

GRADUATE MEDICAL EDUCATION

POLICIES AND PROCEDURES

DIVISION



Feb. 2019

Presented by: The Florida State University College of Medicine



FSU College of Medicine Graduate Medical Education (GME)

Institutional Sponsorship Policies and Guidelines

Rev. Feb. 2019

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5. Transferred programs (full review)
6. As periodically determined by the DIO

A Special Review will be scheduled within 45 days of a program's being identified as underperforming.

The Special Review Committee will be designated and will include, at a minimum, the DIO or designee acting as Chair of the Special Review Committee, an administrative member of the GMEC, a program director or faculty member from another program, and residents or fellows who are not members of the program under review.

The members of the program to be interviewed should include, but are not limited to, the program director, other key faculty members and peer selected residents/fellows. Other individuals as determined by the Special Review Committee also could be interviewed.

The Special Review Committee will conduct the special review through examination of materials, data and other information provided by the program and through interviews with identified individuals.

The Special Review Committee will prepare a written report to be presented to the GMEC for review and approval. At a minimum, the report will contain:

1. A description of the quality improvement goals to address identified concerns;
2. A description of the corrective actions to address identified concerns; and,
3. The process for the GMEC to monitor outcomes of corrective actions taken by the program.

Monitoring of Outcomes

The GMEC will monitor outcomes of the Special Review by documenting discussions and follow up in the GMEC minutes.

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Revision Date November 2016
Date Approved by FSU GMEC: 2.22.18

Section VI: Program and Institutional Policies

6.1 POLICY: CLINICAL EXPERIENCE AND EDUCATION

PURPOSE:

This policy is to state how the Graduate Medical Education Committee (GMEC), as the Florida State University College of Medicine governing body for graduate medical education, institutes and supports limits on resident/fellow work hours, while assuming responsibility for addressing the impact of compliance with the Accreditation Council for Graduate Medical Education (ACGME) duty hour requirements.

DEFINITION:

An aim of the ACGME Clinical Learning Environment Review (CLER) is to monitor a sponsoring institution's maintenance of a learning environment that promotes and advances appropriate care transitions, supervision, fatigue mitigation, and duty hours' compliance, and the institution's support of professionalism throughout all of its residency and fellowship programs. Each program must have written policies and procedures consistent with the ACGME Institutional and Common Program Requirements for resident/fellow duty hours. The Graduate Medical Education policy is to provide residents/fellows with a sound academic and clinical education that is carefully planned and balanced with concerns for patient safety and resident well-being.

POLICY:

Resident/Fellow clinical experience and education for each GME program must not be excessive and must be consistent with the Program Requirements of the relevant review committee. Individual programs or specialty review committees may impose more stringent clinical experience restrictions, in which case the program will be held to that standard; however, in no case may an individual program impose a policy less restrictive than the institutional policy, ACGME common program requirements, or specialty specific review committee requirements. On-call time and duty hours should be consistent with the educational needs of the resident/fellow and not be motivated by excessive reliance on the residents/fellows to fulfill institutional service obligations.

Maximum Hours of Clinical and Educational Work per Week

Clinical and educational work hours must be limited to no more than 80 hours per week, averaged over a four-week period, inclusive of all in-house clinical and educational activities, clinical work done from home and all moonlighting.

Mandatory Time Free of Clinical Work and Education

All programs must design an effective program structure that is configured to provide residents/fellows with educational opportunities, as well as reasonable opportunities for rest and personal well-being. Residents/Fellows should have eight hours off between scheduled clinical work and education periods. There may be circumstances when residents/fellows choose to stay to care for their patients or return to the hospital with fewer than eight hours free of clinical experience and education. This must occur within the context of the 80-hour and the one-day-off-in-seven requirements. Residents/Fellows must have at least 14 hours free of clinical work and education after 24 hours of in-house call. Residents/Fellows must be scheduled for a minimum of one day in seven free of clinical work and required education (when averaged over four weeks). At-home call cannot be assigned on these free days.

Maximum Clinical Work and Education Period Length

Clinical and educational work periods for residents/fellows must not exceed 24 hours of continuous scheduled clinical assignments. Up to four hours of additional time may be used for activities related to patient safety, such as providing effective transitions of care, and/or resident/fellow education. Additional patient care responsibilities must not be assigned to a resident/fellow during this time.

Clinical and Educational Work Hour Exceptions

In rare circumstances, after handing off all other responsibilities, a resident/fellow, on their own initiative, may elect to remain or return to the clinical site in the following circumstances:

- to continue to provide care to a single severely ill or unstable patient;
- humanistic attention to the needs of a patient or family; or,
- to attend unique educational events.

These additional hours of care or education will be counted toward the 80-hour weekly limit.

A Review Committee may grant rotation-specific exceptions for up to 10 percent or a maximum of 88 clinical and educational work hours to individual programs based on a sound educational rationale. In preparing a request for an exception, the program director must follow the clinical and educational work hour exception

policy from the *ACGME Manual of Policies and Procedures*. Prior to submitting the request to the Review Committee, the program director must obtain approval from the FSU COM GMEC and DIO.

Moonlighting

Moonlighting must not interfere with the ability of the resident to achieve the goals and objectives of the educational program, and must not interfere with the resident's fitness for work nor compromise patient safety. Time spent by residents in internal and external moonlighting must be counted toward the 80-hour maximum weekly limit. (Reference policy 6.3 Moonlighting)

In-House Night Float

Night float must occur within the context of the 80-hour and one-day-off-in-seven requirements.

Note: The maximum number of consecutive weeks of night float, and maximum number of months of night float per year may be further specified by the applicable Review Committee.

Maximum In-House On-Call Frequency

Residents/Fellows must be scheduled for in-house call no more frequently than every third night (when averaged over a four-week period).

At-Home Call

Time spent on patient care activities by residents/fellows on at-home call must count toward the 80-hour maximum weekly limit. The frequency of at-home call is not subject to the every-third-night limitation, but must satisfy the requirement for one day in seven free of clinical work and education, when averaged over four weeks. At-home call must not be so frequent or taxing as to preclude rest or reasonable personal time for each resident/fellow. Residents/Fellows are permitted to return to the hospital while on at-home call to provide direct care for new or established patients. These hours of inpatient patient care must be included in the 80-hour maximum weekly limit.

Consistent with Institutional Policy, all outside activity (moonlighting) must comply with all clinical experience and education requirements noted above. Program specific policies must address all items above. All policies must be in compliance with all Institutional and Review Committee specific policies for the specialty. Programs must demonstrate valid and reliable methods to demonstrate compliance with the clinical experience and education guidelines. The GMEC will monitor compliance of programs via quarterly review of clinical experience logs. ACGME resident surveys, special program reviews, annual program evaluations, and interviews will also be reviewed as appropriate. Aggregate reports and violations will be monitored.

In addition to all noted above, the institution further requires that assigned clinical responsibilities (including offsite call) must not preclude adequate rest and reasonable personal time. In this regard, program directors should carefully monitor the frequency of extended shifts, moonlighting activity and instances of urgent or emergent patient care requiring the resident's/fellow's return to the worksite during periods of call from home.

