

# GLOBAL MEDICAL, INC.

## ADVANCED SPINE RESEARCH FELLOWSHIP

### PROGRAM OVERVIEW AND GUIDELINES

#### **1.0 Scope**

The Musculoskeletal Education and Research Center serves as the research division of Globus Medical. The primary vision and mission of MERC is one defined by integration, development and expansion to create a multidisciplinary research center with core areas of research excellence across a broad spectrum of scientific disciplines. Non-clinical research fellowships enable young health care professionals to gain additional knowledge and research training in the field of applied musculoskeletal research.

#### **2.0 Overview of the Advanced Spine Research Fellowship Program**

The non-clinical research fellowship (a.k.a. advanced spine research fellowship) program based at the Musculoskeletal Education and Research Center is designed to provide National and International clinicians the opportunity to participate in musculoskeletal research, with an emphasis in clinical and basic science. The overall objective of this non-clinical research training program is for fellows to become proficient in the methodological aspects of conducting basic scientific or clinical research and generate scientific manuscripts suitable for publication in peer review journals. The capabilities of MERC include biomechanical testing and finite element analysis, histology laboratories, radiography, scanning electron microscopy, in vivo modeling, clinical research and fellowship training programs. Of high collateral importance is the availability of the newly established Bohlman-Cushing-Dandy Memorial Library and Archives for the benefit of full-time and fellowship researchers. Orthopaedic surgeons and neurosurgeons – from national and international training programs - have the opportunity through this program to work as non-clinical research fellows together with MERC research scientists and staff. The research facility adheres to Good Laboratory Practices and provides a basic scientific and clinical research environment in which researchers and clinicians share the opportunity to pursue their musculoskeletal research interests and goals. The ultimate objective in this program is to develop and maintain a premier musculoskeletal research center and facilitate research initiative towards the treatment of musculoskeletal disorders. It is the ongoing, concerted research efforts with non-clinical research fellows from around the world that, in part, provides innovative and advanced technology for the surgical care and treatment of patients with musculoskeletal pathology. This fellowship program is designed for candidates with commitment, a pioneering and teachable spirit, and strong desire to succeed. As a multidisciplinary organization, the MERC non-clinical fellowship opportunity offers a rigorous and highly competitive research training program within an intellectually challenging, innovative and supportive environment – one that will provide fellows with a solid foundation for future research endeavors.

### 3.0 Program Description

The MERC non-clinical research fellowship is an opportunity for a full immersion research fellowship, with the unique perspective of being located in and sponsored by a leading world-wide musculoskeletal company. Following an orientation program of mandatory Globus Medical compliance training, selected scientific readings and laboratory standard operating procedures, the research program itself will include selection of a study topic and pertinent experimental endpoints, study design, conducting the experiment, analysis of the data acquired, and presentation / publication of the results in a peer-reviewed journal. An emphasis will be placed on addressing clinically relevant issues of new surgical reconstruction techniques using instrumentation. The overall objective of this non-clinical research training program is for fellows to become proficient in the methodological aspects of conducting basic scientific and / or clinical research. Fellows will be required to propose research protocols as part of their application based upon understanding the capabilities of the MERC facility. Fellowship positions will be offered annually to national and international applicants for terms of 3, 6 or 12 months (minimum of 6 months for international applicants), and all applicants must commit for the full term selected and approved. Fellows will have the additional opportunity to interface with local academic medical centers and attending clinical staff from facilities such as the University of Maryland. This interface will include attendance at Grand Rounds, observing operative procedures (strictly no patient contact) and opportunity to present basic science or clinical research projects or related topics at the annual Globus Medical Fellows' meeting, Annual MERC Symposium or other scientific venues as approved by the Director of Musculoskeletal Research.

#### Outline of the Proposed Research Program:

Following an orientation program and compliance training required by Globus Medical Inc., the research program itself will include selection of a study topic, pertinent experimental endpoints, study design, conducting the experiment, analysis of the data acquired and presentation / publication of the study data in a peer-reviewed scientific journal. To this end and as a component of the *Non-Clinical Research Fellowship Application*, each fellow will propose an area of research interest and, if available, a study protocol.

During the fellowship period, the research fellow will report to the Director of Musculoskeletal Research with weekly meetings to assess study progress. At the completion of the non-clinical spinal research fellowship, each fellow is expected to have completed 1 to 3 manuscripts in which they are the primary author and co-authored 3 to 5 basic science or clinical studies which are all suitable for peer review journal publication. The duration of the fellowship will determine these study numbers.

Overall, the fellow is expected to have a fundamental understanding of the following scientific disciplines upon completion of this research program: spinal biomechanics, micro-computed tomography, undecalcified bone histology and histomorphometry, functional animal models for spinal research, scanning electron microscopy, computational and statistical analyses and basic methods for clinical research. The

fellow's program of study may result in greater exposure to one or more of these core areas of research. Importantly, the program in which the non-clinical research fellow will be engaged is solely for the purpose of observation, teaching and research, and no element of direct or indirect patient care services is involved. Having successfully completed this non-clinical fellowship, a diploma from the Musculoskeletal Education and Research Center Program will be awarded.

