Optimal Resources for Emergency General Surgery

2022 EGS-VP Standards
# Table of Contents

Executive Summary ........................................ ii  
Background on ACS and AAST ............................... iii  
Acknowledgments ............................................ iv  

EGS-VP STANDARDS  

Institutional Administrative Commitment (IAC) ........ 1  
  IAC.1 Hospital Commitment ................................ 3  
  IAC.2 Culture of Patient Safety and High Reliability .... 4  

Program Scope and Governance (PSG) .................... 7  
  PSG.1 Definition and Scope of an Emergency General Surgery Program ........................................ 9  
  PSG.2 Emergency General Surgery Medical Director .... 10  
  PSG.3 Emergency General Surgery Program Management Resources ..................................... 11  
  PSG.4 Emergency General Surgery Committee .......... 12  

Facilities and Equipment Resources (FER) ................. 15  
  FER.1 Hospital Accreditation ................................ 17  
  FER.2 Emergency Department .............................. 18  
  FER.3 Operating Room Availability .......................... 19  
  FER.4 Intensive Care Unit .................................... 20  
  FER.5 Post-Anesthesia Care Unit ........................... 21  
  FER.6 Laboratory and Blood Bank ............................ 22  
  FER.7 Image Viewing Capabilities .......................... 23  

Personnel and Services Resources (PSR) .................. 25  
  PSR.1 EGS Surgeon Qualifications ......................... 27  
  PSR.2 Designated Provider for EGS Consults ............... 29  
  PSR.3 Surgical Team Availability ............................ 30  
  PSR.4 Operating Room Team Availability ................... 31  
  PSR.5 Anesthesia Services .................................. 32  
  PSR.6 Diagnostic Radiology Services ....................... 33  
  PSR.7 Therapeutic Endoluminal and Interventional Radiology Services ...................................... 34  
  PSR.8 Pain Management Services ........................... 35  
  PSR.9 Nutrition Services ..................................... 36  
  PSR.10 Allied Health Services ............................... 37  
  PSR.11 Surgical and Medical Specialty Services .......... 38  
  PSR.12 Patient Support Services ............................ 39
<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient Care: Expectations and Protocols (PC)</strong></td>
<td>41</td>
</tr>
<tr>
<td>PC.1 Standardized Care Pathways</td>
<td>43</td>
</tr>
<tr>
<td>PC.2 EGS Provider Response Pathway</td>
<td>44</td>
</tr>
<tr>
<td>PC.3 Patient Education</td>
<td>45</td>
</tr>
<tr>
<td>PC.4 Informed Consent Process</td>
<td>46</td>
</tr>
<tr>
<td>PC.5 Anesthesia Pathway</td>
<td>47</td>
</tr>
<tr>
<td>PC.6 Massive Transfusion Protocol</td>
<td>48</td>
</tr>
<tr>
<td>PC.7 Rescue Protocol</td>
<td>49</td>
</tr>
<tr>
<td>PC.8 Geriatric Patient Care Protocols</td>
<td>50</td>
</tr>
<tr>
<td>PC.9 Discharge Planning and Disposition Pathways</td>
<td>51</td>
</tr>
<tr>
<td>PC.10 Readmission and Transfer Protocols</td>
<td>52</td>
</tr>
<tr>
<td><strong>Data Surveillance and Systems (DSS)</strong></td>
<td>55</td>
</tr>
<tr>
<td>DSS.1 Data Collection</td>
<td>57</td>
</tr>
<tr>
<td>DSS.2 Surveillance of EGS Data</td>
<td>58</td>
</tr>
<tr>
<td><strong>Quality Improvement (QI)</strong></td>
<td>61</td>
</tr>
<tr>
<td>QI.1 Quality Assessment and Improvement</td>
<td>63</td>
</tr>
<tr>
<td>QI.2 Case Review Process</td>
<td>64</td>
</tr>
<tr>
<td>QI.3 Peer Review Process for the Individual Surgeon</td>
<td>65</td>
</tr>
<tr>
<td>QI.4 Quality Improvement Collaborative Participation</td>
<td>66</td>
</tr>
<tr>
<td><strong>Education: Professional and Community Outreach (EDU)</strong></td>
<td>69</td>
</tr>
<tr>
<td>EDU.1 Patient Advocacy and Education</td>
<td>71</td>
</tr>
<tr>
<td><strong>Research: Basic and Clinical Trials (RES)</strong></td>
<td>73</td>
</tr>
<tr>
<td>RES.1 Clinical Trials and Scholarly Activities</td>
<td>75</td>
</tr>
</tbody>
</table>
Important Information

These standards are intended solely as qualification criteria for the American College of Surgeons Emergency General Surgery Verification Program (EGS-VP) verification. They do not constitute a standard for care and are not intended to replace the medical judgment of the surgeon or health care professional in individual circumstances.

In addition to verifying compliance with the standards as written in this manual, the EGS-VP may consider other factors not stated herein when reviewing a hospital or hospital system for verification and reserves the right to grant or withhold verification based on its judgement of the totality of the program.
Executive Summary

The American College of Surgeons (ACS) and the American Association for the Surgery of Trauma (AAST) are pleased to present the Emergency General Surgery Verification Program, a national quality verification program focused on the care and treatment of patients with emergency general surgery (EGS) diseases.

The EGS field covers a wide variety of both surgical and nonoperative care, with procedural areas of significant diversity. Further, there is considerable variation across hospitals and healthcare systems in organizing and overseeing this specialty care, which adds additional complexity. Given these unique aspects of EGS care, the ACS and AAST designed this program to address variations in clinical care and quality improvement by offering a set of standards, guidelines, and resources to elevate the quality experience of the EGS patient, practitioner, and institution.

As the output of a joint effort between the ACS and AAST, this program aims to leverage both organizations’ unique expertise in healthcare quality and surgical clinical care to achieve that goal. Building upon the legacy of the ACS accreditation and verification programs’ nine domains and four-part model for quality, Optimal Resources for Emergency General Surgery outlines the full complement of resources, supports, pathways, and multidisciplinary involvement necessary to begin and extend the quality journey for an EGS Program. Drawing from the same quality improvement foundation that has led to improved outcomes in trauma, cancer, bariatric surgery, and children’s surgical care, among others, this program offers the opportunity to set similar standards of improvement in the diverse field of EGS care.

