RULES AND REGULATIONS
OF THE MEDICAL STAFF
OF
FORT HAMILTON HOSPITAL

Revised and Approved by the
Board of Directors 11/3/2016
# MEDICAL STAFF RULES AND REGULATIONS

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FORT HAMILTON HOSPITAL

MEDICAL STAFF

RULES AND REGULATIONS

ARTICLE I

HOSPITAL UTILIZATION

1.1 DEFINITIONS

Emergency is defined as an immediate threat to life, limb or body organ.

Urgent is defined as impending threat to life, limb or body organ.

1.2 NON-EMERGENCY ADMISSION

1.2-1 Each patient shall be the responsibility and shall remain under the care of a practitioner with adequate and appropriate clinical privileges. Such practitioner shall be responsible for the medical care and treatment of the patient, the prompt completion and accuracy of the medical record, patient instruction and informed consent, and for transmitting reports of the condition of the patient to the patient and/or his/her family and to any referring practitioner, if applicable. Whenever these responsibilities are transferred to another practitioner, a note covering the transfer of responsibility shall be entered on the order sheet of the medical record. The practitioner responsible for the patient shall assure that the history and physical examination are performed and recorded as required.

1.2-2 Except in an emergency, no patient shall be admitted to the hospital until a provisional diagnosis or valid reason for admission has been determined. In the case of an emergency, such statement shall be recorded promptly.

1.2-3 All patients requiring admission to the hospital may request the practitioner of their choice insofar as their medical condition comes within the clinical privileges and practice of the practitioner so chosen. In the event that the patient does not have a regular physician with appropriate clinical privileges or cannot or does not request a practitioner of choice, either the hospitalist or the practitioner “on call” for the department or service concerned with the treatment or disease which necessitates admission shall be responsible for accepting, admitting and caring for the patient. The responsibility for accepting patients while “on call” shall apply equally to all patients regarding of their payer status.
1.2-4 Any practitioner with appropriate clinical privileges may give admission orders for inpatients in their care or for provision of the outpatient services where provided. This includes physicians, dentists, podiatrists, allied health providers and other practitioners authorized by the governing body to request such services.

Outpatient orders may be accepted from licensed practitioners not on staff at the hospital for tests within the scope. If necessary, Corporate Integrity can be asked to review unknown providers to verify CMS participation and licensure.

For outpatient testing requests that involve procedures which pose some immediate risk to the patient, a provider with privileges is required. The ordering provider may be referred to the Medical Staff Office where arrangements can be made for physician to physician discussion and referral to an appropriate provider staff who could facilitate such orders at the discretion of the Medical Staff President.

Hospital personnel may accept such orders within the scope of their licensure, certification or registration.

1.3 EMERGENCY ADMISSION

1.3-1 In any emergency case in which it appears that the patient should be admitted to the hospital, the practitioner or his/her designee shall, when possible, first contact the patient registration department to ascertain whether there is an available bed in the most appropriate patient care area. If such is not the case, the practitioner shall be provided an alternative arrangement or location within the hospital.

1.3-2 Practitioners admitting emergency cases shall be prepared to justify to the executive committee of the medical staff and/or hospital administration that the said emergency admission was a bonafide emergency. The history and physical examination must clearly justify the patient being admitted on an emergency basis and must be recorded or dictated as soon as reasonably possible after admission but in compliance with required time frames.

1.4 PATIENT CARE UNIT UTILIZATION CRITERIA

1.4-1 Criteria established to indicate appropriate use of, admission to, and discharge from all patient care inpatient units for adult and pediatric patients shall be followed. If any question as to the validity of admission to or transfer or discharge from any inpatient care unit arises, that question shall be resolved through consultation with the president of staff, or his/her designee.

1.5 CONTINUED HOSPITALIZATION
1.5-1 As requested, the attending practitioner shall document in the medical record the need for continued hospitalization according to the requirements and guidelines included in the hospital’s policies and procedures. This documentation shall include:

(a) an adequate written record of the reason for continued hospitalization,
(b) regular ongoing notation of patient progress, and
(c) plans for post-hospital care.

1.5-2 Upon appropriate request, the attending practitioner shall report to the applicable department chairperson or his/her designee the necessity for continued hospitalization for any hospitalized patient, including an estimate of the number of additional days of stay and the reason therefore.

1.6 OBSERVATION STATUS

1.6-1 An observation bed is designated as any available bed with the exception of any in the Nursery. Whenever possible, the patient shall be placed on the unit most appropriate for the patient’s required level or focus of care.

All observation patients shall be seen by the attending physician and disposition determined within 23 hours.

Observation beds shall be utilized for the following purposes:

(a) rule out and symptomatic disease processes,
(b) cases likely to respond quickly to care,
(c) non-routine preparation for diagnostic testing, or
(d) post operative recovery for ambulatory surgery cases where the patient requires specific medical care beyond that usually associated with surgery.

Documentation shall reflect:

(a) patient assessment
(b) reasons for observation status,
(c) services indicated
(d) treatments received,
(e) patient response, and
(f) discharge arrangements and instructions for follow-up care or inpatient admission.

1.7 CLINICAL DECISION BED STATUS
1.7-1 The clinical decision bed program offers services to patients presenting in the emergency department whose current behaviors, cognitive abilities and/or level of intoxication prohibits immediate evaluation for the need for admission, treatment, referral and/or dismissal. In such cases, the patient may be assigned to a clinical decision bed until appropriate evaluation is possible if he/she meets the following criteria:

(a) referred to the clinical decision bed program by an emergency department physician,
(b) at least 18 years of age,
(c) medically stable, and
(d) agrees to placement in the clinical decision bed.

The expected length of stay in a clinical decision bed is 0-12 hours. During this time, the patient will be evaluated by a masters prepared social worker who will then provide a recommendation for patient disposition to the physician then in charge of the patient’s care.

1.8 USE OF NON-PSYCHIATRIC UNITS FOR ADULT PSYCHIATRIC PATIENTS

1.8-1 The use of non-psychiatric beds for adult psychiatric patients is acceptable if, in the opinion of the physician, the patient has a critical medical or surgical need which supersedes the psychiatric need. Such admissions shall have a psychiatrist consultation within 24 hours of admission or as soon as the patient’s condition allows such and the patient shall be transferred to the psychiatry unit as soon as he/she is sufficiently, medically stable.

1.9 PATIENT TRANSFERS

1.9-1 Internal transfer priorities are as follows:

(a) from general medical/surgical area to the ICU or other monitored bed,
(b) from emergency department to appropriate patient bed,
(c) from obstetric patient care area to general medical/surgical area, when medically indicated,
(d) from intensive care unit to general medical/surgical area,
(e) from placement in an area designated temporarily as a specific clinical service area to the appropriate area for that patient.

