



HOSPITAL • ST. LOUIS

BJC HealthCareSM

MEDICAL STAFF RULES & REGULATIONS

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ARTICLE I - ADMISSIONS

Section 1: Who May Admit Patients

Patients may be admitted to the Hospital only by Active members of the Medical Staff. Patients shall be assigned to the Department and/or Division concerned in the treatment of the condition which necessitated admission. Every patient admitted to the Hospital must have a designated Medical Staff member who is responsible for his/her care. Patients presenting for admission who have no personal physician/dentist shall be assigned an attending physician/dentist.

Section 2: Responsibilities of Admitting Physician/Dentist

Information pertinent to the patient's general health as well as information necessary to protect the patient and others from harm shall be provided by the admitting physician/dentist.

Section 3: Provisional Diagnosis Requirements

Except in emergency, no patient shall be admitted to the Hospital until after a provisional admitting diagnosis has been made and recorded in the medical record. In case of an emergency, the provisional diagnosis shall be stated as soon after admission as possible.

Section 4: Required Pre-Admission/Admission Tests

The requirement for pre-admission tests is based on the needs of individual patients. Each patient admitted to the Hospital shall have diagnostic studies performed as necessary for the diagnosis and treatment of his/her condition.

Section 5 – Patient Acceptance

The Hospital shall accept patients regardless of race, gender, disability, age, national origin or sexual preference (See also, SLCH Policy entitled Patient Age Guidelines for Admission concerning patients aged 18 years or older).

Section 6 – Family Members

A Medical Staff member shall not render direct patient care to a member of his/her immediate family without expressed written permission from his/her Department Chief. "Immediate Family" includes a spouse, parent, child or sibling. A Medical Staff member may, however, serve as a consultant on a case involving an Immediate Family member.

ARTICLE II - ATTENDING PHYSICIAN/DENTIST

Section 1: Responsibilities of Attending Physician/Dentist

- a) Physician

The attending physician shall be responsible for the medical care and treatment of his/her patient, for prompt completion and accuracy of the medical record, for necessary special instructions and for transmitting reports of the patient's condition to the referring physician, other relevant care providers and the parent(s)/guardian of the patient. The attending physician shall also be responsible for the medical supervision of all who participate in the delivery of care for his/her patient.

b) Dentist

The attending dentist shall be responsible for the care and treatment of his/her patient, for prompt completion and accuracy of the medical record, for necessary special instructions and for transmitting reports of the patient's condition to the referring physician/dentist, other relevant care providers and the parent(s) guardian of the patient. Attending dentists shall have the same responsibilities as physicians except that, at all times, the patient's general medical condition shall be the responsibility of a physician. See Article VII Dental Care, Section 2 of these Rules and Regulations.

ARTICLE III - COLLABORATIVE PRACTICE AGREEMENT

Section 1: Definition

Collaborative practice AGREEMENTS may be entered into by physicians, physician assistants ("PA") and advanced practice nurses ("APN"). Such arrangements shall be established through written agreements for the delivery of health care services and must include the approval of the appropriate Department Chair of Washington University School of Medicine and the President of the Hospital through the Credentialing Subcommittee reviewed by the Children's Medical Executive Committee ("CMEC"). Collaborative practice agreements authorize physician assistants and advanced practice nurses to provide assessments, diagnosis, treatment, and to prescribe, administer and dispense drugs as the delivery of such health care services is within the scope of practice of the physician assistant or advanced practice nurse and is consistent with his or her skill, training and experience. Collaborative practice arrangements do not, however, authorize physician assistants and advanced practice nurses to prescribe controlled substances.

Section 2: Definition – APN and PA in Collaborative Practice

An advanced practice nurse is a registered nurse who has had education beyond the basic nursing education and is certified by a nationally recognized professional organization as having a nursing specialty, or who meets criteria for advanced practice nurses established by the Missouri State Board of Nursing. Advanced practice nurses will be credentialed and approved by the medical staff organization in accordance to the administrative policy attached entitled "Advanced Practice Registered Nurse Credentialing and Scope of Practice Policy".

Use of the term "advance practice nurse" in the Medical Staff Rules and Regulations refers to those advanced practice nurses who have entered a collaborative practice arrangement at St. Louis Children's Hospital and who have received a Document of Recognition from the State Board of Nursing in accordance with applicable Missouri statutes and regulations.

Section 3: Relationships between APNs, PAs and Attending Physicians

When a Physician Assistant and APN in collaborative practice has been delegated responsibility by his or her collaborating physician to care for a patient, it remains the collaborative physician's responsibility to coordinate the patient's care with any other attending physician responsible for the patient.

ARTICLE IV - INFORMED CONSENT

Section 1: Definition

"Informed consent" means consent obtained by a physician, dentist, advanced practice nurse OR PROVIDER for the patient's course of treatment for those procedures he/she will perform, or, for placement of PICC lines only, registered nurses who are trained to insert a PICC and will be personally performing the procedure. Informed consent should be obtained from the patient, his/her parent(s) or person(s) responsible for care based on discussion of the nature, benefits, significant risks and alternatives to the proposed treatment, care or services.

Section 2: Responsibility of Obtaining Informed Consent

At the time of admission or as soon thereafter as practical, the Hospital's standard admission consent form(s) must be obtained and signed by the parent(s) or person(s) responsible for care or, when appropriate, by the patient. The admitting department shall notify the attending physician/dentist whenever such consent has not been obtained.

After admission, it shall be the responsibility of the appropriate physician/dentist to obtain consent from the patient, his/her parent(s), person(s) responsible for care, or other authorized representative, e.g. individual authorized under durable power of attorney for healthcare decisions in accordance with the Hospital policy on Informed Consent (Attached as St. Louis Children's Hospital Informed Consent).

1. In cases requiring anesthesia, the anesthesiologist shall obtain consent for administration of the anesthesia.
2. In cases requiring sedation, the physician, dentist, or provider shall obtain consent for administration of sedation.

An advanced practice nurse in collaborative practice who performs procedures may obtain informed consent for procedures the APN will perform. Nurses who are trained in PICC placement may obtain consent for PICC placements they personally perform.

Telephone consent from a parent or person responsible for care of the patient is permissible in such circumstances as long as it is obtained by physician/dentist and witnessed by a licensed health care professional. Telephone consent must be documented in the medical record and signed by the physician dentist and the witness.

Except in emergencies, no procedure shall be performed without a documented consent in the patient's medical record prior to the performance of the procedure. Oral consents are permitted if obtained by a physician/dentist and witnessed by a licensed health care professional. Such oral consents must be documented in the medical record.

Section 3: Emergency Care and Treatment Without Consent

1. Emergency care and treatment may be provided to a patient without consent when, in the judgment of the treating physician/dentist, any delay may increase the risk to the patient's life, health, mental health or welfare, or unduly prolong suffering. In such cases, the treating physician/dentist shall document in the patient's medical record the reasons for rendering care without consent. If the treating physician/dentist is a resident or fellow, the note shall be finalized by the attending physician/dentist.
2. When emergency treatment (other than surgery or special procedures) is begun without parental or guardian consent, attempts to reach the parent(s) or person(s) responsible for care by telephone shall be initiated as soon as possible.

Section 4: Duration of Validity of Informed Consent

Signed consent is valid for the duration of an admission unless significant change in the patient's condition warrants consent based on new information. Signed consent for outpatient procedures is valid unless there has been significant change in the patient's condition since consent was first obtained.

ARTICLE V - CONSULTATIONS

Section 1: Required Consultations

Consultation shall be obtained whenever the responsible physician or other responsible practitioner believes that such consultation may prove beneficial to the patient, when the patient's condition requires expertise beyond the scope of the responsible practitioner, or if appropriate, at the request of the parent or person(s) responsible for care.

Section 2: Definition of a Consultant

Members of the Medical Staff or their designees may serve as consultants. In special situations, qualified practitioners not on the Medical Staff who have been granted temporary privileges may be invited to visit patients in the Hospital and advise the requesting practitioner, as well as observe the course of treatment. Such consultants may not assume responsibility for the patient; responsibility for the patient remains with the attending physician/dentist.

Section 3: Composition of Consultations

A consultation includes an examination and/or observation of the patient, review of the record and timely communication with the requesting physician/dentist. A recorded opinion finalized by the consultant must be included in the medical record. If a medical/psychiatric consultation is performed by a designee who is not a member of the Medical Staff, it must be countersigned by a member of the active Medical Staff. When operating procedures are involved, the consultation note, except in emergency, shall be recorded prior to the operation.

ARTICLE VI - DEATHS

Section 1: Pronouncement of Death

Death is officially pronounced by a physician and documented in the medical record. Documentation shall include the events leading to the death, date and time the patient was pronounced dead and the signature of the physician and his/her appellation.

Section 2: Determination of Brain Death

Brain death shall be determined in accordance with current St. Louis Children's Hospital policy, attached as Exhibit 3. Medical record entries for death by neurologic criteria shall be made in accordance with this policy.

Section 3: Reporting of Deaths to the Medical Examiner

Physicians shall report deaths of children fifteen years and under to the St. Louis City or County Medical Examiner in accordance with the State statute. In addition, State statute requires reporting of death as a result of:

- A. Violence by homicide, suicide or accident;
- B. Thermal, chemical, electrical, or radiation injury;
- C. Criminal abortion including those self-induced;
- D. Disease thought to be of a hazardous and contagious nature or which may constitute a threat to public health; or
- E. When any person dies
 - 1. Suddenly when in apparent good health,
 - 2. When not attended by a physician or licensed practitioner during the period of thirty-six hours immediately preceding the death,
 - 3. While in the custody of the law or while an inmate in a public institution, or
 - 4. In an unusual or suspicious manner.

Section 4: Autopsies

It shall be the duty of all physicians/dentists to request consent for autopsy in the following situations (as recommended by The College of American Pathologists):

- A. Deaths in which autopsy may help to explain unknown and unanticipated medical complications.
- B. Deaths in which the cause of death or a major diagnosis is not known with reasonable certainty on clinical grounds.
- C. When the autopsy may help to allay concerns of the family, physicians and/or the public regarding the death.

- D. When unexpected or unexplained deaths occur during or following any dental, medical, or surgical diagnostic procedures and/or therapies.
- E. Natural deaths which are subject to, but waived by, a forensic medical jurisdiction such as (1) persons dead on arrival at hospitals, (2) deaths occurring in hospitals within twenty-four (24) hours of admission, and (3) deaths in which the patient sustained or apparently sustained an injury while hospitalized.
- F. Deaths resulting from high-risk infectious and contagious diseases.
- G. All perinatal and pediatric deaths.
- H. Deaths at any age in when it is believed that autopsy would disclose a known or suspected illness which also may have a bearing on survivors or recipients of transplant organs.
- I. Deaths known or suspected to have resulted from environmental or occupational hazards.

No autopsy shall be performed without the proper written legal consent and administrative approval. No autopsy shall be performed without a complete medical history, including establishing status regarding Kreutzfeldt-Jakob disease. All autopsies shall be performed by a Hospital Pathologist or by a physician delegated this responsibility.

ARTICLE VII - DENTAL CARE

Section 1: Oral and Maxillofacial Surgeons

Qualified oral and maxillofacial surgeons may perform the history and physical examination in accordance with their delineated privileges. Patients with medical problems outside the scope of the oral and maxillofacial surgeon's expertise require joint evaluation and management with a physician.

Section 2: Other Dental Specialists

Services not requiring general anesthesia may be provided by the dental specialist who is responsible for the dental-related history and physical examination and for administration and monitoring of local anesthesia and sedation in accordance with the St. Louis Children's Hospital Medical Staff policy on sedation.

Services requiring general anesthesia require a history and physical examination performed by a physician as specified in the Surgical Care section of this document. Patients with medical problems require joint evaluation and management with a physician. See Article II Attending Physician/Dentist, Section 1.b of these Rules and Regulations.

ARTICLE VIII - DISCHARGES

Section 1: General

At the time of discharge, the medical record must reflect all relevant diagnoses and operative procedures performed and an assessment of the patient's needs for services after hospitalization. Discharge instructions, prescriptions and any referrals should be finalized and reviewed with the patient and family/adult care provider prior to discharge.

Section 2: Leaving Against Medical Advice

If a patient leaves the Hospital against the advice of the physician/dentist, or without proper discharge, a notation of the incident shall be made in the patient's medical record. When possible, the patient or family/adult care provider shall be asked to sign the Hospital's release form.

ARTICLE IX - EMERGENCY SERVICES

Section 1: General

The Emergency Unit provides initial evaluation and treatment to pediatric patients seeking unscheduled care at St. Louis Children's Hospital for medical, dental and/or surgical problems. All patients presenting to the Emergency Unit will receive a medical screening examination to determine whether an emergency condition exists. This exam will be performed by a registered nurse, an advanced practice nurse (including pediatric nurse practitioner), or a physician. An attending physician or designee will be available at all times for consultation regarding medical screening examinations. Specifics regarding Emergency Unit physician's responsibilities and coverage, documentation, consent to treatment, collaborative practice arrangements and admission to the Hospital are enumerated in the Emergency Unit policy and procedure manual. The contents of such manual shall be developed by the Emergency Unit Policy and Procedure Committee and approved by the Children's Medical Executive Committee.

All emergency department patients shall be assessed prior to discharge by a physician or an advanced practice nurse.

Section 2: Coverage

At least one (1) attending physician shall be on duty twenty-four (24) hours per day, seven (7) days per week to provide emergency services.

Each Department Chief is responsible for providing call lists of House Staff and/or attending physicians on duty or on call to respond to calls from the Emergency Department. On-call or on-duty physicians taking emergency call shall arrive at the Emergency Department within thirty (30) minutes of being summoned. The Trauma attending physician on-call or on-duty shall arrive at the Emergency Department within fifteen (15) minutes of being summoned.

ARTICLE X - INTENSIVE CARE UNITS

Section 1: Admission and Discharge Criteria

Admission to and discharges from the intensive care units shall be in accord with the policies and procedures reviewed by the appropriate hospital and medical staff leaders and approved by the Children's Medical Executive Committee.

ARTICLE XI - MEDICAL RECORDS

Section 1: General Rules.

A medical record shall be created for each patient, and it shall be the responsibility of the attending physician, or his/her designee (House Staff, APN in collaborative practice) to maintain the record complete, current, legible, dated, timed, authenticated, recorded, pertinent, and in accordance with the policies recommended by the Health Information Management (HIM) Subcommittee and established by the Medical Executive Committee. The medical record includes both paper and electronic documents which include: patient's name, unique identifying medical record number, pertinent identifying personal data, a history of present illness, if injury, how it occurred, past history, family history, physical examination, admitting diagnosis, Medical Staff orders, progress notes, nurses' notes, discharge summary, final diagnosis and evidence of informed consent. Where applicable, the medical record should also contain reports from clinical laboratory, radiology, consultations, echocardiogram, surgical procedures, therapy, anesthesia, pathology, autopsy, referral information from other agencies and providers, any other reports pertinent to the patient's care and treatment.

Section 2: History and Physical Examinations – Inpatient/Outpatient

1. History and Physical Examination: For patients admitted/registered to the hospital for inpatient services; outpatient services such as surgery and diagnostic tests or procedures requiring anesthesia or sedation; a physician, APN, or physician assistant must perform and document a history and physical examination ("H&P") within 24 hours after the patient's admission/registration, or prior to any surgery requiring anesthesia services (except in the case of emergencies), whichever comes first. An update to an H&P performed within 30 days prior to admission may be used if an updated examination of the patient occurs as described below. The supervising or precepting physician for the non-physician practitioner performing the history and physical examination must sign and retains full responsibility for the history and physical examination.