Program directors shall ensure that training regarding the symptoms of fatigue and their effects on performance is provided to faculty and residents/fellows. Additionally, the FSU COM requires new residents/fellows to complete an online module on fatigue/sleep deprivation prior to initial orientation. Program directors shall define a schedule for monitoring resident/fellow work hours. During periods of monitoring, residents/fellows are required to document their work hours accurately and completely. Program directors shall periodically review the data with the goal of ensuring compliance with this and the program's clinical experience and education policies, adjust schedules as necessary to mitigate excessive service demands and/or fatigue, and report their findings and responses to the GME Office and/or the Graduate Medical Education Committee upon request.

Each program is required to have a written clinical experience and education policy consistent with this Institutional Policy. Policies for ACGME programs must also address any additional limits on resident/fellow work-hours, and any specialty-specific clinical experience definitions and optimal clinical workload included in

the relevant ACGME (sub) specialty Program Requirements. The program's policies must be communicated to all members of the faculty, resident/fellow staff, and medical staff.

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Revision Date February 2018
Date Reviewed by FSU GMEC: 2.22.18

6.2 POLICY: LEARNING / WORK ENVIRONMENT

PURPOSE:

This purpose of this policy is to establish learning and work environment standards for residents and fellows and ensure the experience is not compromised by excessive reliance on residents/fellows to fulfill non-physician service obligations. Accordingly, all hospitals/clinical sites where residents/fellows work must provide appropriate support services to minimize work extraneous to the education program.

DEFINITION:

Each program director must establish and implement formal written policies and procedures governing duty hours and work environment for residents/fellows, which comply with this institutional GME policy and the Common and Specialty-Specific Program Requirements. Programs must be committed to and responsible for promoting patient safety and resident/fellow well-being in a supportive educational environment. The learning objectives of the program must be accomplished through an appropriate blend of supervised patient care responsibilities, clinical teaching, and didactic educational events; and must not be compromised by excessive reliance on residents/fellows to fulfill non-physician service obligations.

POLICY:

The ACGME has delineated the concept of clinical experience and the learning environment into multiple overarching categories, with corresponding specifications, listed below.

Professionalism, Personal Responsibility, and Patient Safety

The program director and institution must ensure a culture of professionalism that supports patient safety and personal responsibility. All residents/fellows and faculty members must demonstrate responsiveness to patient needs that supersedes self-interest. Physicians must recognize that under certain circumstances, the best interests of the patient may be served by transitioning that patient's care to another qualified and rested provider. Residents/Fellows and faculty members must demonstrate an understanding and acceptance of their personal role in the following:

1. Assurance of the safety and welfare of patients;
2. Provision of patient- and family-centered care;
3. Assurance of fitness for duty;
4. Management of time before, during, and after clinical assignments;
5. Recognition of impairment, including illness and fatigue, in themselves and in peers;
6. Attention to lifelong learning;
7. Monitoring personal patient care performance improvement indicators; and
8. Honest and accurate reporting of duty hours, patient outcomes, and clinical experience data.

Transitions of Care

1. Programs must design clinical assignments to minimize the number of transitions

- in patient care;
2. Sponsoring institutions and programs must ensure and monitor effective, structured hand-over processes to facilitate both continuity of care and patient safety; and
3. Programs must ensure that residents/fellows are competent in communicating with team members in the hand-over process.

Clinical Responsibilities

The clinical responsibilities for each resident/fellow must be based on PGY-level, patient safety, resident education, severity and complexity of patient illness/condition and available support services (further specified by Residency Review Committees [RRCs]).

Teamwork

Residents/Fellows must care for patients in an environment that maximizes effective communication. This must include the opportunity to work with residents/fellows and faculty as a member of effective inter-professional teams that are appropriate to the delivery of care in the specialty (further specified by RRCs).

Clinical Experience and Education

Programs will comply with resident/fellow clinical experiences and education guidelines and definitions as set forth in the applicable Program Requirements and Clinical Experience and Education policy.

Work Environment

- *Food Services:* Residents/Fellows on duty must have access to adequate and appropriate food services. Food is provided to residents/fellows who take in-house call.
- *Call Rooms:* Call rooms are provided for residents/fellows who take in-house call and are segregated by gender.
- *Support Services:* Adequate ancillary support for patient care shall be provided for residents/fellows at all times.
- *Medical Records:* Medical records systems that document the course of each patient's illness and care must be available at all times and adequately support quality patient care, education of residents/fellows, quality assurance and provide a resource for scholarly activity. Electronic medical records are preferred, and affiliated clinical institutions are requested to comply with implementation as soon as possible.
- *Security/safety:* Appropriate security and personal safety measures must be provided to residents/fellows at all locations while on duty and while in transit between parking areas and duty assignments.

Oversight

1. Each program must have written policies and procedures consistent with the Institutional and Program Requirements for resident clinical experience and education environment. These policies and procedures must be distributed to the residents/fellows and faculty.
2. Back-up support systems must be provided when patient care responsibilities are unusually difficult or prolonged, or if unexpected circumstances create resident/fellow fatigue sufficient to jeopardize patient care.
3. Each program director should review each resident's/fellow's rotational schedule to assure compliance with this institutional policy and the Common Program Requirements, and should document and monitor unusual patient care circumstances that require an extension of a duty period as specified above and in the Common Program Requirements.
4. Each program director should regularly monitor resident/fellow clinical experience and education hours for compliance with this institutional policy and the Common Program Requirements. Monitoring of clinical experience and education hours is required with frequency sufficient to ensure an appropriate balance between education and service.
5. The Graduate Medical Education Committee shall monitor compliance with this policy through the:
 - a. Annual program evaluations;
 - b. Annual GME Survey of Residents/Fellows; and

- c. Periodic monitoring of individual programs.

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Date Approved by FSU GMEC: 2.22.18

6.3 POLICY: MOONLIGHTING

PURPOSE:

The Accreditation Council for Graduate Medical Education (ACGME) requires that the Sponsoring Institution have policies regarding professional activities outside the educational program. The Florida State University College of Medicine Graduate Medical Education (GME) Program establishes this policy regarding resident moonlighting to ensure program compliance with the (ACGME) requirements.

POLICY:

Individual residency programs are accredited by their Residency Review Committee (RRC) and must adhere to specialty review committee requirements regarding moonlighting. Although RRC's vary, the general scope is that any professional activities which are outside the established educational program must not interfere with the resident's established educational process or the quality of patient care. Residents shall not be required to engage in professional activities outside the educational program.

COMMON DEFINITIONS.

Moonlighting is defined as compensated clinical work performed by a resident during the time that he/she is a member of a residency program. This policy addresses two categories of moonlighting:

Programmatic: The clinical work occurs within the specific residency program and its participating institution(s), and is simply an extension of the same type and location of clinical work performed as a requirement of the GME program. Programmatic moonlighting includes internal work only.

Non-Programmatic: The clinical work is not an extension of the residency program and its participating institution(s), and in no circumstance is the resident to hold him/herself as an employee of the GME program while engaged in such activities. Non-programmatic moonlighting may include internal or external work.

PRIMARY RESPONSIBILITIES.

Institution and Program

It is the responsibility of the program director to decide whether or not moonlighting will be allowed. The program director must comply with the institution's policies and procedures. The conditions under which a resident may be allowed to participate in programmatic and/or non-programmatic moonlighting must meet ACGME requirements.

If a program director allows a resident to moonlight, a *Programmatic Moonlighting Approval Form* is required if the moonlighting is programmatic, and a *Non-Programmatic Moonlighting Approval Form* is required if the moonlighting is non-programmatic. The appropriate approval form is then made a part of the resident's file as required by the ACGME.