1.9-2 No patients will be transferred without appropriate involvement of the attending practitioner.
1.9-3 All patient transfers shall be accomplished according to the applicable hospital policies.

1.9-4 If a patient’s behavior is violent and therefore a risk to other patients, employees or himself/herself or if his/her behavior is a serious problem because of emotional or mental problems, he/she shall be transferred to a more appropriate unit or facility as expeditiously as practicable under the circumstances and in accordance with applicable law.

1.9-5 Indications for patient transfer to another acute care facility shall include:

(a) the need for specialized care not available at this facility,
(b) patient, family or practitioner’s request, or
(c) other sound medical reasons.

1.9-6 Conditions necessary for transfer to another acute care facility include:

(a) medical screening and stabilization. A patient in labor or with an emergency medical condition which has not been stabilized may be transferred if a practitioner deems that, based on reasonable risks and benefits to the patient and on information available at the time, the medical benefits reasonably expected from the provision of appropriate medical treatment at another medical facility outweigh the increased risks to the patient’s medical condition of transferring the patient,
(b) the risks and benefits of the transfer have been explained to the patient and/or his/her designee and the patient and/or his/her designee authorized the transfer,
(c) there are available space and qualified personnel at the receiving facility,
(d) the appropriate medical records are provided to the receiving facility,
(e) qualified personnel, transport equipment and life support measures are used during the transfer as needed, and
(f) the physician initiating the transfer has contacted and received agreement from a physician at the receiving facility to accept transfer of and responsibility for the patient.

1.10 PATIENT DISCHARGE

1.10-1 Patients shall only be discharged upon the order of the attending practitioner. Should a patient leave the hospital against the advice of the attending practitioner, or without proper discharge, a notation of the incident shall be made in the patient’s medical record by the attending practitioner.

1.10-2 In the event of a hospital death, the deceased shall be pronounced dead by the attending practitioner or another licensed medical physician per hospital policy. A physician need not personally examine
the body. A nurse, paramedic or other competent observer as defined by Ohio Administrative Code (OAC) 4731-14 may report findings on the telephone for the physician to make the death pronouncement. The body shall not be released until authorized by pronouncing physician. The physician is responsible for the death certificate.

1.10-3 Authorization for tissue and/or organ donation from the deceased shall be requested from the next of kin or legal guardian per Ohio law, unless there is prior knowledge or indication of intentions contrary to donation by the deceased.
ARTICLE II

DOCUMENTATION REQUIREMENTS

2.1 MEDICAL RECORD RESPONSIBILITY

2.1-1 All practitioners providing care to the patient shall be responsible for accurate, pertinent, timely, legible, and current documentation in the patient’s medical record regarding care which they provided.

2.1-2 Reports regarding services delivered by and procedure results from all hospital departments and services that render care to the patient at the direction of a practitioner having clinical privileges shall be generated and made apart of the patient’s medical record by that department or service.

2.1-3 Counter-signature of medical record entries shall be done as required by and delineated in applicable hospital and medical staff policy, and in compliance with all laws and regulations. Medical record documentation requiring counter-signature shall be as follows:

(a) all verbal orders,
(b) all entries written by students authorized to document in the medical record,
(c) admission and medication orders and histories and physicals, written by allied health practitioners holding clinical privileges at this hospital,
(d) all orders written by consulting practitioners who are not members of the medical staff as provided for in these medical staff rules and regulations, and
(e) all orders written by an emergency department physician for inpatient care.

2.2 HISTORY AND PHYSICAL REQUIREMENTS

2.2-1 A complete history and physical exam must be completed and recorded within 24 hours after inpatient admission or registration, but prior to invasive procedure (whichever comes sooner) and prior to the administration of any anesthesia (except local), unless the delay incurred places the patient at an unreasonable level of risk. This requirement also applies to any outpatient service that includes an invasive procedure and/or any anesthesia (except local).
History and physical documentation must be present on the medical record before any invasive procedure occurs.

Only practitioners who have been granted privileges at Fort Hamilton Hospital to do so may perform medical histories and physical examinations.

The practitioner may delegate all or part of the physical examination and medical history to other practitioners and shall sign for and assume full responsibility for these activities. The medical history and physical examination must be completed and documented by a physician, an oral maxillofacial surgeon, or other qualified licensed individual who has been granted privileges to do so at Fort Hamilton Hospital in accordance with state law and hospital policy.

It is recognized that occasionally a practitioner who has not been granted privileges at our facility may refer a patient for continued care. If that practitioner writes a timely H&P, the H&P may be accepted, but must be reviewed and updated by a privileged member of our medical staff.

Any history and physical conducted more than 30 days prior to admission or registration must be repeated.

If a practitioner consistently does not provide history and physical documentation as required, he or she shall be referred to the medical executive committee for appropriate intervention. Documentation of such referral shall be placed in the practitioner’s quality file.

2.2-2 When the history and physical is completed within 30 days of admission, an updated medical history and physical examination is required within 24 hours of admission or registration including any changes in the patient’s condition since the initial examination. An updated medical record entry documenting the repeat physical examination is added to the original history and physical and entered into the medical record within 24 hours after admission or registration and prior to any or a procedure requiring anesthesia services. The notation must include any changes to the following:

- Relevant additions to the history,
- Changes to the physical findings, and
- Pertinent diagnostic data.
2.2-3 At a minimum, all histories and physicals must include the following components to be considered complete:

- Chief complaint and/or pre-operative diagnosis
- Details of present illness
- Inventory of body systems, when appropriate based on the complexity of the patient’s condition.
- Relevant physical exam
- Relevant past, family and social histories (appropriate to the patient’s age)
- Pertinent diagnostic data

2.2-4 For obstetrical patients, since the prenatal course of care is generally initiated with a complete history and physical, and systematic updates occur throughout the pregnancy, the entire prenatal record may be utilized as the history and physical upon admission. However, the history and physical must be updated to include relevant additions to the history, changes to the physical findings and pertinent diagnostic data on admission as soon as is reasonably possible but prior to any invasive procedure and/or delivery, if patient safety is not compromised.

This requirement also applies to any obstetric or outpatient service that includes an invasive procedure and/or any anesthesia (except local). In emergency situations in which there is inadequate time to perform a complete history and physical exam prior to intervention, a brief note including the pre-procedure diagnosis shall be recorded prior to the procedure.

2.2-5 Results of pre-anesthesia sedation evaluation must be documented on the appropriate specified form prior to the procedure as follows:

- Anesthesia pre-operative evaluation form, or
- Pre-sedation analgesia assessment form.