Areas of focus within the program’s 43 standards include demonstration of hospital commitment, appropriate facilities and equipment, clinical continuity across the five phases of care, robust data collection and analysis, quality improvement activities, and dedicated, trained personnel and services. Hospitals participating in the program will have the opportunity to address each area of focus within their EGS service, with feedback and open discussion focused on areas of excellence and opportunities for improvement.

Though the field of emergency general surgery has significant variation in its implementation and care models, the EGS Verification Program offers a roadmap for all institutions to improve the outcomes of the EGS patient and support the experience of surgeons, multidisciplinary team members and hospitals invested in the care of these patients.
Background on ACS and AAST

About the American College of Surgeons
The American College of Surgeons (ACS) is a scientific and educational organization of surgeons that was founded in 1913 to raise the standards of surgical practice and improve the quality of care for all surgical patients. The College is dedicated to the ethical and competent practice of surgery. Its achievements have significantly influenced the course of scientific surgery in America and have established it as an important advocate for all surgical patients. The College has more than 84,000 members and is the largest organization of surgeons in the world. For more information, visit facs.org.

About the American Association for the Surgery of Trauma
The American Association for the Surgery of Trauma (AAST) is dedicated to discovery, dissemination, implementation, and evaluation of knowledge related to acute care surgery (trauma, surgical critical care, and emergency general surgery) by fostering research, education, and professional development in an environment of fellowship and collegiality. The AAST is the premier academic trauma surgery organization in the United States and has over 1,700 members from 30 countries. For more information, visit aast.org.
Acknowledgments

Clinician Advisors
Raul Coimbra, MD, PhD, FACS, Chair, EGS Working Group
Stanley Ashley, MD, FACS
Scott Coates, MD, FACS
Clay Cothren Burlow, MD, FACS
Michael Chang, MD, FACS
Marie Crandall, MD, FACS
Kimberly Davis, MD, MBA, FACS
Robert Lim, MD, FACS
Patrick Reilly, MD, FACS, FCCP
Caroline Reinke, MD, FACS
Michael Rotondo, MD, FACS
Stephanie Savage, MD, FACS
Shahid Shafi, MD, FACS
David Spain, MD, FACS
Kristan Staudenmayer, MD, FACS

ACS Staff Contributors
Patricia Turner, MD, MBA, FACS, Executive Director
Clifford Y. Ko, MD, MS, MSHS, FACS, FASCRS, Director,
Division of Research and Optimal Patient Care
David B. Hoyt, MD, FACS, Former Executive Director
Sameera Ali, MPH, Administrative Director, Division of
Research and Optimal Patient Care
Amy Robinson-Gerace, Senior Manager, Verification
Program Development
Stephanie Mistretta, MA, LCSW, Project Manager, Verification
Program Development
Shelby Eagle, MPH, Project Manager, Verification
Program Development
Anna Treudt, Project Manager, Verification Program
Development
Leticia Jones, Project Coordinator, Verification Program
Development

AAST Staff Contributors
Sharon Gautschy, Executive Director
Institutional Administrative Commitment (IAC)
# Hospital Commitment

## Definition and Requirements

Hospital leaders demonstrate commitment through engaged leadership and financial resources to support the Emergency General Surgery (EGS) Program and ensure alignment with the hospital’s strategic priorities.

There is top-level leadership commitment to quality and safety within the EGS Program and appropriate allocation of resources, through demonstration of the following:

- Resource allocation to and engagement with the EGS Program
- Hospital-level leadership has established formal channels for effective communication to align with EGS Program priorities
- Mechanisms for feedback from ongoing EGS initiatives and quality and safety issues to hospital-level leadership

## Documentation

- Provide a letter from hospital leadership (such as CEO or equivalent) demonstrating the commitment to the EGS Program, which includes:
  - A high-level description of the EGS Program, including program leadership, annual volume, procedure mix, and commitment and organization of multidisciplinary care services for EGS patients
  - Any initiatives involving the EGS Program in the previous 12 months that were initiated to ensure quality and safety
  - Hospital leadership’s involvement with the EGS Program
  - The current and future commitment to and financial investment in the EGS Program
  - The hospital’s commitment to maintaining compliance with verification program standards
- Provide an organizational diagram showing the EGS Program’s relationships to other departments and internal governing bodies, specifically those that oversee patient safety, quality, and fiscal administration of the EGS Program

## Resource

IAC.2 Culture of Patient Safety and High-Reliability

Definition and Requirements

There is an organized effort to create a culture of patient safety and high reliability within the EGS Program. Exemplary programs will have systems in place to evaluate and continuously improve culture.

A hospital's culture reflects the aggregate attitude and values of its leaders and members and sets the climate for how patient safety is perceived and reinforced. The culture of a patient care hospital has been described as a five-step ladder model, including the following five designations:

- **Passive**: Adverse events are expected or considered unavoidable
- **Reactive**: Presence of systems to address sentinel events when they occur, without active surveillance
- **Calculative**: Presence of systems to prevent problems and actively surveil for sentinel events
- **Proactive**: Presence of systems to proactively anticipate both sentinel events and morbidities
- **Generative**: Quality and safety at the core of every aspect of infrastructure

Actively pursuing a generative safety culture and practice of high-reliability principles is core to the hospital's mission, embedded and identifiable throughout the institution. There is safety culture training and regular, formal assessment of safety culture across all EGS providers. Results drive tailored improvement initiatives and ongoing safety culture education.

This commitment to a culture of patient safety and high reliability is demonstrated by the following:

- Ongoing safety culture measurement, with feedback to frontline staff and demonstrated effort to act on the basis of results
- Results of safety culture surveys are communicated to EGS staff
- Training on safety culture as part of the onboarding process for new staff and ongoing maintenance of training for existing staff
- Robust mechanisms in place for monitoring and managing safety events, including regular and robust monitoring of event reporting data such as the capture of and education on near misses, safety huddles, and broadly distributed safety dashboards
- Continuous effort to improve the safety culture to create a generative culture where quality and safety are at the core of every aspect of the hospital’s infrastructure

Documentation

- Provide reports from safety culture assessments (for example, Safety Attitudes Questionnaire [SAQ] and Hospital Survey on Patient Safety Culture [HSOPS]) in which the EGS service participated over the previous three years, if any
- Provide the most recent quality dashboard with EGS–specific measures, if any
- Provide a listing of recent training/education initiatives for the EGS team on safety culture/safety attitudes, including dates of training (for example, TeamSTEPPS)

