



# Entrustable Professional Activities

## EPA 2 for Pediatric Hematology-Oncology

### EPA 2: Enroll and Treat Patients on Clinical Research Trials

#### Supervision Scale for This EPA

1. Trusted to observe only
2. Trusted to execute with direct supervision and coaching
3. Trusted to execute with indirect supervision and discussion of information conveyed for most simple and some complex cases
4. Trusted to execute with indirect supervision but may require discussion of information conveyed for a few complex cases
5. Trusted to execute without supervision

#### Description of the Activity

Clinical research trials have played a key role in improving outcomes for children with hematologic and oncologic disorders.

Participation is in many ways considered standard of care for these patients. Thus, it is essential for pediatric hematology/oncology subspecialists to learn the skills necessary to properly enroll and treat patients on clinical research trials.

The specific functions which define this EPA include:

1. Reviewing and selecting the appropriate clinical research trial to offer a given patient
2. Explaining details of a clinical research trial to patients and families of varying educational backgrounds
3. Obtaining informed consent for participation on a clinical research trial
4. Fulfilling all requirements necessary to enter a patient on a clinical research trial
5. Properly adhering to study requirements and reporting adverse events as indicated
6. Ensuring patient safety and recognizing when the best interest of the patient necessitates deviation from the study protocol

#### Judicious Mapping to Domains of Competence

- Patient Care
- Medical Knowledge
- Practice-Based Learning and Improvement
- Interpersonal and Communication Skills
- Professionalism
- Systems-Based Practice
- Personal and Professional Development



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### Competencies Within Each Domain Critical to Entrustment Decisions

PC 1:	Gathering information
PC 7:	Developing management plans
PC 11:	Using information technology
MK 2:	Practicing EBM
PBLI 10:	Engaging in lifelong learning
ICS 1:	Communicating with patients/families
P 2:	Demonstrating professional conduct
SBP 2:	Coordinating care
SBP 5:	Working in interprofessional teams
PPD 8:	Dealing with uncertainty

### Context for the EPA

**Rationale:** Great strides have been made in the treatment of children with cancer and blood disorders over the past several decades, leading to significant improvements in cure rates for many diagnoses. These improvements have in large part been due to participation of a high percentage of these patients on clinical trials designed to assess and directly compare the current standard treatment with an experimental treatment. To continue to make these advancements, it is critical that trainees in pediatric hematology/oncology understand the importance of properly conducted clinical research to our field, acquire the necessary knowledge and skills to enroll and treat a patient on a clinical trial, and, to the extent possible, have their patients actively participate on clinical research trials.

**Scope of Practice:** Scope of practice involves any child from birth to young adulthood who has been diagnosed with a cancer or blood disorder and who may be eligible for participation on a treatment study. It will require that the pediatric hematologist/oncologist practice at an institution that is able to provide the support needed, such as a functioning institutional review board and adequate research assistant support, to meet the requirements and regulations necessary to open and successfully run treatment studies. Since pediatric cancer is a rare disease and it is difficult to successfully carry out single-institutional research studies, it is important that the institution is able to collaborate with other institutions and participate on multi-institutional studies, through such organizations as the Children's Oncology Group.

### Curricular Components That Support the Functions of the EPA

1. Reviewing and selecting the appropriate clinical research trial to offer a given patient
  - Makes a specific diagnosis of a hematologic or oncologic disorder in a patient and is able to generate a treatment plan based on the best available current evidence
  - Recognizes when a patient may qualify for a clinical research study that offers a promising experimental therapy or provides the opportunity to participate in other nontreatment-related research to advance the field (e.g., a tissue banking study, a supportive care study, a quality of life study, or a survivorship registry)
  - Accesses the appropriate entities (Children's Oncology Group, National Cancer Institute, other organizations as indicated, as well as local resources) to identify any relevant treatment studies to offer a patient



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- Discerns which studies are appropriate to offer and prioritizes studies based on study availability, patient eligibility, scientific rationale, and quality of the evidence, taking into account the patient's priorities and goals
  - Recognizes when a treatment study is not available, how and when it is appropriate to treat according to a previous study and what adjustments need to be made in that case (e.g., knowing which labs or imaging studies are related to a study question and not indicated for patients treated off study, recognizing which arm of the study was most successful and should be followed)
2. Explaining details of a clinical research trial to patients and families of varying educational backgrounds
    - Knows and fully understands and can explain the details of a treatment protocol, explaining the background and rationale, study objectives, study structure, treatment arms, outcomes to be measured, and potential risks and benefits
    - Interprets the essentials of the study in layman's language to a patient in a way that they can easily comprehend, using written and visual aids as indicated
    - Effectively explains and demystifies for the patient the concept of randomization, if indicated by the study design, as well as other concepts related to clinical research such as clinical equipoise, standard of care, stopping rules, and DSMBs
    - Effectively tailors the discussion to the particular needs and concerns of the patient, taking into account their level of medical literacy, belief system, and cultural background
    - Offers and effectively utilizes an interpreter as needed when English is not the patient's preferred language, appropriately documenting the encounter in the medical record
  3. Obtaining informed consent for participation on a clinical research trial
    - Demonstrates awareness of patient rights and protections and the role of the IRB in ethical clinical research, fully appreciating the importance of a proper and thorough consent process in clinical research
    - Supplies the patient and family with sufficient information and time to fully comprehend the risks and the benefits of participation on a particular study so that they are able to make a truly informed decision
    - Avoids pressure or coercion in seeking to obtain consent
    - Properly completes the necessary paperwork to document that informed consent (and, when appropriate, assent from a patient who is a minor) has been obtained
  4. Fulfilling all requirements necessary to enter a patient on a clinical research trial
    - Effectively evaluates and interprets a protocol's inclusion/exclusion criteria to determine that a patient is eligible for participation
    - Determines and obtains the baseline laboratory and imaging studies required for study entry
    - Properly documents what is required for the study in the patient's medical record
    - Works effectively and collaboratively with the research team to assure that all requirements are being properly met
  5. Properly adhering to study requirements and reporting adverse events as indicated
    - Reads and follow a treatment roadmap, obtaining necessary studies at the required time points
    - Accesses the common terminology criteria for adverse events to evaluate and grade any suspected toxicities of therapy



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- Promptly reports any significant adverse events or deviations from the study
  - Interacts regularly with the study chair as needed to obtain clarification regarding study requirements or to discuss patient management
6. Ensuring patient safety and recognizing when the best interest of the patient necessitates deviation from the study protocol
- Uses clinical judgment to assess when the needs and safety of the patient outweigh the needs and requirements of the study
  - Knows and understands and follows the stopping rules for a study

### EPA Authors

Mark P Atlas, MD (lead), Alexander Chou, MD, Tim Garrington, MD, Michelle Hermiston, MD, PhD, Rima Jubran, MD, MPH, MACM, Jennifer C. Kesselheim, MD, EdM, Richard L Tower, MD, MS

### Curricular Components Author

Tim Garrington, MD, Mark P Atlas, MD, Julie Krystal, MD, MPH, Michelle Hermiston, MD. PhD