2.2-6 In emergency situations in which there is inadequate time to perform a complete history and physical exam prior to intervention, a brief note including the pre-procedure diagnosis shall be recorded prior to the procedure.

2.3 Progress Notes/ Assignment of Cases:

(1) Unattached patients shall be attended by Medical Staff Appointees with appropriate Privileges and shall be assigned by the Clinical Service concerned in the treatment of the disease which necessitated admission.

(2) It is expected that private patients shall be attended by their own Practitioner. All Practitioners with Clinical Privileges are required to provide continuity of care to all
patients in their practice for whom they are responsible, and to provide care that is effective, safe, patient and family centered, efficient, timely and within the parameters of granted Privileges. In the event that a Practitioner plans to be away from the Hospital for a scheduled absence (e.g. vacation or absences for personal reasons, but not including a leave of absence as defined in the Credentials Policy Manual), such Practitioner shall make adequate arrangements prior to departure for coverage for his/her private patients that are inpatients or who may present to the Emergency Department while the Practitioner is away on such planned absence. The Practitioner, unless in a group practice in which all Practitioners have common Privileges or in a designated call coverage group made known in advance to the Medical Staff Services Department, shall notify the Medical Staff Services Department and the Emergency Department of such period of scheduled absence, and shall identify the covering Practitioner who shall have similar Medical Staff Privileges, have agreed in writing to provide this coverage, and be located within the Hospital's geographic service area and close enough to provide timely care for the private Practitioner's inpatients and/or Emergency Department patients. If the Practitioner is also scheduled to be on-call during the scheduled absence, he/she must also arrange for backup on-call coverage with another Practitioner who meets the above criteria, and shall notify the departments identified above and other Hospital areas/departments as may be required in the Manuals, and/or Medical Staff/Hospital policies. In the case of the patient requiring admission who has no attending Practitioner on the Medical Staff and does not elect or is unable to choose one, he/she shall be referred to the appropriate Clinical Service on-call Practitioner.

(3) Practitioners to whom unattached patients are referred have a responsibility to provide care to the patient at least once for the problem for which the patient was referred, regardless of ability to pay and to provide continued care or secure referral to another proper available care provider.

(4) Practitioners, who assume responsibility for unattached patients, are expected to respond to a request from the Emergency Department to provide consultative or in Hospital care in a timely fashion, to meet patient care needs.

(5) All patients who are placed in a Hospital bed as an inpatient or observation status are required to be seen by the admitting or consulting Practitioner (who is permitted by the State and Hospital to admit patients to a hospital) in a timely fashion with documentation of that visit in the medical record. Medicare patients must be under the care of a M/DO. Patients transferred or admitted to an ICU shall be seen by the attending or consulting Physician within a time frame consistent with the clinical condition of the patient, usually no longer than twelve (12) hours. Patients placed in a non-ICU bed as an outpatient (ambulatory), observation status or admission, shall be seen by the admitting or consulting Practitioner within a time frame consistent with the clinical condition of the patient, but within twenty-four (24) hours. All patients, with the exception of normal newborns or patients awaiting nursing home placement who shall been seen at least weekly require daily patient visits by the attending Practitioner with privileges or his/her covering Practitioner and these visits must be documented in the progress notes as a part of usual care. Medical student progress notes will not be a part of the medical record until they are signed by a supervising resident or Physician. To provide appropriate continuity of care for patients
who are hospitalized by Practitioners other than the patient’s primary care Physician, the attending is responsible to communicate, when appropriate, with the primary care Physician regarding the patient’s Hospital course and the plan of care post hospitalization.

2.4 OPERATIVE, INVASIVE AND/OR HIGH RISK AND OTHERPROCEDURAL FINDINGS & REPORTS

2.4-1 An operative, invasive or other high-risk procedure progress note is entered in the medical record immediately after the procedure, if the full operative, invasive or other high-risk procedure report cannot be placed into the record immediately after the operation or procedure.

2.4-2 An operative report describing techniques, findings, and tissues removed or altered must be written or dictated immediately following an invasive procedure and signed by the practitioner. The operative report includes at least:

- Name and hospital identification number of the patient,
- Date and times of the procedure,
- Name(s) of the surgeon(s) and assistants or other practitioners who performed surgical tasks (even when performing those tasks under supervision),
- Pre-operative and post-operative diagnosis,
- Name of the specific procedure(s) performed,
- Type of anesthesia administered,
- Complications, if any,
- A description of techniques, findings, and tissues removed or altered,
- Surgeons or practitioners name(s) and a description of the specific significant surgical tasks that were conducted by practitioners other than the primary surgeon/practitioner (significant surgical procedures include: opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues), and
- Prosthetic devices, grafts, tissues, transplants, or devices implanted, if any.

2.4-3 Operative reports shall be dictated or written immediately after the completion of surgery and authenticated, timed and dated by the surgeon. At the direction of the medical executive committee, any practitioner not providing an operating note and/or report as required shall be notified verbally and with follow-up written verification of such by designated hospital personnel. Practitioners so notified will have 24 hours after said verbal notification to complete the required documentation. If the practitioner still has not provided the required operative documentation after 24 hours, then hospital privileges of the practitioner shall be suspended with the exception of those required to
provide continued care to that practitioner’s patients currently hospitalized and/or scheduled at Fort Hamilton Hospital. Such remaining privileges shall only be applicable to that practitioner’s patients hospitalized and/or scheduled at the time of the suspension. Such privileges shall be completely suspended when that practitioner’s patients hospitalized and/or scheduled at Fort Hamilton Hospital are not longer hospitalized and/or scheduled unless the outstanding operative documentation has been completed. Continued care of a suspended practitioner’s hospitalized and/or scheduled patients shall remain the responsibility of the practitioner during his suspension period. Documentation of each suspension shall be placed in the physician’s medical staff file.

2.5 OBSTETRICAL RECORDS

2.5-1 The current obstetrical medical record shall include a complete prenatal record. It may be a legible copy of the attending practitioner’s office record transferred to the hospital prior to admission. In such instances, an interval admission note shall be written by the attending practitioner that includes pertinent changes to the patient’s situation per section 2.2-2 above.

2.6 GENERAL DOCUMENTATION REQUIREMENTS

2.6-1 All clinical entries in the patient’s medical record shall be accurately dated, timed and authenticated by the author. Authenticated means to prove authorship by written signature or acceptable method. The use of rubber stamp signatures is acceptable if the practitioner whose signature the rubber stamp represents is the only one who has possession of the stamp and is the only one who uses it.