Resources


Elster EA, Makary MA, Saldinger PF, Schumacher MG. Chapter 7: Creating a culture that is focused on safety and high reliability. In: Hoyt DB, Ko CY, eds. *Optimal Resources for Surgical Quality and Safety*. American College of Surgeons; 2017: 85–96


Program Scope and Governance (PSG)
Definition and Scope of an Emergency General Surgery Program

Definition and Requirements

The hospital must undertake initial evaluation of patients presenting with common Emergency General Surgery (EGS) conditions and provide definitive care for at minimum the following:

- Acute abdomen/peritonitis
- Soft tissue infection
- Gallbladder disease
- Gastrointestinal obstruction
- Pancreatitis
- Diverticular disease
- Appendicitis
- Acute gastrointestinal bleed
- Perforated peptic ulcer disease
- Incarcerated hernia

The hospital must have an algorithm for patients referred to the EGS service that ensures standardized, consistent care (such as for management of upper/lower GI bleeds) based on broad input from multidisciplinary providers. The EGS service does not have to be a formal, dedicated service line defined by the hospital but must meet the minimum requirements outlined herein.

The standards, as written herein, apply to all patients that meet local criteria for referral to the formal or informal EGS service.

Documentation

- Provide the hospital's local algorithm that indicates when patients are referred to the EGS service that includes the conditions outlined above
- Provide the EGS Surgeon Roster Pre-Review Questionnaire table
- Provide EGS service schedule for the previous 3 months, with names of the surgeon(s) assigned for each week
- Provide the EGS Volume Pre-Review Questionnaire table noting the percentage of EGS volume in relation to overall volume at the hospital
Definition and Requirements

The EGS Medical Director is a qualified physician leader who has demonstrated appropriate training, experience, authority, and commitment to effectively lead the program. The Medical Director maintains oversight and accountability for clinical care and quality across the EGS Program, including the following:

1. Reviews mortality and adverse event rates, including subsequent distribution of review findings
2. Addresses clinical practice variation
3. Establishes quality and safety standards and guidelines for use in the EGS Program
4. Monitors primary clinical outcomes data to identify surgical issues
5. Develops and implements EGS-specific quality improvement initiatives
6. Provides strategic leadership and prioritization of EGS quality initiatives and goals
7. Provides oversight and leadership of the EGS Committee
8. Participates in governance, including approving EGS privileges for surgeons

Documentation

- Provide official job description for the EGS Medical Director position, including percentage of full-time employment dedicated to this role
- Provide an organizational diagram inclusive of the Medical Director position and all other EGS Program staff (Standard PSG.3) that illustrates the reporting structure and relationships to institutional leadership
- Provide the curriculum vitae for the individual serving as the Medical Director
Program management, quality improvement, and clinical data abstraction roles and responsibilities must be established within the EGS Program. These may be fulfilled by either full- or part-time dedicated employees and can be joined or split depending on the size and organization of the hospital. Official job descriptions must reflect the responsibilities outlined below and support dedicated time and compensation commensurate to the duties assigned.

- **EGS Program Manager:** An individual, either clinical or nonclinical, with appropriate experience dedicated to managing and coordinating the administrative functions of the program and supporting the Medical Director. The Program Manager role provides oversight of program support, including but not limited to:
  - Establishing and maintaining a collaborative working relationship with the Medical Director to assist with program needs and goals
  - Establishing and maintaining a functional system of collaboration for programmatic, data, and quality improvement (QI) needs
  - Management of administrative functions within the EGS Program, including supporting committee meetings and ensuring adequate program resources

- **Quality Improvement Support:** There must be dedicated support for EGS–specific quality improvement activities either through an individual or team within the EGS program or at the hospital level. Designated individual/team should have demonstrable and appropriate training, experience, and success in quality improvement methodology and leading data-driven QI initiatives.

- **Clinical Data Abstraction and Analysis:** There must be support for clinical data abstraction and analysis specific to the EGS Program, either through an individual within the EGS Program, at the hospital level, or through a contracted service. There should be demonstrable and appropriate training, experience, and maintenance of necessary certifications and database access to abstract and report on data relevant to the program. Clinical data abstraction and quality improvement support functions work closely together to ensure data accuracy and meaningful QI initiatives.

- **Documentation**
  - Provide official job descriptions for each job function outlined within the standard
Program Scope and Governance (PSG)

PSG.4 Emergency General Surgery Committee

Definition and Requirements

The EGS Committee is comprised of the EGS Medical Director, program manager, quality improvement support representative, clinical data abstraction representative, all surgeons performing EGS as defined in Standard PSG.1, and multidisciplinary care team members that serve EGS patients. The committee provides infrastructure that fosters communication throughout the EGS Program and within the larger hospital.

The committee oversees and facilitates quality improvement efforts within the EGS Program, ensuring that a multidisciplinary perspective guides these activities. The committee meets at a minimum quarterly, and members must attend at least 50% of the meetings. The committee serves three primary functions:

• Provide program administrative and operational oversight (including protocol review and development)
• Conduct retrospective case review, outcomes data review, and quality improvement activities (see Standards DSS and QI for further details)
• Conduct protected peer review and periodic review of surgeon-level outcomes to identify individuals needing additional interventions/proctoring. As determined by state and local bylaws, peer review committee members may be a subset of the core EGS Committee members.

Designated physician liaisons from the following disciplines must participate in case review, outcomes data review, and quality improvement activities:

• Emergency medicine
• Anesthesia
• Critical care
• Radiology, including interventional radiology
• GI/Endoscopy
• Internal medicine

Designated administrative and nursing liaisons from the following departments must also participate in case review, outcomes data review, and quality improvement activities:

• Executive team
• Emergency department
• Operating room
• PACU
• ICU
• Inpatient units treating EGS patients (optional)
• Lab
• Blood bank
• Pharmacy

Documentation

• Provide the Pre-Review Questionnaire table with committee membership roster, dates of meetings, and attendance within the previous 12 months
• Provide meeting minutes for the most recent committee meeting
• Provide an organizational chart showing the EGS Committee’s position within the overall hospital framework
• Provide the EGS Committee charter inclusive of written goals and statement of purpose
Facilities and Equipment Resources (FER)
FER.1  Hospital Accreditation

Definition and Requirements

The hospital and its providers meet all local and federal regulatory requirements and maintain a license by the appropriate state licensing authority. The hospital must also maintain accreditation by The Joint Commission or an equivalent, nationally recognized healthcare hospital-accrediting body.