For inpatients and outpatients (as described above), the documentation of a history and physical must include, when pertinent:

- a. the chief complaint;
- b. history of present illness;
- c. past medical history;
- d. family history;
- e. psychosocial history;
- f. review of systems,
- g. medication and allergies
- h. physical examination;
- i. provisional diagnosis or clinical impression;
- j. treatment plan.

For Dental care, the history and physical examinations must include:

- a. chief complaint;
- b. details of disease;
- c. injury and/or defect of the jaws and/or contiguous structures; and
- d. its implications on the patient's general health.

If an H&P was performed within 30 days prior to a patient's admission to the hospital, a reasonably durable, legible copy of the history and physical report may be used for the patient's current hospital admission (including outpatient surgeries or procedures requiring anesthesia or sedation), provided that the attending physician or other authorized individual within 24 hours of admission but prior to any surgery or procedure requiring sedation, examines the patient, documents any additions to the history or changes in the patient's current physical findings and signs the history and physical examination to update the examination. If, upon examination, the authorized practitioner finds no change in the patient's condition since the H&P was reviewed, he/she may just document the H&P was reviewed, the patient was examined, and that "no change" has occurred in the patient's condition since the H&P was completed.

If a H&P is not completed and documented before the time stated for the surgery/procedure, the surgery/procedure shall be cancelled or, when feasible, delayed until the history and physical examination is completed unless the attending physician documents that the surgery or procedure is an emergency.

All history and physical examinations entered by medical students must be countersigned, and amended, if necessary, by the responsible licensed preceptor physician, who is either a member of the House Staff or an Attending Physician. These rules govern all medical student clinical preceptorship assignments, whether titled "clinical clerkship," "externship" or any other term that might be used.

Section 3: Progress Notes

Progress notes must be recorded by the physician/dentist, medical student, physician assistant, or advanced practice nurses in a collaborative arrangement to ensure continuity of care and document the patient's problems, progress and assessment. Progress notes entered by medical students must be co-signed by a licensed physician.

Section 4: Operative Notes

The attending surgeon or his/her designee will enter an operative progress note in the medical record immediately following the completion of the operation or procedure and before the patient is transferred to the next level of care; unless the surgeon or his/her designee accompanies the patient from the operating room to the next unit or area of care where he/she will enter the operative progress note.

The operative progress note shall contain: (1) the name of physician and assistant(s); (2) preoperative diagnosis (3) postoperative diagnosis (4) procedure(s) performed, if any; (5) findings; (6) estimated blood loss; (7) specimens removed; and (8) complications.

The attending surgeon or his/her designee will record an operative report immediately following the operative procedure. The operative report shall contain the elements listed above as well as the patient name and hospital identification number, date and times of surgery/procedure, description of surgical technique; type of anesthesia administered, and any prosthetic devices, grafts or devices implanted. The attending surgeon will finalize the operative report.

Section 5: Procedure Notes

A written procedure note shall be recorded in the progress notes immediately following the procedure. The procedure note shall contain: (1) the name of physician or provider and assistant(s); (2) preoperative diagnosis (3) postoperative diagnosis (4) procedure(s) performed, if any; (5) findings; (6) specimens.

Section 6: Discharge Summaries

A discharge summary shall be documented in the patient's medical record within thirty (30) days of the patient's discharge consistent with the Medical Record Delinquency Policy, attached as Exhibit 4. All discharge summaries shall include: 1) the reason for hospitalization; 2) significant findings; 3) complications; 4) procedure(s) performed and treatment(s) rendered; 5) condition of patient at discharge; 6) examinations and reports, including pathology; and 7) instructions given to the patient and/or his/her family members or responsible persons, to include instructions for follow-up, medications, diet, physical activity, and final diagnosis. For patients who expire, the summary should include the exact date/time of death and consent for autopsy. A discharge summary may be documented by Medical Staff members, House Staff, APNs in collaborative practice or Physician Assistants within supervision agreements as determined by the respective Department Chief. The Medical Staff member, House Staff or APN shall sign the summary, either electronically or by hand. A copy of the hospital discharge summary will be sent to the admitting and/or referring physician or practitioner.

A final progress note or discharge note may be substituted for the discharge summary in the case of patients with problems of a minor nature as defined by the Medical Staff and who require a hospital stay of less than 48 hours.

Section 7: Symbols and Abbreviations

Only those symbols and abbreviations recommended by the Health Information Management Subcommittee and approved by the Children's Medical Executive Committee shall be used. A copy of this list shall be placed on file in the Health Information Management Department.

Section 8: Access and Confidentiality of Records.

All records are the property of the Hospital and the original may only be removed by court order, subpoena, for microfilming or for offsite storage. Records may accompany patients who require medical care in other parts of the medical center. These records shall be available only as authorized by state law. Access to medical records by all others may be had only by authorization of the patient, the patient's parent or legal guardian, or the executor of the patient's estate. Such authorization must be renewed at the end of ninety (90) days, unless the authorization allows otherwise. All physicians, dentists and advanced practice nurses who

provided care to the patients may review the medical records on those patients. Physicians/dentists may have access to medical records for bona fide study and research consistent with preserving the confidentiality of the patient.

Section 9: Delinquency

All medical records shall be completed within 30 days after discharge. If the medical record is not completed 30 days after discharge, it shall be considered delinquent pursuant to the Medical Record Delinquency Policy. Report of the delinquent record is made to the responsible physician with a copy sent to the respective department chief and the Health Information Management Subcommittee. The department chief and/or appropriate division director is held responsible for the completion of the delinquent record. No medical record shall be filed until it is complete except on the order of the Health Information Management Subcommittee pursuant to the Medical Record Delinquency Policy. (See Exhibit 4) Physicians/dentists who fail to complete medical records within the allotted time are subject to disciplinary action in accordance with Hospital Bylaws.

Section 10: Medical Student Notes

Histories and physicals and orders entered by medical students must be reviewed and countersigned, and amended if necessary, by the student's supervising physician prior to being acted upon or implemented.

Section 11: Computerized Patient Record & Electronic Signature

The use of the computerized patient record and electronic signature and related policies shall be recommended by the Health Information Management Subcommittee and approved by the Children's Medical Executive Committee.

ARTICLE XII – ORDERS

Section 1: General Rules

All practitioner orders shall be in writing or by electronic entry and signed by the responsible Medical Staff member as soon as possible but no later than the calendar day after the order is given.

Active members of the medical staff may delegate writing or electronic entry of orders to a designee (House Staff or PA, APN in collaborative practice). However, practitioner orders shall be the ultimate responsibility of the physician. In addition, an APN / PA may write or enter orders consistent with his/her clinical privileges and Missouri law.

Admission orders must be signed by a member of the Medical Staff with active admitting privileges.

Orders must be entered clearly, legibly and completely. Orders which are illegible or improperly entered will not be completed until clarified.

A medical student in a clinical preceptorship position may write orders on the order sheets or enter orders in the electronic version of the Hospital medical records. A medical student must clearly write or enter his/her name and appropriate designation as a medical student so that the orders are clearly identifiable as the work of a student and are not confused with those of a physician. The nursing staff shall not implement any such order until the order has been finalized and amended, if necessary, by a licensed preceptor physician.

Section 2: Medications

Medications may be administered by, or under the supervision of, licensed personnel in accordance with Missouri State law. Medications will be dispensed to patients only upon a physician, advanced practice nurse in collaborative practice, physician assistant with a supervision agreement or dentist's order. Generic drug names are preferred in writing medication orders; all medication orders must comply with the standards outlined in the Provider Orders Policy (see Exhibit 5).

The Pharmaceutical, Diagnostics & Therapeutics Subcommittee shall be responsible for the formulary of medications used in the Hospital, and the addition, restriction or deletion of drug products from the formulary. Medication must be listed in the latest edition of Approved Drug Products with Therapeutic Equivalence Evaluation (U.S. Department of Health and Human Services, Food and Drug Administration), or Facts and Comparison to be considered by the Subcommittee, with the exception of drugs prescribed for bona fide clinical investigations. Exceptions to these rules must be approved by the Pharmaceutical, Diagnostic & Therapeutics Subcommittee.

The Pharmacy may dispense a generic or chemical equivalent for medications in accordance with state and federal laws, unless the proprietary name of the medication is used, followed by the words "No Substitute."

The Pharmaceutical, Diagnostics & Therapeutics Subcommittee shall adopt specific regulations for other aspects of medication procurement, storage, distribution, dispensing, administration, documentation and disposal. These regulations are subject to approval of the Children's Medical Executive Committee.

Section 3: Order templates

Templates for hospital orders shall require the approval of the Health Information Management Subcommittee prior to use. Such orders shall not supersede specific orders entered by physicians, advanced practice nurses, physician assistants or dentists. The pre-printed forms shall always be signed and dated by the physician, advanced practice nurse, physician assistant or dentist.

Section 4: Verbal and Telephone Orders

In an effort to minimize miscommunication of orders, St. Louis Children's Hospital strongly encourages the use of written or electronic orders from physicians and other practitioners authorized to record such orders when they are present in the hospital, or provide written or

electronic orders via remote means.

Verbal or oral telephonic communication of orders should be limited to urgent situations where immediate written or electronic communication is not feasible and sound medical practice dictates the institution of therapy prior to the time in which a written or electronic order can reasonably be provided by the physician or practitioner.

Verbal or telephone orders for medications shall be given only to registered nurses, respiratory therapists, (for respiratory-related medications only), transport team or emergency department paramedics (under the direction of the supervising physician or nurse), radiology technologist, or to pharmacists. Verbal and telephone medication orders must be recorded using the Provider Orders Policy stated in Exhibit 5 of these Medical Staff Rules and Regulations. Physicians and other practitioners shall communicate orders unrelated to medications only to licensed, registered or certified professional individuals within the scope of such individual's specialty.

In order to verify and validate the order, the person receiving the verbal or telephone order will record, then read back to the prescriber or individual transmitting the order. The person receiving the verbal or telephone order will document the order in the patient's medical record specifying whether it is a verbal or telephone order and record his/her name and title in accordance to hospital policy.

The prescriber or his/her designee (as permitted by these Rules & Regulations) will finalize all verbal and telephone orders within 48 hours of the order being given. The prescriber, or his/her designee, should review orders daily and should finalize as soon as possible, especially before patient transfer to another medical/surgical service.

Section 5: Do Not Resuscitate Orders

Do Not Resuscitate orders entered in accordance with the protocol developed by the Children's Medical Executive Committee and approved by the St. Louis Children's Hospital Board of Trustees may be implemented upon an entered order on the physician's order sheet. (Exhibit 6)

Section 6: Automatic Review Orders

An automatic review of antibiotics and Schedule II controlled substances orders is established by the Pharmaceutical, Diagnostics & Therapeutics Subcommittee and approved by the Children's Medical Executive Committee, except in cases where the physician, advanced practice nurse in collaborative practice, physician assistant (excluding order for controlled substances) or dentist states a specific number of days or doses in the order.

Pharmacists shall review patient medication orders and discuss with the physician, dentist, physician assistant or advanced practice nurse the need to continue the medication.

All medications not listed in the above categories shall also be reviewed by the pharmacist for appropriateness of continuing therapy.

All medication orders shall be automatically canceled when the patient goes to surgery.

Section 7: Medications Brought from Home

Patients may not use medications that are not dispensed from the St. Louis Children's Hospital Pharmacy with the exception of:

1. Investigational drugs which are kept by the patient or parent/guardian;
2. Total Parenteral Nutrition (TPN) solutions
3. Oral contraceptives
4. Medications that are integral to the patient's ongoing care, which are not included on the SLCH Medication Formulary, and are to be continued during hospitalization.

Other exceptions may be made to this list by the Pharmaceutical Diagnostics & Therapeutics Subcommittee.

When patients are allowed to take medications (one of the above exceptions) that they have brought into the Hospital, the physician/dentist must record an order for the non-formulary medication, including the notation, to "administer patient's own medication" with an indication of the medication, dose, route and frequency. Such medications shall be stored in the medication area of the nursing unit, under appropriate storage conditions. Administration of such medications shall be documented according to policy. The identification and potency of medications brought from home shall be the responsibility of the attending physician/dentist, house officer or clinical pharmacist.

Any medication that is brought by patients to the Hospital, but is not one of the above exceptions, shall be returned to the parents or person(s) responsible for care with instructions to take the medications home.

Section 8: Self-Administration of Medications

A physician, physician assistant, advanced practice nurse or dentist must enter an order for self-administration of medications in the patient's medical record.

Section 9: Special Treatment Procedures

Documentation is necessary in the patient's medical record for special treatment procedures. Psychiatric restraint or seclusion or behavioral modification procedures that use aversive condition require written orders and time limitations in the patient's medical record (see Restraint Policy attached as Exhibit 7).

Section 10: Advance Directives

Advance Directives may be utilized in accordance with the policy adopted by the Children's Medical Executive Committee, attached as Exhibit 8. A copy of the directive shall be placed in the patient's medical record.

ARTICLE XIII - SURGICAL CARE

Section 1: Surgery

A history and physical, pre-operative diagnosis and appropriate lab test results must be recorded in the patient's medical record prior to any surgery. Outpatients must be provided instructions for follow-up care. Except during emergency situations, surgery should only be performed after the patient or his/her person(s) responsible for care have given informed consent. The consent form signed by the patient or the person(s) responsible for care shall be included in the medical record.

Section 2: Presence of Attending Surgeon

The patient will not enter the operating room until the attending surgeon is present on the hospital grounds or not further than a five minute walk to the operating room. Any exception to this rule requires the approval of the attending anesthesiologist. The attending surgeon must be present during the critical portion of the case.

Section 3: Emergency Surgery

In emergencies, surgery can be performed before a full pre-operative work-up is completed, provided the surgeon documents that delay would cause a hazard to the patient.

Section 4: Surgical Specimens

Specimens removed during a surgical procedure are ordinarily sent to the pathologist for evaluation. The medical staff, through the Surgical Services Subcommittee and in consultation with the pathologist, decides the exceptions to sending specimens removed during a surgical procedure to the laboratory (See surgical specimen exemptions attached as Exhibit 9). Surgical specimens may be used for research purposes in accordance with the state and federal law, and only with appropriate consent.

ARTICLE XIV - ANESTHESIA

Section 1: Pre-Anesthesia Evaluations

All patients having general, regional or monitored anesthesia must have a Pre-anesthesia evaluation performed and recorded in the medical record within 48 hours of a planned surgical procedure. The pre-anesthesia evaluation is the responsibility of the anesthesiologist. The evaluation should include the history and physical examination; anesthetic, drug and allergy history; essential laboratory data; and any other diagnostic test results to establish the patient's potential risks of anesthesia. These procedures may be waived in the event of an emergency, provided the surgeon documents the emergency in the patient's record. All pre-anesthesia evaluations performed by a certified registered nurse anesthetist or other attending physician designee shall be reviewed and countersigned by an anesthesiologist prior to the administration of anesthesia. The anesthesiologist shall review the patient's condition immediately prior to the

induction of anesthesia, and any changes in patient condition or anesthetic plan will be noted in the medical record.

Section 2: Parameters of Care

Record keeping, monitoring and equipment safety verification will be carried out in accordance with the recommendations published by the American Society of Anesthesiologists, but at a minimum, during anesthesia, patient monitoring, dosage of all drugs and agents used, type and amount of all fluids administered, including blood and blood products, the technique or techniques used, unusual events during the anesthesia period, and the status of the patient at the conclusion of anesthesia must be documented.