Because residency education is a full-time endeavor, the Program Director must approve and monitor all moonlighting to ensure that moonlighting does not interfere with the ability of the resident to achieve the goals and objectives of the educational program.

THE RESIDENTS.

The resident must be a current resident in the program, and must be in good standing.

PGY-1 residents are not permitted to moonlight.

Residents on J-1 visas may not moonlight, as mandated by the Educational Committee for Foreign Medical Graduates.

A resident wishing to moonlight must obtain prior written approval from his/her program director. (*Ref. Institution and Program section above, para. 2*)

Because residency education is a full time endeavor, residents must ensure that moonlighting does not interfere with their ability to achieve the goals and objectives of their educational program. Residents are responsible for ensuring that moonlighting and other outside activities do not result in fatigue that might affect patient care or learning.

A resident's failure to comply with the *Moonlighting Policy* is a breach of contract and grounds for termination.

PROGRAMMATIC MOONLIGHTING.

The Program Director must ensure, direct, and document supervision and faculty support appropriate for the level of training of residents at all times. While performing these services, residents are not to act as independent practitioners. Faculty schedules must be structured to provide residents with continuous supervision and consultation.

Residents must be provided with efficient, reliable systems for communicating with supervising faculty. Faculty are also responsible to recognize the signs of fatigue and adopt and apply practices to prevent and counteract the potential negative effects.

NONPROGRAMMATIC MOONLIGHTING.

Residents must be licensed for unsupervised medical practice in the state where such activity occurs, including DEA licensure as applicable and any other requirements for clinical privileging at the employment site. There must be an exchange of permission letters between the Program Director and appropriate staff at the institution where the moonlighting will occur if the moonlighting is done externally.

Residents are not covered under the University's professional liability insurance program as the activity is outside the scope of University employment. The resident is responsible for his/her own professional liability coverage (either independently or through the entity for which the resident is moonlighting) and must provide documentation of such.

Non-programmatic moonlighting hours must be documented (including days, hours, location, and brief description of type of service[s] provided).

WORK HOURS.

All moonlighting hours must be documented, and they must comply with the written policies regarding Clinical Experience and Education as per the training program and the ACGME. The Program Director may not approve residents for any internal moonlighting that requires residents to exceed the 80-hour per week (on average per 4-week, or as defined by specialty specific Review Committee) rule or other provisions of the clinical experience and education requirements.

MAINTAINING APPROVAL.

The Program Director will monitor resident performance in the Program to ensure that moonlighting activities are not adversely affecting patient care, learning or resident fatigue. The GME Committee will periodically review reports by the Program Director(s) regarding moonlighting activity.

If at any time the Program Director determines that a resident's moonlighting schedule is adversely impacting the resident's performance in the training program, the Program Director may withdraw the permission to moonlight.

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PROGRAMMATIC MOONLIGHTING APPROVAL FORM

PARTS 1 & 2 TO BE COMPLETED BY THE RESIDENT:

Rev. 2/2018

Part 1: GENERAL INFORMATION:

Name _____ Date _____
Program _____ Program Location _____ PGY _____

Part 2: I UNDERSTAND THE FOLLOWING:

- a. All moonlighting must have the full knowledge and approval of the Residency Director; and the resident must provide a monthly moonlighting schedule to the Residency Office.
- b. Only those residents in good standing will be allowed to moonlight. That is, only those residents who have average to above average evaluations, have not had issues with medical records within the last six months, and have taken and passed step 3 of the *United States Medical Licensing Examination* (USMLE).
- c. No PGY-1 resident is permitted to moonlight.
- d. No resident shall moonlight while on back-up call, post-call, nor pre-call.
- e. No resident shall moonlight while on an inpatient rotation, nor while on Float
- f. Under no circumstance is a resident allowed to moonlight while on medical leave nor after calling in for a sick day.
- g. The resident must bear in mind that all programmatic moonlighting constitutes part of the 80 hr. work week. Under no circumstance is the resident to exceed the 80 hr. total. The moonlighting resident must document to the Residency Director what their weekly hours are, including a breakdown of residency clinical experience and education hours and moonlighting duty hours.
- h. The RRC very clearly stipulates that under no circumstance is moonlighting to interfere with the resident's responsibilities to their residency. Moonlighting is a privilege, which can and will be permanently revoked if a resident is found to be derelict in their responsibilities as listed above. Continuing to moonlight after this privilege has been revoked will constitute grounds for immediate dismissal from this residency program.
- i. Under federal statutes no moonlighting is permissible for residents holding a J1 Visa.

I acknowledge that I have carefully read and fully understand the policies regarding programmatic moonlighting as stated in this Approval Form as well as the Moonlighting Policy.

Resident Signature _____ Date _____

PART 3 TO BE COMPLETED BY THE PROGRAM DIRECTOR:

Part 3: DIRECTOR'S ATTESTATIONS:

The resident is not on academic probation; the total hours in the resident's educational program and the moonlighting activities will not exceed the limits set forth by ACGME; and this opportunity does not replace any part of the clinical experiences integral to the resident's training program, and the resident will be under faculty supervision while engaging in moonlighting activities.

Program Director Signature _____ Date _____



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NONPROGRAMMATIC MOONLIGHTING APPROVAL FORM

PARTS 1 & 2 TO BE COMPLETED BY THE RESIDENT:

Rev. 2/2018

Part 1: GENERAL INFORMATION:

Name _____ Date _____

Program _____ Program Location _____ PGY _____

Part 2: I UNDERSTAND THE FOLLOWING:

- a. All moonlighting must have the full knowledge and approval of the Residency Director; and the resident must provide a monthly moonlighting schedule to the Residency Office.
- b. Only those residents in good standing will be allowed to moonlight. That is, only those residents who have average to above average evaluations, have not had issues with medical records within the last six months, and have taken and passed step 3 of the *United States Medical Licensing Examination* (USMLE).
- c. No PGY-1 resident is permitted to moonlight.
- d. No resident shall moonlight while on back-up call, post-call, nor pre-call.
- e. No resident shall moonlight while on an inpatient rotation, nor while on Float.
- f. Under no circumstance is a resident allowed to moonlight while on medical leave nor after calling in for a sick day.
- g. The resident must bear in mind that all nonprogrammatic moonlighting constitutes part of the 80 hr. work week. Under no circumstance is the resident to exceed the 80 hr. total. The moonlighting resident must document to the Residency Director what their weekly hours are, including a breakdown of residency clinical experience and education hours and moonlighting duty hours.
- h. The RRC very clearly stipulates that under no circumstance is moonlighting to interfere with the resident's responsibilities to their residency. Moonlighting is a privilege, which can and will be permanently revoked if a resident is found to be derelict in their responsibilities as listed above. Continuing to moonlight after this privilege has been revoked will constitute grounds for immediate dismissal from this residency program.
- i. Under federal statutes no moonlighting is permissible for residents holding a J1 Visa.

I acknowledge that I have carefully read and fully understand the policies regarding programmatic moonlighting as stated in this Approval Form as well as the Moonlighting Policy.

Resident Signature _____ Date _____

PART 3 TO BE COMPLETED BY THE PROGRAM DIRECTOR:

Part 3: DIRECTOR'S ATTESTATIONS:

The resident is not on academic probation; the total hours in the resident's educational program and the moonlighting activities will not exceed the limits set forth by ACGME; and this opportunity does not replace any part of the clinical experiences integral to the resident's training program, and the resident will be under faculty supervision while engaging in moonlighting activities.

