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CLINICAL RESEARCH

SAFETY CHECKLIST

Ensuring the safety of human subjects is a clinical research sponsor's most important responsibility. One needs only to look back to the history of clinical research to see many instances where researchers disregarded ethical practices and safety in the name of scientific advancements or personal agendas.

As a sponsor, how can you be certain your study progresses without unreasonable risks to subjects? How can you ensure investigative sites are taking all the proper precautions to protect human subjects?

FOLLOW THIS CHECKLIST FOR GUIDANCE.

IDENTIFY AND DOCUMENT SAFETY RISKS.

Prior to beginning your trial, take time to review your processes in detail and identify potential safety risks at every stage. Consider what could go wrong, what is the likelihood it will go wrong, what are the chances your team will be able to detect the issue, and what are the consequences? Also consider expected adverse events and risks associated with the investigational product and study procedures.

EVALUATE RISKS AND DEVELOP A PLAN FOR MITIGATING THEM.

Some risks are considered acceptable, while others are not.

The ICH Q9 standards for quality risk management advises clinical researchers evaluate each identified risk and determine:

- What is the acceptable level of risk for this study?
- Is the risk above an acceptable level?
- What can be done to reduce or eliminate risks?
- Are new risks introduced as a result of the identified risk being controlled?

As you evaluate risks, consider information from study team members, historical or pre-clinical data, and subject matter experts. Risks can be categorized using either a qualitative or quantitative scale. **Consider the use of safety oversight services to help mitigate potential risks.**

DETERMINE APPROPRIATE LEVEL OF SAFETY OVERSIGHT.

Many studies are required to have objective, third-party oversight from a Data Safety Monitoring Board (DSMB), Clinical Events Committee (CEC) or both. Beyond meeting basic requirements, these independent boards add a layer of patient protection and credibility to your research. The DSMB will review cumulative information from your study and monitor safety oversight throughout the trial, while a CEC will adjudicate specific adverse events and determine whether or not they are related to the study.

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SELECT YOUR DSMB AND/OR CEC.

Although these boards operate independently, they are effectively an extension of your study team and should be assembled with discretion.

Here are a few factors to consider as you select yours:

- Independence
- Relevant expertise
- Time and availability to fulfill duties
- Attention to detail
- Meeting flexibility
- Professionalism

DETERMINE HOW YOUR TEAM WILL MANAGE SAFETY OVERSIGHT ACTIVITIES

When it comes to managing your trial, you have more than enough to worry about. Overseeing your safety monitoring boards shouldn't be one of them. A Contract Research Organization (CRO) is one way to easily manage communications between your staff and your safety monitoring boards. It can offer another layer of independence to manage safety board member agreements, compensation and more, eliminating the potential for conflicts of interest. A CRO can arrange meetings and maintain required documentation for the safety oversight board, further ensuring the board's independence and objectivity.

IMARC has established an extensive network of physicians and specialists to offer safety monitoring so you can be confident in your study results. Our CRO will manage all administrative duties of safety monitoring, including assembling experts, arranging and documenting meetings and providing Sunshine Act financial reporting.

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TO LEARN MORE ABOUT OUR SAFETY MONITORING SERVICES, CONTACT US TODAY.