Documentation

- Provide recent copies of licensure and hospital accreditation/certification from the various regulatory programs that designate the hospital, including but not limited to The Joint Commission, DNV, and so on
- Provide current improvement plans to address findings from the most recent hospital accreditation review, if any
FER.2 Emergency Department

**Definition and Requirements**

The hospital must have an Emergency Department (ED) staffed 24/7/365 by an in-house, licensed medical practitioner capable of practicing independently. The ED must have a designated medical director. It is desirable that the medical director is board-certified or eligible by the American Board of Emergency Medicine or equivalent.

**Documentation**

- Provide the call schedule for Emergency Department coverage for the previous month
- Provide job description for ED medical director and ED liaison to the EGS Committee if the individual fulfilling this role is different than the ED medical director

**Resource**

FER.3 Operating Room Availability

Definition and Requirements

The hospital must maintain at least one adequately equipped operating room staffed for Emergency General Surgery cases with 24/7/365 availability.

Documentation

- Provide the call schedule for operating room staff (such as nursing staff and radiology technicians) for the previous month
- Provide the hospital’s written policies and procedures for operating room/procedure suite availability, use, and staffing/personnel requirements
## Intensive Care Unit

### Definition and Requirements

The hospital must have an intensive care unit (ICU), defined as a specialized treatment unit caring for severely ill and/or injured patients that require constant monitoring and support utilizing specialized equipment, advanced resources, and trained critical care staff at an increased staff-to-patient ratio.

The unit must have the equipment and appropriately trained personnel to monitor and resuscitate patients. At minimum, this must include the capability for continuous pulse oximetry, capnography, hemodynamic monitoring, rapid transfusion, rapid rewarming, and invasive and noninvasive ventilation.

There must also be a capable and qualified critical care team composed of at minimum a qualified physician or surgeon to provide intensive care available 24/7/365. Fully trained and qualified staff sufficient to meet the needs of patient care, including critical care nursing, trained respiratory therapists, and an ICU pharmacist, must also be available 24/7/365.

The ICU must also establish a standardized escalation of care plan to include a list of situations in which the ICU physician must be notified. Suggested escalation criteria include but are not limited to:

- New admissions or transfers
- Initiation or rapid escalation of vasoactive medications
- Significant bleeding requiring unexpected transfusion of blood products
- Decisions to return to the operating room or goals of care
- Unplanned escalation of ventilator support or pending intubation
- New dysrhythmias or concerns for myocardial infarction
- Need to initiate renal replacement therapy
- Cardiac arrest or patient death

Primary management of the surgical patient may be either by the surgeon or the intensive care unit physician, depending on local policies. Interface and team-based care between surgeons and intensivists must occur regardless of care structure, and the hospital must have a written protocol that establishes expectations for open communication and a collaborative relationship between the attending surgeon and intensivists.

### Documentation

- Provide hospital policy for ICU staffing (such as nursing ratios and overnight backup call schedules)
- Provide ICU physician, resident, and/or advanced practice provider call schedule for the previous month
- Provide standardized escalation of care plan
- Provide the hospital’s policy detailing the composition, availability, and leadership of the critical care team
- Provide the hospital’s written protocol that establishes expectations for open communication and a collaborative relationship between the attending surgeon and intensivists
**FER.5 Post-Anesthesia Care Unit**

**Definition and Requirements**

There must be a post-anesthesia care unit (PACU) available 24/7/365 for patients following surgery for observation in the immediate postoperative period. This unit must be staffed by dedicated personnel trained to manage and recognize postoperative complications. The intensive care unit (ICU) may be used for post-anesthesia recovery.

Minimum requirements include
- Pulse oximetry monitoring
- Difficult airway cart
- Advanced Cardiovascular Life Support (ACLS)-trained staff
- Fully stocked crash cart (with airway equipment, medications, IVs, and oxygen)

**Documentation**

- Provide the hospital's written policies and procedures for post-anesthesia care/observation unit availability, use, and staffing/personnel requirements
Facilities and Equipment Resources (FER)

FER.6 Laboratory and Blood Bank

Definition and Requirements

Laboratory must be available either on- or off-site 24/7/365 for the standard analyses of blood, urine, and other body fluids, coagulation studies, blood gas analysis, and microbiology.

Blood bank must be available 24/7/365 with sufficient blood products to manage urgent surgical cases.

Documentation

- Provide the hospital's written policies for the availability of laboratory and blood bank services
**FER.7 Image Viewing Capabilities**

**Definition and Requirements**

The hospital must have the technical capability to receive, upload, and view imaging obtained at outside facilities. It is strongly recommended to have a mechanism for remote image viewing for physicians.

**Documentation**

- Provide the hospital's written policies for capabilities regarding imaging obtained at outside facilities
Personnel and Services Resources (PSR)
PSR.1 Emergency General Surgery Surgeon Qualifications

Definition and Requirements

There must be thorough processes for credentialing and privileging that ensure all surgeons are qualified and able to provide safe and appropriate surgical care. This includes a formal onboarding process with the involvement of the Emergency General Surgery (EGS) Medical Director in developing and approving privileging criteria. The institution's credentialing body must adhere to current nationally recognized privileges.

To obtain and maintain active privileges to perform EGS procedures (renewed at least every two years), all surgeons performing EGS procedures must fulfill the following requirements:

- **Licensure and Certification:** State medical licensure in good standing. The surgeon must be certified or eligible for the American Board of Surgery, American Osteopathic Board of Surgery, Royal College of Physicians and Surgeons of Canada, or specialized area of practice (see alternative pathway).

- **Surgical Training and Experience:** At a minimum, attending surgeons performing EGS must have completed a general surgery residency or equivalent.

- **Ongoing Education and Professional Engagement:** Surgeons must meet the CME requirements as established by the American Board of Surgery for Continuous Certification. Surgeons must also maintain active membership in related professional societies and attend regional/national quality meetings, with minimum attendance of at least one meeting over a three-year period.

