects. It also gives guidelines as to when CQI projects should be submitted to IRB for approval.

CQI vs Research:

This website includes a link to a CQI vs Research Form that is required to be filled out by the student and submitted directly to Dr. Peter Iafrate at iafrate@ufl.edu.

If approved the student will receive a letter from Dr. Iafrate and the project should continue.
IRB Research Categories:

- **Exempt:**
  - review of educational/instructional practices/techniques.
  
  - Surveys, interviews or projects involving observational behavior - **confidentiality must be maintained**.
  
  - Data that is **existing** … including patient data without PHI identifiers… **de-identified**.
  
  - Projects evaluating public benefit or service programs.
  
  - Taste and food quality programs or surveys
IRB Research Categories:

• Expedited:
  - Studies on drugs not requiring an IND
  - Studies involving non-invasive sample collections and collection of data thereof
  - Any prospective data clinically generated
  - Studies involving the collection of voice, digital or image data
  - Survey research with links to PHI
IRB Research Categories:

- Anything else is **FULL BOARD** and we do not want to *go there* unless there is clear need and a desire on the part of the research team… and student if time permits.
Research Compliance Issues

• Any protocol revision, no matter how minor, must be approved by the IRB before you make the change
• Don’t enroll more subjects then you are approved for (a subject could be a medical record)
• Follow your protocol exactly
• Report any adverse events
• Don’t let the protocol expire, it can only be approved for no longer than 1 year.
What is the role of the Mentor/Faculty Advisor?

- Faculty advisors shall affirm that the student/trainee/fellow is knowledgeable about the regulations and policies governing research with human participants.
- The student has sufficient training and experience to conduct the particular study in accordance with the approved protocol.
- Shall meet with the student on a regular basis to monitor study progress and to ensure compliance with UF policies and federal regulations.
General Questions and Answers

- **Does a project need IRB approval?**
  a. Meets the definition of research?
    - Publishing or Presenting outside of the classroom
  b. Where is the research being done?
    - If at UF, Shands, or VA send to IRB-01
    - If not, does the outside site have an IRB?
      - If yes, send to that IRB first, once approved, send to IRB-01
      - If no, you still must send to IRB-01
  c. Call the IRB Office (273-9600) and ask before you start
General Questions and Answers

• **What training does the student need?**
  a. You must complete the HIPAA for Researcher module located
  b. The IRB offers training on many topics dealing with human subjects research

• **Does the student need a mentor?**
  a. Yes, all students must include a mentor on any protocol submitted to the IRB.
  b. Students should choose a mentor wisely
    i. Someone that has conducted human subjects research in the past, and knows the rules.
    ii. Someone who will train them on all aspects of human research.
General Questions and Answers

• Where can one store subject’s personnel information?
  a. Must be on an encrypted database.
  b. Never allow student to take subject data home, or store on a personal computer.

• What is required when the research is complete (or decided to not do it any more)
  a. You must notify the IRB that the study is being closed
  b. Not doing so is a violation of the federal regulations
General Questions and Answers

• How closely do should the protocol be followed?
  a. Once approved by the IRB, you must follow your protocol exactly
  b. If you need to change something, you must get approval from the IRB prior to making the change
  c. Make sure a potential study subject fit your inclusion\exclusion criteria

• What if more subjects are needed then first thought?
  a. You must obtain approval from the IRB before you enroll more subjects then you were approved for.
  b. If you enroll more without approval, then minimally you may have to destroy that data
Types of Research Projects
Recommended

1. Retrospective Chart Reviews
   – All data must exist at the time you submit the protocol

2. Evaluation of an existing service
   – All you do is analyze data that will be normally collected as part of the patient’s clinical care

3. Anonymous Surveys
   – Never collect any identifiers
IRB has gone electronic! – 8/1/2012

• myIRB or myIRB manual

• If you are trying to access myIRB from a computer outside of the HSC you will need to use the HSC VPN to access the system. Download the HSC VPN at: http://vpn.health.ufl.edu/

• Continual discussions as to whether PharmD students or any other health professions students will be granted PI status on IRB protocols… stay tuned… I am!!!
IRB Information
Required Paperwork or Help

IRB Website:

http://www.irb.ufl.edu/

IRB Phone Number: 273-9600

Ask for Peter Iafrate or Renee Collins
Ask, before you act!