Program Director Signature _____ Date _____

6.4 POLICY: SUPERVISION

PURPOSE:

To establish supervision standards and responsibilities for all graduate medical education programs, ensuring quality of care and patient and resident safety. Residents/Fellows will be supervised by faculty physicians in a manner that is consistent with the Accreditation Council for Graduate Medical Education common program requirements and specialty-specific conditions for programs.

DEFINITION:

Supervision will consist of three levels: Direct, Indirect, and Oversight

Direct supervision requires that the faculty member must be physically present in the hospital or clinic with the resident and the patient.

Indirect supervision with direct supervision immediately available requires the supervising faculty member to be physically within the hospital or other site of patient care and is immediately available to provide direct supervision and direction.

Indirect supervision with direct supervision available means that the supervising faculty member is not physically present within the hospital or other site of patient care, but is immediately available by mean of telephonic and/or electronic modalities, and is available to provide direct supervision.

Oversight means that the supervising physician is available to provide review of procedures and/or encounters with feedback provided after care is delivered.

POLICY:

This policy establishes minimum requirements for resident supervision. Individual residency training programs are required to establish additional program specific requirements for their faculty, medical staff and residents/fellows. Program Directors are responsible for outlining policies for residency/fellowship supervision at each postgraduate year. These should be reviewed annually and made available in either written or electronic format to all residents/fellows and medical staff serving as faculty and supervising residents/fellows in each program.

The program director is ultimately responsible for supervision of the resident/fellow. Responsibility for specific supervision will be assigned to a faculty member supervising the resident on rotation. The privilege of progressive authority and responsibility, conditional independence and a supervisory role in patient care delegated to each resident/fellow must be conferred by the program director and program faculty.

All patients receiving care at the affiliated hospitals are assigned to a member of the hospital's medical staff, designated as that patient's attending physician. The medical staff have ultimate responsibility for the quality of medical services provided to patients. Residents/Fellows are not full members of the hospital's organized medical staff, but are recognized as health care providers involved in patient care under the supervision of an appointed faculty member or an appropriate medical staff member as defined in the hospital's/clinical partner's medical staff bylaws. It is the responsibility of the medical staff to ensure that each resident/fellow is supervised in patient care responsibilities. Requirements for on-site supervision will be established by the program director in accordance with established ACGME requirements and monitored through residency/fellowship program review, with institutional oversight through the GMEC. Careful supervision and observation are required to determine the ability of a resident/fellow to manage patients and to perform procedures or interpret diagnostic studies.

The attending physician responsible for the care of patients with whom residents/fellows are involved will provide the appropriate level of supervision based on the nature of the patient's condition, the likelihood of major changes in the management plan, the complexity of care and the experience and judgment demonstrated by the residents/fellows being supervised. The supervising faculty member or medical staff member, within the limits of his/her clinical privileges, may extend specific patient care responsibilities to the resident/fellow commensurate with the resident's/fellow's demonstrated competence. It is the decision of the faculty, with advice from the program director, as to which activities the resident/fellow will be allowed to perform within the context of the assigned levels of responsibility. The overriding consideration must be the safe and effective care of the patient.

Although they are not licensed independent practitioners, residents must be given graded and progressive levels of responsibility while assuring quality care of patients, such that residents learn to act in a supervisory and teaching capacity with less experienced residents and students. The level of supervision required by residents/fellows at various levels of training must be consistent with the requirements for progressively increasing resident/fellow responsibility during the program and its requirements of the individual Review Committees.

The faculty and program director will evaluate the residents/fellows on an ongoing basis in the provision of patient care to determine whether residents/fellows are developing progressively increased ability to critically evaluate patients and make independent decisions. This will be evaluated in the formative and summative evaluation process and communicated in the monthly faculty evaluation meetings, held with the program director, or his/her associates, faculty and chief residents. Senior residents will not be permitted to perform supervisory rotations or take supervisory night call until they have demonstrated adequate competency in patient care. In some cases, interns or second year residents will be required to complete additional clinical rotations with close clinical supervision before they are permitted to perform supervisory rotations. In developing the master schedule for the year, individual abilities and competency of each resident will be carefully evaluated. Increasing ability to demonstrate autonomy in clinical decision making and critical thinking skills will be a requirement to progress to the final year of training. The program director, supervising faculty and chief residents will monitor each resident's/fellow's performance and make a determination at the end of each academic year as to whether the resident has demonstrated the competencies required to progress to the next level of training, or at the end of training, has demonstrated the competency to practice independently without supervision.

PROCEDURES.

All resident/fellow patient care activities are supervised by credentialed providers of the medical staff who are ultimately responsible for the care. The medical staff must be credentialed in that institution for the specialty care and diagnostic/therapeutic procedures for which they are supervising residents/fellows. Each program director will define the policies in the program with regard to completion of procedures. Each program will compile a list of resident clinical activities permitted by level of training, with the required level of supervision for each activity and any requirements for performing an activity without direct supervision. The program director will review annually the resident clinical privilege delineation. At least annually, or more frequently as indicated, the program director will determine if residents can progress to the next level of training. This assessment will be documented in the annual evaluation of the residents.

Attending physicians and/or hospitalists must be available to supervise procedures directly 24 hours a day, unless the resident/fellow has been credentialed to perform a procedure independently, or a senior resident who has been credentialed to supervise a procedure, is available to provide supervision. The attending physician for the patient will ultimately decide whether a resident/fellow may perform a procedure without direct supervision. Should the urgent need arise, hospital based medical staff may provide direct supervision for the resident/fellow. In an emergency, defined as a situation in which immediate care is necessary to preserve life or prevent serious impairment of health, residents/fellows are permitted to perform everything possible to save

a patient from serious harm. The appropriate faculty member or medical staff member will be notified as soon as possible.

The program director will determine, in conjunction with the affiliated hospitals, a mechanism for notifying medical staff and ancillary personnel of the clinical privileges afforded to each resident/fellow. This can be accomplished by core privileges for each level of training.

INPATIENT SUPERVISION.

All supervision for inpatient care must be directed by a credentialed medical staff provider. Medical staff supervision of care for hospitalized patients must be documented in the inpatient record. Documentation of the degree of supervision will be by progress note or signature from the attending physician and also reflected within the resident's/fellow's progress notes. The resident/fellow must document in their admission and daily progress notes that the care plan was discussed with the attending physician, including documenting the attending's name. The attending physician should also document in their admission and progress notes that the case was discussed with the resident/fellow and document the resident's/fellow's name. Residents/Fellows are expected to write admission and daily orders and progress notes according to the protocol of the service. Residents/Fellows must also follow institutional policies regarding verbal order and physician computer order entry.

When initially admitting a new inpatient, the resident/fellow should speak with the attending assigned to that patient to discuss the findings and formulate a plan for that patient. Each patient encounter will be discussed in detail with the attending on rounds and monitored by either a senior supervisory resident or attending during all facets of the rounding experience. These discussions should occur with a frequency appropriate to the clinical acuity of the patient and must take place no less frequently than once daily. This will improve the ability of residents/fellows to develop increased autonomy and maximize the ability of the faculty to monitor the resident's/fellow's progression. Inpatient supervision will be direct at least once a day, and may be indirect with supervision either immediately available or available electronically for the remainder of the day. On all rotations, interns will be directly supervised by an attending physician or a supervisory resident/fellow.

OUTPATIENT.