- **Privileging:** Credentialing, privileging, and core onboarding procedures are specific to specialty to ensure that all surgeons are qualified and able to provide safe and appropriate surgical care. The local EGS Committee (see Standard PSG.4) must offer a pathway for surgeons in the following circumstances:
  - New surgeons (either recent graduates or new to hospital) requesting privileges
  - Established surgeons renewing existing privileges
  - Established surgeons requesting new privileges or new technologies
  - Established surgeons reestablishing privileges following a break in practice
  - Safe introduction of innovative procedures and technologies (for example, robotic operations)

The pathway must outline a process for Focused Professional Practice Evaluation (FPPE) and training requirements that include the following:

- Didactic educational component
- Skills training: inanimate
- Skills training: supervised/proctored
- Incorporation into practice
- Measurement of results

Introduction of Minimally Invasive and Innovative Surgical Technologies

Minimally invasive surgical capabilities for EGS are desirable but not required. However, those facilities/surgeons introducing minimally invasive procedures (laparoscopic, thoracoscopic, advanced endoscopic, and robotic) or other innovative technologies must demonstrate the following, based on the ACS CESTE Model:

- **Formalized Curriculum:** Didactic education should include a thorough curriculum on the operational use of the new technology and appropriate indications and contraindications for applying the particular surgical approach.

- **Expert Proctoring:** Initial skills training should include inanimate simulation with graded evaluation of skills acquisition. A significant number of initial procedures should be done with expert proctoring. Constructive feedback and process improvement should be part of the proctoring process. Incorporation into practice should be applied selectively, with low-risk cases chosen initially and then the incremental application for more complex cases.

- **Outcomes Monitoring:** Outcomes for minimally invasive and innovative surgical technologies must be closely monitored and include clinical, financial, and patient-centered outcomes.
**Documentation**

- Provide hospital privileging criteria for surgeons performing EGS procedures
- Provide written process for safe introduction of new surgical procedures or technology, including the most recent example of a Focused Professional Practice Evaluation (FPPE) process

**Resources**


**PSR.2** Designated Provider for Emergency General Surgery Consults

**Definition and Requirements**

There must be a designated provider 24/7/365 to provide EGS consults in person or by phone. This may be a surgeon, surgeon-in-training, or advanced practice provider.

There must also be a triage protocol to determine the timeliness of EGS consultation. Exemplary institutions will be able to demonstrate compliance with the protocol for most cases.

**Documentation**

- Provide EGS provider consult schedule for the previous month
- Provide EGS Consult Roster Pre-Review Questionnaire table detailing all non-surgeons actively taking EGS consult call
- Provide written triage protocol for EGS consultation
- Provide logs tracking timeliness of consult, if any
PSR.3 Surgical Team Availability

Definition and Requirements

The hospital must have a call schedule that ensures an EGS surgeon or surgical team member is physically available 24/7/365 within 30 minutes of request. This response may be provided by an attending surgeon, resident surgeon, or advanced practice provider. The hospital must have a formal process for tracking compliance with 30-minute availability. Exemplary hospitals will be able to show appropriate responses for most calls.

Documentation

- Provide EGS call schedule for the previous month
- Provide written protocol detailing cases/conditions with required 30-minute response time (see Standard PC.2)
- Provide logs tracking timeliness of availability, if any
Definition and Requirements

The operating room (OR) must be adequately staffed 24/7/365 by an EGS surgeon and operative team, including anesthesia providers, OR nurses, and scrub technicians.

Staff is not required to be in-house but must be available within the following response times:

<table>
<thead>
<tr>
<th>Time</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within 30 minutes</td>
<td>For emergency conditions, including life- or limb-threatening conditions</td>
</tr>
<tr>
<td>Within 6 hours</td>
<td>For urgent, non-emergency conditions</td>
</tr>
<tr>
<td>Within 12 hours</td>
<td>For semi-urgent, non-elective conditions requiring timely intervention</td>
</tr>
</tbody>
</table>

Documentation

- Provide arrival log or other tracking mechanisms for OR team availability compliance
PSR.5 Anesthesia Services

Definition and Requirements
A physician anesthesiologist or certified anesthesia provider under a physician anesthesiologist's direction within an anesthesia care team model must be readily available 24/7/365 to provide anesthesia care for EGS patients.

Documentation
- Provide call schedule for anesthesia, demonstrating 24/7/365 coverage for the previous month
- Provide the hospital's written policy documentation regarding supervision of certified non-physician anesthesia providers and care team model supervision, if applicable

Resource
Diagnostic Radiology Services

Definition and Requirements

The following imaging modalities must be available in the hospital 24/7/365 for emergency diagnostic imaging: plain film x-ray and CT scanning. Ultrasonography must also be available seven days a week.

A radiologist credentialed by the hospital must be available within 60 minutes of request 24/7/365 in person or by teleradiology to interpret imaging studies.

Documentation

- Provide a listing of diagnostic radiology services available at the hospital, including the hours of availability
PSR.7 Therapeutic Endoluminal and Interventional Radiology Services

Definition and Requirements

Interventional radiology and endoscopic interventions must be available at the hospital or by transfer to other hospitals with the following response times. The times listed below are not meant to prescribe time to intervention but only timely availability of consultative services as the patient’s clinical condition requires:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Time from Request</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sepsis source control (shock)</td>
<td>60 minutes</td>
</tr>
<tr>
<td>Sepsis source control (no shock)</td>
<td>3 hours</td>
</tr>
<tr>
<td>Biliary drainage (endoscopic retrograde cholangiopancreatography [ERCP] or percutaneous transhepatic cholangiography [PTC]) for biliary sepsis/cholangitis (not in shock)</td>
<td>12 hours</td>
</tr>
<tr>
<td>Bleeding (ongoing or shock)</td>
<td>60 minutes</td>
</tr>
<tr>
<td>Intermittent bleeding, hemodynamically stable</td>
<td>12 hours, if needed</td>
</tr>
<tr>
<td>Complete large bowel obstruction (closed-loop) with signs of peritonitis</td>
<td>60 minutes</td>
</tr>
<tr>
<td>Complete large bowel obstruction (closed-loop) without signs of peritonitis</td>
<td>3 hours</td>
</tr>
</tbody>
</table>
PSR.8 Pain Management Services

**Definition and Requirements**

The hospital must have dedicated pain management support services, including the following:

- **Acute Pain Management Capabilities**: Experienced acute pain management services must be available onsite, with ability to place nerve blocks and epidurals for pain management. Services must be available seven days a week during business hours for epidural placement and 24/7/365 either onsite or via phone consultation for epidural management.

- **Chronic Pain Management Capabilities**: It is recommended that there is an established chronic pain management clinic in the hospital. If not present onsite, there must be a referral process to an established chronic pain management clinic outside the hospital.

