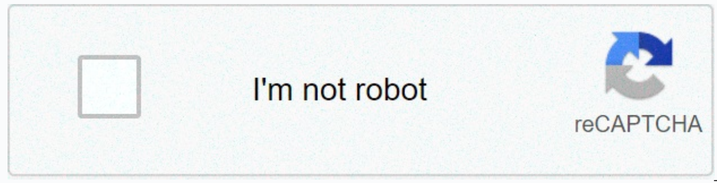

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Serious adverse event reporting guidelines

At Advarra, we often get questions about what events should IRB report. We understand that reporting events can be difficult: some of them are considered specifically in regulations; some of them are covered in normative legal documents; some of them must be defined by individual IRBs policies. In this blog post, we take a look at what regulations are doing and not talking about IRB reporting requirements and how Advarra has addressed some uncertain grey areas. In 2009, the FDA released a guidance document on adverse events reporting IRBs, which is designed to assist the research community in interpreting requirements to file reports of unforeseen problems, including certain reports of adverse events to the IRB. For research conducted under IND, the guidance states: Investigators are required to immediately notify the sponsor of any adverse effect that may reasonably be regarded as an induced, or likely caused, drug. If the adverse effect is alarming, the investigator immediately reports an adverse effect (21 CFR 312.64[b]). Sponsors are specifically required to report all investigators involved (and the FDA) in a written IND safety report any adverse experience associated with the use of the drug, which is both serious and unexpected and any findings from tests in laboratory animals, suggesting a significant risk to human subjects (21 CFR 312.32[c][s][1][a][a][A][B]] And, as a rule, sponsors are obliged to keep each participating investigator informed of new observations detected or reported to the sponsor about the drug, especially in relation to adverse effects and safe use (21 CFR 312.55[b]). Investigators are obliged to promptly notify the VRB... all unpredictable problems associated with risks for human actors or others, including adverse events to consider unpredictable problems (21 CFR 56.108[b][1], 21 CFR 312.53[c][c][1][vii], and 21 CFR 312.66). So what does this mean in practice? Investigators tell the sponsor: Any adverse event that is defined as caused (or probably caused) by the drug. Report sponsors to investigators and the FDA: Any adverse events involving drug research that are serious and unexpected, as well as any findings from the animal study that suggests a significant risk to human subjects. Sponsors should also keep investigators informed of any new sightings regarding the drug, especially adverse events and safe use issues. Investigators tell the IRB: All unpredictable problems related to risks to human actors or others, including adverse events, are unpredictable problems. Objective: Determining which adverse events should be considered unpredictable problems guaranteeing submission to the IRB. In addition to several serious, unusual adverse events, it is commonly considered to be strongly associated with drug exposure (e.g., Stevens Johnson syndrome, trauma anaphylaxis), single-/isolated adverse event reports usually make meet the criteria of the UPA. The FDA argues in its Safety Reporting Guidance Requirements for INDs and BA/BE Studies that the FDA believes the sponsor is better positioned than a separate investigator to evaluate the overall safety of the investigative drug because the sponsor has access to serious adverse event reports from multiple research sites and multiple studies and is able to aggregate and analyze those reports. In addition, the sponsor is more familiar with the mechanism of action of the drug, class effects and other information. For these reasons, investigators should immediately report any serious adverse event to the sponsor, regardless of whether the investigator considers the event drug-related (21 CFR 312.64[b]). What is an unpredictable problem associated with risks to human actors or others (UARP)? An unpredictable problem, or UPA, which is defined only in the FDA guidance, is: Unexpected (in terms of nature, severity or frequency) given the information provided in the documents related to the research and the characteristics of the subject population studied; Related or possibly related to participation in the study; and suggests that the study puts subjects or others at greater risk of harm than was previously known or acknowledged. This means that SAE is expected to be defined in the training documentation, but occurs with greater frequency or severity, as defined by the sponsor's assessment, should the IRB report as an unpredictable problem. But SAEs, which have been identified unrelated to the study, or are directly related to the subject's disease, should not be represented in the IRB. And for SAEs, where relatability has yet to be determined and further analysis is required, submissions to the IRB should only take place once it has been determined that SAE was linked to the test article. According to the FDA, [i]t it is important to note that some events that do not meet the criteria for reporting in the IND safety report will be treated as unpredictable risk problems for a person's subjects (e.g., informed issues of consent or confidentiality, certain adverse events that may not be caused by the investigating drug, such as events that occur before testing the administration of an article as a result of a period of rinsing or through a screening procedure). SAEs, which occur at other facilities and are provided to each investigator (such as IND security reports or suspected unexpected serious adverse reactions [SUSARs]), should only be presented to the IRB after the sponsor's assessment that the events (s) actually meet the criteria for an unpredictable problem. For multisite research, a sponsor typically reports an unpredictable problem on behalf of all sites. It is important to note that unpredictable problems will lie with the research, such as updating the protocol (e.g. additional security monitoring, updating the inclusion/exclusion criteria, etc.), changes to the ICF brochure and/or investigator, etc. (in 200 total) receive notification about the UPA promptly, but not later than 2 weeks or 10 working days from the moment of identification. In Advarra, when SAEs or security reports that do not meet the UAP criteria are submitted to the IRB, the submission party will receive confirmation of receipt only. The item will not be reviewed by the IRB. When these items are submitted by sponsor or CRO, Advarra's default process is to create a receipt confirmation for all open sites, although sponsors/CROs may opt out of this process. For specific Advarra reporting requirements, please refer to our IRB handbook available in the Advarra CIRBI Platform References section. Not sure if an event should be reported to the IRB? Ask the research coordinator for help. Back to resources Adverse event is any undesirable experience associated with the use of medical product in the patient. The event is serious and should be reported to the FDA when the patient outcome: Report death if you suspect the death was the result of an adverse event, and include a date if known. A life-threatening report if it is suspected that the patient is at significant risk of dying during an adverse event, or the use or continued use of a device or other medical product may have resulted in the patient's death. Hospitalization (initial or prolonged) Hospitalization report or continued hospitalization resulted from an adverse case. Emergency room visits that do not lead to hospitalization should be assessed for one of the other serious outcomes (e.g., life-threatening; necessary intervention to prevent permanent disorders or damage; another serious medically important event). Disability or persistent report of damage if an adverse event resulted in a significant violation of a person's ability to perform normal life functions, i.e. adverse event resulted in significant, sustained or permanent changes, disturbances, damages or impairments in the patient's function/structure, exercise and/or quality of life. Congenital anomaly/Birth defect report if you suspect exposure to a medical product before conception or during pregnancy can lead to adverse outcomes in the child. Mandatory Intervention to Prevent Persistent Impairment or Damage (Devices) Report if you believe that medical or surgery was necessary to prevent permanent impairment of body function, or to prevent permanent damage to body structure, any situation suspected through the use of a medical product. Other serious (important medical events) report when an event does not match other outcomes, but the event can endanger the patient and may require medical or surgery (treatment) to prevent one of the other outcomes. Examples include allergic brochospasm (a serious respiratory problem) requiring treatment in intensive care, serious blood discrases (blood disorders) or seizures/seizures that do not Hospitalization. The development of drug abuse or drug abuse will also exemplify important medical events. Resources for you

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