#### **4.0 Requirements for MERC Non-Clinical Research Fellowships**

Fellowship applicants and formal applications must be consistent with the following requirements as a prerequisite for approval. Any applicant that does not meet the following fundamental requirements will not be approved.

- 4.1 Successful completion of an accredited Medical Doctorate (MD), Doctorate of Osteopathic Medicine (DO) or Fellowship of the Royal College of Surgeons (FRCS) degree.
- 4.2 Currently enrolled in an accredited orthopaedic or neurosurgery residency or fellowship program and in good standing with the institution, program and department chairman.
- 4.3 Applicants must provide a letter of recommendation from their department chairman or fellowship director.
- 4.4 Applicants must have completed and submitted a formal *Non-Clinical Research Fellowship Application* and research proposal as part of the submission process.
- 4.5 Applicants must have a stated interest in pursuing a career in the field of orthopaedic or neurosurgical spine surgery.
- 4.6 National Research Fellows: Proof of salary support from their residency program is required.
- 4.7 International Research Fellows: All rules and applicable guidelines according to the US Department of State for J-1 Visa applicants (<http://j1visa.state.gov/participants/>) and (<http://travel.state.gov/content/visas/en/study-exchange/exchange.html>) must be followed. As mandated by the US Department of State and Educational Commission for Foreign Medical Graduates (ECFMG) for J-1 Visa recipients, a supporting letter of documentation is required indicating a monthly stipend in the amount of \$1,600 will be provided to the applicant by the applicant's home institution / university for general living expenses or the fellow can document liquid assets equal to \$1,600 for each month of the fellowship. Furthermore, it should be stated within the letter that the monthly stipend will continue for the duration of the fellowship period. The research applicant should indicate on their application the amount of financial support provided by their home institution.
  - 4.7.1 Proficiency in conversational English, as determined by an interview with the Globus Medical Director of Musculoskeletal Research is required and mandated by the ECFMG for Foreign Medical Graduate (FMG) applicants. The non-clinical fellow should have completed medical school (MD, DO or FRCS degree) and be in

the process of completing an orthopaedic or neurosurgical residency or fellowship from an approved foreign medical institution, and the applicant should come highly recommended from their chief of service as having a sincere interest in the field of research to be accepted for this position.

- 4.7.2 Proof of health insurance is mandatory for all international research fellows and is the responsibility of the research fellow to obtain and maintain throughout the duration of the fellowship. The U.S. Code of Federal Regulations (22 CFR § 62.14) mandates that all J-1 exchange visitors secure comprehensive health insurance effective on the program start date indicated on Form DS-2019 and maintain coverage, without interruption, for the full duration of stay in the United States in J-1 status. Any J-1 exchange visitor who refuses to comply with health insurance requirements will be considered to be in violation of his/her status and subject to termination from the J-1 program ([www.ecfm.org/evsp/mandatory-medical-insurance.html](http://www.ecfm.org/evsp/mandatory-medical-insurance.html)).

#### 4.8 Funding and Housing

- 4.8.1 All funding from Globus Medical to non-clinical research fellows will abide by the Globus Medical, AdvaMed and MedTech applicable policies and procedures regarding health care professionals.
- 4.8.2 Funding may include attendance with associated expense support at one or more scientific meetings at the discretion of the Director of Musculoskeletal Research.
- 4.8.3 Globus employees are not permitted to expense meals with the Fellow with the exception of modest business meals with members of the Research Department or Executive Team.
- 4.8.4 Product Development and Sales employees/distributors are not permitted to include the Fellow in any business meals

#### 4.9 Fellowship Term(s)

- 4.9.1 National based fellows shall be for terms of 3, 6 or 12 months. The preferred time interval is 6 or 12 months, which gives the fellow sufficient time to complete the research and writing components. International fellows are required to stay at least 6 months but a 12 month term is preferred and given priority. Additions to the term length (i.e. 6 to 12 months) may be considered and approved by the RFAC at least 60 days prior to the scheduled end of the initial term. Extension of the J1 Visa and any other applicable documents mandated by US Department of State are the fellow's responsibility. The maximum duration for any fellowship period will be two years (24 months).
- 4.9.2 Non-clinical Research Fellow or "Research Scholars" as defined by the ECFMG will be considered contract workers and not official

full-time employees of Globus Medical, Inc. Badge access to the premises will be provided and processed through the Globus Medical Department of Human Resources.

#### 4.10 General Provisions

4.10.1 The non-clinical research fellowship will be non-promotional in nature. Its singular goal will be to advance the education of the fellow within the scope of the fellowship.

### 5.0 Process

#### 5.1 Submission of Fellowship Applications

Fellowship applications must be submitted by the fellow's institution and be consistent with the following requirements as a prerequisite for approval. Any application that does not meet the following fundamental requirements will not be reviewed.

