OHIO STATE UNIVERSITY MEDICAL CENTER and MARSHALL UNIVERSITY JOAN C. EDWARDS SCHOOL OF MEDICINE PROGRAM AFFILIATION AGREEMENT FOR GRADUATE MEDICAL EDUCATION ROTATIONS

THIS PROGRAM AFFILIATION AGREEMENT FOR GRADUATE MEDICAL EDUCATION ROTATIONS (Affiliation Agreement) is effective the 1st day of May, 2013, between OHIO STATE UNIVERSITY ON BEHALF OF ITS MEDICAL CENTER, Hematology and Medical Oncology Fellowship Program (hereinafter OSU) and MARSHALL UNIVERSITY JOAN C. EDWARDS SCHOOL OF MEDICINE, 1400 Hal Greer Blvd., Huntington, WV 25701, (hereinafter AFFILIATE), Oncology Fellowship Program.

WHEREAS, OSU is committed to and involved in training residents and medical students in fields of medicine; and

WHEREAS, OSU and AFFILIATE enter into this Affiliation Agreement to provide opportunities for the AFFILIATE Resident/Fellow to rotate at OSU in the Hematology and Medical Oncology Fellowship Program.

NOW, THEREFORE, OSU and AFFILIATE agree that:

A. GME Relationships and Educational Responsibilities.

1. Responsible Officials. The AFFILIATE Program Director will remain responsible for ensuring that the OSU Rotation Director appropriately oversees the administrative, educational and supervisory functions of the rotations while the residents are at OSU.

2. Educational Goals and Objectives. The educational goals and objectives for the elective rotation in Hematology and Medical Oncology Fellowship are provided in Attachment A.


a. The AFFILIATE Fellow shall rotate at OSU for a period of one month.

b. The AFFILIATE Fellow shall continue to receive his/her salary through the residency program at AFFILIATE. AFFILIATE will continue to employ the rotating resident while at OSU. A fee of $500.00 will be charged by the OSU Hematology and Medical Oncology Program for each resident/fellow rotating at OSU.

c. Insurance and benefits for residents in AFFILIATE sponsored programs shall be provided through AFFILIATE. Information concerning the insurance and benefits is communicated to residents as part of the resident contract or the benefit summary attachment to the resident contract.
4. Resident Rotations
   a. The AFFILIATE Program Director shall ensure that the resident is a graduate of an accredited medical school enrolled in a postgraduate medical education program accredited by the applicable accrediting body for which AFFILIATE is the Sponsoring Institution.
   b. Residents rotating through OSU shall be subject to the regulations of the organized Medical Staffs and the medical education policies and standards of OSU.

   a. Teaching and Supervision of Fellows. The OSU Rotation Director for Hematology and Medical Oncology, Steven Devine, MD will be responsible for the overall supervision and teaching of the AFFILIATE resident rotating at OSU. At the discretion of the OSU Rotation Director, other faculty members may be assigned to provide the direct supervision and education of the AFFILIATE resident while at OSU.
   b. Formal Evaluation. The OSU Rotation Directors will be responsible for ensuring the proper evaluation of AFFILIATE resident at the conclusion of their rotation at OSU. At the discretion of the Rotation Director, other faculty members who are directly supervising and teaching the resident may be asked to complete evaluations of the AFFILIATE resident.
   c. Policies and Procedures Governing Resident Education.
      1. Policies and procedures governing resident education shall be those of the sponsoring institution for the Hematology and Medical Oncology Fellowship Program, i.e. AFFILIATE, as set by the sponsoring institution’s GMEC.
      2. The Residency Program Director at AFFILIATE and the Rotation Director at OSU shall require residents to adhere to all employment, patient care and Corporate Compliance policies of OSU when based at OSU, and with all educational and employment policies of the Residency and Fellowship Programs at OSU.
      3. The Rotation Directors at OSU may require an assigned resident to be removed from clinical activities at OSU in the event of an occurrence of an incident deemed serious by the Chief Medical Officer of OSU or the OSU Rotation Directors. If such action is taken, it will be immediately communicated to the AFFILIATE Program Director. Such resident shall refrain from any involvement at OSU until the Residency Program Director and the
OSU Chief Medical Officer agree to the resident’s return. The resident shall have the right to appeal such a decision as defined in the resident contract for AFFILIATE sponsored programs and the GMEC Manual for AFFILIATE sponsored programs.