On outpatient assignments, each patient encounter will be discussed with the supervisory faculty, who must be immediately available for direct supervision. Interns will have direct supervision. Senior residents who have been deemed capable of more autonomy may be indirectly supervised with direct supervision available or with oversight as they near the completion of their training and demonstrate the capacity to practice independently.

Clinical facility policies on resident supervision and credentialing may vary from this institutional policy, in which case the policy of the clinical facility will supersede this policy, as long as the appropriate level of supervision is provided.

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Revision Date November 2016
Date Approved by FSU GMEC: 2.22.18

6.5 POLICY: TRANSITION OF CARE

PURPOSE:

This policy is to state how the Graduate Medical Education Committee (GMEC), as the Florida State University College of Medicine (FSU COM) governing body for graduate medical education, institutes and supports protocol and standards in order to ensure the quality and safety of patient care when transfer of responsibility occurs during duty hour shift changes, as well as when other scheduled or unexpected circumstances occur. Transition of care is essential to patient care and safety; inclusion of skills in transition of patient care in the patient safety curriculum for residents/fellows is a requirement of the Accreditation Council of Graduate Medical Education (ACGME).

DEFINITION:

Transition of Care: Transition of care is an interactive process involving the communication of specific and essential patient information from one caregiver to another.

Transition of care occurs regularly, but not limited to, the following conditions:

- Change in provider or change of service, including change of shift for nurses, resident/fellow sign-out, and rotation changes for residents/fellows.
- Change in the level of patient care, including inpatient admission from an outpatient procedure, diagnostic area, or emergency department.
- Transfer to or from a critical care unit.
- Temporary transfer of care to other healthcare professionals within a procedure or diagnostic area(s).
- Discharge, including release to home or another facility such as skilled nursing.

POLICY:

Each residency/fellowship program must have a specific policy applicable to transition of care that is consistent with the ACGME, in addition to this policy, and document and monitor a structured hand-off process to promote continuity of care and patient safety. The process should ensure residents/fellows do not exceed clinical experience and education guidelines as set by the ACGME.

Clinical duties should be planned to minimize the number of transitions in patient care. Resident/fellow and attending schedules should be accessible to all members of the health care team. Clear communication is essential to this process.

All residents/fellows and faculty members must know and be trained in the use of the transition of care policy. Faculty supervision of the hand-off process may be direct or indirect depending on the trainees' level of experience involved in a particular instance. All patients for whom a resident/fellow is responsible must be included in the handoff. It is preferable that standard procedures for hand-offs are used throughout the clinical institution.

The following are some key patient safety practices critical to effective transition of care:

- Current, minimum content must be conveyed.
- Hand-over discussions and documents must be Health Insurance Portability and Accountability Act compliant, and therefore, should occur in a non-public space.
- Interruptions must be limited.
- The opportunity to ask and respond to questions must be provided.

The FSU COM Graduate Medical Education Committee ensures and monitors effective structured handover processes to facilitate both continuity of care and patient safety through annual review of program specific handover policies and ACGME resident/fellow and faculty survey results.

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Revision Date January 2018
Date Reviewed by FSU GMEC: 2.22.18

Section VII: Risk Management and Disaster

7.1 POLICY: GENERAL AND PROFESSIONAL LIABILITY PROTECTION

PURPOSE:

This policy is to provide notice of the general and professional liability protection provided by the Florida State University College of Medicine Self-Insurance Program (FSUCOM SIP) for the benefit of residents, fellows and faculty, together with reporting procedures to be followed thereunder.

STATEMENT OF COVERAGE:

The FSUCOM SIP provides general and professional liability protection to the FSU Board of Trustees (FSUBOT), for the negligent acts and omissions of its agents, which include FSUCOM residents, fellow, and faculty when acting within the course and scope of their duties. As agents of the FSUBOT, residents, fellows and faculty have personal immunity in tort and the sole remedy for the negligent acts and omissions of these residents, fellows, and faculty is by an action against the FSUBOT (see §768.28(9), Florida Statutes). The FSUBOT is protected for such liabilities by the FSUCOM Self-Insurance Program up to the \$200,000/\$300,000 limits set forth in §768.28(5), Florida Statutes, and also has claims bill protection should such a bill be introduced and passed by the legislature.

POLICY:

Residents, fellows and faculty are required to give immediate notice upon becoming aware of any incident that may potentially subject themselves and/or the FSUBOT to any risk or liability. The failure to provide prompt notice of incidents is a prime contributor to physicians being named in malpractice suits that should have been resolved in advance of litigation. Timely notice of incidents enables the SIP to gather information and arrive at an early determination of the merits of the claim or possible claim. The best guideline to follow is medical common sense sustained by an ever-present awareness of the possibility of a claim. The standard practice should be when in doubt, always report and do so promptly.

REPORTING PROCEDURE:

All FSUBOT health care providers are obligated to report to FSUCOM SIP and the FSUCOM GME Office any occurrence that has or may have caused harm to patients and environmental factors that unduly expose patients to harm. All reports should be made to the FSUCOM SIP Office at 352.273.7006, and the FSU COM GME Office at 850.645.6867. Residency/fellowship programs will also have a reporting structure at that clinical site which should be followed.

Items to be reported include, but are not limited to, the following:

- Adverse Occurrences
- Sentinel Events
- Near Misses
- Medical Device Malfunctions
- Any event that has produced an actual, potential or perceived injury
- Any other unexpected outcome or event where established policy or procedure was not followed and
- Any practice, situation, premise or product defect that may produce an injury if left uncorrected

Examples of reportable occurrences include but are not limited to the following:

- Unexpected death
- Brain and/or spinal damage
- Wrong invasive procedures:
 - Wrong patient
 - Wrong site
 - Wrong procedure
 - Includes prepping
- Unintentional retained foreign bodies
- Sensory or reproductive organ impairment
- Surgical repair of injury from a surgical procedure (Unless risk of the injury was documented in the informed consent.)
- Disability or disfigurement
- Maternal or fetal injury or death
- Allegations of rape, sexual abuse or misconduct
- Delayed or misdiagnosis
- Failure to obtain informed consent

Action(s) required when observing or through involvement in an adverse occurrence include, but are not limited to the following:

- Meet the patient's needs
- Notify supervisor or attending
- Objectively document clinical facts in the medical record; do not include personal notes, references to mandatory reports or calls to FSUCOM SIP
- Call FSUCOM SIP; do not use E-mail
- Residents/Fellows notify program director

Legally, a claim for negligence or medical malpractice will include the following:

- The patient was owed a duty of care that was not met
- The prevailing standard of care was breached during the patient's care
- The breach in care was the proximate cause of injury or death
- The injury or death resulted in damages

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Revision Date February 2018
Date Reviewed by FSU GMEC: 2.22.18

7.1 POLICY: QUALITY IMPROVEMENT

PURPOSE:

The Accreditation Council for Graduate Medical Education Institutional Requirements requires that each sponsoring institution must ensure that residents/fellows have access to data to improve systems of care, reduce health care disparities, and improve patient outcomes; as well as opportunities to participate in quality improvement (QI) initiatives. The purpose of the hospital wide and/or clinical site quality improvement program is to assess and improve the quality and safety of patient care and service at hospitals/clinical sites conducting Graduate Medical Education.