5.1.1 Forms: The *Non-Clinical Research Fellowship Program Overview* and *Non-Clinical Research Fellowship Application* forms are available through the Globus Medical website – MERC division (<http://www.globusmedical.com/education/non-clinical-research-fellowships>).

5.1.2 Sales personnel may not initiate, complete or submit a *Non-Clinical Research Fellowship Application* Form.

5.1.3 Applications must be submitted and received by MERC by the posted deadline on the Globus Medical website, and fellowship periods will begin at various time intervals based on the applications received and rotation schedules. For this reason, fellowship durations of at least 6 or 12 months will be given priority.

5.1.4 The responsible member of MERC will review all applications to ensure they meet the fundamental requirements and for completeness. They will obtain additional information as needed.

5.1.5 The Director of Musculoskeletal Research will review all applications for suitability of the applicant, research proposal and the ability of MERC to support such proposal before they are submitted to the External Review Committee. Applications may be denied at this point if the research proposed or desired program of study is not in keeping with the research capabilities of MERC. If so, a form letter will be sent to the applicant thanking them for their interest and time in applying for the fellowship program but their application was not accepted.

### 6.0 Fellowship Program Research Facilities

#### 6.1 MERC Laboratory Research Facilities:

- 6.1.1 Biomechanical Testing Laboratory – Consists of three independent six-degree-of-freedom (6DOF) units configured with Certus optoelectronic tracking system, LabView software and fluoroscopic image intensifiers. Two 858 MTS load frames and pumps (one biaxial / one uniaxial) for static and fatigue testing. Strain gauge technology for intradiscal pressures, spinal instrumentation and osseous strain measurements. Dual energy x-ray (DEXA) GE Lunar Prodigy scanner for quantification of specimen bone mineral density and surgical instruments. Software packages for Finite Element Analysis and statistical analysis (SPSS).
- 6.1.2 Histology and Histomorphometry Laboratories – Capable of decalcified and undecalcified histological processing of tissues. Histomorphometry system and image analysis for performing quantitative calculations of any bone or soft tissue parameter (e.g. trabecular bone volume or osteoclast cell counts). Image J and Matlab programs are available for image processing. Immunohistochemistry lab designed for performing specialty macrophage and cytokine stains of soft tissue or decalcified specimens. Plain and polarized light microscopes (n=3) interfaced with two 55” LCD wall mounted monitors for viewing histology images and histomorphometry techniques.
- 6.1.3 Radiography / Photography / Videography Laboratories – Micro-computed tomography system is available for visualization and quantification of osseous or material parameters. High volume image capture and analysis programs are available for quantitative analysis of fluoroscopic images, plain films, computed tomography and magnetic resonance images (Image J and Matlab software programs). Dark room facilities and Faxitron unit are available for producing histologic microradiographs.
- 6.1.4 Scanning Electron Microscopy and Particle Analysis Laboratory - Scanning electron microscopy (SEM) and Coulter counter (counts metallic or polymeric particles).
- 6.1.5 In-Vivo Animal Modeling – All in-vivo animal studies will commence following approval by the appropriate Institutional Animal Care and Use Committee (IACUC). Most importantly, all procedures involving in-vivo models strictly abide by and comply with applicable sections of the current versions of the following regulations and guidance documents: 1) Animal Welfare Act Regulations (9 CFR); 2) U.S. Public Health Service Office of Laboratory Animal Welfare (OLAW) Policy on Humane Care and Use of Laboratory Animals; 3) Guide for the Care and Use of Laboratory Animals (Institute of Laboratory Animal Resources, Commission on Life Sciences, National Research Council, 1996) and all participating facilities are accredited by the American Association for the Accreditation of Laboratory Animal Care International (AAALACi).



- 6.1.6 Bohlman-Cushing-Dandy Memorial Library and Archives - Due to the enormous generosity of Ms. Amanda Prescott, Dr. Henry Bohlman's widow, the Bohlman family and Dr. Bohlman's close friends, the availability of Dr. Henry H. Bohlman's career-long collection of radiographic archives, 35mm slides, personal library and memorabilia have been donated to MERC. MERC is honored to be caretakers and stewards of Dr. Bohlman's work and see his wishes realized to fruition -- create a living digital archived database dedicated to the education and training of future generations of spine surgeons. Dr. Bohlman was the consummate educator and his collection is dedicated to all devoted spine surgeons, of all countries, of all socioeconomic backgrounds for the benefit of patients suffering from spinal deformities and neurologic compression. This career long collection of Dr. Bohlman includes 60,000+ x-rays, slides, personal library and memorabilia.
- 6.1.7 Clinical Research - Retrospective studies and prospective studies are conducted to examine clinical outcomes. A team of researchers within MERC focuses on post-market studies, which represent an important aspect of evidence-based medicine and present opportunities to improve products and further develop innovative solutions.