B. Term, Termination and Other Contractually Stipulated Matters.

Term of Affiliation Agreement. This Affiliation Agreement shall commence on May 1, 2013, and shall continue in effect through May 1, 2018. This Affiliation Agreement may be renewed upon mutual agreement in writing and signed by the parties hereto.

C. Professional Liability Insurance.

OSU shall maintain professional liability insurance or a self insurance program covering its facilities and faculty.

AFFILIATE shall provide insurance coverage for any AFFILIATE resident rotating at OSU for any alleged medical malpractice and/or comprehensive general liability arising from events occurring while the resident is placed at any OSU facilities.

“Facilities” means any place where OSU provides medical care to patients; at which residents treat or administer to such patients and which are under the control of OSU as the result of ownership or supervisory responsibility.

D. HIPAA Regulations

The parties acknowledge and agree that all patient identifiable information (the “PHI”), as defined in the 1996 Health Insurance Portability and Accountability Act and the Standards for Privacy of Individually Identifiable Health Information at 45 C.F.R. Part 160 and Part 164, (the “Privacy Rule”) and other rules issued pursuant thereto (collectively hereinafter referred to as “HIPAA”), exchanged between the parties pursuant to this Agreement is confidential information utilized for purposes of providing treatment to patients without regard to medium of storage or method of transmission of such information. The parties agree to keep all PHI confidential and to comply with the applicable requirements of the Privacy Rule.

It is the intent of the parties to comply with the requirements of HIPAA. Any ambiguity in this Agreement shall be resolved to permit the parties to comply with the HIPAA. If necessary, the parties agree to use good faith efforts to amend this Agreement from time to time in order to assure that this Agreement is consistent with HIPAA and regulations promulgated there under. The obligations of the parties under this Section shall survive the expiration or termination of this Agreement.
E. Miscellaneous.

a. Notice. Any notice, offer, demand or communication required or permitted to be given under any provision of this Affiliation Agreement shall be deemed to have been sufficiently given or served for all purposes if delivered by certified mail, postage and charges prepaid, addressed to the address of the parties set forth below. Either party may change its address for purposes of this Affiliation Agreement by giving the other notice thereof in the manner provided for the giving of notice. Unless otherwise required by the Affiliation Agreement, notices under this Affiliation Agreement shall be directed to the following persons:

TO OSU: Graduate Medical Education
Ohio State University Medical Center
125 Doan Hall
410 West 10th Avenue
Columbus, Ohio 43210

TO AFFILIATE: Maria Tria Tirona, MD, FACP
Program Director
Marshall University
Joan C. Edwards School of Medicine
1400 Hal Greer Blvd.
Huntington, WV 25701

b. Governing Law. This Affiliation Agreement shall be construed and enforced in accordance with, and governed by, the laws of the state of Ohio.

c. Amendments. No amendment or modification to this Affiliation Agreement shall be effective unless the same is in writing and signed by authorized representatives of the parties. Amendments to this Affiliation Agreement shall be effective as of the date stipulated therein.

d. Assignability. Neither party may assign its rights or obligations under this Affiliation Agreement except with the written consent of the other party. Any attempted assignment in violation of this provision shall be null and void.

e. No Third Party Rights. This Affiliation Agreement is intended solely for the benefit of the Participating Institutions, and it shall not be construed to create any benefits for or rights in any other person or entity, including patients, residents, faculty, employees and their representatives.

(The remainder of page has been left blank intentionally.)
IN WITNESS WHEREOF, the parties have executed this Affiliation Agreement on the date(s) set forth below.

MARSHALL UNIVERSITY
JOAN C. EDWARDS SCHOOL OF MEDICINE

Maria Tria Tirona, MD
Affiliate Program Director
Date 6/6/13

Paulette Wehner, MD, DIO
Senior Associate Director for Graduate Medical Education
Date 6/6/13

Joseph Shapiro, MD
Dean
Date 6/6/13

THE OHIO STATE UNIVERSITY
MEDICAL CENTER

Kristie Blum, MD
Program Director, Hematology and Medical Oncology
Date 5/30/13

Steven Devine, MD
BMT Rotation Director
Date 5/30/13

Bryan L. Martin, DO
Associate Dean for GME, DIO
Associate Medical Director, UH
Date 5/13/2013

Andrew M. Thomas, MD, MBA
Medical Director, University Hospital
Date 5/14/2013

Outside Rotator to OSU 5
ATTACHMENT A
Objectives to be achieved in
Hematology and Medical Oncology Fellowship,
BMT Rotation at OSU

Goals

1. To provide specialized training and experience in the design and conduct of clinical studies of emerging oncology drugs. It is anticipated the Clinical Investigator Research fellow will submit at least two letters of intent and write at least one clinical research protocol in its entirety.

