RESEARCH CURRICULUM

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Research Curriculum

REQUIRED rotation

Objective: To provide research training for fellowship trainees in the Hematology/Oncology fellowship program with the goal that the trainee would obtain the basic tools for conducting research and critically reading the ever-changing medical literature that provides the basis for clinical practice.

Background:

The need for training fellows in the methods of conducting any research (clinical, translational or basic) along with training in writing and publishing manuscripts is an important and stated goal of the fellowship-training period. Due to complex ethical, regulatory and scientific issues surrounding research, structured training is needed for fellows. The goal for all fellows is to not only learn and be familiar with these aspects of research, but also to be involved in manuscript writing by the end of their training.

With this in mind, the following guidelines are proposed for the research agenda during the fellowship training period for all fellows. Broad and general goals for each are followed by a timeline to achieve these goals. A major project must be completed and written for publication in the three years. It is also encouraged that the trainees initiate additional projects and submit these in the form of abstracts and publications.

The trainees will be presented basic methods of conducting research didactically (see Appendix 1). The importance of basic, translational methods will be presented as well as methods for the performance of these. Institutional training must be completed (Appendix 2). The basics of statistical analysis will be presented and each fellow will work with a statistician from the initiation of the projects. The ethical and regulatory aspects of research will be presented and the trainees will be responsible for obtaining approval from the Institutional Review Board and the Protocol Review and Monitoring Committee of the Arkansas Cancer Research Center. As well, they will serve three to six months on each of these committees.

The fellows will present and participate in a journal review monthly in which they, along with faculty and a statistician, will review studies published in the medical literature. The trainees will participate in a monthly Editorial Review meeting.

The research training will be an ongoing process throughout the three years. One month during the first year will be provided to initiate the research project. Time will be provided in the subsequent years to work on the research projects, depending on interest and aptitude. The trainees' progress will be monitored closely by the research director. The trainee may participate in laboratory research, clinical training or retrospective analysis of clinical and/or laboratory data to answer a clinical question.

Goals for the first year:

- Have one-on-one discussions with staff (divisional as well as outside the division).
- Seek out divisional staff who may already have ongoing research projects in which fellows might have an interest.
- Seek out opportunities to write abstracts for upcoming scientific meetings and conferences.
- Identify a mentor for research and research projects.
- Complete (all) institutional regulatory aspects involved with research and identify a research project and mentor within 9 months of joining the program and begin research project.

A written plan must be approved before initiating the project. A written plan must be approved by the research director by the end of **month 6**.

By **month 9** of the fellowship, fellows are expected to spend one month one-on-one with their chosen mentors to generate a valid hypothesis, specific aims and study design, which will need submission to regulatory review committees.

Examples of research/scientific projects encouraged for the first year:

1) Retrospective chart reviews.
2) Review articles (under guidance of mentors).
   (This does not qualify as the research project.)
3) Participation in ongoing investigator-initiated clinical trials
   or laboratory research.

Goals for the second year:

- Finish the research project as well as initiate manuscript writing by the end of second year. Abstract submission is encouraged.
- Initiate the research project after obtaining IRB and/or other committees' approval and complete the project.
- Fellows (under mentorship of chosen faculty) should make all attempts to initiate their project by the beginning of their second year in fellowship and work through the year to complete the project.

The second year of fellowship will likely have more elective months given to fellows who have demonstrated at the end of the first year not only an interest in research, but also have accomplished the research goals of the first year.

In order to accomplish the second year research goals, every attempt should be made to keep the specific aims of the proposal attainable by the end of the second year.

The goal of any project remains the generation of sufficient data by **month 36** of the fellowship so that the fellow can be helped to generate a manuscript.

Appendix 1

Didactic Research Program

Design of Phase I, II and III Trials

1. Protocol development and implementation
    a. Defining trial objectives and outcomes (response criteria)
    b. Defining patient populations
    c. Use of surrogate endpoints
    d. Toxicity assessment and grading
    e. Quality of life assessment and endpoints
    f. Reporting responsibilities
    g. Data collection
        (1) Data capture and database development
        (2) Maintaining quality and integrity
    h. Statistical analysis
        (1) Sample size determination
    i. Early stopping rules
2. Meta-analysis
3. Ethical, regulatory and legal issues
    a. Institutional Review Board
    b. Informed consent
    c. Conflict of interest
    d. Other groups in trial development

Apendix 2

Research Certification Approvals

Check off training sheet for Researchers at ACH

Standard HIPAA Compliance training – http://hipaa.uams.edu/

Human Subject Protection Training – www.uams.edu/ORC

HIPAA for Research Training – www.uams.edu/ORC

Check off training sheet for Researchers at the Arkansas VA

Office of Research Development Training –
http://www1.va.gov/resdev/fr/PRIDE/training/

VHA Privacy Policy - http://www1.va.gov/resdev/fr/PRIDE/training/