Section 3: Discharge from Post-Anesthesia Care Unit and Post-Anesthesia Evaluations

A patient must be discharged from the Post Anesthesia Care Unit by a physician. A post-anesthesia evaluation for any patient remaining in the hospital for at least 24 hours and having any general, regional or monitored anesthesia shall be entered into the medical record within 24 hours after surgery reflecting evidence of the patient's present physical condition, tolerance to anesthesia, and any unusual events or post-anesthesia complications and the management of any such event or condition.

Section 4: Sedation

Sedation within the Hospital shall be carried out in accordance with the current guidelines described in the Procedural Sedation Guidelines.

ARTICLE XV - TRANSFERS

Section 1: Transfer of Attending Physician/Dentist Responsibility for In-House Transfers

Whenever attending physician/dentist responsibilities are transferred to another attending physician/dentist or clinical service, an order for the transfer of responsibility is documented.

Section 2: Transfers in Emergency Situations

Designation of the chief medical officer and specific transfer protocols are contained in the Hospital's Emergency Preparedness Manual.

Section 3: Transfers Out of the Facility

It shall be the responsibility of the transferring physician/dentist to make arrangements with the accepting physician/dentist and Administration of the accepting Hospital. Transfers shall be carried out in accordance with applicable state and federal guidelines (EMTALA). All pertinent medical information shall accompany the patient.

Section 4 – Transfers during Disaster

Whenever the Hospital disaster plan is declared to be in operation, all transfers and transports shall be made in accordance with the Hospital's Emergency Preparedness Plan and Procedures.

ARTICLE XVI - PREGNANT PATIENTS

Section 1: Treatment

Except in an emergency, patients known to be pregnant are not admitted for treatment of pregnancy. Patients known to be pregnant or discovered to be pregnant may be treated for illness or injury unrelated to pregnancy with consultation by an obstetrician as indicated or they may be transferred according to applicable transfer procedures.

ARTICLE XVII - HOUSE STAFF

Section 1: Definition

The House Staff shall consist of interns, residents, clinical fellows and research fellows. House Staff will not be considered members of the Medical Staff, and will only have those rights specifically set forth in this Section, and as explained in more detail in the Procedure for Review of Academic and Disciplinary Decisions Relating to Residents (Exhibit 10) and procedures adopted by the Washington University/Barnes Jewish Hospital/St. Louis Children's Hospital Graduate Medical Education Consortium.

Section 2: Criteria

House Staff must hold or secure, and maintain, either a permanent or temporary license to practice medicine from the Missouri State Board of Registration for the Healing Arts and meet the requirements of the Department within which they would like to practice.

Section 3: Prerogatives

House Staff may attend to patients under the supervision and direction of physician members of the Medical Staff. House staff may also perform specific services as authorized by these Rules and Regulations.

Section 4: Supervision

House Staff, including fellows, shall be supervised by members of the Medical Staff in carrying out their patient care responsibilities in accordance with the procedures set forth in the Medical Staff Bylaws, these Rules and Regulations, and Hospital policies, and if applicable, any process and procedure adopted by the GME consortium. Such supervision may be evidenced by, among other things, attestation of House Staff entries and/or a parallel note in the medical record for activities such as:

1. History and physical examination must be reviewed and attested by the responsible member

of the Medical Staff;

2. Operative notes dictated by House Staff must be reviewed and attested by the responsible surgeon member of the Medical Staff, and
3. Discharge summaries submitted by House Staff may be reviewed and attested by the responsible member of the Medical Staff.

ARTICLE XVIII - MISCELLANEOUS

Section 1: Practice Coverage

Each attending physician/dentist must assure timely, adequate, professional care for his/her patients in the Hospital by being available, or having available, an alternative physician/dentist with whom prior arrangements have been made and who has at least the equivalent clinical privileges at the Hospital. If a Medical Staff member fails to name an alternate, the appropriate Department Chair, Division Director or his/her designee shall have authority to call any member of the Active Staff to care for the absent physician's patients.

Section 2: Emergency Preparedness Plans

An Emergency Preparedness Manual shall be developed by the Emergency Preparedness Committee. This manual shall contain information and action plans to assist in dealing effectively with emergencies such as earthquakes, fire, severe weather, mass casualties etc.

Section 3: Revision of Rules and Regulations

The CMEC and the St. Louis Children's Hospital Board of Trustees may provisionally approve minor corrections and changes to these Rules and Regulations when such correction or change is necessary due to spelling, punctuation, grammar, and context or as required by laws, state or federal regulation or Joint Commission standards. No prior notice of such change to or vote of the Medical Staff is required. All changes approved by the CMEC shall be reported to each Department Chief for circulation to its members.

For any substantive changes to the Rules and Regulations, the CMEC may approve the changes, as long as the proposed changes have been communicated to the Medical Staff at least seven (7) days prior to the CMEC meeting either by email or some other similar method, where the changes are to be considered and the Medical Staff has had an opportunity to comment. The CMEC shall consider any comments when it votes on the proposed changes.

Section 4: Allied Health Professionals

Policies related to allied health professionals shall be reviewed and endorsed by the Children's Medical Executive Committee.

Section 5: Exhibits Attached to Rules and Regulations

Unless otherwise stated in the Medical Staff Bylaws, the Exhibits referenced in these Rules and Regulations are for information purposes only and may be revised, as necessary, to reflect current practices by the Hospital in conjunction with the Children's Medical Executive Committee.

Section 6: Smoking Policy

Smoking will not be permitted in any of the facilities of the Hospital.

Section 7: Safety Committee Authority

The Vice President of Facilities or appropriate designee is authorized to take immediate, unilateral action regarding hazardous conditions which could result in personal injury to individuals or damage to equipment or buildings.

Section 8: Infection Control Committee Authority

The Infection Control Committee and its Chair or appropriate designee is authorized to implement infection control measures in the case of an epidemic or potential exposure to communicable infectious diseases.

Adopted by the CMEC: 06/09/93

Adopted by the Medical Staff: 06/14/93

Ratified by the Board of Trustees: 06/28/93

Amended: 09/26/94, 11/25/97, 02/22/00, 09/26/00, 09/25/01, 12/19/01, 06/04/02, 09/09/02, 09/23/03, 06/08/04, 09/28/04, 11/23/04, 10/25/05, 10/24/06, 06/05/07, 09/16/08, 12/03/08, 12/02/09, 12/07/10, 9/29/15

APRN CREDENTIALING AND SCOPE OF PRACTICE

I. Policy

Advanced Practice Registered Nurses' Credentialing and Scope of Practice Policy

II. Purpose

To provide a consistent and systematic authorization process within St. Louis Children's Hospital ("SLCH") of Advanced Practice Registered Nurses who provide patient care services without appointment to the medical staff organization but who are granted privileges and scope of practice through the medical staff credentialing and privileging process.

III. Definitions

A. Advanced Practice Registered Nurses (APRN) are health care practitioners who are not eligible for SLCH Medical Staff membership and who are qualified to provide clinical services to patients, working collaboratively with a medical staff member. They may provide services only as permitted by this institution and as stipulated by the individual's professional license and the laws of the State of Missouri. Such APRNs must be qualified by academic and clinical or other training to practice in a clinical or supportive role in providing services. Medical Staff Services oversees the credentialing/ privileging process for all APRNs. There are two types of Advanced Practice Registered Nurses:

1. Affiliated APRNs – Those Advanced Practice Registered Nurses who are permitted to provide patient care services and are not employed by SLCH.
2. SLCH employed APRNs – All SLCH Employed APRNs have a job description and file in the human resources department. A hospital manager or director, along with the HR department oversees the initial hiring process for SLCH employed APRNs.

IV. Categories of Authorization

A. APRNs in the following job categories must be credentialed whether the person is an Affiliated APRN or an SLCH employed APRN:

1. Nurse Practitioner
2. Certified Registered Nurse Anesthetist

- B. Employees of SLCH who are not listed in section IV, paragraph A, are authorized to provide services as detailed in their job description in accordance with Human Resources policies and procedures and are not governed by this policy.
- C. Requests to add new APRN categories or to modify an existing job category must be submitted in writing to Medical Staff Services. Any relevant documentation needed to review and recommend category additions or deletions will be requested. All requests must be approved by the APRN Review Committee, the Credentials Committee, the CMEC, and the Board of Trustees.
- D. Application and Consent – application for specified privileges must be submitted by the APRN in writing on the hospital-approved form. The application must furnish complete information. The APRN must sign the application and in so doing:
 - 1. Attests to the correctness and completeness of all information furnished and acknowledges that any material misstatement in or omission from the application constitutes grounds for denial of privileges or for automatic revocation of previously authorized privileges; and
 - 2. Agrees to abide by all applicable SLCH policies and the Medical Staff Bylaws.

V. Requirements

- A. Pathways for Credentialing
 - 1. To be eligible to provide services, an Affiliated APRN must:
 - a) Be contracted to provide services within SLCH; or
 - b) Have written approval from the clinical service chief or department chair and the appropriate administrative department to provide services under the supervision of an SLCH medical staff member as an Affiliated APRN; and
 - c) Have completed the credentialing process.
- B. To be eligible to provide services, an SLCH employed APRN must be currently employed by SLCH and have completed the credentialing process.
- C. All categories of APRN must comply with hospital HIPAA requirements, attend orientation, and complete any training modules required for SLCH clinical systems.
- D. All categories of APRN will be reevaluated through Medical Staff Services, every two years in a parallel process to Medical Staff reappointment.
- E. Affiliate APRN staff will also be evaluated annually by their collaborating physician. A copy of such evaluation and a copy of the most recently completed skill checklist will be sent to the Medical Staff office for inclusion in the APRNs credentialing file.
- F. All employed APRN staff will be evaluated annually by their collaborating physician and hospital manager/director in accordance with Human Resources policies. A copy of such evaluation and a copy of the most recently completed skill checklist will be sent to the Medical Staff office for inclusion in the APRNs credentialing file.

VI. Scope of Services/Privileges

- A. The APRN Review Committee oversees the development, review and approval of authorization criteria, privileges and other relevant specifications of the following types of providers:
 - 1. Advanced Practice Nurse
 - 2. Certified Registered Nurse Anesthetists
- B. All APRN staff covered under the scope of this policy must work under the appropriate supervision of an SLCH medical staff member with clinical privileges that include at a minimum, all privileges within the scope of practice of the APRN.
 - 1. The designated collaborating physician or his/her designee provides general supervision of the activities and services of the advanced practice nurses.
 - 2. The designated collaborating physician or his/her designee shall provide supervision and direction for the care of specific patients.
- C. Each individual APRN must have a scope of practice approved by the designated collaborating physician and the appropriate Medical Staff Department Chair or clinical service chief.
 - 1. The scope of practice must specify the qualifications, scope of responsibilities, locations (unit) where services are to be provided, level of supervision necessary, and responsible party(ies) and may not exceed the general boundaries as established by this policy or the Missouri State Rules and Regulations applicable to APRNs.
- D. Affiliated APRNs must provide evidence of professional liability insurance in the amount of \$1,000,000 per occurrence/\$3,000,000 annual aggregate, with an insurer acceptable to SLCH. If such insurance is provided on a claims made basis, the APRN must provide evidence of an extended reporting endorsement in the event of cancellation or termination. Hospital employed APRNs are covered by SLCH's professional liability program.

VII. Procedure**A. General Qualifications**

In general, to be permitted to perform services at SLCH, an applicant must:

- 1. Be a graduate of a recognized and accredited school or have completed a requisite course of study and training in his/her discipline with a focus or emphasis on pediatrics;
- 2. Be legally qualified, licensed, certified/registered to practice in the given discipline by the State of Missouri;
- 3. Have demonstrated clinical competence in his/her discipline;
- 4. Meet the specific qualifications and requirements established by SLCH;
- 5. Be a Pediatric Nurse Practitioner, Family Nurse Practitioner or a Neonatal Nurse Practitioner;
- 6. Meet the professional liability coverage conditions established by SLCH;
- 7. Be recommended as competent by his/her sponsor or employer; and
- 8. Agree to abide by the Medical Staff Bylaws, Rules and Regulations and related policies, procedures, and codes of conduct established for employees and Medical Staff members.

B. Application

1. Each applicant must complete the application form supplied by SLCH Medical Staff Services. Each application form shall be completed and delivered to the SLCH Medical Staff Services Office and the BJC Credentials Verification Office (BJC CVO)
2. The BJC CVO will verify information contained within the application (when applicable) and will collect such additional information as deemed necessary to permit an adequate and complete evaluation of the individual's request for permission to provide services.
3. Once all required information and verifications are obtained, the application and accompanying documents shall be submitted to the following for review and processing.
 - a. The Medical Staff Services Office will review the completed and verified application. Any issues or concerns will be flagged for follow-up as needed.
 - b. Following the APRN Review Committee review and recommendation, the candidate's application will be forwarded to the Credentials Committee and Medical Executive Committee for action.
 - c. All applications will be sent to the Board of Trustees for final approval.
 - d. If the APRN candidate meets the qualifications described in the temporary privilege section of Medical Staff Bylaws they may be granted temporary privileges, as necessary.

NOTE: The credentials verification and privileging process, the recommendation and approval process; and the process for reappraisal is parallel to the existing processes applying to medical staff members.

C. APRN Review Committee

1. The APRN Review Committee will be chaired by a nursing director who will also serve as a member of the Credentials Subcommittee.
2. Additional members may be appointed from among APRNs employed by or affiliated with SLCH. The chairs of the Credentials Subcommittee, and the Chief Nursing Officer will also be voting members of the committee.

D. Ongoing Assessment of Current Competence

1. Competence Assessment: APRNs will undergo continuing assessment of competence and ability to perform their responsibilities/scopes of service as outlined in Medical Staff Bylaws.
2. The competency of the APRNs will be assessed by the collaborating physician or his/her designee and will be documented on an on-going basis and at least annually as part of the review process.
3. Components of the competence assessment include but are not limited to the outcome of ongoing hospital wide monitoring activities, peer review activities, the ongoing evaluation by the APRN's collaborating physician as required by Missouri law.
4. Ongoing hospital wide monitoring activities will include but will not be limited to quality and utilization review data, incidents or near misses, and sentinel events.

5. “Peer review” is defined as the evaluation of the APRN’s professional performance related to the care of a patient, including identification of opportunities to improve care, by individuals with the appropriate subject matter expertise to perform this evaluation. A “peer” is defined as an individual practicing in the same profession or a profession with at least an equivalent level of expertise in the clinical care under review.
6. All peer review information will be considered confidential and will be performed no less than three times every six months.
7. All APRNs will undergo a biennial reappraisal through the APRN Review Committee, the Credentials Committee, the Children’s Medical Executive Committee, and the Board of Trustees.

E. Affiliated APRN

1. APRNs either employed by or under contract with Washington University may be given permission to provide services, as stipulated by the individual APRN’s license consistent with this policy. APRNs employed by other Medical Staff members must submit a statement from their employer concurring with the request for permission to provide services.
 - a. The statement must confirm the physician contracts with/employs the professional and the physician will, at all times, be responsible for the practice of the APRN, or if unavailable, will designate another member of the Medical Staff who will assume such responsibility.
 - b. If the appointment or privileges of the physician employer/contractor are suspended or terminated, the APRN’s appointment to the allied health professional category along with all activities within the Hospital will also be automatically suspended or terminated until another physician employer/contractor has been identified and approved by SLCH.
2. SLCH may also contract with an individual physician, and/or an independent corporation to provide additional professional services consistent with this policy. These services may expand existing services or may be new services. These categories of individuals will be handled in the same manner as noted above.

