Clinical Investigator's Pathway

A. General Requirements:

Requirement	Date(s) Completed
Develop a Research Committee[1]	
Participate in a Site Initiation Visit (SIV) at the University of Michigan	
Attend a data managers meeting with a principal investigator (DATA SAFETY MANAGEMENT MEETING) at the University of Michigan[2]	
Write a clinical trial (see didactics below for additional information and requirements)	
Attend / participate in a Protocol Review Committee (PRC)review of a clinical trial as assigned by the PRC chair[3]	
Attend in an Institutional Review Board (IRB) meeting as an observer[4]	
Attend a Cancer Center Data Safety Monitoring Board (DSMB) meeting[5]	
Apply for extramural funding (including ASCO YIA and ASH Training Award) / workshop participation	
Write a data-based peer-reviewed manuscript (based upon primary or retrospective data or a peer-reviewed review manuscript)	
2nd year (3rd year) research in progress presentation[6]	
3rd year (4th year) final research presentation[6]	
If on the T32 Training Grant, attend the basic science / research journal club	
If on the T32 Training Grant (**and/or)** deemed necessary by the mentoring committee, attend Grantsmanship Review (See Laboratory Science Pathway)	
Referee 1-2 manuscripts as a peer review for publication	
Submit an abstract to a national meeting and present your abstract if accepted	
Attend a National Meeting (ASCO, ASH, AACR)	
OPTIONAL[7]	
School of Public Health Summer Course/OJOC (on job on campus) program	
Attend : ASCO Vail Workshop, ASH Clinical Research Training Institute, AACR Molecular Biology and Clinical Workshop	
Attend a Programs Research Group Meetings	
Other scholarly activity (research/workshops /review articles, book chapters, etc.)	

[1]The **Research Committee** will be a committee developed by the fellow and his/her mentor to consist of 2-3 individuals who are involved in the field of the fellow's research; one should be an independent reviewer who has knowledge of the field but does not necessarily have a vested interest in your project. These individuals may be clinical oncologists, basic scientists, surgeons, radiation oncologists, etc. The committee should meet at a minimum of two times each year to review and provide feedback for the

fellow's research project(s). The fellow along his/her mentor will arrange the meetings at time points which are most suitable to his/her project(s).

[2]if actively involved in a protocol, enrolling and following patients, you need to attend these meetings monthly.

[3] To attend a PRC meeting, please contact Cari Richards - ckrzyzan@umich.edu or (734)-647-5232 to set up an appointment to attend

[4] To attend an IRB meeting, please contact Judith Birk - jbirk@umich.edu or (734)-763-4768 to set up an appointment to attend

[5] To attend a DSMB meeting, please contact Cari Richards - ckrzyzan@umich.edu or (734)-647-5232 to set up an appointment to attend

[6] Those participating in the MD/PhD program will give "research in progress presentations during their 2nd, 3rd years with the final research presentation being given during their 4th year.

[7]Activities that are not required but may be considered; **NOTE: If you choose to participate in one or more optional activities, you may be asked to cover the expenses as fellowship or division funds may not be available.**

B. Didactics for Clinical Investigators:

1. Introduction to Clinical Trials (Dr. Dan Hayes)

Topics may include, but are not limited to:

1. Purpose of clinical trials
2. Phase 1
    a. Phase Ib (what is the difference from a phase II)
    b. Alternative trial designs – TITE-CRM for phase I for example
3. Phase 2
    a. Randomized phase II versus a Phase III
    b. Simon 2 stage trial design
4. Phase 3
5. Examples of each
6. Strengths / weaknesses of each

2. Populations & Statistics in Clinical Trials (Dr. Lynn Henry / Kelly Kidwell)

Topics may include, but are not limited to:

a. Phase I
    a. MTD versus alternative endpoints for phase I trials (optimal biological dose)
    b. Combination drug trials in phase I – how to adjust?
    c. Dose escalation in phase I - modified Fibonacci escalation design

b. Sample size determination
c. Delta – what does it mean and why is it important
d. Power – what does it mean and why is it important
e. One-sided versus two-sided alpha - what does it mean and why is it important

3. Writing Letters of Intent (LOIs) (Dr. Maha Hussain)

Topics may include, but are not limited to:

1. Prior communication with companies – cooperative groups
    a. CDAs / GDAs – what are they and why they need to be in place
2. What to include in an IND (too simple versus too complex)
3. Samples
    a. CTEP
    b. industry

4. Writing a Clinical Trial (Dr. Ajjai Alva)

Topics may include, but are not limited to:

1. Sections
    a. Introduction
    b. Study Objective and Endpoint Definitions
    c. Study Design
    d. Patient Selection (Inclusion and exclusion criteria)
    e. Study Treatment
    f. Assessments
    g. Adverse events – definitions and reporting
    h. Data analysis and statistical methods
    i. Quality control/assurance
    j. Data Handling and record keeping
    k. Ethics
    l. References
    m. Tables / Appendices

5. MICHR and Additional Research Support for Clinical Trials

Topics may include, but are not limited to:

Kevin Weatherwax - INDs

a. What is an Investigational New Drug Application
b. Which research requires and IND
c. Application process
d. Updating requirements

Dr Blake Roessler– Michigan Clinical Research Unit (MCRU)

a. What is MCRU
b. What support exists
c. How is it funded

6. **Committee Approval – Walking a Trial Through to Approval (Hutchinson / Kalemkerian)**

Topics may include, but are not limited to:

1. Protocol Review Committee (PRC)
2. IRB
3. Ancillary committees
4. Clinical Research Calendar Review & Analysis Office (CRAO)

7. **Writing Consents for Clinical Trials - (Judith Birk/Diana Miller)**

Topics may include, but are not limited to:

Sections

1. Purpose of the Study
2. Information about Study Participants (subject)
3. Information about study participation
4. Information about Risks and benefits
5. Other Treatment Options
6. Ending the study
7. Financial Information
8. Confidentiality of Subject Records and Authorization to release protected health information
9. Contact Information
10. Record of information provided
11. Signatures

8. **Data Management / Regulatory (Patty Bebee/other CTO members)**

Topics may include, but are not limited to:

1. Adverse Events (AEs) – definitions and use
2. Serious Adverse Events (SAEs) – definitions and use
3. Case Report Forms (CRFs)
4. Endpoints - why duration matters - $$$
5. Budgets

9. **Grant Writing (Dr Pavan Reddy)**

Topics may include, but not limited to:

1. Writing a Grant/submission
2. Feedback and scoring
3. Grant resubmissions

10. U of M Clinical Support for Investigator Initiated Clinical Research (Dr. Scott Schuetze)

Topics may include, but are not limited to:

1. CTRAC
    a. Eligibility
    b. How to apply
    c. How applications are judged
    d. What is funded / what is not

11. **Responsibilities of a Principle Investigator (Dr. Maha Hussain)**

Topics may include, but are not limited to:

1. The investigator is responsible for ensuring that all research activities have IRB approval before human subjects are involved and that the research activity follows the approved protocol exactly.
2. The investigator is responsible for informing the research staff of the regulations governing research and of NCI IRB protocol policy.
3. The investigator or designee is responsible for obtaining the informed consent of subjects before the subject is involved in the research.
4. The investigator is responsible for getting IRB approval for any proposed change to the protocol. Approval by the IRB and IND holder is necessary before implementation of any such changes.
5. The investigator is responsible for and must notify the IRB and IND holder of any physical or psychological adverse events experienced by a patient because of participation and also of any emergent or potential problems.
6. The investigator is responsible to notify the IRB of any action (i.e., clinical hold, safety letters) by the IND holder or FDA pertaining to study or agent.
7. The investigator is responsible for obtaining continuing approval from the IRB on a maximum 12-month basis. The IRB can only, by Federal regulations, give approval for up to a period of 12 months. Higher risk research will be given approval periods of less than 12 months.
8. The investigator is responsible for making provision for the safe retention of complete records of human subjects and all research materials.
9. The investigator is responsible for ensuring the confidentiality and security of all information obtained from and about human subjects.

10. In collaborative activities with other institutions, the investigator is responsible for verifying that IRB approval has been obtained from all participating institutions.

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ASCO Young Investigator Award (YIA) and ASH Research Training Award for Fellows (RTAF) Workshop

The fellowship program organizes an annual workshop in mid-July to assist fellows in their preparation for fellowship training award applications. All 3rd and 4th year fellows planning to apply for one of these awards are expected to attend. Fellows should bring a draft of their NIH biosketch as well as proposed specific aims to this event. At the workshop, several hematology and oncology faculty, including recent recipients of these awards, are present to provide fellows feedback. There will also be samples of successful YIA and RTAF awards from recent graduates for fellows to review. The workshop will also help fellows to establish a proposed timeline for a successful training award application.

**********Didactic Course Details**********

-Approximately 1 to 1 ½ hours in length

-Will be scheduled as a "Boot Camp" over a 2-4 week period in July/August of each year

-Julia Sitterly to assist with scheduling