**Documentation**

- Provide hospital policies regarding the availability of pain management services, including a list of available services
PSR.9 Nutrition Services

Definition and Requirements

A full set of nutritional services must be available to care for EGS patients, including support for complex patient needs.

The following nutritional services must be available onsite 24/7/365:

- **Parenteral Nutrition Access**: A qualified, credentialed provider must be available to obtain necessary central or peripheral access for TPN or PPN.
- **Enteral Nutrition Access**: A qualified, credentialed provider must be available to obtain enteral nutrition access.

Additionally, trained professionals, such as registered dieticians, must be available for nutrition consultation to optimize nutrition during normal business hours.

Documentation

- Provide hospital policies regarding the availability of nutrition services, including a list of available services
Allied Health Services

Definition and Requirements

The hospital must provide a full complement of allied health services employing trained professionals working in coordination with the medical and surgical team to provide comprehensive pre- and post-surgical support.

The following specialty services must be available onsite and staffed with qualified personnel:

- Physical therapy
- Occupational therapy
- Respiratory therapy
- Pharmacy

All services must be available seven days a week. Additionally, there must be a documented program for early ambulation.

Documentation

- Provide documented plan for early ambulation
- Provide the call schedule for physical, occupational, and respiratory therapy for the previous month showing hours of coverage and consultation availability
- Provide the call schedule for inpatient pharmacy for the previous month showing hours of coverage and consultation availability
Definition and Requirements

The following surgical and medical specialty services must be available and staffed with qualified personnel (board certified/board eligible when applicable) upon request. Consultation may be either onsite or via written transfer or telemedicine agreement for the treatment of EGS patients. Specialty services must include:

**Surgical Specialists**
- Bariatric surgery
- Cardiothoracic surgery
- Colorectal surgery
- Gynecologic surgery
- Hepatobiliary surgery
- Plastic surgery
- Urologic surgery
- Vascular surgery

**Medical Specialties**
- Cardiology
- Critical care/Intensivist
- Endocrinology
- Gastroenterology
- Geriatric Medicine
- Hematology
- Hospitalist/Internal medicine
- Infectious Disease
- Nephrology
- Pulmonology
- Urology

**Documentation**
- Provide transfer agreement documents for those specialties that are unavailable at the hospital, if any
Patient Support Services

Definition and Requirements

The hospital must provide all patients with access as needed to patient support services personnel. Support services must provide individualized assistance to patients, families, and caregivers to ensure adherence to the patient's care plan and timely access to resources and supports. Patient support personnel must have sufficient clinical knowledge and experience to understand and effectively communicate interdependencies, timing, and options for care.

The following patient support services must be made available as needed to EGS patients:

- Case management services
- Ethical consultation
- Palliative care services
- Pastoral care services
- Social services
- Speech/Language therapy services
- Translation/Interpreter services
- Wound/Ostomy services
Patient Care: Expectations and Protocols (PC)
Standardized Care Pathways

Definition and Requirements

Standardized, team-based processes must be in place to ensure surgical quality, safety, and reliability in all five phases of care for the primary morbid condition requiring surgery. The hospital must have established disease- and procedure-specific standardized care pathways and corresponding order sets that address a formal protocol for Emergency General Surgery (EGS) patients across all of the following phases of care:

1. Preoperative phase (EMS), including Emergency Department transfer process, expedited primary care referral process, and timely ED referral process
2. Immediate preoperative phase
3. Intraoperative phase
4. Postoperative phase
5. Postdischarge phase

Standardized processes may include but are not limited to:

- Standardized preoperative evaluation and risk assessment process
- Preoperative optimization/surgery readiness protocols for high-risk patients, such as Strong for Surgery or centralized perioperative care clinic, to assess multimodal patient needs including nutrition, medication use, smoking cessation, and pain control
- Geriatric-specific protocols
- Intraoperative procedures such as timeouts, handoffs, and debriefs
- Multimodal pathways for Enhanced Recovery After Surgery (ERAS), including optimization of nutrition; standardized, opioid-sparing analgesic and anesthetic regimens; and early mobilization
- Discharge and postdischarge protocols to ensure safe pain and wound management, appropriate follow-up, and continuity of care

Exemplary hospitals will have standardized patient care processes across all five phases of care and regularly measure compliance with protocols. Additionally, there will be mechanisms to ensure appropriate education, review, maintenance, and identification of new opportunities for protocol development and standardization. Such hospitals will be able to demonstrate compliance with order sets and clinical pathways in most cases and will have reliable methodology for tracking compliance and noting areas of deviation.

Documentation

- Provide all available and “in-use” protocols, algorithms, and clinical pathways for the consistent management of EGS patients
- Provide documentation demonstrating compliance rates for order sets and pathways, if any are in use

Resources


**PC.2** Emergency General Surgery Provider Response Pathway

**Definition and Requirements**

The hospital must have defined, written criteria to activate an EGS provider consultation. This activation may be tiered, depending upon the severity of illness:

- The highest level response time of 30 minutes (defined as from the time of consultation request) for an EGS provider is reserved for critically ill and/or hemodynamically unstable patients.
- Time to intervention for hemorrhagic shock and septic shock unresolved by interventional radiology or endo intervention is one hour at maximum (defined as the time between the decision to operate to anesthesia start time).

**Documentation**

- Provide the hospital's written policy for EGS consultation with tiered activation levels if utilized.
Patient Education

Definition and Requirements

The hospital has documented plans and materials for EGS patient education, including postoperative education:

- Explanation of the expected course of care, including instructions regarding wound/ostomy/drain management, diet, medications, pain management, lifestyle, and physical activity modifications
- Signs and symptoms of complications such as tachycardia, fever, shortness of breath, excessive pain, and vomiting, including when and whom to call
- Ongoing involvement in treatment planning and access to care coordination

Documentation

- Provide all patient education materials currently in use with EGS patients
**PC.4 Informed Consent Process**

**Definition and Requirements**

The informed consent process must include a clear explanation of goals, risks, benefits, and alternatives for indicated procedures(s) and must be clearly documented in the medical record of all EGS patients. The hospital must demonstrate a process for EGS patients that includes discussion and documentation of the following, when appropriate:

- Goals of Care
- Power of Attorney
- Advance Directives
- Patient Consent

**Documentation**

- Provide each of the following forms:
  - Goals of Care
  - Power of Attorney
  - Advance Directives
  - Patient Consent
Definition and Requirements

The hospital must have an anesthesia pathway that addresses common considerations for EGS patients. This pathway must be jointly developed and endorsed by the chief of anesthesiology or anesthesia liaison to the EGS Committee and the EGS Medical Director. At a minimum, the pathway must address the following:

- Sepsis management
- Acute bleeding management
- Complex airway management
- Postoperative pain management, including opioid-sparing techniques

Documentation

- Provide the anesthesia pathway jointly endorsed by the chief of anesthesiology or anesthesia liaison to the EGS Committee and the EGS Medical Director
**PC.6 Massive Transfusion Protocol**

**Definition and Requirements**

The blood bank must have a documented protocol for managing life-threatening hemorrhage, including capabilities for rapid transfusions.