F. Professional Ethics, Standards of Conduct

1. Each APRN must know and follow applicable SLCH policies, including policies that relate to service excellence, standards of care and professional conduct. Some of these key policies include but are not limited to the BJC Code of Conduct, Policy Against Harassment, Drug Free Workplace Policy and the Workplace Violence Policy.
2. The professional conduct of each APRN shall be governed both by the professional ethics established by the profession, by law and in accordance with the mission and philosophy of SLCH.

G. Professional Relationships

1. Each APRN shall be bound by the same principles of confidentiality as apply to SLCH employees and medical staff members.
2. The authority of the APRN to direct Hospital personnel is specifically outlined in the scope of practice.

H. Suspension, Modification or Termination of Permission to Provide Services

1. Each APRN may be subject to the suspension, modification, or termination of permission to provide services. Those APRNs who are employed by SLCH will also be subject to discipline and corrective action in accordance with human resources policies and procedures.
2. If there is an issue or concern related to the APRN's conduct or ability to provide clinical services these issues will be reviewed by the APRN Review Committee. If the APRN is employed by SLCH then the hospital manager/director and human resources will also be involved and consulted.
3. The APRN Review Committee will review all issues concerning scope of practice and clinical competence. The committee will allow the APRN and his/her physician sponsor or Department Chair, if applicable, to participate in this review process. The committee may also review any relevant medical records, documents or reports and may consult with any individual who the committee determines to have relevant information or expertise.
4. If the APRN Review Committee determines that it is necessary to suspend, modify or terminate the services of the APRN then it shall make a written report and forward this report to the Credentials Committee to make a final recommendation. The Credentials Committee shall make its final recommendation based on the report and any additional information that the Credentials Committee determines is necessary. This information will be forwarded to the CMEC and the Board of Trustees.
5. If a decision is made to suspend or terminate the services of an APRN this shall be communicated in writing to the APRN.
 - a. An APRN will be entitled to a limited appeal review process for adverse determinations either recommended by the Credentials Committee, CMEC, or by the Hospital affecting an APRN's appointment, reappointment, suspension, termination, or scope of practice and involving his/her clinical practice (collectively, "Adverse Determination").
 - b. In order to obtain such a review, the affected APRN within 30 days must submit a written request to the CMEC setting forth a detailed account of the circumstances and the reason(s) for requesting such a reconsideration review.
 - c. The CMEC shall review such request at its next regularly scheduled meeting. The affected APRN may request to attend that portion of the CMEC meeting to present his/her position concerning the reconsideration review request.
 - d. The CMEC shall determine the appropriateness of the Adverse Determination, and if desired, may request additional information from the APRN, Credentials Committee or others.

- e. The CMEC will deliberate outside the presence of the affected APRN and make its recommendation concerning the appropriateness of the Adverse Action.
- f. The CMEC shall then forward its recommendation to the Board of Trustees for its review, consideration and final determination. After final Board determination, the Hospital shall inform the affected APRN of the determination.
- g. If the APRN is an employee of SLCH, the APRN will also be afforded the grievance process as outlined in the Human Resources policies and procedures. If the APRN is not an employee then there is no further review or appeal process.
- h. The APRN Review Committee may also review issues or complaints regarding the conduct of a APRN and may make a recommendation to the Credentials Committee for its review; however, SLCH Administration maintains the right to make the final decision regarding the suspension or termination of services of any APRN who engages in unprofessional or unlawful conduct.

RECOMMENDED/APPROVED BY:

Advanced Practice Registered Nurses Council
Patient Care Services, Credentials Committee,
Children's Medical Staff Executive Committee,
Board of Trustees

INFORMED CONSENT

The purpose of this policy is to define when consent is necessary and the steps to obtain and document informed consent.

Related Policies: Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery
Communication with Non-English Speaking or Hearing/Speech Impaired Patients and Families

I. Informed Consent Process

A. The Discussion:

Informed consent is the process by which a Licensed Independent Practitioner¹ provides adequate information to a patient, parent, or primary caregiver to allow him/her to make an informed decision about a proposed treatment or procedure. The information discussed with the patient, parent or primary caregiver must include:

1. A description of the proposed care and treatment (including any anesthesia to be used); the reasons why the patient needs the care and treatment; and, what happens if the patient declines the care and treatment; and
2. Material risks and benefits to the patient, including likelihood of each; and
3. Any reasonable alternatives to the care and treatment, including material risks and benefits of the alternatives; and
4. The individuals who will be providing treatment, performing the surgical intervention and/or administering the anesthesia (i.e. residents, fellows, students, and others) and, for surgical procedures, whether physicians other than the operating practitioner, including but not limited to residents, will be performing important tasks² related to the surgery, and in those cases, the consent discussion is encouraged to include the following:
 - i. Residents may participate in the surgery based on the level of competency and under the supervision of the operating practitioner/teaching surgeon; and
 - ii. Those residents performing surgical tasks will always be under the supervision of the operating practitioner/teaching surgeon; and

¹ The licensed healthcare professional performing the treatment or procedure without direct supervision, within the scope of the individual's license and consistent with individually granted privileges— ie, physician, dentist, LIP or APN.

² Important surgical tasks include: opening and closing, dissecting tissue, removing tissue, harvesting grafts, transplanting tissue, administering anesthesia, and implanting devices.

- iii. The operating practitioner/teaching surgeon will be present during all key portions of the surgery.

5. An opportunity to ask questions and receive additional information if requested.

A licensed independent practitioner or Allied Health Professional working within the scope of his/her practice must ensure the patient is appropriately informed and consents to the specific procedure or treatment.

B. When to Have the Discussion:

Generally: Before each new medical and/or surgical treatment or procedure. Informed consent is required for: anesthesia administration; every surgical procedure; autopsy; organ/tissue donation; blood and blood products; sedation and procedures performed under sedation or anesthesia; and treatment governed by research protocol.

Patients who are in certain therapeutic programs involving a course of the same treatments may consent to an entire course of routine therapy prior to the first treatment, and a single consent form may be signed for the entire course of treatment (not to exceed one year) if:

1. The patient, parent or caregiver consents to the entire course of treatment at once, and;
2. No material change occurs in the risks and/or benefits of treatment alternatives; the mode of treatment; the patient's medical condition; or the patient's capacity to consent; and
3. The patient, parent or caregiver does not revoke consent; and consent is re-obtained and re-documented at least annually.

Examples of therapeutic programs covered by this provision include, but are not limited to, the following: chemotherapy, repetitive blood or blood product transfusion; retroperitoneal dialysis and hemodialysis; and plasmapheresis procedures.

C. Who Should Obtain Informed Consent?

1. **Who should have the discussion with the Patient/Parent/Caregiver?**

Physician or licensed independent practitioner performing procedure or treatment or, in the case of organ donation, the designated requestor/representative of an organ procurement organization (i.e., Mid-America Transplant Services).

2. **Who should obtain the Patient's/Parent's/Caregiver's Signature on the Procedure Form?**

A healthcare provider (often nurse) who can verify with patient/parent/caregiver what procedure or treatment is occurring and whether the patient/parent/caregiver has any questions or concerns.

3. If the physician or licensed independent practitioner has already had the consent discussion with the patient prior to the patient's admission (for example, in a clinic or

the office), a healthcare provider must verify with the patient/parent/caregiver the consent discussion occurred and obtain the patient/parent/caregiver's signature on the Procedure Form (see paragraph I.C.2 above).

D. Who May Consent (see also Attachment A – Minor Consent Chart):

1. Emergency³ Treatment for Minors (patients 17 years or younger)

- a) When a medical emergency exists, treatment may be provided and must be limited to the emergency medical condition, even if the patient's representative is unable to provide consent.

In such cases, the treating physician, whenever practical, may obtain clinical consultation with at least one other licensed physician to confirm the need for such intervention.

- b) Consent for emergency treatment is implied so long as:

- i. No representative previously withheld consent; or
- ii. A representative previously withheld consent, but the minor's condition has changed in a material and morbid way and no representative is available, authorized, and willing to consent for treatment.

- c) The nature of the emergency and the need for treatment must be clearly documented in the medical record.

2. Non-Emergent Treatment for Minors

A parent/representative or caregiver must consent for medical treatment of minors except as described below.

If the parent/representative or caregiver is unable to or refuses to consent for treatment, and none of the situations described in Sections 2, 3, or 4 below exist, call Risk Management for assistance.

- a) Minors with Capacity to Consent to Medical Treatment. Certain minors may consent to medical or surgical care on their own behalf without parental consent. These include patients who are:

- i. Married; or
- ii. Have a child (if a minor, then, may consent for herself/himself and the child); or
- iii. Self-sufficient (i.e. lives on own).

- b) Minors May Consent to His/Her Own Medical Treatment for following:

³ Emergency is defined as: when, in competent medical judgment, the proposed surgical or medical treatment is immediately or imminently necessary and any delay occasioned by an attempt to obtain consent would reasonably jeopardize the life, health or limb or result in disfigurement or impairment of faculties.

- i. Drug or Substance Abuse
- ii. Communicable Diseases
- iii. Pregnancy and Pregnancy Prevention Care (except abortions)

There may be situations involving very young minors or mentally impaired minors that may lack capacity to understand the proposed treatment and the risks and benefits of the proposed health care plan. Call Risk Management to assist in those situations.

3. Adult (18 years or older or minors who are deemed to have capacity to consent – see Section 2 above) Patients With Capacity To Make Health Care Decisions
 - a) If a patient has the capacity to understand the nature of the proposed treatment or procedure, the risks and benefits of that procedure and the ramifications of not going through with the procedure, the patient is deemed to have the capacity to consent to or refuse the treatment.
 - b) Generally, a physician or LIP shall assume that an adult patient presenting for treatment has the capacity to make health care decisions, unless there is evidence to the contrary. The capacity to consent is required at the time the consent is given.
4. Adult (18 years or older or minors who are deemed to have capacity to consent – see Section 2 above) Patients **Who DO NOT Have** Capacity To Make Health Care Decisions

When non-emergent medical or surgical treatment is required for incompetent adults or adults who lack capacity to give informed consent, informed consent should be obtained from the following person(s) (in this order):

- a) Legal Representative
 - i. Guardian. A court may appoint a guardian of the patient's "person" to consent to care on behalf of the patient. The guardianship papers must expressly grant the authority to consent for medical care and treatment. For admission to a mental health facility for mental health treatment, the guardianship papers must say the guardian has the power to make mental health treatment decisions;
 - ii. If no court appointed guardian exists, ask if the patient has a Durable Power of Attorney for Health Care (DPAHC). Individuals may execute a DPAHC authorizing another person to act as an "attorney-in-fact" to make health care decisions on their behalf.
- b) Family Members: If a patient has no guardian or DPAHC, consent for treatment may be obtained from the patient's closest available relative in the following order of priority and limited to: spouse, adult children, parents, adult brothers/sisters, and adult grandchildren. If there are questions about the situation (i.e., capacity, motive or patient's wishes), contact Risk Management.

II. Issues with Informed Consent

A. What is the Duration of an Informed Consent?

Informed consent should be obtained and documented no longer than 60 days prior to a procedure, surgery, or treatment. In addition, as noted above in Section I.B, informed consent can also be valid for the duration of a continuous course of treatment.

B. What if the Patient/Parent/Caregiver Refuses To Consent To Medical Treatment?

An adult patient with capacity, or a parent/care giver of a minor child, or the minor child if he/she is deemed to have capacity to consent generally has the right to refuse medical treatment.⁴ If the patient/parent/caregiver refuses specific treatments and/or therapies, notify the patient's physician or licensed independent practitioner so that risks of refusing the treatment and/or therapies can be reviewed with the patient/parent/caregiver. Document in the medical record the refusal and the explained consequences of such refusal. Include in the documentation the name of the physician or licensed independent provider notified and date and time of when notified.

C. What if the Patient/Parent/Caregiver Refuses to Consent to the Administration of Blood and/or Blood Products?

If a patient 18 years or older or a minor who is qualified to consent on his/her own behalf refuses to consent to administration of blood or blood products, then no such products will be given.

If a parent or caregiver refuses to consent for the administration of blood or blood products, such refusal should be handled as follows:

- a) If an emergency situation currently exists and the treating physician(s) deem blood or blood products necessary to avoid death or permanent disability, blood/blood products shall be administered.
- b) If the emergency situation is only potential (*e.g. the patient needs immediate surgery and more likely than not the patient will need blood during surgery*) and the parent or caregiver does not consent to the administration of blood, the parent or caregiver should be informed of the right to seek legal recourse. Should the emergency situation arise, blood/blood products shall be administered unless there is a court order prohibiting the administration of blood/blood products.
- c) The treating physician(s) should document in the medical record the emergent situation, the conversations with the parent or caregiver and decision to proceed with blood/blood product administration given the risks of death and/or permanent disability.

If there is a definite and clear need for future or recurring blood/blood products and the parent or caregiver refuses

⁴ Sometimes there may be issues when multiple parents and/or caregivers are not in agreement about consent. In those circumstances, contact Risk Management for assistance.

- The treating physician or his/her representative shall contact SLCH Risk Management who will coordinate with Social Services and BJC Legal to obtain a court hearing and attempt to obtain a court order allowing the administration
- Social Services shall ensure the family is informed of the proceedings and the ability to access the Juvenile Court.
- Any documentation from the Juvenile Court should be placed in the medical record.

III. Documentation of Informed Consent

- A. Consent should be obtained using forms approved by SLCH and/or BJC Legal Services.
- B. The physician or licensed independent practitioner must document the consent in the medical record. If consent is not obtained, e.g. in an emergency, the reason for such failure should also be documented in the medical record.
- C. A copy of any papers authorizing a legal representative to consent to treatment on behalf of the patient (e.g., DPAHC, Letters of guardianship) should be filed in the patient's medical record.
- D. The Consent for Surgery or Diagnostic Procedure form is available for use at the hospital. A copy of which is attached as Appendix A. If the patient will undergo a Surgery or Other Procedure that requires use of this document, it is the expectation of the hospital that all blanks be filled in prior to the Surgery or Procedure being performed. If there is not a separate note available verifying the consent discussion between the physician or LIP and the patient, it is the responsibility of the physician, LIP or AHP to specify the operation or procedure on the Procedure Consent form. It is the responsibility of hospital staff to ensure that the Consent Form is completed and in the patient chart prior to the treatment being performed. The form may be completed in advance (at a clinic or office visit prior to the surgery) and forwarded to the hospital by the LIP or AHP.
- E. A process must be in place in every area in the hospital that uses this form to ensure that the form is properly executed and is in the patient's medical record prior to the surgery (except in the case of an emergency Surgery or Procedure. The pre-procedure verification for all areas is set forth in the hospital policy entitled, "Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery).

IV. Communication Barriers

When language barriers, hearing or speech impairments impede informed consent, communication must be facilitated with appropriate support for interpretation. Whenever possible, trained spoken language and sign language interpreters will be available through the Center for Diversity & Cultural Competence by calling 747-5682. The medical record should indicate who acted as interpreter and the language used.

A physician or licensed independent practitioner obtaining consent from a patient who may have difficulty with communication because of a physical handicap must arrange for consent discussions to take place using a communication medium in which the patient is fluent. In the rare event that trained interpretation is not available due to the rarity of the language or

the physical inability of the patient/family to use telephone interpretation, documentation should show that all alternatives were considered and rejected as less effective in that situation than the use of self-described, bilingual family members or staff.