2.6-2 A record of accepted medical symbols and abbreviations used shall be kept on file in the medical records department.

2.6-3 All entries in the patient’s medical record shall be legible.

2.7 CONSULTING PRACTITIONER DOCUMENTATION REQUIREMENTS

2.7-1 Reports of consultations shall show evidence of a review of the patient’s medical record by the consultant, listing of pertinent findings from examination of the patient by the consultant, the consultant’s opinion and the consultant’s recommendations. The content of the consultation report should reflect those found in the history and physical exam (2.2). The consultation report must be dictated or written within 24 hours after the patient is seen. This report shall become part of the patient’s medical record. A limited statement such as “I concur” does not constitute an acceptable report of the consultation. Except in an emergency, so verified on the medical record when operative procedures are involved, the consultation note shall be recorded prior to the surgery taking place. Participation in management, which permits the attending physician and the names physician to write orders, however, overall chart responsibility remains with the attending physician.
2.7-2 If a consulting practitioner is not a member of the medical staff at this hospital but wishes to write orders on the medical record, these orders shall be cleared with the staff practitioner in charge of the case before they are carried out and the staff practitioner shall counter-sign the orders within a reasonable period of time.

2.8 DISCHARGE DOCUMENTATION AND COMPLETION OF MEDICAL RECORDS

2.8-1 Final diagnosis shall be recorded in full, dated and signed in the medical record by the attending practitioner at the time of discharge of all patients. The attending practitioner shall be responsible for establishing the final diagnosis.

2.8-2 A discharge summary shall be written or dictated on all medical records of discharged patients seven (7) days after discharge. The discharge summary shall include the outcome of the treatment, procedures, or surgery; the disposition of the case; provisions for follow-up care for an outpatient surgery patient or an emergency department patient who was not admitted or transferred to another hospital. In all instances, the content of the medical record shall be sufficient to document the diagnosis, treatment and end result. All summaries shall be authenticated by the responsible practitioner. A final progress note may be substituted for the discharge summary for patients with problems and interventions of a minor nature including those patients who require less than 48-hour hospitalization, normal newborn infants, and uncomplicated obstetric deliveries. The summary must contain the outcome of hospitalization, the case disposition, and any provisions for follow-up care. The final diagnosis must be included in the discharge summary.

2.8-3 All required documentation shall be completed within 30 days of discharge date, thereby making the medical record complete. All practitioners with incomplete medical records shall receive notification from hospital staff to allow reasonably sufficient time for completion before the records’ documentation becomes delinquent. Hospital privileges of practitioners with delinquent medical records shall be suspended with the exception of those required to provide continued care to that practitioner’s patients currently hospitalized and/or scheduled at Fort Hamilton Hospital. Such remaining privileges shall only be applicable to that practitioner’s patients hospitalized and/or scheduled at the time of suspension. Such privileges shall be completely suspended when that practitioner’s patients currently hospitalized and/or scheduled at Fort Hamilton Hospital are no longer hospitalized and/or scheduled unless the delinquent medical record has been completed. Continued care of a suspended practitioner’s hospitalized patients shall remain the responsibility of the practitioner during his suspension period. Documentation of each suspension shall be placed in the physician’s medical staff file.

If a practitioner is unavailable to complete his/her required medical record documentation for a period of time due to vacation or other
absence, he/she shall not have his/her clinical privileges suspended as detailed above provided that:

(a) the practitioner gave prior notification of such absence to medical records of medical staff services personnel, and the absence is for a period greater than 7 days, and
(b) the delinquent documentation is completed within 7 days of the practitioner’s return to practice.

The medical records not completed within the original time requirements shall still be considered delinquent and counted as such. The above is intended to allow practitioners absent for more than 7 days an opportunity to avoid clinical privilege suspension.

2.9 EMERGENCY SERVICES DOCUMENTATION

2.9-1 A permanent medical record shall be made and kept for every patient receiving care in the emergency department. This documentation shall be incorporated into the patient’s hospital medical record if one exists. The emergency medical record shall include:

(a) adequate patient identification,
(b) information concerning the time of the patient’s arrival, means of arrival and by whom transported,
(c) pertinent history of the injury or illness including details relative to first aid or emergency care given to the patient prior to his arrival at the hospital,
(d) description of significant clinical, laboratory and radiologic findings,
(e) diagnosis and treatment given,
(f) condition of the patient on discharge or transfer, and
(g) final disposition, including instructions given to the patient and/or his family relative to necessary follow-up care.

2.9-2 Each patient’s emergency department medical record shall be dated, timed and authenticated by the practitioner in attendance who is responsible for its clinical accuracy.
ARTICLE III

MEDICAL STAFF MEMBERSHIP/CLINICAL PRIVILEGES

3.1 EXCLUSION FROM PARTICIPATION

It is the policy of Fort Hamilton Hospital not to employ or grant medical staff membership or clinical privileges to any practitioner listed by a federal agency as excluded, debarred, suspended, or otherwise ineligible to participate in federal or state healthcare programs.

Practitioners applying for medical staff membership, clinical privileges, reappointment and/or limited clinical privileges, shall be required to sign a statement affirming that they have not been excluded, debarred, suspended, or otherwise ineligible to participate in federal or state healthcare programs. A practitioner may not be granted clinical privileges until the signed affirmation has been submitted to the hospital.

As a condition of receiving and maintaining medical staff membership and/or clinical privileges, the practitioner agrees to immediately notify the Quality Management Services office if the practitioner receives notice or becomes aware of being excluded, debarred, suspended, or otherwise ineligible to participate in federal or state healthcare programs. A practitioner, who becomes excluded, debarred, suspended, or otherwise ineligible to participate in federal or state healthcare programs may be subject to suspension or revocation of his/her medical staff membership and/or clinical privileges per the medical staff bylaws as well as these rules and regulations.

3.2 FAST TRACK CREDENTIALING

To expedite appointment, reappointment, or renewal or modification of clinical privileges, the board of trustees may delegate the authority to make those decisions to a committee of at least two board members who will meet as often as necessary for this purpose.

All credentialing criteria and requirements defined in the medical staff bylaws including positive recommendations by the credentials committee and the medical staff executive committee must be met prior to action by the credentialing committee of the board of trustees.

If the committee’s decision is adverse to the applicant, the matter is referred back to the medical staff executive committee for further evaluation.
The full board of trustees considers and, if appropriate, ratifies all positive committee decisions at its next regularly scheduled meeting.