**Documentation**

- Provide the hospital's written Massive Transfusion Protocol, including available products, required response times, and rapid transfusion protocols.
PC.7 Rescue Protocol

Definition and Requirements

There must be a 24/7/365 on-call team available for immediate consultation of patients outside the intensive care unit who may require evaluation and escalation of care due to acute decompensation.

Documentation

- Provide the protocol governing activation of rescue team response (may also be known as rapid response team)
Geriatric Patient Care Protocols

**Definition and Requirements**

The hospital must have protocols specific to the care of older adults that address the unique needs of this population across the five phases of care. These protocols should be integrated into standardized care pathways for EGS patients.

Protocols specific to the care of older adults include but are not limited to the following:

- Identification of vulnerable geriatric or frail patients
- Identification of patients who will benefit from the input of a healthcare provider with geriatric expertise
- Assessment of frailty
- Prevention, identification, and management of dementia, depression, and delirium
- Process to capture and document what matters to patients, including preferences and goals of care, code status, advanced directives, and identification of a proxy decision-maker
- Medication reconciliation and avoidance of inappropriate medications
- Screening for mobility limitations and assurance of early, frequent, and safe mobility
- Implementation of safe transitions to home or other healthcare facility

**Documentation**

- Provide any protocols specific to the care of older adults currently in use with EGS patients

**Resource**

PC.9 Discharge Planning and Disposition Pathways

Definition and Requirements

The hospital must have written discharge and disposition protocols/pathways for patient follow-up, including access to all applicable services onsite or via referral. Pathways may include but are not limited to:

- Surgical team follow-up
- Primary care physician/specialist follow-up and communication
- Follow-up imaging/studies
- Wound care follow-up
- Medication access and availability

Hospitals must also demonstrate disposition pathways for patients requiring complex postdischarge care, including skilled nursing facilities, long-term acute care, and inpatient and outpatient rehabilitation.

Documentation

- Provide any standardized discharge and disposition pathways applicable to EGS patients
- Provide any existing transfer agreements with post-hospitalization disposition facilities
PC.10 Readmission and Transfer Protocols

Definition and Requirements

When the patient's needs for definitive care exceed local resources, the hospital must have a transfer protocol and agreement with a hospital that is resourced to provide a higher level of care, if needed. These may include patients with:

- Physiologic instability, including:
  - Systolic blood pressure < 90mm Hg despite 2L fluid
  - Need for vasopressors to keep systolic blood pressure >90mm Hg
  - Altered mental status
  - Lactate > 4 despite 2L fluid
  - New onset oliguria or anuria despite 2L fluid
  - Laboratory values concerning for acute end-organ failure

- High-grade disease (AAST Grades IV and V)
- Extremes of age and/or frailty
- Significant comorbidities (such as a history of transplantation, immunosuppression, or end-stage disease)

There must also be a written protocol with all transferring and receiving hospitals that includes the following:

- The transferring hospital must initiate and ensure direct communication between transferring and receiving physicians and ensure an appropriate transportation mode to the receiving hospital
- The transferring hospital must provide all necessary medical documentation, including test results and radiology images, to the receiving hospital by the time the patient arrives at receiving hospital

The hospital must also be capable of receiving patients for readmission 24/7/365, regardless of condition. Where patients are known to a specific hospital or hospital system, efforts must be made to readmit and/or transfer the patient to the known destination hospital. Circumstances preventing such readmission or transfer may include:

- The hospital where the original surgery was performed is at capacity and the hospital where the patient is currently located has technical expertise and capability to care for the patient
- The hospital where the original surgery was performed does not have the technical expertise and capability to treat the complication

In any situations where the patient is not readmitted to the primary hospital, there must be robust communication between the surgical team at both institutions to facilitate timely and appropriate care.

Documentation

- Provide all written transfer policies with both sending and receiving hospitals
- Provide transfer protocol for patients requiring a higher level of care, if applicable

Resource

Data Surveillance and Systems (DSS)
In addition to capturing required safety measures, adverse events, and clinical outcomes, exemplary hospitals will have methods and protocols for capturing and reviewing EGS-specific process measures and patient-reported outcomes (PROs). These measures should be available for review by the EGS Committee at set intervals and used to develop quality improvement initiatives.

While it is recognized that not all hospitals will participate in a formal registry at the time of initial verification, it is expected that all hospitals will be able to meet registry data collection requirements within one year of their first verification site visit.

**Documentation**

- Provide the most recent (patient deidentified) data reports from each registry or data source the hospital monitors for quality improvement purposes, including patient experience data, hospital-wide event reporting, surgical outcomes data, and EGS-specific data
- Provide the Data Collection Pre-Review Questionnaire table for all measures not captured in data/registry reports requested above
- Provide the hospital's policy/training on reporting quality and safety events
- Provide the hospital's process for identifying EGS cases, inclusive of both operative and non-operative, including the source(s) used
- Provide the hospital's written protocol for patient follow-up
- Provide the hospital’s protocols and methods for developing, tracking, and evaluating process and patient-reported outcomes measures, if any

**Resources**


**Surveillance of Emergency General Surgery Data**

**Definition and Requirements**

The EGS Committee must have a defined process for data review and list of adverse events that are monitored on an ongoing basis. At a minimum, these events must include:

- All mortalities (in-hospital and within 30-day of discharge)
- Transfer out to a higher level of care
- Unexpected return to the operating room within 30 days of discharge
- Unplanned readmissions within 30 days of discharge
- Emergency Department visits within 30 days of discharge
- Transfer to hospice care
- Significant complications (to be defined locally)

**Documentation**

- Provide documentation regarding processes for data review and capture of adverse events within EGS
- Provide any documentation defining additional significant complications
Quality Improvement (QI)
QI.1 Quality Assessment and Improvement

**Definition and Requirements**

There are dedicated and sufficient resources to support formal quality and process improvement based on high-quality, reliable data specific to the Emergency General Surgery (EGS) program.