POLICY:

It is the policy of the Florida State University College of Medicine that all Graduate Medical Education (GME) Programs will be active participants in the quality improvement activities of the affiliated clinical institutions at which the program is based. Institutions and residency programs participating in GME must conduct formal quality improvement programs which not only review complications and deaths, but also address systems issues where modification may lead to improved patient care and outcomes. All residents/fellows must receive instruction in and must participate in appropriate components of the institution's quality improvement program. Residents/Fellows must demonstrate the ability to investigate and evaluate their own care of patients, as well as the care provided by other healthcare workers. This should include the ability to review records and analyze care based on a careful assimilation and appraisal of scientific evidence, established standards of care, and institutional policies; recognizing systems issues that contribute to sub-optimal patient care; and, demonstrating the ability to continuously improve patient care based on constant self-evaluation and life-long learning. This will enable the trainee to incorporate attributes of life-long learning and prepare him/her to embark upon maintenance of certification activities.

Each residency or fellowship program must have a process to ensure that quality improvement and patient safety are part of the daily educational structure of the residency. Including patient safety and quality improvement in the curriculum can be accomplished in many ways including morbidity and mortality conferences, morning reports, pre-operative conferences, participation in root-cause analyses, and many other methods. Education programs and resident involvement in patient safety and quality improvement must be carefully documented.

Programs must be able to demonstrate residents/fellows in their training program can:

- a. Identify strengths, deficiencies, and limits in their own or in others' knowledge and expertise;
- b. Set learning and improvement goals for their own deficiencies they have identified and identify and perform appropriate learning activities;
- c. Systematically analyze their own practice and that of other healthcare providers using quality improvement methods, and implement changes with the goal of practice improvement;
- d. Incorporate formative evaluation feedback from QI activities into daily practice;
- e. Locate, appraise and assimilate evidence from scientific studies related to patients' health problems; and,
- f. Use information technology to optimize learning.

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Revision Date November 2016
Date Approved by FSU GMEC: 2.22.18

7.3 POLICY: INSTITUTIONAL GME DISASTER POLICY

PURPOSE:

The purpose of this policy is to outline procedures in the event of disruption by emergencies, catastrophic events, or natural disasters.

POLICY:

It is the policy of the Florida State University College of Medicine Graduate Medical Education Programs to have procedures in place to meet its service and educational obligations in the event of a disaster or interruption in patient care that includes assistance for the continuation of resident/fellow assignments.

Definition of Disaster

As defined by the World Health Organization, a disaster is an occurrence disrupting the normal conditions of existence and causing a level of suffering that exceeds the capacity of adjustment of the affected community.

Declaration of Disaster

The Accredited Council for Graduate Medical Education (ACGME) may invoke the Extraordinary Circumstances policy in response to circumstances that significantly alter the ability of a sponsor and its programs to support resident education. The ACGME is committed to assisting in reconstituting or restructuring residents' educational experiences as quickly as possible. Examples of extraordinary circumstances include abrupt hospital closures, natural disasters, or a catastrophic loss of funding.

Resident/Fellow Information:

All programs will maintain a roster of all residents that includes at a minimum, the following information: *name, address, pager number, all available phone numbers (home, cell, etc.), all available e-mail addresses, and emergency contact individual(s) and their contact information*. This information will be updated at least annually before July 31, and as appropriate to maintain accuracy. The programs will maintain this roster with internal backup, as well as external backup at the Florida State University (FSU) College of Medicine.

As possible, residents/fellows may continue their roles and participate in disaster recovery efforts. Resident/Fellow reporting will continue during disaster recovery. Residents/Fellows will continue to receive their salary and benefits during the disaster event recovery period, and/or accumulate salary and benefits until such time as utility restoration allows for fund transfer.

Medical-Legal Aspects:

There are multiple mechanisms that may afford liability protection to FSU residents who are or will be working in the affected areas of disaster response in the State of Florida from incurring personal liabilities. In the capacity of assignment by Florida National Guard and/or Department of Homeland Security, residents may become temporary employees of Health and Human Services (HHS) and therefore are subject to and protected by the Federal Tort Claims Act. It is preferred, whenever possible, that notwithstanding other capacities in which residents may serve, they also perform within their FSU function when they participate in disaster recovery efforts. While acting within their FSU function, residents will maintain their personal immunity to civil actions via the state's sovereign immunity and the University's Self-Insurance Program.

Communication with ACGME:

The Designated Institutional Official will communicate with the Institutional Review Committee Executive Director with information and/or requests for information.

Similarly, the Program Directors will contact the appropriate Review Committee Executive Director with information and/or requests for information.

Residents/Fellows should communicate with the appropriate Residency Director (or Residency Review Committee if unable to reach director) with information and/or requests for information. In the ACGME Web Accreditation Data System, ACGME will provide instructions for changing resident e-mail information as needed.

Resident/Fellow Transfers / Program Reconfiguration:

If, because of a disaster, at least an adequate educational experience cannot be provided for each resident the sponsoring institution will:

- (a) Arrange temporary transfers to other programs/institutions until such time as the residency/fellowship program can provide an adequate educational experience for each of its residents/fellows;
- (b) Cooperate in and facilitate permanent transfers to other programs/institutions. If more than one program/institution is available for temporary or permanent transfer of a particular resident/fellow, the transferee preferences of each resident will be considered. Programs/institutions will make the keep/transfer decision expeditiously so as to maximize the likelihood that each resident/fellow will timely complete the resident year; and
- (c) Inform each transferred resident/fellow of the minimum duration of his/her temporary transfer, and continue to keep each resident/fellow informed of the minimum duration. If and when a program decides that a temporary transfer will continue to and/or through the end of a residency year, it must so inform each such transferred resident/fellow.

Within ten days after the declaration of a disaster, the Designated Institutional Official (DIO) will contact ACGME to discuss due dates that ACGME will establish for the programs, (a) to submit program reconfigurations to ACGME; and, (b) to inform each program's residents of resident transfer decisions. The due dates for submission shall be no later than 30 days after the disaster unless other due dates are approved by ACGME.

A form will be available on the ACGME website for institutions offering to accept temporary or permanent transfers from disaster affected institutions that must be completed. Upon request, ACGME will provide information from the form to the affected programs and residents/fellows.

ACGME will expedite the process for reviewing (and approving or not approving) submissions by programs relating to program changes to address disaster effects, including the addition or deletion of a participating institution, change in the format of the educational program, and/or change in the approved resident complement.

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Date Approved by FSU GMEC: 2.22.18

Section VIII: Additional Policies

8.1 POLICY: NON-ACCREDITED RESIDENCY/FELLOWSHIP PROGRAMS

PURPOSE:

The Florida State University College of Medicine and its affiliated clinical training institutions may elect to develop training programs for which accreditation by the Accreditation Council for Graduate Medical Education

is not available. This policy will establish the procedure for the development and oversight of non-accredited programs.

POLICY:

Non-accredited residencies/fellowships will be conducted by the core program, if applicable, but subject to GMEC oversight. These programs should be a minimum of 12 months in length. Non-accredited programs should provide an educational experience of comparable quality to other graduate medical education programs, while in no way interfering with, or detracting from, the training of residents and fellows in other sponsored GME programs.

The GMEC must review and approve all new programs, any changes in training complement, changes in program length or structure, and the appointment of new program directors.

An application for a new program must include the following: clinical need for the program, impact of the program upon other training programs, the rotation schedule, the projected budget, sources of funding, the rationale for number of trainees in the program, the didactic schedule, including core curriculum goals and objectives, as well as assessment tools.