An applicant is ineligible for the expedited process if at the time of appointment or if since the time of reappointment, any of the following has occurred:

- incomplete application,
- adverse or limited recommendation by the medical staff executive committee,
- current challenge or previously successful challenge to licensure or registration,
- involuntary termination of medical staff membership at another organization,
- involuntary limitation, reduction, denial, or loss of clinical privileges, or
- final adverse judgment in a professional liability action.

### 3.3 REINSTATEMENT OF CLINICAL PRIVILEGES

A practitioner with clinical privileges who has been convicted of a felony involving moral turpitude or who has undergone institutional treatment for alcoholism or drug addiction shall, upon application, have his/her clinical privileges restored only after thorough reevaluation of his competence by the credentials committee and the executive committee of the medical staff and upon approval of the governing board of the hospital. Following this evaluation, if his/her privileges are restored, he/she shall be required to serve a probationary period, during which his/her performance shall be monitored by his/her colleagues and other responsible observers as may be designated by the credentials committee, the medical staff executive committee and/or the governing board of the hospital.

### 3.4 CONTINUING EDUCATION

Each individual’s participation in continuing education is documented and considered in decisions about reappointment to the medical staff or renewal or revision of clinical privileges.

### 3.5 CREDENTIALING IN EMERGENCIES

Emergency privileges may be granted by the SVP or president of staff (or their designees) when the hospital’s emergency management plan has been activated and the hospital is unable to adequately address immediate patient needs. Disaster privileges may be granted to volunteer practitioners who present, at a minimum, a valid government-issued photo
identification issued by a state or federal agency (i.e., driver’s license or passport) and at least one of the following:

- A current picture hospital ID Card
- A current license to practice
- Identification indicating that the individual is a member of a Disaster Medical Assistance Team (DMAT), or MRC, ESAR-VHP, or other recognized state or federal organizations or groups
- Identification indicating that the individual has been granted authority to render patient care, treatment, and services in disaster circumstances (such authority having been granted by a federal, state, or municipal entity)
- Identification by current hospital or medical staff member(s) who possesses personal knowledge regarding volunteer’s ability to act as a licensed independent practitioner.

Primary source verification of licensure will begin as soon as the immediate situation is under control and completed within 72 hours from the time the volunteer practitioner presents during a disaster. In extraordinary circumstances, primary source verification will be completed as soon as possible.

The medical staff will oversee the professional practice of volunteer license independent practitioners by direct observation, monitoring or medical record review.

The organization will make a decision (based on information obtained regarding the professional practice of the volunteer) within 72 hours related to the continuation of the disaster privileges initially granted.

3.6 LICENSURE VERIFICATION

Ohio medical licensure shall be verified as follows:

- initial appointment,
- reappointment,
- licensure renewal, and
- at change of medical staff status.

At initial appointment, licensure held in all states shall be verified subject to approved telemedicine credentialing criteria per these bylaws and rules and regulations.
3.7 DISRUPTIVE BEHAVIOR

It is the policy of the Fort Hamilton Hospital that all medical staff providers adhere to the hospital’s disruptive behavior policy, including physicians and other providers with privileges covered by the medical staff bylaws and rules and regulations. Disciplinary action will be subject to the medical staff rules and regulations and/or bylaws.
ARTICLE IV

ADMINISTRATIVE ISSUES/ADMINISTRATIVE POLICIES AND PROCEDURES

4.1 RELEASE OF MEDICAL RECORDS

4.1-1 Written consent of the patient or his/her legal designee is required for release of medical information to persons not otherwise authorized to receive this information.

4.1-2 Medical records may be removed from the hospital’s jurisdiction and safekeeping only in accordance with a court order, subpoena or statute. All medical records are the property of the hospital and shall not otherwise be removed. Unauthorized removal of medical records from the hospital is grounds for suspension of the practitioner for a period of time to be determined by the executive committee of the medical staff.

4.1-3 In case of readmission of a patient, all previous medical records, as are available per organizational record retention policies, shall be available for the use of the attending practitioner. This shall apply whether the patient is attended by the same practitioner or another.

4.2 MASS CASUALTY PLAN

4.2-1 There shall be a plan for the care of mass casualties at the time of any major disaster, based upon the hospital’s capabilities in conjunction with other emergency facilities in the community. It shall be developed by a disaster planning committee composed of hospital personnel with appropriate input from the medical staff. The plan shall be approved by the medical staff and the governing body of the hospital.

4.2-2 The mass casualty plan shall make provision within the hospital for:

(a) availability of adequate basic utilities and supplies including gas, water, food and essential medical and support supplies,
(b) an efficient system of notifying and assigning personnel,
(c) unified medical command under the direction of the medical director of the emergency department or a designated substitute,
(d) conversion of adequate usable space into clearly defined areas for efficient triage, patient observation and immediate care,
(e) prompt transfer, when necessary and after preliminary medical and/or surgical intervention, to the facility most appropriate for administering definitive care,
(f) an identification system to adequately identify casualty patients,
(g) procedures for the prompt discharge or transfer of patients in the hospital who can be moved without jeopardy,
(h) a system to control and address the needs of relatives of casualty patients and to control access to triage areas, and
(i) establishment of a public information and community relations center to provide organized dissemination of information.

4.2-3 Practitioners shall be assigned to posts either in the hospital, in nearby areas, and/or mobile casualty stations. The medical director of the emergency department and the senior vice president of the hospital or their designees shall work together to coordinate the mass casualty plan. In cases of evacuation of patients from one section of the hospital to another or evacuation from hospital premises, the medical director of the emergency department shall authorize the movement of patients. All policies concerning direct patient care shall be the joint responsibility of the departmental chairpersons and the senior vice president of the hospital or their designees.

4.2-4 The mass casualty plan shall be rehearsed at least twice a year, preferably as part of a coordinated drill in which other community emergency service agencies participate. The drills shall be as realistic as possible and shall involve the medical staff as well as administrative, nursing and other hospital personnel. Actual evacuation of patients during drills shall be optional. There shall be a written report and evaluation of all drills.

4.3 RESPONSIBILITY FOR SAFETY

Each physician has a responsibility to participate in TFHH safety program to reduce the risk of injury to patients, staff, and visitors by:

- identifying and reporting opportunities to improve safety performance,
- complying with safety standards and regulations,
- participating in or providing safety education,
- participating in the monitoring and evaluation of safety related performance improvement data, and
- communicating unanticipated outcomes to patients and/or families using methods which minimize individual blame or retribution.

4.4 DEPARTMENT/SERVICE-SPECIFIC POLICIES AND PROCEDURES

4.4-1 Department/service-specific policies and procedures which are developed and implemented jointly by the medical staff and hospital personnel shall be adopted and reviewed according to departmental mechanisms, and revised, as needed.
4.5 MEDICAL STAFF RULES AND REGULATIONS REVIEW AND REVISION

4.5-1 These medical staff rules and regulations shall be reviewed and revised by the executive committee of the medical staff at least every three years but more frequently if necessary.