RECOMMENDED/APPROVED BY: Risk Management

ST. LOUIS CHILDREN'S HOSPITAL
DETERMINATION OF DEATH BY NEUROLOGICAL CRITERIA
(BRAIN DEATH)

Introduction

Guidelines for determining death by neurological criteria (also referred to as “brain death”) have developed over time in Missouri in a form consistent with national policy. Based on the refinement and testing of the document commonly referred to as the Harvard criteria (JAMA 205:337-340, 1968), in 1981 both national policy and state law regarding the determination of death were established (JAMA 246: 2184, 1981; Mo Med 86:628-631, 1989). These directives indicate that, as with irreversible failure of circulation and respiration, irreversible failure of brain and brainstem function is death. The Missouri state law RSMo §194.005 is consistent with national recommendations and states:

For all legal purposes, the occurrence of death shall be determined in accordance with usual and customary standards of medical practice, provided that death shall not be determined to have occurred unless the following minimal criteria are met:

1. When respiration and circulation are not artificially maintained, there is an irreversible cessation of spontaneous respiration and circulation; or
2. When respiration and circulation are artificially maintained and there is total and irreversible cessation of all brain function, including the brainstem, and such determination is made by a licensed physician.

The procedures for establishing death by neurological criteria in children were clarified in 1987 when several professional groups joined together to publish a statement (Guidelines for Determination of Brain Death in Children. Ann Neurol 22:616-617, 1987). An update of the 1987 task force recommendations was published in 2011 (Guidelines for the determination of brain death in infants and children: an update of the 1987 Task Force recommendations. Crit Care Med. 2011 Sep;39(9):2139-55.) The definition of death is universal and applies to persons of all ages.

Guidelines

Examination by a Medical Staff Member who is a neurological specialist (medical neurology or neurosurgery) must be obtained to determine whether death by neurological criteria is present. A second Medical Staff Member, usually the patient's neonatology or critical care attending physician, must also perform the exam. The exams by both physicians must be documented in the patient's medical record using St. Louis Children's Hospital death by neurological criteria examination form. The exams by the two physicians do not need to be done in a particular order. The neurological specialist may perform the first or second exam.

Age and recommended observation periods

Neonates (37 wks gestation to term infants 30 days of age): Two examinations separated by 24 hours.

Infants and children (>30 days to 18 years): Two examinations separated by 12 hours.

It is possible that unusual circumstances may require an alternate period of observation. In some circumstances, a shorter interval (4-6 hrs) may be preferred. In this situation, the reason for an alternate period of observation should be clearly documented and affirmed by at least one of the physicians performing the determination of death by neurological criteria.

Elements of Diagnosis

1. Whenever possible, the patient must be known to have a disease which can cause death by neurological criteria. Cause must be structural disease or other known irreversible cause. Recoverable disorders, such as drug poisoning, toxin, metabolic disorder, severe electrolyte disturbances, hypothermia (temperature 35°C or lower), or shock should be excluded. In certain situations, such as can occur with cases of cardiac arrest or severe traumatic brain injury, assessment of neurological function may be unreliable immediately. In such situations, if there are concerns about, or inconsistencies in, the examination, evaluation should be deferred for 24-48 hours or longer.
2. Sedative and anti-convulsant medication levels should be low or mid-therapeutic range. Neuromuscular blocking drugs (NMBDs) should be discontinued and recovery of neuromuscular transmission monitored with a conventional peripheral nerve stimulator. When recovery to a 4/4 TOF count occurs, without qualitative presence of fade, response to a sustained 5-second tetanic stimulation at 100-Hz should be observed at hourly intervals until absence of fade is confirmed to ensure low risk for significant residual muscle weakness (see Appendix 1 for more details). Reversal of neuromuscular blockade after a 4/4 TOF count is achieved may be administered to hasten spontaneous recovery of neuromuscular transmission, if not contraindicated. If there is uncertainty regarding such potential confounds, an ancillary test should be performed. Alternatively, the evaluation can be deferred.
3. There must be complete loss of brain function:
 - a. There must be no brain-mediated motor responses. The patient must have no spontaneous movement or vocalization, and the patient must not move or vocalize to noxious stimuli. Noxious stimuli should consist of pressure upon the patient's supraorbital ridges, sternum, and nail beds of each extremity. There must be no decorticate or decerebrate posturing.

- b. There may be rudimentary spinal reflex responses such as deep tendon reflexes, plantar reflexes, triple flexion of the legs, superficial abdominal reflexes, erection of penis or nipple. Reflexive movements such as hip flexion with elevation of one or both upper extremities have also been described. These reflexes do not contradict the diagnosis of death by neurological criteria.
- c. The pupils may be either widely dilated or midway between constriction and dilation. Stimulation with a bright light must fail to produce any pupillary constriction.
- d. The eyes must be motionless. Oculocephalic (“doll’s eye”) and oculovestibular (ice water caloric) responses must be absent.
- e. The gag, cough, sucking, and rooting reflexes must be absent.
- f. Spontaneous ventilatory efforts (including agonal breaths) must be absent. An apnea test (Appendix 2) should be performed, if there is no contraindication.

Ancillary Tests

Ancillary studies can support the diagnosis of death by neurological criteria, but have their own inherent limitations.

Ancillary tests can be used to assist the clinician in making the diagnosis of death by neurological criteria in the following situations:

- 1) To reduce the observation period or interval between examinations;
- 2) When components of the examination or apnea testing cannot be completed safely as a result of the underlying medical condition of the patient; if an apnea test cannot be performed, and ancillary test is required;
- 3) If there is uncertainty about the results of the neurologic examination;
- 4) If a medication effect may interfere with evaluation of the patient an ancillary test should be performed.

Specific ancillary tests must be interpreted by an attending physician and include:

- 1) Nuclear medicine perfusion scan. This test may be preferred when medications that may suppress the EEG are present (i.e. pentobarbital).
- 2) Cerebrovascular imaging. Examples of this imaging include computed tomographic angiography and percutaneous catheter cerebral angiography.
- 3) EEG. If performed, EEG must be carried out according to an electrocerebral silence protocol (protocol available in the SLCH EEG lab).

Documentation of Death by Neurological Criteria

- A. Each of the two examining physicians specified in the guidelines section (page 1) must be present during their respective examinations and should certify in writing in the patient’s chart that death by neurological criteria is present using the St.

Louis Children's Hospital documentation form (for available in AdHoc and Appendix 3).

- B. To facilitate consensus and acceptance of the concept of death based on neurological criteria, support from Spiritual Care and Social Work may be sought. Death by neurological criteria will be pronounced/declared by the physician who has performed the second exam while the respirator is still ventilating the patient. The pronouncement/declaration and time of death will be entered into the progress note section of the patient's chart using the St. Louis Children's Hospital death by neurological criteria examination form. The patient's family is not asked to participate in or to make the decision that the patient is dead. The family is informed when the diagnosis is confirmed and the declaration/pronouncement is made. A reasonable amount of time should be allowed for the family to visit prior to removal of the ventilator.

COMMUNICATION WITH FAMILY AND OTHERS

Although not part of the process of establishing death by neurological criteria, we include the following to help staff with the next step. The following information should be conveyed to the family by the examining physician or that physician's designee:

1. That even though there is cardiac activity, the brain is dead and that respiration is being artificially maintained. There is no possibility of recovery.
2. That because of anticipated problems with cardiac and vascular function, it would be impossible to maintain cardiac activity in this manner indefinitely, and it is undesirable to do so.
3. That although there is no hope for recovery, the situation is such that other organs and tissues can be salvaged and used for humanitarian purposes. The permission of the family is requested for evaluation of the patient by the organ and tissue procurement agency.
4. If, in the judgment of the patient's physician, the family should not be approached for permission to salvage organs or tissue, the physician should so indicate in the patient's medical record
5. The office of the St. Louis City Medical Examiner must be informed of all deaths of minors and as otherwise required by law for non-minors. It is often helpful to contact the office at the time of the first examination since possible conflicts between the needs for forensic information and the family's desire to donate organs or tissue are more successfully resolved if there is time to consider the specific case details.

Record of Review of Policy:

2/90 Drafted by James P. Keating, M.D., Chairman, Critical Care
Subcommittee. Approved by Children's Advisory Committee. Adapted

	from WUMC guidelines (revision dated 3/17/89) and Task Force on Determination of Brain Death in Children (Ann Neurol 22:616, 1987).
3/90	Modified by T. S. Park, M.D., J. J. Volpe, M.D, and J. P. Keating, M.D.
7/90	Presented to Critical Care Subcommittee for comment and discussion.
5/91	Presented to Critical Care Subcommittee for additional comment and discussion.
2/92	Modified by J. P. Keating, M.D. (member, Critical Care Subcommittee) and presented to Critical Care Subcommittee.
3/2/92	Discussed at meeting of PICU attendings (Drs. J. Kemp, J. Grant, B. Markovitz, M. Connor, A. Strauss, C. Canter, M. Watcha, J. Keating, C. Weldon).
3/3/92	Presented with modifications to Critical Care Subcommittee.
3/10/92	Draft incorporating suggestions from 3/3/92 meeting and additional written suggestions (Drs. E. Dodson, M. Noetzel, K Yamada, P. Dodge, et al).
4/7/92	Final review by Critical Care Subcommittee members; minor changes approved.
5/11/92	Approved by Children's Medical Executive Committee.
3/03/05	Presented to Clinical Care Subcommittee for review; minor changes approved.
10/10/09	Modified by the Brain Death Guidelines Working Group (Nikoleta Kolovos, Michael Noetzel, T.S. Park, Jeff Leonard, Allan Doctor, Aaron Hamvas, Amit Mathur, Heidi Fields and Jose A. Pineda). Presented by Jose A. Pineda and approved by the CMEC.
6/10/13	Modified by the Brain Death Guidelines Working Group (Nikoleta Kolovos, Michael Noetzel, T.S. Park, Jeff Leonard, Allan Doctor, Aaron Hamvas, Amit Mathur, Heidi Fields and Jose A. Pineda). Presented to the CMEC subcommittee for the UBJPT and the CMEC.

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APPENDIX 1: PERIPHERAL NERVE STIMULATOR PROCEDURE (TRAIN OF FOUR MONITOR)

a) Neuromuscular blockade drugs (NMBDs) should be discontinued as soon as possible in patients with suspected death by neurological criteria.

b) Drug-induced impairment of neuromuscular blockade and recovery of function are assessed with a peripheral nerve stimulator. Pulsed or continuous 5-second tetanus electrical stimulation is delivered to the ulnar nerve at the wrist and the evoked muscle twitch response at the hand's adductor pollicis muscle (AP) is monitored. Conventional peripheral nerve stimulators (often called nerve stimulator, twitch monitor, TOF monitor etc.) may be used for a rough "qualitative" assessment of neuromuscular blockade, but are not ideal to assess for sufficient recovery of residual blockade to permit spontaneous ventilation and tracheal extubation. The most accurate monitors to assess residual neuromuscular blockade are "quantitative" measures of the evoked response to electrical nerve stimulation including EMG, Mechanomyography (MMG), Kinetomyography (KMG) and Acceleromyography (AMG).

b.1) Conventional Peripheral Nerve Stimulator for Train-of-four stimulation (TOF Count) to evaluate therapeutic neuromuscular blockade: Electrical stimulation consists of 4 square wave supramaximal nerve stimuli of 0.2 msec duration at 50 Hz applied to a peripheral motor nerve. The TOF count correlates with degree of neuromuscular blockade. For frame of reference, qualitative presence of only the first and/or second twitch (1-2/4 TOF count) is considered to be satisfactory neuromuscular blockade with sufficient abdominal wall muscle relaxation to facilitate open abdominal surgery. However, a qualitative 4/4 TOF count does not indicate full recovery because significant neuromuscular blockade may still exist due to presence of residual NMBDs.

b.2) Train-of-four ratio to evaluate for residual neuromuscular blockade and readiness for tracheal extubation: This refers to the ratio of the peak-to-peak amplitude of the fourth muscle twitch response in comparison to the first twitch response. The degree of fade of muscle contraction in response to repetitive stimulation is proportional to the intensity of neuromuscular block. In the setting of a 4/4 TOF count, "qualitative" tactile or visual assessments of fade are not accurate measures for residual muscle weakness because most individuals cannot reliably detect fade if the quantitative TOF ratio is between 0.4 and 0.9. Residual neuromuscular blockade was originally defined as a TOF ratio < 0.7. Because of documented risk for impaired pharyngeal function, reduced inspiratory airway flows, partial upper airway obstruction and aspiration with ratios between 0.7-0.9, a TOF ratio ≥ 0.9 is considered adequate for extubation (the risk for

adverse respiratory events secondary to residual muscle weakness following tracheal extubation is considered to be minimal). Note that many clinical tests of neuromuscular function are satisfactory at TOF ratio of 0.7 (ie 5 sec head lift, sustained 5 sec leg lift, sustained 5 sec hand grip strength, eye opening etc.)

(CONTINUED)

b.3) 100-Hz Tetanic stimulation for 5 seconds: In the absence of inhaled general anesthesia, the qualitative detection of fade with 5 seconds of sustained tetanic electrical stimulation at 100-Hz does correlate with a quantitative TOF ratio of up to TOF ratios of 0.8-0.88. THIS IS THE RECOMMENDED PROCEDURE TO EVALUATE RESIDUAL NMB IN PATIENTS WITH SUSPECTED DEATH BY NEUROLOGICAL CRITERIA AT ST. LOUIS CHILDREN'S HOSPITAL:

When recovery to a 4/4 TOF count occurs, without qualitative presence of fade, response to a sustained 5-second tetanic stimulation at 100-Hz should be observed at hourly intervals until absence of fade is confirmed to ensure low risk for significant residual muscle weakness. Reversal of neuromuscular blockade after a 4/4 TOF count is achieved may be administered to hasten spontaneous recovery of neuromuscular transmission, if not contraindicated.

APPENDIX 2: RECOMMENDED PROCEDURE FOR OXYGENATED APNEA TESTING (OAT)

The OAT is a test of the respiratory response to significant hypercapnea; it is not intended to test the response to hypoxemia. During the OAT (for patients with initial $p\text{CO}_2 < 40$ mmHg) arterial $p\text{CO}_2$ must increase from baseline to > 60 mmHg; or (for patients with an initial $p\text{CO}_2 > 40$ mmHg), $p\text{CO}_2$ must increase at least 20 mmHg higher than baseline). The OAT must be performed with each examination. If the OAT cannot be completed, an ancillary test is required.

OAT in patients without lung or cyanotic heart disease.

Prior to interrupting the ventilator, the patient should be ventilated with 100% oxygen for at least 5 minutes. Blood gas analysis should be performed and the following criteria should be met before the apnea test can be initiated: $\text{pH} > 7.30$, $p\text{CO}_2 > 35$ mmHg, $p\text{O}_2 > 100$ mmHg. If any of these criteria are not met, it may not be possible to perform apnea test without hypoxia developing.

If the above criteria have been met, the patient may be disconnected from the ventilator and connected to a non-self inflating resuscitation bag (also known as anesthesia bag). Self-inflating bags are not to be used for this purpose. The bag should be set up to administer 100% oxygen and continuous positive airway pressure (CPAP) that matches the patient's current positive end-expiratory pressure (PEEP) as set on the ventilator. The patient will then be observed continuously for 10-15 minutes. Observation of respiratory effort may be facilitated by use of continuous capnometry. If no spontaneous ventilatory effort is observed, the test is interpreted as consistent with absence of brain stem function. If circulatory instability occurs at any time, the patient should be reconnected to the ventilator. Pulse oximetry must be performed throughout the test. Arterial blood gas determination at the termination of the test is necessary to determine adequate hypercapneic stimulation (see above).

OAT in patients with lung disease, but without chronic CO_2 retention.