There must a single program director appointed who has the appropriate qualifications and experience in the discipline who has ultimate authority for all aspects of the program. The program director must be approved by the GMEC. The program director will report to the core program director. If no core program directors exists, the program director will report to the Institutional DIO or the Chief Academic/Medical Officer. Program directors of non-accredited programs must coordinate with other accredited program directors to coordinate and optimize resident and fellow experiences. The program director must assure that the program is adequately resourced. The program director must submit an annual evaluation and action plan to the GMEC. The program director must comply with clinical experience and training hours approved by the GMEC in designing the program.

Selection of trainees shall be the responsibility of the non-accredited program director and core program and follow institutional eligibility requirements. Residents/fellows in non-accredited programs will receive stipends and benefits corresponding to the schedule adopted by the GMEC, according to level of training. Non-accredited residents/fellows are subject to FSU College of Medicine GME policies and procedures and will follow applicable medical staff policies and program policies of the clinical training institution.

Program faculty should be selected in such a manner that there is not an adverse impact on other educational responsibilities for accredited programs. There must be a sufficient number of faculty with requisite qualifications to instruct and supervise all residents/fellows. The faculty should demonstrate a strong interest in the education of the residents/fellows and have time dedicated for teaching, supervision, and evaluation. Curriculum should be developed according to the ACGME core competencies. Requirements for scholarly activity should be outlined in the program documents.

The faculty should evaluate rotations in a timely manner. Minimum evaluations should occur quarterly. Formal feedback should be provided every 6 months. A summative evaluation should be documented at the end of the training. Continuation in the program, promotion to the next level of the program, if applicable, and successful completion of the program are subject to the FSU College of Medicine Promotion Policy and specific program requirements.

Trainees are subject to all requirements for hiring stipulated by the hiring clinical institution. In lieu of a training license, the resident/fellow may have a full and unrestricted medical license issued by the appropriate board of medicine or board of osteopathic medicine in Florida, in which case the trainee may bill independently for clinical services performed within the institution.

The FSU College of Medicine Salary and Benefits Policy will apply to trainees in non-accredited programs.

8.2 POLICY: FLORIDA STATE UNIVERSITY COLLEGE OF MEDICINE (FSU COM) PHARMACEUTICAL/VENDOR POLICY AND GUIDELINES

PURPOSE:

The purpose of this policy is to establish guidelines to ensure that patient care and medical education are not influenced by considerations other than what is in the best interests of patients and/or trainees.

STATEMENT:

It is the policy of the FSU COM that pharmaceutical/industry access to students, faculty, fellows and residents, is prohibited on FSU COM property, including regional medical school campuses. However, discussion with representatives for the purpose of obtaining unrestricted educational grants is allowed. This policy applies to all FSU COM full-time faculty and part-time faculty (clerkship directors, clerkship faculty, elective faculty) when performing their duties on FSU COM property.

SCOPE:

I. Accepting Offers

Gifts- Individuals subject to this policy (faculty, fellows, residents, students, and staff) may not solicit or accept any gifts from pharmaceutical company/industry representatives. Additionally, the use of any vendor's material with the vendor's name or logo is strongly discouraged in public or patient care areas.

Food - The direct provision of any meals, desserts, etc. by pharmaceutical/industry representatives on FSU COM property is prohibited. This includes the provision of meals during any organized, scheduled educational activity (e.g., grand rounds, journal club, faculty development, etc.) or reception. Industry representatives who wish to provide support to the FSU COM may, however, do so in the form of an unrestricted educational grant to the FSU COM. Such grants are expended for food solely at the discretion of COM departments/divisions/regional campuses/residency programs.

Entertainment - Faculty members, fellows, residents, students, or employees of the FSU COM participating in social events, including meals, funded directly by pharmaceutical company/industry may not use their official status as part of FSU. Moreover, faculty, fellows, residents and employees of the FSU COM may not accept the use of supplier/vendor property, airplane transportation, travel packages, or similar favors from industry as agents of FSU.

Compensation - Full time faculty, fellows, residents or employees may not accept gifts or compensation for listening to a sales talk by an industry representative, including the defraying of costs for simply attending a CME or other activity or conference. Honoraria provided directly by pharmaceutical/other industry are not allowed if faculty or employment status with the FSU COM is acknowledged.

II. Site Access

Pharmaceutical/Industry Representatives are not allowed access to faculty, students, fellows, residents or staff on FSU COM property, including its regional campuses, except for the purpose of discussing/providing unrestricted educational grants.

III. Educational Funds

Industry representatives may provide support for medical educational purposes in the form of unrestricted educational grants. Initial contact with industry representatives for the purpose of discussing or obtaining unrestricted educational grants is permitted.

Scholarships / Educational Grants

No educational grant, financial award, donation, or expense reimbursement may be given directly to a fellow, resident or medical student by an industry representative. Any educational grant must be provided to the College of Medicine. Faculty and staff who are invited to present or lead conferences or meetings funded directly by pharmaceutical/other industry may not acknowledge their faculty status as part of the program.

Note: These provisions do not apply to meetings of professional societies that may receive partial industry support, i.e., meetings governed by ACCME Standards.

IV. Disclosure of Relationships with Industry

All College, Program and Sponsoring Institution-sponsored medical education events must include full and appropriate disclosure of sponsorship and financial interests above and beyond those already governed by the Standards for Commercial Support promulgated by the Accreditation Council for Continuing Medical Education. Department Chairs, Program Directors and Faculty should disclose any financial relationships with Industry, including but not limited to ownership of practice and hospital sites at the time of appointment to these positions, annually through the FSU COM Personnel Office, and as actual, potential, or the appearance of Conflicts of Interest arise. Faculty with supervisory responsibilities for students, fellows, residents and/or staff should ensure that the faculty's conflict or potential conflict of interest does not affect or appear to affect his or her supervision of the student, fellow, resident or staff member. Individuals having a direct role making institutional decisions on equipment or drug procurement must disclose to the FSU COM Administration / Personnel Office, prior to making any such decision, any financial interest they or their immediate family have in companies that might substantially benefit from the decision. Such financial interests could include equity ownership, compensated positions on advisory boards, a paid consultancy, or other forms of compensated relationship. They must also disclose any research or educational interest they or their department have that might substantially benefit from the decision. The administration will decide whether the individual must remove him/herself from the purchasing decision.

Note: This provision excludes indirect ownership, such as stock held through mutual funds.

V. Training/Communication Regarding Potential Conflicts of Interest

All faculty, attendings, fellows, residents, students and applicable staff shall be provided with information regarding potential conflicts of interest in interactions with industry to include:

- A. A copy of these guidelines on vendor interactions.
- B. Copies of the ethics statements of pertinent medical specialty societies and how to apply those guidelines to practice.
- C. Seminars and/or faculty development sessions describing:
- D. How activities can influence judgment in prescribing decisions and research activities.
- E. How to manage encounters with Industry representatives.
- F. How to handle patient requests for medication, particularly direct-to-consumer advertising of drugs.
- G. The purpose, development, and application of drug formularies and clinical guidelines and discussing such issues as branding, generic drugs, off-label use, and use of free samples.

VI. Procedure, Monitoring and Responsibility

We want to ensure patients, students, fellows and residents know we are focusing on their welfare, not on any commercial interest and eliminate the appearance of industry's inappropriate influence over the medical community. Therefore, all FSU COM faculty, students, fellows, residents and staff will be given a copy of this Policy and Guidelines document.