4.5-2 The governing board of the hospital shall approve all revisions to these medical staff rules and regulations.

4.6 MEDICAL STUDENT/RESIDENT POLICY

4.6-1 In order to accompany a practitioner at Fort Hamilton Hospital, a medical student or resident must be currently enrolled and participating in a formal training program and must have the approval of that training program to accompany the Fort Hamilton practitioner. The medical student or resident must be assigned to a specific practitioner or practitioner group which shall serve as a preceptor.

4.6-2 The medical student or resident must be registered with Medical Staff Services at or before his/her first visit to Fort Hamilton using the prescribed form. Registration information shall include full name and address, birth date, medical license number (if applicable), medical school or current hospital affiliation, physician/group preceptor, and expected dates of training at Fort Hamilton. In addition, documentation that the individual is a medical student/resident in good standing with his/her training program and evidence of current malpractice/liability coverage shall be submitted with the completed registration form.

4.6-3 The preceptor shall be responsible for the conduct and training experience of the medical student/resident, and must personally supervise all training experiences. Any concerns regarding the medical student/resident or related issues shall be directed to the preceptor. Disagreements or questions will be decided in consultation with the department chairperson and/or president of the medical staff.

4.6-4 If the medical student/resident observes or attends any patient intervention which normally requires informed consent, the patient’s medical records shall contain:

(a) the appropriate consent form signed by the patient or his/her legally authorized representative, and
(b) an inclusion in medical record documentation of the identity of the medical student/resident by name and title.

4.7 REPORTING REQUIREMENTS
4.7-1 Each committee or department chairperson shall forward documentation of recommended disciplinary action to the executive committee and/or other committee as appropriate. Such documentation shall be maintained in the physician’s quality file.

4.7-2 Information reported to the National Practitioner Data Bank is considered confidential and shall not be disclosed except for the purpose of carrying out credentialing and/or professional review activities within Fort Hamilton Hospital. Individual healthcare practitioners who obtain information about themselves from the NPDB are permitted to share that information with whomever they choose.

4.7-3 Final adverse actions reportable to the state medical board of Ohio per the medical staff bylaws include:

(a) Final decision of an adverse professional review action against a practitioner’s clinical privileges lasting more than thirty (30) days,
(b) Voluntary surrender of medical staff membership or clinical privileges by a practitioner while under investigation for possible incompetence or improper professional conduct,
(c) Voluntary surrender of clinical privileges or medical staff membership in lieu of conducting an investigation, and
(d) Corrections or revisions to professional review actions that have been previously reported to OSMB and/or the data bank.

4.7-4 In the event a member of the medical staff loses his/her medical staff membership or has his/her clinical privileges terminated as a result of an adverse action which is final (meaning the practitioner has either exhausted all appellate rights provided in the fair hearing process set forth in the medical staff bylaws and/or rules and regulations, or has waived or otherwise not availed himself/herself of such rights in a timely manner), then the president of such hospital may furnish written notice of such final adverse action to the president of the medical staff of all other hospitals affiliated with “the Alliance.” This written notice shall be in addition to any other notices required of the hospital as a participation entity in the National Practitioner Data Bank. The purpose of such notice is to alert our other affiliated Alliance hospitals of the situation. No such notice will be sent to other area hospitals, all of which should have access to information reported to the National Practitioner Data Bank.
ARTICLE V

MEDICAL STAFF QUALITY FUNCTIONS

The important processes or outcomes in which the medical staff participates include but are not limited to:

5.1 OPERATIVE AND OTHER INVASIVE AND NON-INVASIVE PROCEDURES THAT MAY PLACE PATIENTS AT RISK.

Review of surgical and other procedures shall be conducted by those departments/services performing such procedures. In reviewing performance of these procedures, the systematic measurement of the following is performed:

(a) selection of the appropriate procedure,
(b) patient preparation,
(c) performance of the procedure and patient monitoring,
(d) post procedure care, and
(e) post procedure patient education.

5.2 MEDICATION USE

Medication use evaluation shall be performed for the purpose of measuring and improving the appropriateness and effectiveness of the use of medications.

The following medication processes are measured:

(a) prescribing or ordering,
(b) preparing and dispensing,
(c) administering, and
(d) monitoring the effects on patients.

5.3 MEDICAL RECORD REVIEW

The medical record review function shall consist of the systematic review of medical records to determine if they are timely, legible, complete, accurate and adequate to serve as a source of needed information.

5.4 BLOOD AND BLOOD COMPONENT USE

The blood use review function shall consist of activities undertaken to monitor and improve the processes involved in the ordering, distribution, handling, dispensing and administration of blood and blood components. The invasive procedures committee of the medical staff may delegate operational oversight of this function as may be appropriate.
5.5 UTILIZATION MANAGEMENT

Concurrent and periodic review processes are carried out to determine the appropriateness of admissions, the clinical necessity of continued hospitalization, and evaluation of the effective and efficient use of services and resources.

5.6 CUSTOMER SATISFACTION

Information from patients, families, staff members and others is collected and used in assessing how well processes are designed and/or operate and in organization planning.

5.7 CONFIDENTIALITY

Quality assurance information including, but not limited to verbal or written references to quality improvement, peer review and/or risk management activities shall be protected against disclosure. (Ohio Revised Code Sections 2305.24-2305.25-2305.251)

5.8 OTHER

Autopsy results, risk management activities and quality control activities are used in conjunction with quality improvement functions to provide important information for systematic screening, maintenance and/or hospital-wide improvement.
ARTICLE VI

ORDERS FOR PATIENT CARE

6.1 VERBAL ORDERS

6.1-1 All orders for treatment shall be in writing. Verbal orders should be used as infrequently as possible. Verbal orders, including telephone orders, shall be considered to be in writing if dictated to and documented on the appropriate order sheet by authorized personnel functioning within the scope of their training and competence. Such personnel shall include registered nurses, licensed practical nurses, licensed dieticians, licensed respiratory practitioners, licensed physical therapists, occupational therapists, speech therapists, certified nuclear medicine and radiation technologists, physicians, dentists, podiatrists, psychologists, certified nurse midwives, certified registered nurse anesthetists and pharmacists.

6.1-2 The practitioner giving verbal orders shall authenticate them by countersigning them in a timely manner. All verbal orders must be dated, timed and authenticated within 48 hours of being given. Verbal orders for restraint or seclusion of medical or surgical patients shall be authenticated within 24 hours. Verbal orders for restraint or seclusion of behavioral health patients shall be authenticated within one hour.