The patient should be placed on 100% oxygen for 20 minutes prior to apnea testing and the arterial $p\text{CO}_2$ should > 35 mmHg. The apnea test may be performed as above but the duration of apnea must be tailored to the starting arterial $p\text{O}_2$. If the $p\text{O}_2$ is above 100 mmHg, apnea testing can usually be continued for at least 2 - 3 minutes (preferably 5 minutes) safely (without the development of hypoxemia).

Criteria for discontinuation of the apnea test:

Oxygen saturation decrease to $< 85\%$; hypotension; any arrhythmia associated with hemodynamic instability; presence of respiratory effort. The presence of respiratory effort will be determined by the attending physician performing the apnea test.

PITFALLS IN USE OF OAT

1. Failure to preoxygenate will lead to hypoxia.
2. Leaving the patient attached to the ventilator during the test may result in small “blips” on the monitor screen (caused by lung compression from cardiac activity or auto-triggering of the ventilator). This may confuse staff or family. The patient should be separated from the ventilator. Oxygen and CPAP are to be provided through a non-self inflating resuscitation bag, and direct visual observation of chest movement or capnometry used by the examining attending physician as the end point.
3. Hemodynamic instability, most commonly caused by severe hypoxic myocardial dysfunction or hypovolemia, in combination with hypercapnea (which is a sine qua non of the OAT) may compromise systemic perfusion. The OAT should not be attempted if, in the judgment of the examining physician, the patient will not remain stable throughout the test.
4. Hypercapnia (>60 mmHg) may not always be present after ten minutes of apnea since the rate of CO₂ production varies. The fifteen minute test may be elected if the patient is stable and oximetry confirms acceptable (SaO₂> 85%) oxygenation at ten minutes. The use of ABG’s to document pCO₂ at ten and fifteen minutes, is required.
5. Interruption of the ventilator for shorter periods (e.g., three minutes) was historically (1978) used to test for apnea in comatose patients. pCO₂ is seldom documented before or at the termination of such testing and, consequently, a positive test (apnea) cannot be interpreted as evidence of brain stem dysfunction. There is also, if the initial pCO₂ is high, the possibility that even brief interruption may cause sufficient additional hypercarbia to result in myocardial dysfunction and acute hypotension. The OAT, conducted as described in the text above, permits the physician to test brain stem function without causing further harm to the patient.

**APPENDIX 3: ST. LOUIS CHILDREN'S HOSPITAL DEATH BY
NEUROLOGICAL CRITERIA MEDICAL RECORD DOCUMENTATION
FORM**

ST. LOUIS CHILDREN'S HOSPITAL
MEDICAL RECORD DELINQUENCY POLICY

OVERVIEW & RESPONSIBILITY

A complete medical record is important for patient safety and future care and treatment of the patient. Elements and timeframes required for a complete medical record are defined in the St. Louis children's Hospital Medical Staff By-laws, Rules & Regulations.

Accordingly, State of Missouri hospital licensing regulations require that all medical records be completed within 30 days of discharge. In addition, The Joint Commission standards require that the hospital monitor the completion of records within the required 30 day time frame. Records remaining incomplete after 30 days are tracked as delinquent records. Delinquent records represent a substantial burden upon the hospital to obtain the appropriate signatures and/or documentation in order to complete the record. For these reasons, the Health Information Management (HIM) Subcommittee will follow and enforce the following policy in order to ensure the timely completion of records.

RESPONSIBLE PHYSICIANS

The Health Information Services (HIS) department monitors completion of medical records and contacts the health care practitioner responsible for completing any portion of the medical record including signatures and medical documentation. The healthcare practitioner completing the discharge instructions/order is responsible for including in the discharge instruction/order the person responsible for dictating the discharge summary and attending of record. If this information is not present, Health Information Services guidelines deem the discharging practitioner and attending of record on the day of discharge as the responsible practitioners for the completion of the discharge summary.

INCOMPLETE MEDICAL RECORD PRACTITIONER NOTIFICATION

Every week, a reminder notice from the Chairman of the HIM Subcommittee listing incomplete medical records will be sent via fax, email or other method to the responsible practitioner(s) (e.g. – House Staff, fellows, nurse practitioners) and Attending of record (Faculty or Community).

In addition, the HIS department will contact designated representatives from each of the services to coordinate medical record availability and facilitate communication between the attending of record and other responsible practitioners to ensure that records are completed prior to becoming delinquent.

Also, prior to the end of each academic year, the HIS department will work with identified representatives to ensure that departing physicians will have completed all medical records prior to departure date. Completion of any incomplete medical records for which the attending of record has departed will become the responsibility of the division/department of the departing physician unless deemed by the HIM Subcommittee to be retired as incomplete.

DELINQUENT MEDICAL RECORD PRACTITIONER NOTIFICATION

Once a record is identified as delinquent, HIS initiates a process through which the responsible practitioner(s) will complete the record. The process will include the following:

- One week prior to each regularly scheduled delinquency meeting (described below) for each delinquent/incomplete medical record, the Hospital President will send (via fax, email or other

method) a Notice of Delinquency letter to each of the responsible practitioner(s) including the Attending of record requiring either immediate resolution to the incomplete status or attendance at the delinquency meeting.

- A Copy of the Delinquency Letter will also be forwarded to the practitioner's department chief, division director, residency program director or fellowship program director, as applicable, stating the practitioner has delinquent medical records.

DELINQUENCY REVIEW COMMITTEE COMMUNICATION

The Notice of Delinquency letter will include the date and time for the practitioner to attend a meeting to discuss the status of the delinquent records. Such meeting will be scheduled to occur at least 7 days from the date of the letter.

The Delinquency Review Committee meeting will include:

- All responsible practitioners required for completion of the record;
- An invitation to the department chief, division director, residency director, and/or fellowship program director, as applicable, for the involved practitioner(s)/service(s);
- The Delinquency Review Committee consisting of the Chairman of the HIM Subcommittee or designate, the President of the Medical Staff or designate, the Vice President of the Health Information Services department or designate;
- The Director of Health Information Services
- Discussion of circumstances that led to the delinquent record status and an expected completion date. After considering this information, the Delinquency Review Committee will set a final deadline for completion and assign any other actions as deemed necessary.

PRACTITIONER NON-COMPLIANCE

Unless the responsible practitioner notifies the Director, Health Information Services in advance of the meeting date that he/she will be unable to attend the meeting, failure to attend the scheduled Delinquency Review Committee meeting will result in the final deadline for completion of the record to be set at five (5) business days from the meeting date with suspension of practitioner's privileges on the sixth business day should the records remain incomplete/delinquent. In such instances, the Delinquency Review Committee will consider a written explanation and proposed completion date if submitted to the HIS Director in advance of the meeting. If the practitioner completes the record(s) prior to the Delinquency Review Committee meeting (as verified by HIS), the meeting may be cancelled. Documentation of the Delinquency Review Committee meeting results and record statuses will be maintained by HIS and forwarded to the responsible practitioners and their department chief, division director, residency program director or fellowship program director, as applicable.

A responsible practitioner who does not meet the deadline set by the Delinquency Review Committee will be relieved of patient care responsibilities (House Staff or other providers) or have suspension of any elective admitting, consultative or elective surgery privileges (Attending) until the involved record is verified as completed by the Health Information Services department.

St. Louis Children's Hospital
Patient Care

ALL1004.1214

Title: Provider Orders

Purpose

To provide a consistent and accurate method for receiving and activating provider orders.

Policy Statements

- A. Orders may be accepted by the following licensed clinical professionals when the specific order falls within the scope of care provided by that discipline, as documented in the discipline's professional practice act:
- Advanced Practice Nurse (APN)
 - Registered Nurse (RN)
 - Registered or Certified Respiratory Therapist (RT)
 - Speech Therapist
 - Occupational Therapist
 - Physical Therapist
 - Audiologist
 - Psychologist
 - Dietitian
 - Pharmacist
 - Perfusionist
 - Paramedics (Transport Team or Emergency Department)
 - Radiology Technician
- B. Verbal and Telephone Orders
1. Verbal orders should be limited to emergency or special situations where electronic or written communication is not feasible and initiation of therapy should not be delayed prior to the time in which an order can reasonably be entered/written by the physician or practitioner.
 2. Verbal and telephone orders may be accepted by:
 - APN
 - RN
 - RT
 - Pharmacist
 - Perfusionist
 - Paramedics (Transport Team or Emergency Department)
 3. Verbal orders will not be accepted from medical students.
 4. Verbal/telephone orders are accepted at the discretion of the clinical staff member and must be co-signed by the responsible provider.
- C. Protocols
- Protocols will be approved by the appropriate sub-committee of the Children's Medical Executive Committee (CMEC) as reflected in the minutes. The process will be coordinated by the Department of Professional Practice and Systems.
1. Protocols that include a medication must be approved by the Pharmacy & Therapeutics sub-committee.
 2. All protocols are available via standardized order sets in the electronic order entry system.

3. Protocols require a provider order to be implemented except in the case where a delay in medical treatment may result in harm (e.g. emergency unit). The RN, RT or Rad Tech will apply clinical judgment to determine the appropriateness of use of the protocol, and depending on clinical indications may determine alternative approaches or different orders are needed from the physician.

Procedure

A. Verbal Orders

The clinician receiving the order must have access to or be logged into the patient's electronic medical record in the Order Entry tab at the time of or prior to taking the verbal or telephone order. The prescriber must remain in continuous contact with that clinician until the electronic order entry is completed, and the receiving clinician reads back the order in its entirety ("read back") with all numbers called out individually.

B. Order Activation

Orders will be activated within the computerized provider order entry (CPOE) system. When CPOE is not available (i.e. paper orders) the clinician will cosign the order set with a signature and date and time to acknowledge and activate the order(s).

C. Protocol Initiation

When ready to implement a protocol, the clinician will:

1. verify presence of an active order to initiate the protocol
2. enter the appropriate elements of the order set for the stated protocol on behalf of the provider with a source of "Protocol"
3. complete the order and document appropriately.

Original Author: Susan Goddard, 12/75 (Physician/APN Orders)

Joint Policy With: Pharmacy

Revised by: Heidi Fields, MSN, RN, CPNP-PC, 12/14

Effective Date: December 2014

Administrative Policy
St. Louis Children's Hospital

DO NOT RESUSCITATE (DNR)

POLICY

Resuscitative measures deemed appropriate by hospital staff who are present at the time of cardiorespiratory collapse will be carried out unless there is a DNR order in the chart.

INSTRUCTIONS

1. An order defining resuscitative efforts to be carried out, and those which will not be done, should be written by an active member of the medical staff who is, or who is acting for, the patient's attending physician.
2. An order defining resuscitative efforts (DNR) may be written in exceptional circumstances by a resident physician only if the resident physician has spoken with the patient's attending physician at the time the order is written, and documents that discussion in the progress notes.
3. In these instances, the attending physician must sign that order within twelve hours, or if the patient dies prior to signing it, the attending physician must come to the hospital to sign the order immediately upon notification of the death.

THE FORM OF THE DNR ORDER

The order should indicate specifically what measures will and will not be employed.

For example: "In the event of cessation of sufficient cardiopulmonary function to maintain life, no chest compressions, no electric shock, no artificial ventilation and no cardiac drugs will be carried out or administered."

CONCURRENT CARE CONCERNS

When appropriate, the physician should also include directions concerning:

1. Adjustment of sedatives/analgesics.
2. Suctioning.
3. Intubation.
4. Antibiotics, antiviral and immunosuppressant agents.
5. Frequency of vital signs and laboratory tests.
6. Blood products.
7. Dialysis.
8. Hydration.
9. Nutrition.
10. Hospice environment in hospital or outside hospital.

DOCUMENTATION OF FAMILY DISCUSSION

1. At the time a DNR order is written, a note must be placed in the progress note section of the medical record which documents the discussion(s) with the patient, parent, or guardian of the medical and other considerations underlying the condition and prognosis.
2. The note should further state that the patient, parent or guardian understands that if resuscitative measures are not undertaken, there is a high likelihood that the patient will die.
3. It is recommended that the note be signed by the physician who is writing the DNR order and cosigned by a nurse, social worker, or a second physician who was present for the discussion. The attending physician may choose to have the patient, parent, or a guardian also cosign this note.
4. All patients with imminent or impending death must be considered for organ and/or tissue donation. Refer to Anatomical Gifts policy.

DURATION

1. The duration of the order will be indefinite unless a specific duration is written or it is countermanded by a later order.
2. If the patient is discharged and readmitted, the order must be rewritten at the time the patient re-enters the hospital if the special resuscitation status is to be maintained.

ADVANCE DIRECTIVES

Advance directives, if provided by the patient, 18 years of age or older, will be reviewed by the attending physician, and, after clarification and/or confirmation by discussion with the patient or his/her proxy (person authorized by the patient to have power of attorney for health care decision making in the event the patient is not able to speak on their own behalf), the attending physician will enter an order in the patient's medical record which defines the resuscitative efforts to be carried out or not attempted and covers the appropriate concurrent care concerns.

CONFLICT WITH ADVANCE DIRECTIVE

1. If the attending physician finds him/herself unable or unwilling to write such an order, he/she must proceed with appropriate steps to resolve the problem immediately. These steps should include notification of the chief of the service of which that attending physician is a member and the administrative supervisor.
2. Arrangements to transfer care of the patient to a consenting attending physician should also be completed as soon as possible.

EMERGENCY UNIT

1. The staff of the Emergency Unit will respond to cardiopulmonary collapse with resuscitative efforts unless the parent/guardian/patient presents a document signed by the parent/guardian/patient and a member of the St. Louis Children's Hospital active medical staff, defining the resuscitative measures which they have agreed will be, and those which will not be, employed.
2. The orders contained in this document should be confirmed by either the patient's physician and/or family member at the time of arrival in the Emergency Unit, or prior to that time, if possible.
3. If there is no such document, an active medical staff member of the hospital may enter a DNR order in the patient's chart as described previously. If the physician cannot be present in the Emergency Unit at the time of the patient's arrival, he/she may ask the Emergency Unit attending physician to enter the order.
4. If the Emergency Unit attending physician does so, the order must be cosigned by the child's physician as soon as he/she or his/her designee can reach the Emergency Unit.

PROCEDURES UNDER ANESTHESIA

1. When a patient with a DNR order is scheduled for anesthesia and/or surgery, the anesthesiologist and surgeon shall discuss with the primary physician, patient's guardian and patient (if appropriate), the issues involved in order to best balance the desires and rights of the patient with the potential physiologic instability resulting from the planned procedure, surgery and/or anesthetic.
2. A medical progress note should document such discussion and any decisions reached. The patient/patient's family should understand that in addition to hemodynamic and respiratory instability as a result of the surgical procedure, any anesthesia or sedation carries the potential for significant untoward physiologic responses to pharmacologic interventions.
3. In most situations reversal is quickly and easily accomplished, but may involve airway manipulation (endotracheal intubation), pharmacological intervention, and brief periods of closed chest compressions.
4. These interventions should not be construed as "resuscitation" if performed for reversal of an unplanned and undesirable response to anesthetic agents or to surgical manipulations. Should reestablishment of adequate vital functions not be readily attainable, the physician caretakers, in consultation with the patient's guardians, will determine the extent of any further support efforts.
5. Patients undergoing emergent anesthesia and/or surgery, when sufficient time for such discussion has not taken place, will have the DNR order suspended prior to induction of their anesthetic.

6. Should a life-threatening event occur during the anesthetic/procedure, the extent of any resuscitative effort will be decided by the physician caretakers in consultation with responsible guardians if possible.
7. The suspended DNR order may be reinstated on the patient's discharge from the Post Anesthesia Care Unit, (PACU) or admittance to the Intensive Care Unit if PACU is not used.

