Clinician Responsibilities When Participating in Expanded Access Programs

This FAQ provides guidance to treating physicians who are interested in participating in Expanded Access Programs ("EAPs"). Refer to documents under Clinical Guidance: Research & Investigational Treatments on the COVID Pulse site for definitions and details pertaining to specific expanded access programs that are activated at various ministries.

What should a treating physician do prior to contacting a company for possible participation in an EAP?
The treating physician should contact the local Institutional Review Board (IRB) as well as the Institutional Official (CMO, CEO) at the ministry to determine whether there are sufficient resources and a local research infrastructure in place to support participation (e.g., investigational pharmacy, consenters, nurses, data collectors). If the treating physician is required to sign any documents prior to initiating the EAP at the ministry, the treating physician should confirm with the Institutional Official prior to signing any such documents and obtain a delegation of signature authority (if required by local governance policies).

Does the treating physician need to contact the local IRB and local legal counsel even when the EAP has a 'central' IRB providing oversight of the EAP?
Yes. In some cases, the EAP will require that all participating sites rely on a national or regional IRB for the necessary IRB review and approval (also called a “central IRB”). This may require an agreement between the ministry’s IRB and the central IRB to document the ceding of authority to the central IRB (also known as an “IRB Authorization Agreement”). If the EAP requires the use of a central IRB for review and approval, contact your local IRB Chair, IRB Administrator, and local legal counsel prior to participation in the EAP to determine whether an IRB Authorization Agreement is also needed.

Are EAPs considered 'research'?
No. Although an EAP is not considered research, it still must meet certain requirements under the Food & Drug Administration's (FDA) research regulations. Many EAPs involve the use of a test article (e.g., a drug, device, or biologic) that has not yet received approval from the FDA. Per the FDA, any use of a non-approved test article in an EAP is considered investigational.

What experience does the treating physician need to have prior to participating in an EAP?
In order to properly supervise the use of the test article, the treating physician should have the requisite scientific training, knowledge, and experience. This is a regulatory requirement. Typically, this training, knowledge, and experience comes from conducting clinical trials. Physicians who participate in EAPs should be familiar with the FDA and OHRP regulations, have completed CITI training, and / or have previous experience in conducting clinical trials.
What training and educational requirements does the physician have to complete prior to becoming a treating physician (investigator) in an EAP?

The physician must complete CITI training as assigned by Trinity Health / local IRB prior to becoming a treating physician in an EAP. For some ministries, the treating physician and the study team must complete CITI training in accordance with local IRB policy and procedures; check with your local IRB Administrator for guidance.

Does an IRB need to prospectively review before treatment under an EAP?

FDA regulations require that EAPs be prospectively reviewed and approved by the IRB before treatment with the test article may begin. Wide-spread Use EAPs typically have a protocol with an informed consent; both documents are to be reviewed (along with all other documents provided by the sponsor) and approved by the IRB before treatment may begin.

Does the physician who participates in an EAP have to follow the central IRB’s policies and procedures/instructions pertaining to informed consent, treating, dosing, data collection, reporting of adverse events, etc.?

Yes. The physician has to follow the central IRB’s policies and procedures/instructions pertaining to informed consent; treating; dosing; data collection, reporting of adverse events to the FDA, and all other regulatory requirements.

Is the local IRB allowed to make any amendments or changes to an informed consent of an EAP?

This varies and is dependent upon the EAP. Usually, the informed consent of the EAP has to be accepted as written. In certain EAPs, a cover page from the local IRB with local contact information is allowed to be added (For example, the Convalescent Plasma EAP allows for a cover page from the local IRB to be added to the informed consent).

In some instances, an amendment may need to be requested in order to ensure that the EAP is able to be conducted in accordance with the Ethical and Religious Directives for Catholic Health Care (ERDs). Your local IRB can assist you in determining whether any amendments are required to address the ERDs and communicate any requested changes (and proposed alternative language) to the central IRB.

References