6.1-3 The use of verbal orders should be limited to those situations in which it is impossible or impractical for the ordering practitioner to write a manual or electronic order. The facility discourages the use of verbal orders when the ordering practitioner is physically present, except in an emergency or during a bedside procedure situation.

6.1-4 All written or verbal orders (including orders for diagnostic procedures, treatment, medication, biological, progress notes, patient assessments, history and physicals, etc.) must be legible, complete, dated, timed and authenticated in written or electronic form by the prescribing physician or other licensed practitioner who is authorized to write orders by the State law and Hospital policy, and who is responsible for the care of the patient even if the order did not originate with such practitioner.

6.2 PRE-SURGERY ORDERS

6.2-1 All previous orders shall be considered cancelled when patients have surgery unless the surgeon, anesthesiologist or attending physician has documented that the preoperative “Do Not Resuscitate” order be extended for the duration of the operative/invasive procedure.
6.3 ROUTINE ORDERS

6.3-1 Routine orders may be formulated by individual practitioners or groups of practitioners. These orders shall be followed at the verbal direction of the practitioner, and shall be dated, timed and authenticated by the practitioner in a timely manner.

6.3-2 Each set of routine orders shall be reviewed and revised as needed by the involved practitioner(s)

6.4 CLINICAL PROTOCOLS AND PATHWAYS

Clinical protocols or pathways are guidelines for care which may be modified according to individual patient care needs based on the professional judgment of the treating physician.

Clinical protocols or pathways will be reviewed, approved, and revised by physicians and other healthcare providers with a strong focus on inclusion of individuals directly impacted by protocol/pathway use.

6.5 PATIENT RESTRAINT/SECLUSION

6.5.1 Use of a physical or mechanical device to involuntarily control the movement of the whole or a portion of a patient’s body to control physical activity when not customarily employed for postural support or during medical, diagnostic or surgical procedures shall be considered patient restraint.

6.5.2 Time-limited orders or medical staff approved protocols shall guide restraint/seclusion use.

6.5.3 Hospital policy shall describe specific restraint guidelines including the use of seclusion for psychiatry patients.
ARTICLE VII

PATIENT CARE REQUIREMENTS

7.1 AUTOPSIES

7.1-1 It shall be the duty of all practitioners to secure meaningful autopsies whenever reasonably possible. No autopsy shall be performed without the physician’s written order and the written consent of the nearest relative or legally authorized agent unless the autopsy is required by law.

7.1-2 All autopsies shall be performed by the hospital pathologist or by a practitioner delegated this responsibility.

7.1-3 Provisional anatomic diagnoses shall be recorded on the medical record within three (3) days and the complete protocol shall be documented in the patient record within thirty (30) days unless exceptions are granted by the medical executive committee relative to special studies.

7.1-4 Medical staff criteria for identifying cases in which an autopsy should be considered include:

   (a) unexpected sudden death where the diagnosis is not reasonably established by known clinical conditions, for patients under the age of 75 years.
   (b) operative death (intraoperative, intraoprocudural, recovery room, or immediate post invasive procedure, including endoscopy.
   (c) immediate post partum death (within 48 hours).

7.2 INFORMED CONSENT

7.2-1 The patient shall have the right to reasonably informed participation in decisions involving his/her health care. To the degree possible, this shall be based on clear, concise explanation of his/her condition and all proposed technical procedures, including the possibilities of any risk of mortality or serious side effects, problems related to recuperation, probability of success and information regarding any significant alternative treatments or procedures. Except in medical emergencies, the patient shall not be subjected to any procedure without his/her voluntary, competent, and understood consent or that of his/her legally authorized representative.

7.2-2 Forms to verify that the patient or his/her legally authorized representative has given his/her informed consent for treatment shall be prepared by hospital personnel.
7.2-3 It shall be the responsibility of the individual practitioner to provide to the patient sufficient information about a proposed treatment or procedure so that informed consent may be given and obtained.

7.3 PATIENT RIGHTS

7.3-1 If the practitioner is unable or unwilling to comply with a patient’s and/or family’s wishes to the extent allowed by law, he/she shall not prevent or unreasonably delay transfer of the patient to another practitioner or health care facility that can comply with the patient’s and/or family’s wishes.

7.3-2 If concerns arise relative to ethical considerations of a proposed action or if it is desirable to discuss the ethics of a particular case, the patient and/or professionals directly involved in the care and management of the patient may request an ad hoc ethics review.

7.4 CONTINUING CARE RESPONSIBILITIES

7.4-1 Each practitioner with clinical privileges shall provide assurance of timely and proper professional care for his/her patients in the hospital by either being available personally or by having available an appropriately credentialed alternate practitioner with whom prior arrangements have been made for this purpose. The alternate must have adequate and appropriate clinical privileges at this hospital.

7.4-2 In case of unexpected unavailability of an attending or covering practitioner, the senior vice president of the hospital, the president of the medical staff, the chairperson of the department concerned, or any of their designees shall have the authority to call upon any member of the medical staff having adequate and appropriate clinical privileges to provide necessary care.

7.4-3 Practitioners shall provide or arrange for continuous care and supervision of hospitalized patients.

7.5 OPERATIVE AND PROCEDURAL REQUIREMENTS

7.5-1 All tissues removed during any operative or other procedure except as noted in hospital policy shall be sent to the hospital pathologist who shall examine the tissue in whatever manner is necessary to arrive at a pathological diagnosis. The pathologist shall date, time and authenticate all reports generated as a result of his/her examination and these reports shall be made part of the patient’s permanent medical record.
7.5-2 Written, signed documentation of informed consent shall be obtained from the patient or a legally authorized agent prior to the commencement of any operative or other procedure that places the patient at significant risk except in those situations wherein the patient’s life is in jeopardy. In an emergency involving an underage, unconscious or incompetent patient in which consent for surgery cannot be immediately obtained from parent, guardian or next of kin, the situation and circumstances, including attempts to obtain consent, shall be fully documented in the patient’s medical record. In such cases, consultation with and signed concurrence by another physician shall be considered before an emergency operative procedure is undertaken, if the patient’s condition permits.

7.5-3 The anesthesiologist, another practitioner or his/her designee shall maintain a complete anesthesia/sedation record including evidence of pre-procedure evaluations (except in emergencies as defined in these rules and regulations), intra-procedural care and monitoring and post anesthesia/sedation follow-up of the patient’s condition. A post anesthesia evaluation must be completed and documented within 48 hours after surgery.