REVERSAL OF DNR ORDER

A request by parent, guardian, or patient to revoke all or part of a DNR order will be honored.

PATIENTS IN MISSOURI CHILDREN'S DIVISION OR ILLINOIS DEPARTMENT OF CHILDREN AND FAMILY SERVICES CUSTODY

Request for DNR Status

The hospital social worker must be notified immediately if the healthcare team wishes to present medical information to support a request for DNR status for a patient in Missouri Children's Division (formerly Division of Family Services) or Illinois Department of Children and Family Services custody. The hospital social worker will contact the Family Courts to facilitate communication regarding a DNR status. The final decision regarding DNR status will be made by the court system and will be communicated to the healthcare team in the form of a legal document that shall be kept in the Medical Record.

Existing DNR Status

Legal documentation of DNR status as determined by the court system shall be kept in the Medical Record. DNR orders will remain in effect unless a new court order signed by a judge is obtained.

RECOMMENDED/APPROVED BY: Patient Care Services

**St. Louis Children's Hospital
Patient Care Services**

NUR1067.0414

Title: Restraints

Purpose

St. Louis Children's Hospital is committed to providing a physical, social, and cultural environment which promotes the initiation of the least invasive and least restrictive measures to support the comfort, security, and safety of the individual and others. The use of restraints and seclusion is limited to clinically appropriate and adequately justified situations after all appropriate alternatives have been utilized.

Policy Statements

In determination of whether a device or practice is a restraint, consider the **INTENT** and effects on the individual patient. Location and type of device is **NOT** a determining factor.

Intent of restraints is to manage harmful behavior – – the decision to use a restraint is driven not by diagnosis, but by comprehensive individual assessment that concludes that for this patient at this time, the alternative use of less intrusive measures poses a greater risk than the risk of using a restraint.

I PROTECTION OF RIGHTS:

Individuals placed in restraint/seclusion must have a protected, private, observable environment that safeguards their personal dignity and well being.

Every patient is provided with the Patient's Rights and Responsibilities brochure which details the rights of a restrained patient.

II SPECIFIC CONSIDERATIONS

A. Definitions

Physical restraint is any manual method, physical or mechanical device (polyurethane/leather limb holders, soft limb holders, elbow immobilizers), material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely.

1. Clinical Restraint

Clinical restraints used to protect patients who may otherwise dislodge endotracheal tubes, tracheostomy tubes, arterial lines, central lines and/or other medical devices and immobilizers that limit patient access to surgical and treatment sites.

2. Behavioral Restraint

Behavioral restraint, is used when the intent is to restrict movement of a patient at risk of injuring self or others due to violent behavior.

3. Chemical Restraint - SLCH does not use Chemical Restraint

Chemical Restraint is the use of any drug used as a restriction to manage a patient's behavior, restrict freedom of movement, and is not a standard treatment or dosage for the patient's condition.

Medications given to hostile, aggressive or violent/self-destructive patients are prescribed with the intent to help the patient work within his treatment regimen- not to restrict behavior or freedom of movement. The intent of the medication administration is NOT to immobilize the patient, although sedation may occur; the intent is to calm the patient to the point where he/she can function within

his/her environment.

4. **Seclusion –utilized only in the EU**
Seclusion is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, staff, or others.
5. **Therapeutic Hold**
Therapeutic Hold is physically holding a patient in a manner that restricts the patient's movement and is against the patient's will. Therapeutic hold can only be applied by only by staff that has completed Safe Training and Responsible Restraints (S.T.A.R.R.)

B. Safety

Safety devices are applied for the primary reason of supporting medical healing in situations where there is an appropriate clinical justification. **Exclusions:**

1. Based on the developmental age of pediatric patients, certain types of protective equipment are age-appropriate and are utilized for patient safety and not with intent to restrain the patient, and therefore are excluded. Examples include, but are not limited to, bed rails, tabletop chairs, high top cribs, highchairs, helmets, or mittens.
2. Safety devices that limit mobility related to medical, dental, diagnostic or surgical procedures and the related post operative care processes such as extremity supports for maintenance of infusions (tape, armboards).
3. Items that provide adaptive support in response to an assessed patient need such as:
 - a. Helmets
 - b. Skeletal traction devices or orthopedic applications
 - c. Supports to assist the patient in sitting or standing and/or to avoid falling.
 - d. Protective Devices (i.e. Bedrolls)
 - e. Developmental Supports/Tools
4. Forensic and correctional restrictions used for security purposes such as handcuffs and metal shackles. Appropriate clinical assessment of a patient who is restrained forensically should include circulation and neurovascular status of involved extremities and the patient's psychosocial status.

C. Patient Assessment

1. The health care team is responsible for assessing the patient's physical/psychosocial needs including signs of physical distress on an on-going basis and the need for continuing use of the specific device and terminating the device when "need" is not evident.
2. Staff understand that their own behavior can also affect the behaviors of aggressive patients and will consider utilizing de-escalation, mediation, self-protection, and other techniques as appropriate. **Notation: The least restrictive method of immobilization should always be used first, regardless of the immobilization mechanism.**
3. Rationale behind the utilization of a designated method and a description of other therapeutic interventions utilized should be included in documentation of the patient's care.
4. The patient's assessment includes consideration of underlying medical conditions that may be contributing to the patient's aggressive, threatening behaviors. These behaviors may result from such conditions as DKA, metabolic imbalances,

and delirium in fevers, which require specific treatment while maintaining patient safety during that treatment.

III PROCEDURE

A. Therapeutic Interventions to be considered prior to restraint application:

- Music therapy
- Bundling
- Parent at bedside
- Distractational therapy
- Medication (as appropriate to assess need, i.e. nausea, pain, muscle spasms)
- Child Life Consult
- Psychology Consult for Behavioral Management
- Sitter at bedside
- Other appropriate nursing interventions

B. **Restraint Process Resources**

1. The Administrative Supervisor on call will serve as a resource for the restraint process.
The Administrative Supervisor may be contacted at the time restraint is initiated as a resource to staff. The Administrative Supervisor will assist and guide in correct interpretation of Restraint policy and procedure which may include reviewing orders and plan of care with the primary care RN. Initiation of restraint is the responsibility of the health care team at the bedside and is not contingent upon response time of the Administrative Supervisor.
2. Refer to the attached Restraint Resource Guide.

C. **Initiation of Restraint**

1. Restraint orders may be written, verbal or telephone; however, a face to face physician evaluation must be done within one hour of initiation of restraint.
PRN restraint orders are prohibited.

Exception: Repetitive self-mutilating behavior

If a patient is diagnosed with a severe chronic medical or psychiatric condition and engages in repetitive, intractable self-mutilating behavior, a PRN order for restraint is acceptable with specific parameters established in the treatment plan.

- a. Psychiatry consult is recommended.
- b. Assessments will be done as for clinical restraints
- c. Documentation must include patient's inability to understand criteria for restraint removal

The orders must specify the following:

- a. The type of restraint to be used
- b. Least restrictive interventions attempted before restraining
- c. Criteria for the patient's early release
- d. Date and time

Face to face evaluation by physician includes:

- a. Assessment of physical / psychological status
- b. Assessment of continued need for restraint

2. In an emergency situation, a registered nurse may initiate restraint. The physician must complete the face to face evaluation and write restraint orders within one hour.

3. In an emergency situation, S.T.A.R.R. staff may initiate therapeutic hold upon appropriate assessment. The physician must complete the face to face evaluation and write therapeutic hold orders within one hour.
4. The physician or RN will explain the reason for the restraint to the patient and/or caregiver to prevent misinterpretation and to promote cooperation. A note must be documented in the medical record that this explanation has been offered. Effort will be made to contact the caregivers not present at time of restraint initiation.
The patient and/or the caregiver will be given the Restraint Teaching Tool to inform and educate them on restraint use. If caregiver is not present at the time of initiation, the Restraint Teaching Tool will be provided at the earliest opportunity
5. The physician or RN will inform the patient and caregiver of the criteria for release of the restraint.

D. **Restraint Renewal Orders**

1. Clinical Restraint
 - a. Clinical Restraint orders must be reviewed and re-written daily based on re-assessed need for continuation of clinical restraints.
 - b. **PRN restraint orders are prohibited**
2. Behavioral Restraint
Behavioral Restraint orders must be reviewed and re-written as follows:
 - a. Children **8 years old and younger: every hour** with face to face physician evaluation.
 - b. Adolescents **between 9 and 17: every two hours** with face to face physician evaluation.
 - c. Adults **18 and older: every four hours** with face to face physician evaluation
 - d. **PRN restraint orders are prohibited.**
3. Therapeutic Hold orders are a one time order.

E. **Discontinuation of Restraint**

Document the reason for discontinuation in patient's medical record.

1. Clinical Restraint:
Restraint may be discontinued when one of the following criteria is met:
 - a. Behavior no longer interfering with medical healing
 - b. Protection of patient airway, tubes/lines, and/or surgical sites no longer required
 - c. Oriented to environment/improved cognition
 - d. Other physician ordered criteria
2. Behavioral Restraint:
Restraint may be discontinued when one of the following criteria is met:
 - a. Patient is no longer dangerous to self
 - b. Patient is no longer dangerous to others
 - c. Any other criteria specified in physician orders.
3. **Exceptions**
 - a. A **temporary release** that occurs for the purpose of caring for a patient's needs - for example, toileting, feeding and range of motion, holding for comfort - is not considered a discontinuation of the restraint and does not require a new order

- b. When the patient is released from restraint per criteria but exhibits behavior that can only be handled by re-application of restraint, a **new** restraint order must be initiated *regardless of the time of the most recent restraint order*.

IV ASSESSMENT OF RESTRAINED PATIENTS

- A. Initial assessment/documentation includes:
 1. Restraint Type and Location
 2. Restraint Reason
 3. Caregiver/patient teaching
- B. Documentation
 1. Clinical Restraints
 - a. Document the following a minimum of every 2 hours:
 - Restraint type and location
 - Restraint reason
 - Need for continuation of restraint
 - Skin integrity and neurovascular status remains intact
 - Patient toileting, fluid and nutritional needs assessed and addressed, while awake
 - Mental/Behavior status
 - Restraint released/loosened, while awake
 - b. Document the following a minimum of every 4 hours
 - Range of Motion exercises will be performed while patient is awake
 2. Behavioral Restraints

All PCT and EMT entries shall be co-signed by RN at end of shift/restraint episode.

 - a. Document the following every 15 minutes:
 - Need for continuation of restraints
 - Mental/Behavior status
 - Skin integrity and neurovascular status remains intact
 - b. Document the following a minimum of every two hours:
 - Restraint type and location
 - Restraint reason
 - Patient toileting, fluid and nutritional needs assessed and addressed, while awake
 - Mental/Behavior status
 - Restraint released/loosened, while awake
 - c. Document the following a minimum of every 4 hours
 - Range of Motion exercises will be performed while patient is awake
 3. Therapeutic Hold
 - a. Document assessment of patient behavior upon which decision was made to implement therapeutic hold
 - b. Date/Time of implementation
 - c. Type and duration of hold
 - d. Names of staff witnessing hold
 - e. Patient response to hold
 - f. Physician notification
- C. Care and Cleaning of Restraint devices
 1. Polyurethane limb holders
 - a. For regular cleaning, wipe the polyurethane with a mild soap and warm water.

- b. When decontamination for bloodborne pathogens is required, contact Environmental Services at 454-2700 to obtain the appropriate solution for this purpose.
2. Leather limb holders that are soiled **cannot** be cleaned, sterilized and/or re-used for another patient. Soiled leather limb holders need to be disposed
3. Devices are **NOT** to be sent with patient upon discharge.

Exclusion:

- Elbow immobilizers used for clinical restraint may be sent home with caregivers due to continued patient safety need after discharge.
 - Soft limb holders may remain on patient during transfer by SLCH Transport Team to another facility
4. Replacement restraints and disposable liners will be ordered by contacting Materials Management

IV COMPETENCY AND QUALITY ASSURANCE

- A. Staff Orientation and Education
 1. Hospital staff are oriented in the use of restraint devices. Skills validation is required during the orientation of nursing and allied health staff as appropriate to document the competency to assess the need for restraints and to apply, manage, and remove restraints in a return demonstration.
 2. S.T.A.R.R. trained staff are taught the use of therapeutic holds. Skill validation is required in the training to document their competency in assessing patient needs for and correct application of therapeutic hold.
 3. On-going competency is validated at a minimum of every 3 years based on the clinical educator's education needs assessment for that unit and/or specific staff member. This validation will include return demonstration of device application.
- B. Quality Improvement
 1. Each episode of behavioral restraint use will be reviewed.
 2. A review of clinical restraint use will be done as appropriate.
 3. Managers will provide feedback to the staff on an individual basis.
 4. Audit results of Restraint use are aggregated by Risk and Compliance and the Regulatory Oversight Committee.
- C. Leadership
 1. Determines the organization's approach to the use of restraint and seclusion.
 2. The hospital must report by telephone, facsimile, or electronically the following information to CMS regional office by the close of the next business day:
 - a. Death that occurs while patient is restrained unless restraint device was soft limb holders, in which case, patient information will be entered into hospital Restraint Log.
 - b. Death occurring within 24 hours of restraint removal
 3. Each death that occurs within 1 week after restraint where it is reasonable to assume that the use of restraint contributed directly or indirectly to that death.
 4. Reports injuries and deaths associated with restraint/seclusion use to appropriate internal and external agencies consistent with law and regulation.
 5. The Restraint Reporting Tool will be completed and reported to CMS by Risk and Compliance. The Restraint Reporting Tool will have date/time of transmission to CMS and be placed into the patient's medical record.

MS Rules and Regulations
Exhibit 7

Revised by: Cheryl Kelley, BSN, RN, 9/13, 4/14

RESTRAINT RESOURCE GUIDE

Clinical Restraints: Used to protect patients who may otherwise dislodge endotracheal tubes, tracheostomy tubes, arterial lines, central lines and/or other medical devices and immobilizers that limit patient access to surgical treatment and sites

Behavioral Restraints: Used when the intent is to restrict movement of a patient at risk of injuring self or others

	Clinical	Behavioral
Consider other therapeutic interventions prior to restraint application	X	X
Contact Administrative Supervisor or Manager of the Day	as needed	X
Initiation of Restraint		
Initial orders may be written, verbal or telephone	X	X
RN may initiate in emergency	X	X
Face-to-face eval by MD within one hour of initiation	X	X
Restraint Orders completed within one hour	X	X
MD/RN to explain reason for restraint	X	X
Must be documented in patient's medical record	X	X
Education	X	X
Provide patient/caregiver with Restraint Teaching Tool	X	X
Educate regarding Restraint Policy	X	X
Inform regarding release criteria	X	X
Restraint Renewal Orders		
All patients: review and renew orders daily based on re-assessed need for continuation	X	
Children under age of 9: every one hour with face-to-face MD eval		X
Adolescents between 9-17: every two hours with face-to-face MD eval		X
Adults 18 and older: every 4 hours with face-to-face MD eval		X
Patient Assessment		
Restraints are applied correctly	Assess and document every two hours	Assess and document every 15 minutes
Skin integrity and neurovascular status of each restrained extremity		
Restraints accomplish the purpose for which they were applied		
Determination of need to continue restraints		
Nursing Intervention		
Nutrition/Hydration/Elimination needs assessed/addressed every 2 hrs while awake	X	X
ROM performed every 4 hours while awake	X	X
Documentation		
Electronic Medical Record - Restraint Flowsheet	X	
Frequency of Vital Signs		
Per MD order	X	X
Discontinuation of Restraints		
May be discontinued when release criteria are met	X	X

Administrative Policy
St. Louis Children's Hospital

ADVANCE DIRECTIVES

POLICY The hospital will respect and strengthen the role of the adult patient in health care decision-making. Staff will comply with current standards, regulations and laws which apply to advance directives. This policy applies to adult patients 18 years of age or older.