The hospital must demonstrate how it uses various data sources to monitor for, identify, and conduct formal quality improvement (QI) activities specific to the EGS Program. The hospital must show evidence of established processes for using objective, risk-adjusted, and externally benchmarked data to drive quality improvement efforts led by the EGS Medical Director. Formal quality improvement initiatives must include and document the following:

- Identification of a problem using case review, registry information, or other high-quality data sources
- Propose an intervention using standardized QI methodology and tools (such as LEAN Six Sigma, DMAIC, and RCA)
- Implement an intervention using objective data to monitor progress
- Share findings and results of the QI initiative with stakeholders
- Continue active surveillance to sustain improvement

The EGS Program is expected to continuously engage in quality improvement initiatives. The program must be able to demonstrate at least one quality improvement initiative annually based on a need or issue identified in EGS care.

**Documentation**

- Provide examples of EGS QI initiatives from the previous year by completing the EGS QI Projects Pre-Review Questionnaire Table
QI.2 Case Review Process

Definition and Requirements

There is a standardized, documented process for formal retrospective case review within the EGS Program to monitor adverse events, assess compliance with protocols, and identify opportunities for improvement and standardization.

The EGS Committee has established and standardized processes for case review that are distinct from a typical morbidity and mortality (M&M) conference and include, but are not limited to, the following:

1. Establishment of a set of defined, explicit criteria to identify possible cases for review (such as individual reporting, near misses, reporting system, and registry)
2. Selection of cases for review based on standardized criteria (see Standard DSS.2) and through periodic random selection
3. Use of a standardized process for case reviews/evaluation and documentation of review and resolution
4. Integration of resolutions and findings with quality improvement activities and clinical care
5. Maintenance of surveillance of identified issues

All EGS cases meeting the criteria listed in Standard DSS.2 must be presented. EGS surgeons must attend a minimum of 50% of all retrospective case review conferences per year if they occur monthly or 75% if they occur bimonthly or quarterly.

The case review process should ensure that the hospital has standardized processes for identifying problems (for example, surveillance mechanisms), reviewing the problems and identifying underlying system-level causes (for example, quality conferences), and preventing similar problems in the future (for example, feedback and education).

Documentation

- Provide documentation of meeting occurrences and EGS surgeon attendance
- Provide case review template (use of a template is suggested but not required)

Resource

QI.3 Peer Review Process for the Individual Surgeon

**Definition and Requirements**

The EGS Committee in conjunction with the hospital’s peer review oversight committee has established and standardized processes to monitor and address quality and safety issues with the individual surgeon through a formal peer review process that respects the patient, institution, and individual surgeon. The peer review committee may be organized according to locally defined rules and structures, but must be composed of sufficient membership to ensure clinical knowledge and diversity of specialization relevant to the area of review.

This process aims to ensure that the hospital has standardized capabilities for identifying and remediating individual surgeons who may be experiencing challenges or need support at any point in their tenure.

Exemplary facilities will have evidence of a robust review process using data to evaluate individual performance by benchmarking to accepted standards and peer performance. The review should occur on a regular and specified schedule to ensure favorable patient outcomes and compliance with standard protocols and pathways. When an issue with individual performance is identified, there are timely procedures in place to ensure patient safety and respectful remediation through mentorship, proctoring, and/or additional education. There are also policies and procedures in place to address the following:

- Safe transition out of practice for the aging surgeon
- Management of disruptive surgeon behavior
- Surgeon/provider wellness programs
- Second victim support for the surgeon and other providers who have experienced a sentinel event or other significant events

**Documentation**

- Provide all policies and procedures pertaining to the peer review process
- Provide the policies/processes for addressing issues such as disruptive behavior, aging surgeons, and surgeon wellness programs

**Resource**

QI.4 Quality Improvement Collaborative Participation

**Definition and Requirements**

Involvement in an EGS–specific state-wide, regional, and/or national collaborative is highly recommended. The collaborative activities must allow for sharing of hospital-level data to identify quality improvement areas and improve access to care for EGS patients. Participation should include at a minimum annual attendance in a collaborative meeting.

**Documentation**

- Provide a listing of any local, regional, and/or national collaboratives in which the EGS Program participates
- Provide recent collaborative data reports (from the previous 12 months) used within the EGS Program, if any

**Resource**

AMERICAN COLLEGE OF SURGEONS
EMERGENCY GENERAL SURGERY VERIFICATION PROGRAM

Education: Professional and Community Outreach (EDU)
Patient Advocacy and Education

Definition and Requirements

Emergency General Surgery (EGS) programs should educate primary care physicians and other providers on the identification and timely diagnosis of EGS conditions to avoid delays in transfer and intervention. The EGS Program must offer one or more education, prevention, and/or early detection programs annually. These programs may take place on- or off-site and may be coordinated with other facilities and/or local agencies.

Documentation

- Provide documentation of educational activities conducted within the previous 12 months, including location of activity and primary audience
Research: Basic and Clinical Trials (RES)
Clinical Trials and Scholarly Activities

Definition and Requirements

**Patient access to research and clinical trials:** Information about the availability of applicable clinical trials is provided to patients through a formal mechanism, such as:
- Pamphlets or brochures in patient packets
- Physician- or nurse-led patient education

**Participation in research:** Hospitals providing treatment to a high volume of Emergency General Surgery (EGS) patients at all acuity levels are encouraged to innovate and advance surgical care through research and other scholarly work. Such activities also serve to develop new leaders in the field of emergency general surgical patient care. Scholarly activities may take the form of:
- Publication of a peer-reviewed article in the previous 12 months
- Participation as a visiting professor or invited speaker at a regional, national, or international EGS conference in the previous 12 months
- Involvement in other research-related activities, including conference attendance, serving as an academic journal reviewer, and participation as a clinical trial site

Documentation

- Provide evidence of current Institutional Review Board (IRB) protocols, if any
- Provide a listing of clinical trials and the number of patients accrued in the previous 12 months, if any
- Provide a list of peer-reviewed publications for the previous three years, if any