7.5-4 Except in emergency situations, all patients scheduled for elective surgery who require anesthesia shall receive pre-admission testing following current hospital policy and anesthesia guidelines. Additional or alternate testing shall be done at the direction of the surgeon or anesthesiologist.

7.5-5 Documentation requirements shall be accomplished prior to operative and other procedures as outlined in these rules and regulations.

### 7.6 EMERGENCY SERVICES

7.6-1 The medical staff shall adopt a method of providing continuous and appropriate medical coverage in the hospital’s emergency department. Such coverage shall be in accord with the hospital’s plan for the delivery of such services including the delineation of appropriate clinical privileges for all practitioners who render emergency care.

In order to determine the need for emergency services, qualified medical personnel shall perform medical screening examinations. Qualified medical personnel shall include medical staff members holding applicable medical privileges. A medical screening examination is the process used to determine, with reasonable clinical confidence, whether a medical emergency exists. Triage is not equivalent to a medical screening examination.
7.7  “ON-CALL” RESPONSIBILITIES

7.7-1 All members of the active medical staff, including provisional active staff members, shall take, or arrange for appropriate substitute, “on-call” coverage on a rotational basis for his/her respective department or service. Exceptions to include or exclude additional medical staff members may be made by the clinical department chairperson in conjunction with the medical staff executive committee.

7.7-2 On-call physicians shall be expected to respond within 30 minutes of receiving the call. In the event that the practitioner “on-call” is unexpectedly unavailable, the department chairperson for the applicable service shall be called for appropriate input, involvement and/or direction.

On call physicians are prohibited from referring patients with emergency conditions to the office for examination and treatment whenever the Emergency Room physician determines that the emergency condition has not stabilized enough to allow dismissal or transfer.

7.8  CONSULTATIONS

7.8-1 Consultations shall be used in an appropriate and timely manner. Although it is primarily the duty of the attending practitioner to establish the diagnosis and treatment for the patient, it is also the duty of the medical staff, through its executive committee and departmental chairpersons, to assure that practitioners with clinical privileges call consultants as needed.

7.8-2 In cases of attempted suicide, psychiatric consultation shall be offered to the patient with the offer or recommendation and the response of the patient being documented on the medical record.

7.8-3 Any qualified practitioner with clinical privileges at Fort Hamilton Hospital may be called upon to provide consultation within his/her area of expertise.

7.8-4 The attending practitioner is responsible for requesting consultation when indicated. Except in an emergency, he/she shall provide written documentation authorizing the requested consultant to attend and/or examine the patient.

7.8-5 If a nurse or other healthcare professional has concerns about the quality or appropriateness of care provided to any patient or thinks that consultation is indicated but has not been requested, he/she shall discuss
the concern with his/her immediate superior at Fort Hamilton Hospital. If
the superior concurs, then the concern shall be reported to the vice
president and chief nursing officer or his/her designee. The vice-president
and chief nursing officer or his/her designee shall, if deemed appropriate,
report the matter to the chairperson of the department within which the
practitioner has clinical privileges. The chairperson shall then investigate
the concern and may elect to request a consultation or take other action
where circumstances exist to justify such action.

7.8-6 Medical staff members are expected to respond to requests for
consultation in a timely fashion that meets patient care demands and the
need for appropriate utilization of services. Time-to-response expectation
for consultations is 24 hours.

7.9 CARE OF PATIENTS ADMITTED FOR DENTAL CARE

7.9-1 A patient admitted for dental care who is to be cared for by a dentist with
appropriate clinical privileges shall be the dual responsibility of the dentist
and a physician member of the medical staff.

7.9-2 In such cases, the dentist’s responsibilities shall be as follows:

(a) documentation of a detailed dental history justifying hospital
admission,
(b) documentation of a detailed description of the examination of the
oral cavity including a pre-operative diagnosis,
(c) documentation of a complete operative report describing the
findings and technique. When tooth extraction is done, the dentist
shall clearly document the number of teeth and fragments
removed. All tissue including teeth and fragments shall be sent to
the hospital pathologist for examination,
(d) progress notes as are pertinent to the oral condition, and
(e) summary statement.

7.9-3 The physician’s responsibilities shall include:

(a) documentation of a medical history pertinent to the patient’s
general health, unless such is provided by the patient’s dentist who
is qualified and credentialed to perform such,
(b) documentation of a physical examination to determine the patient’s
condition prior to anesthesia and surgery, unless such is provided
by the patient’s dentist who is qualified and credentialed to
perform such, and
(c) supervision of the patient’s general health status while
hospitalized.
7.9-4 The discharge of the patient shall be on written order of the dentist with the written concurrence of the collaborating physician.

7.10 MEDICATIONS

7.10-1 Medications prescribed for administration to patients shall be from the approved hospital drug formulary except when special circumstances warrant otherwise. When non-formulary medications are prescribed for administration to patients, a non-formulary request form shall be completed and at least one of the following criteria must be met:

(a) The drug has been approved for sale in the United States by the Food and Drug Administration,
(b) The drug is being used in conjunction with a clinical investigational study in compliance with regulations of the Food and Drug Administration, or
(c) The medication dosage is to be compounded for a specific patient in accordance with regulations of the Ohio State Board of Pharmacy and the Food and Drug Administration.

7.10-2 Investigational drugs shall only be used with the properly obtained and documented informed consent.

7.10-3 Medication orders written and administered prior to surgery must be reordered as part of the post-operative order if they are to be continued.

7.11 INVESTIGATIONAL INTERVENTIONS

7.11-1 Investigational medications shall only be administered to patients as indicated in these rules and regulations.

7.11-2 Investigational medical devices and other diagnostic or therapeutic interventions shall be used only with properly obtained and documented informed consent.

7.11-3 Investigational medical devices and other diagnostic or therapeutic interventions shall be used only in full accordance and compliance with any and all applicable laws and regulations and as recommended by the institutional review committee.

7.11-4 Institutional review committee guidance shall be available to provide for:

(a) prospective and ongoing review of research done at or participated in by Fort Hamilton Hospital and/or its practitioners holding clinical privileges,
(b) assessment of risks and benefits of such research to human subjects,
(c) an informed consent process, and
(d) a system of assurances of compliance with applicable regulatory requirements.

Policies and procedures shall be defined by and delineated in hospital and medical staff documents developed for this purpose.

Fort Hamilton Hospital and its medical staff may accomplish this function in concert with other healthcare organizations as may be appropriate.

7.12 INPATIENT MINIMUM AGE REQUIREMENT

The minimum age for medical/surgical inpatients is 16 years of age. This does not apply to obstetric or out-patient surgery patients.