DEFINITIONS

1. An **ADVANCE DIRECTIVE** refers to a document(s) in which an individual state his or her desires for medical care and treatment should he or she be unable to physically or mentally communicate care decisions and/or designates another individual to express his or her desires for medical care and treatment.
 - A. **DURABLE POWER OF ATTORNEY FOR HEALTH CARE (DPOA)**
Is a document in which an individual names someone else (an “agent” or “attorney-in-fact”) to make health care decisions in the event the individual becomes unable, either physically or mentally, to make decisions for himself or herself. The DPOA may include instructions concerning specific choices/identified circumstances for making health care decisions for the agent.
A valid Durable Power of Attorney for Health Care must be:
 - 1) In writing;
 - 2) Titled “Durable Power of Attorney for Health Care”;
 - 3) Include a provision to the effect that “THIS IS A DURABLE POWER OF ATTORNEY FOR HEALTH CARE AND THE POWER OF MY ATTORNEY IN FACT, WHEN EFFECTIVE, SHALL NOT TERMINATE OR BE VOID OR VOIDABLE IF I BECOME DISABLED OR INCAPACITATED”;
 - 4) Signed at the end, dated, and
 - 5) Notarized.
 - B. **HEALTH CARE DIRECTIVE** is a document that permits a patient to state, in advance, his/her wishes regarding the use of life prolonging procedures. It may be relied upon when an individual is unable to communicate his/her health care decisions provided such expressions are clearly stated. It can be accepted if notarized or signed by two (2) witnesses, or both.
 - C. **LIVING WILL (or sometimes referred to as DECLARATION)** is a document executed in accordance with Missouri Law in which a person, called a Declarant, states his or her wishes regarding the withdrawal or the withholding of medical

treatment if they are diagnosed as terminally ill and is not able to make treatment decisions. Living Wills do not allow for withhold or withdrawal of artificially supplied hydration and nutrition, do not cover persistent vegetative state conditions and will have no effect if a Declarant is pregnant.

A valid Living Will must be:

- 1) In writing;
- 2) Signed by the person making the Living Will (“Declarant”), or by another person in the Declarant’s presence and by his/her express direction.
- 3) Dated; and
- 4) If not entirely in the Declarant’s handwriting, signed in the presence of two (2) or more witnesses at least eighteen (18) years of age.

(**Note:** An individual who signs a Living Will at the request of the Declarant cannot also act as a witness).

2. **ADULT** means a person who is 18 years of age or older.
3. **AGENT** refers to a person appointed to make decisions for another individual, such as an attorney in-fact under a durable power of attorney for health care.
4. **DECISION-MAKING CAPABILITY** means the ability to understand and appreciate the nature and consequences of a decision regarding medical treatment and the ability to reach and communicate an informed decision in the matter.

POLICY STATEMENTS

1. Employees and staff physicians must honor an individual’s Advance Directives unless the directives require a provider to break the law or a provider is unable to follow the directive as a matter of personal conscience.
2. Any employee who is unable to comply with an individual’s Advance Directive may withdraw from care of the individual upon the transfer of care of the individual to others. (Refer to policy “Refusals in Patient Care/Treatment”)
3. Any physician on the staff of the hospital who is unwilling or unable to comply with an individual’s Advance Directive shall make arrangements for the transfer of the patient’s care to another physician. Health care providers can not disregard a Declarant’s wishes (pursuant to a Living Will) without serious reasons in the best interest of the patient and must document in the medical record.
4. The adult patient’s wishes, as expressed in an Advance Directive will direct the patient’s care even if the family’s wishes are contrary. Any conflict with end of life care decisions should be immediately referred to the Hospital/Medical Ethics Subcommittee.

5. **Situations involving pregnancy:**
 - a) In the event a pregnant woman presents an Advance Directive, the Hospital Medical Ethics Subcommittee and BJC Legal Services will be contacted.
 - b) Declarations of Life Support under a Living Will have no effect during the course of a Declarant's pregnancy. In the event that there is an unresolvable conflict between a patient's or designee's instructions and the hospital's policy, the hospital staff will assist the patient/family in a transfer to a more compatible provider.
6. **Emergency situations:** It may be impossible for health providers to be certain whether or not a treatment will lead to a significant recovery. Treatment will continue until the provider makes a determination consistent with the Advance Directive and the patient is not able to make treatment decisions.
7. **Do Not Resuscitate Orders (DNR):** Adult patients always have the right to direct their own health care. If a patient requests a specific treatment limitation, it may be written as part of a DNR order. In some instances, the hospital may request additional consent forms should a patient request a continuation of his or her DNR orders in the operating room or other interventional area. (Refer to policy "Do Not Resuscitate" (DNR) Policy)
8. **Surgical Procedures:** When a patient with an Advance Directive is scheduled for anesthesia and/or surgery, the anesthesiologist and surgeon will discuss with the primary physician, patient's representative/guardian and patient (if appropriate), the issues involved in order to best balance the desires and rights of the patient with the potential physiologic instability resulting from the planned procedure, surgery and/or anesthetic. A medical progress note should document such discussion and any decisions reached. (Please refer to the Do Not Resuscitate Policy for additional information.)
 - a) Patients undergoing emergent anesthesia and/or surgery, when sufficient time for such discussion has not taken place, will have their Advance Directive suspended prior to induction of their anesthetic.
 - b) Should a life threatening event occur during the anesthetic/procedure, the extent of any resuscitation effort will be decided by the physician caretakers in consultation with the responsible guardians, if possible.
 - c) The suspended Advance Directive may be reinstated on the patient's discharge from the Post Anesthesia Care Unit, (PACU) or admittance to the Intensive Care Unit if the PACU is not used.

PROCEDURE

1. At the time of hospital admission and/or registration, hospital registration will ask patients if they have an advance directive, including whether they have appointed a Durable Power of Attorney for Health Care or if they need information concerning his or her rights under state and federal law to make care and treatment decisions, including the right to formulate an Advance Directive concerning life sustaining care. The registrar

- completes form CN3-7400-589 (Addendum A to the policy) and places it in the patient's medical record.
2. If the patient has an Advance Directive from a state other than Missouri or Illinois, Registration will contact BJC Legal Services to determine its validity in Missouri.
 3. If the Advance Directive requests services not provided at SLCH, the patient and/or family or agent (under a DPOA) will be advised as soon as possible by the attending physician.
 4. If an Adult patient is incapacitated or unable to receive Advance Directive information, such information may be given to family or a representative. Advance Directive information will be provided to the patient as soon the patient has capacity or ability to receive such information.
 5. No individual shall be discriminated against or have care conditioned on whether or not an individual has executed an Advance Directive.
 6. A copy of the Advance Directive shall remain a part of the individual's permanent record. Return the original Advance Directive to the patient/family.
 7. Advance Directives will be effective during the patient's admission unless revoked by the patient in accordance with applicable law. Upon subsequent admissions (if any), hospital registration will update the patient's information concerning Advance Directives consistent with this policy.
 - a) It is the responsibility of the patient or attorney-in-fact to provide a copy of any updated Advance Directive to the hospital.
 - b) If this is a readmission, hospital registration will contact Health Information Services (unless otherwise electronically available) to obtain a copy of the patient's Advance Directive and ask the patient if the Advance Directive remains current. If not current, hospital registration will contact the Chaplain for the Chaplain to discuss the Advance Directive with the patient and/or family.
 - c) All Advance Directives provided to the hospital must comply with applicable law to be valid. Contact BJC Legal Services or hospital Risk Management if there are any questions concerning the validity of an Advance Directive.
 8. If an individual presented an Advance Directive during a previous admission and is now incapacitated and unable to communicate care and treatment decisions, physicians and staff should speak with the Agent (attorney-in-fact) or family to determine whether the patient has rescinded or amended the Advance Directive or created a new Advance Directive. If there are concerns about the validity of the document, contact hospital Risk Management or BJC Legal Services.
 9. The patient has the right to review, change, or revoke an Advance Directive at any time.

10. If an adult patient does not have an Advance Directive, then the patient may communicate health directive information to his or her physician, registered nurse, or others with such communication having evidentiary weight or validity in determining the patient's wishes; provided the communication is given by the patient.
11. For assistance with any Advance Directive need and/or issue, contact the Chaplain on call.
12. A patient may revoke his/her Advance Directive at anytime by either oral or written communication. If revoked, contact the Attending Physician and the Chaplain on call.

PATIENT TEACHING

1. Patients who need information may receive written information on Advance Directives from the Patient Registration Department or Chaplain.
2. In-service regarding these policies shall be available to any employee and attendance required for Patient Registration; Department of Clinical Social Work and Chaplaincy; Administrative Supervisors; registered nurses; and physicians from active staff and house staff.
3. Education of our community shall be accomplished by providing written information, consultation from internal resources and providing external presentations on request.

REFERENCES:

Missouri Attorney General Inside Life Choices, March 2009
Missouri Revised Statutes Chapter 459. R.S.Mo and Section 404.800 et seq. RS MO
Medicare Conditions of Participation 42 CFR §482.13(b)(3).

RESOURCE/CONTACTS:

Chaplaincy, Hospital Registration Department

RECOMMENDED/APPRAOVED BY: Patient Care Services

**SLCH RULES AND REGULATIONS
SURGICAL SPECIMIN EXEMPTIONS**

The following specimens are exempted from both gross and microscopic examination by a pathologist:

1. Foreskin from circumcision
2. Skin or scar without lesions
3. Portions of bone without known or suspected abnormalities
4. Hardware
5. Lenses
6. Ossicles from the middle ear
7. Ligament, tendon, menisci, scar during reconstruction
8. Foreign bodies
9. Excess skin and fat
10. Teeth, fingernails and toenails
11. Tissue removed for research
12. Tissue removed for testing at an outside facility/laboratory
13. Tonsils and adenoids
14. Calculi such as renal stones
15. Traumatically injured extremity
16. Hernia contents

Edited: July 2015

Administrative Policy
St. Louis Children's Hospital

**PROCEDURE FOR REVIEW OF ACADEMIC AND DISCIPLINARY
DECISIONS RELATING TO RESIDENTS**

POLICY

Preamble

Both Washington University School of Medicine and the Hospitals (Barnes-Jewish and St. Louis Children's) recognize that the primary responsibility for academic and disciplinary decisions relating to residents and residency programs resides within the departments and the individual residency programs. Academic and performance standards, and methods of resident training and evaluation, are to be determined by the departments and programs and may differ among them.

The interests of the residents, the Medical School and the Hospitals are best served when problems are resolved as part of the regular communication between the residents and departmental officials in charge of the training program. Thus residents are encouraged to make every effort to resolve disagreements or disputes over academic or disciplinary decisions or evaluations by discussing the matter with the Department Chair, Division Chief or Program Director, as appropriate. The Office of the Associate Dean for Medical Education (Graduate Medical Education) is available to provide confidential guidance in this effort. The department may also have available a more formal procedure for review.

If the matter is not resolved, either by informal or formal means, at the departmental level, and the action taken by the department involves, (1) suspension, termination or non-reappointment; (2) reduction, limitation or restriction of the resident's clinical responsibilities; (3) extension of the residency or denial of academic credit that has the effect of extending the residency; or (4) denial of certification of satisfactory completion of the residency program, the resident may request a review of the departmental decision, which will follow the procedure set forth below. Decisions or actions other than those described in the preceding sentence are not subject to review under this procedure.

The availability of this procedure for review of certain kinds of decisions in no way is intended to affect the right of the department and/or the Hospital to counsel and evaluate residents routinely on performance or progress in the normal course of the training program.

1. Associate Dean - The resident shall make the request for review in writing within 30 calendar days after the departmental decision to the Associate Dean for Medical Education, (Graduate Medical Education) describing the matter in dispute and all previous attempts at resolution. The Associate Dean shall forward a copy of the request to the Program Director, who shall have the opportunity to respond in writing within 10 calendar days, a copy of which shall be

Administrative Policy**Procedure For Review Of Academic And Disciplinary
Decisions Relating To Residents**

furnished to the resident. (Copies of all correspondence relating to the review shall be furnished by the Associate Dean's office on a confidential basis to the President of the Hospital in the case of resident/clinical fellow.) The Associate Dean shall discuss the dispute with the resident and the Program Director (and the Hospital, if appropriate) in an effort to resolve the matter. If the matter is not resolved within 30 calendar days from the date of receipt of the request for review, the Associate Dean shall notify the resident in writing that the matter has not been resolved and that the resident has a right to request a hearing. If the matter is resolved, the Associate Dean shall summarize the resolution in a letter to the resident, Program Director and President of the Hospital in the case of a resident/clinical fellow.

Periodically, the Associate Dean shall report to the GMEC on the nature of matters brought to his or her attention under this procedure and the nature of the resolution, if any.

2. Hearing Panel - The resident shall make the request for a hearing in writing to the Chair of the GMEC within 7 calendar days after the date of the notice from the Associate Dean that the matter has not been resolved. The Chair of the GMEC shall appoint a five-member hearing panel, three members to come from the GMEC membership - one program director, who shall act as chair of the hearing panel, one senior resident and one Hospital representative - and two members to come from the elected representatives of the clinical departments to the Executive Committee of the Faculty Council or the Faculty Rights Committee of the School of Medicine. No member of these bodies who has been involved in the dispute in any way shall serve on the hearing panel.

A hearing date shall be set by the chair of the hearing panel within 30 calendar days of the receipt of the resident's request for a hearing. At least 7 calendar days before the hearing, the Program Director shall furnish the chair of the hearing panel and the resident with a statement of reasons for the action taken, along with any supporting documentation. The resident shall have the opportunity to respond in writing at least two calendar days before the hearing, copies to be furnished to the chair of the hearing panel and the Program Director.

At the hearing, both the resident and the Program Director may present evidence and witnesses, subject to limitations set by the chair based on the relevancy or time, and may examine the evidence and witnesses presented by the other. The members of the hearing panel may also ask questions and request the presence of additional witnesses if deemed necessary. A stenographic record of the hearing will be made. The resident may be accompanied by one advisor, identified by name and title at least 6 days before the hearing, who may advise the resident but not otherwise participate in the hearing. The hearing shall not be construed as a formal legal proceeding, and formal rules of law or evidence shall not apply.

Administrative Policy***Procedure For Review Of Academic And Disciplinary
Decisions Relating To Residents***

Subsequent to the conclusion of the hearing, the hearing panel shall deliberate in private and reach a decision as to its recommendation by majority vote. It shall make a written report and recommendation to the Dean of the Medical School and President of the Hospital within 15 calendar days after the conclusion of the hearing, copies of which shall be sent to the resident, the Program Director and the Associate Dean.

The recommendation of the hearing panel shall be accepted, rejected or modified by the Dean and President, or their designees, in writing, within 15 calendar days after the date of the recommendation and report. Copies shall be sent to the chair of the hearing panel, the resident, the Program Director and the Associate Dean. The decision of the Dean and President, or their designees, shall be final.

3. Applicability - This procedure applies to all residents/clinical fellows in ACGME-accredited residency programs at Barnes-Jewish Hospital, St. Louis Children's Hospital and Washington University School of Medicine, as well as residents in certain non-ACGME-accredited programs as designated by the GMEC.

RECOMMENDED/APPROVED BY:

Graduate Medical Education Consortium
Children's Medical Executive Committee