The Graduate Medical Education Committee (GMEC) must ensure that the Sponsoring Institution monitors vendor interactions with residents/fellows and GME programs. FSU COM administration, department heads, division heads, campus deans, program directors, etc. are responsible for compliance with this policy and for ensuring the personnel under their supervision understand and comply with this policy. If FSU COM faculty and/or staff have any questions concerning the interpretation of this policy and guidelines, or its applicability to a particular circumstance, they should first consult with their supervisor. If their supervisor is unable to answer the question or provide appropriate guidance, or if, because of the circumstances, it would be inappropriate to discuss the matter with the supervisor, then the personnel and/or staff member should contact the FSU COM Sr. Associate Dean's office. If any FSU COM personnel and/or staff member is aware of any violation or threatened or potential violation of this policy, or suspects that a violation of this policy has occurred, they must also refer to the FSU COM Sr. Associate Dean's office.

VII. Exceptions

- A. This policy does not apply to part-time faculty (clerkship directors and clerkship faculty) engaged in their roles at venues other than FSU COM property; i.e., private offices, hospitals or other sites.
- B. This policy does not include faculty research and related activities, which are included in the Florida State University Faculty Policies and Procedures for Dealing with Misconduct in Research and Creative Activity (<http://dof.fsu.edu/facultyhandbook/Ch6/Ch6.20.html>). Individuals should contact the FSU COM Office of Research (<http://med.fsu.edu/research/office/default.asp>) with regard to publishing articles under their name and FSU COM title, in disclosing their related financial interests etc.

Pertinent Definitions

Attending - The faculty member with primary responsibility for the care of a patient and/or the education of a student or resident/fellow in a particular case.

Conflicts of Interest - Any situation in which an individual is in a position to exploit his/her professional or official capacity in some way for personal benefit.

Faculty - Physicians/Professors who possess the requisite expertise, documented educational and administrative abilities, and experience to teach residents and students.

Meetings - Any gathering on FSU COM property involving FSU COM personnel. Such gatherings would include but not be limited to faculty development meetings, resident/fellow or student meetings, grand rounds, departmental, divisional or regional campus meetings.

Personnel - Faculty, staff, fellows, residents, and medical students of the FSU COM.

Representative - Includes any individual who is employed by or who represents any entity defined under 'Vendor/Industry'.

Sponsorship - Vendor/Supplier funding

Unrestricted Educational Grants - It is recommended that industry representatives provide financial support for FSU COM events directly to the COM in the form of an unrestricted educational grant to then be spent by the COM departments/divisions/regional campuses/residency programs for educational activities at their discretion. Appropriate recognition of the industry representative's contribution should be given by the department/division/regional campus/residency program. Educational grants must not be made, conditioned, or related in any way to pre-existing or future business relationships with Industry. Vendors should separate their grant making functions from their sales and marketing functions. Accordingly, if vendor or patient-service representatives or other corporate representatives wish to discuss a corporate contribution of cash, equipment, supplies, or services, the employee should immediately notify the Dean or the Sr. Associate Dean for Medical Education and Academic Affairs/DIO. This individual, or a designee, should then become the principal point of contact with the vendor.

Vendor/Industry - Includes those businesses, corporations, or entities that supply or wish to supply equipment, goods, services, or other medical related products to physicians, administrators, students, residents, staff or hospitals.

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Date Approved by FSU GMEC: 2.22.18

8.3 POLICY: RESEARCH

PURPOSE:

The Florida State University College of Medicine's Division of Research (Division) is responsible for all matters pertaining to research proposals developed by College of Medicine faculty members until such time as the contract, grant, or sub-contract is awarded (pre-award procedures). Post-award procedures are handled by the College's Office of Finance and Administration, Research Accounting section.

POLICY:

It is the responsibility of the Division to assure College of Medicine compliance with college, university and grant agency requirements. The Division's Office of Research Administration must review the proposal, and the Senior Associate Dean for Research must sign approval for the College of Medicine prior to submission of the proposal to the University Office of Sponsored Research.

1. Any contract or grant proposal by a member of the College of Medicine fellow/resident/faculty/staff must be submitted through the College of Medicine Division's Office of Research Administration if that individual uses his/her FSU title or the college or university name on the proposal. Furthermore, clerkship/College of Medicine community faculty may not use their FSU College of Medicine credentials, the FSU College of Medicine name, FSU or FSU College of Medicine staff/personnel, or FSU or FSU College of Medicine students in any fashion in the application for or conduct of research, whether internal or external to the FSU or FSU College of Medicine, without the express written consent and approval of the Associate Dean for Clinical Research and the College of Medicine Research Advisory Committee (RAC). Unauthorized research conduct and application in the name of FSU or FSU College of Medicine can result in termination of faculty appointment or affect the faculty's standing within FSU College of Medicine.
2. Human subjects research proposals by College of Medicine-affiliated faculty and other personnel also must be submitted to the College's RAC for internal review prior to submission to the FSU Human Subjects Committee (IRB) and any other applicable external IRB.
3. Research proposals may be submitted to the University Office of Sponsored Research only if a full-time FSU faculty member is listed as Co-PI (university policy). Exceptions may be granted by the FSU Vice President for Research.
4. Each PI/Co-PI should work with his/her appropriate faculty administrator (Department Chair, Residency or Fellowship Program Director) to determine a reasonable percent effort for the proposal and include the corresponding salary required for that percent effort, if the sponsoring agency allows PI salary.

5. The College of Medicine does not permit cost-sharing in excess of that required by the sponsoring agency. Exceptions to this policy must be approved by the Senior Associate Dean for Research, Dean of the College of Medicine, and the FSU Vice President for Research.
6. If Recombinant DNA, Human or Animal Subjects, Radioactive/Hazardous Materials, or Workshops/Conferences are involved, the project must be approved by the appropriate FSU Compliance Officer (FSU Biohazard Committee, FSU Human Subjects Committee, Animal Use and Care Committee, Environment Health and Safety Director, Center for Professional Development Director) prior to funding.

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Date Approved by FSU GMEC: 2.22.18

8.4 POLICY: RESIDENCY CLOSURE / REDUCTION

PURPOSE:

The purpose of this policy is to protect the residents and fellows and provide for a smooth and orderly transition in accordance with ACGME recommended guidelines should closure or reduction of a program be required.

POLICY:

The sponsoring institution and any affiliated clinical institutions must inform the GMEC, the Designated Institutional Official, and the affected residents or fellows as soon as possible when it intends to reduce the size or close one or more ACGME-accredited programs or when the sponsoring institution intends to close. All program directors must report to the Designated Institutional Official any plans for change in residency size. Reductions should be designed to maintain a high standard of educational experience that continues to comply with ACGME standards. Significant changes in program size must be discussed at the GMEC regarding the educational impact on that program, as well as other associated programs.

In the event that the FSU College of Medicine decides to reduce the number of residency positions in and/or close any GME program, the residents will be notified as soon as possible. Should a Residency Program downsize for any reason, it will make a good faith effort to accomplish the reduction by accepting fewer residents into the entry level of the program through a phase-out plan. Any such reduction must include provision for a continued training program for existing residents/fellows. If necessary, the sponsoring institution and the individual residency/fellowship program will assist residents in finding another position in the same specialty at the appropriate PGY level; however, every effort will be made to allow residents in the program to complete their training through the FSU College of Medicine Residency Program with funding for their support remaining intact.

Florida State University College of Medicine
Graduate Medical Education
Policies and Procedures
Revision Date November 2016
Date Approved by FSU GMEC: 2.22.18