2. To provide clinical experience in the management of patients participating in oncology drug development trials. It is anticipated that fellows will consent, enroll, and follow patients on clinical trials relevant to their subspecialty area of interest (i.e. benign hematology, lymphoma, leukemia, breast, lung, gastrointestinal tumors, etc.). Fellows will be expected to attend clinic at least 2 half-days/week and participate in weekly toxicity meetings between the principal investigator, research nurses, and data managers.

3. To provide specialized training in statistics required for clinical trial design.

4. To provide specialized training in the design and interpretation of ancillary laboratory studies utilized in the oncology drug development process including pharmacokinetic, pharmacogenetic, and pharmacodynamic studies.

5. To promote an understanding of pharmaceutical industry and government drug development issues.

Supervision and Mentorship

Each fellow will choose a physician faculty mentor based on their subspecialty interest, who will provide guidance for the completion of the required projects detailed below. This mentor should have an interest in clinical research and be an active participant in the Phase I/II programs at the Ohio State University. The fellowship Program Director will monitor individual performance and handle any disciplinary issues. Supervision for specific program components will be provided by appropriate faculty depending on the activity and requirements.

Required projects

It is important for fellows participating in clinical investigator training to experience the complete spectrum of oncologic drug development from concept development to scientific writing. Therefore, during protected research time (12 months for medical oncology fellows and 18 months for hematology/oncology fellows), participating fellows should complete the following projects:

1. Two letters of intent, soliciting consideration of a clinical trial concept from the National Cancer Institute (NCI, CTEP), cooperative group (i.e. Cancer and Leukemia Group B), or pharmaceutical industry.
2. One protocol. The fellow should design, write, and submit at least one phase I or II protocol to the NCI or OSU IRB.
3. The fellow should select 1-2 ongoing protocols and serve as the junior PI on these studies, assisting in patient recruitment, consent, and patient management. The fellow should also attend weekly or bi-monthly meetings of the PI, research nurse, and data managers where toxicity is analyzed and dose escalation decisions made.
4. The fellow will attend at least 2 half days of clinic/week (one half-day of this requirement should be their continuity clinic) in their area of interest.
5. The fellow is encouraged to analyze and assimilate data for publication from either a completed clinical trial or a retrospective database.
6. Clinical investigator fellows are encouraged to participate in the writing of abstracts and presentations at research meetings.

Required Conferences
Clinical investigator fellows are required to attend all of the following conferences:
1. Journal Club, Mon noon, B410
2. Fellow Business Meeting, every 3rd Mon noon, B410
3. Basic Lecture Series, Tues 7:30 am, B410
4. Clinical Review Conference, Tues noon, B410
5. Weekly Drug Development Meeting (Phase I/II meeting): Wed noon, B410
6. Tumor Board, Thurs 8:30 am, 518 James
7. CCC Grand Rounds, Friday 8:00 am, 518 James

National Meetings
Fellows in the Clinical Investigator research pathway will be encouraged to attend the following meetings during the course of their fellowship.

1. American Society of Clinical Oncology (ASCO) annual meeting
2. American Association of Cancer Research (AACR) annual meeting
3. American Society of Hematology (ASH) annual meeting
4. AACR/ASCO Methods in Clinical Cancer Research Workshop, held annually (July or August)
5. ASH Cancer Research Training Institute – held annually (July or August)
6. Spring and Fall NCI Phase I meetings
7. AACR/NCI/EORTC Drug Development Meeting

Additional Coursework
Clinical investigator research fellows are also encouraged to participate in any of the following institutional and national training programs.
1. Summer Program in Applied Biostatistical and Epidemiological Methods Course: Offered yearly by the OSU Center for Biostatistics/School of Public Health, in July.
2. Masters of Public Health Program, OSU
3. Internships at the National Cancer Institute for 1-2 month blocks

Laboratory Research
The fellow will have the opportunity to undertake laboratory research in a variety of laboratory disciplines including investigations related to cancer cell biology, pharmacology, molecular biology and translational biology. Owing to the relatively limited time of the fellowship and the large
number of other demands, only limited, problem-oriented, translational projects related to new anticancer drug development can be undertaken.
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