



IRB Tips for Success



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This is the second in a series of articles on “Finding the Right IRB.” It covers tips for successfully working with your institutional or independent review board (IRB).

Sponsors and contract research organizations (CROs) that assume legal responsibilities of project management and monitoring of investigator sites must step up their efforts to ensure that sites are trained in IRB requirements as outlined within the Food and Drug Administration (FDA) Code of Federal Regulations (CFR). Many IRBs, including accredited IRBs, also follow Good Clinical Practice

(GCP) and International Conference on Harmonisation (ICH) guidelines, which have been incorporated into the tables below.

Training on IRB requirements should include the following for sites, and occur prior to IRB submission.

General requirements for IRB submissions are listed in Table A. More specific requirements for drug and device

submissions are listed in Tables B and C. Table D provides typical IRB questions that apply to most research.

There are also specific requirements for drug submissions and device submissions that should be taken into account when preparing sites for IRB submission, submitted below as Tables B and C Questionnaire Checklist, respectively.

TABLE A – General IRB Requirements

Preparing the Sites	Special Instructions/Notes
Determine whether any part of the research will be conducted in a facility by a clinical investigator (CI) in which another IRB may have jurisdiction.	Facilities that usually have their own local IRB include universities, hospitals, and similar facilities that often host research studies. If the site is bound by a local IRB and wants to use a central IRB, then the applicable IRB jurisdiction transfer document will need to be approved by the Local IRB to allow the Central IRB jurisdiction.
Obtain all available information regarding IRB internal procedures and deadlines for submission of study documents including the Original Protocol, Protocol Amendments, Informed Consent form (ICF), Assent forms, HIPAA Authorization, Patient information and advertisements.	Knowledge of IRB procedures and deadlines allows for more efficient submissions and more rapid study start-up.
Ensure the applicable IRB templates for the ICF, Assent Forms (if applicable) and HIPAA authorization documents are used to develop the study-specific documents.	Using the most current IRB specific templates helps to prevent delays associated with multiple IRB review revision cycles.
Obtain the IRB specific language for the ICF and requirements for associated documents (e.g., memo, clinical study agreement) regarding compensation.	Some IRBs may require “formal” written agreements or documentation by the sponsor for the payment of research-related injuries.
Obtain a list of any necessary emergency equipment that may be required by the IRB to be at the site.	Depending upon study design and procedures, some IRBs may request that the site have specific emergency equipment at the site (eg, crash cart). Proximity to medical emergency facilities may also be an important consideration.
Become familiar with the IRB requirements for submission of reporting of Adverse Events, Serious Adverse Events and Protocol Deviations, Violations, and Exemptions.	IRBs have their own reporting requirements and procedures for reporting events and incidents. The reporting requirements generally include definitions or categories with guidance as to what types of events or issues must be reported to the IRB, and specific direction for how and when to submit the necessary information. IRBs are also required to have procedures that define prompt reporting of Unanticipated Problems involving risk to human subjects or others.
Become familiar with the IRB internal deadlines for submission of Continuing Review Reports and Final Reports.	Most IRBs have strict internal deadlines for submission of Continuing Review Reports and Final Reports. Compliance with the applicable deadlines ensures that site will avoid suspension, termination and/or being reported to the FDA for non-compliance. Resubmission of regulatory documents to the IRB can also be quite costly.

TABLE A – General IRB Requirements, continued

Preparing the Sites	Special Instructions/Notes
Be prepared to answer questions regarding state and local laws.	IRBs and study sites must also be compliant with all applicable state and local laws: • Applicable laws may include those governing the legal age requirement and authorization to consent on behalf of a child or using a legally authorized representative (LAR).

TABLE B – Drug Submission IRB Questionnaire Checklists for Sites

Preparing the Sites	Special Instructions/Notes
What is the funding source for the project?	IRBs will consider whether payment arrangements by sponsors, CROs, or investigators may place the participants at risk of coercion or undue influence. Typically, funding comes from either industry (pharmaceutical) or privately funded sources. Note that some IRBs will not review research for which the investigator holds the IND or for federally funded projects (eg, NIH, DOD, DOE, NCI) for which the researchers may directly receive funding.
Is an IND number required?	If an IND number is required, there are certain exemption criteria 21 CFR§312.2(b) that must be met to qualify. Be prepared with information regarding the IND number and IND Sponsor or to provide the evidence that an IND is not required. The sponsor may be able to provide additional information regarding the IND.
Has the study been previously submitted to another IRB? If so, what was the outcome in terms of review, approval or termination of the research?	If a study has been previously reviewed by another IRB, be prepared to submit copies of the outcome of another IRB’s review (eg, approval, refusal to review, or termination of research).
Is this a “first-in” human study?	The IRB is interested in this question because a toxicologist review may be required. The IRB will also want to know if there are no human data available to review.
Has the FORM FDA-1572 been completed by the site?	This form is required for “drug” studies only.
Is the study taking place in Massachusetts or California? If so, there are additional requirements.	Depending on the state the study takes place in, the IRB will require the following: • Researcher License • Drug Enforcement Agency (DEA) license for controlled substance • California Bill of Rights • Review by Research Advisory Panel of California (RAPC)
Does this study require review by a Data Safety Monitoring Board (DSMB) or Data Monitoring Committee (DMC)?	If a DSMB or DMC is used by the sponsor, the IRB may require additional information or documentation regarding the IRB (eg, Membership List or Charter).
Is the drug already approved by the FDA?	If the drug is FDA approved, be prepared to submit evidence of approval such as the Package Insert.



Preparing the Sites	Special Instructions/Notes
Is the device study being conducted under an Investigational Device Exemption (IDE) number? If so, who is the sponsor of the IDE?	Be prepared to provide evidence documenting the IDE number on some type of sponsor correspondence.
Who is funding the research submitted in the IDE?	Again, some IRBs will not review federally funded research.
Does the device meet the requirements of either an abbreviated IDE or IDE?	There are specific requirements to meet either an abbreviated IDE or IDE listed in [21 CFR § Part 812]. The IRB may require documentation from the FDA regarding the IDE number.
Has the FDA or another IRB already made a risk determination?	The IRB will require documentation if a risk assessment has been made.
Is there a charge to participants for using the medical device? Has the FDA agreed to the amount being charged?	If participants are charged for the device, the regulations require that the amount being charged must not exceed the cost of manufacture and testing.
Is a report of prior investigations available?	If yes, the IRB will require documentation regarding prior investigations.
Is there a manual available to the clinical staff and to the subjects about how to operate the device?	The IRB will review any information regarding the operation of the device for the research staff or the subject.

Preparing the Sites	Special Instructions/Notes
Is there proof of training and experience by the CI to conduct the research study?	IRBs want to ensure that CIs are qualified, adequately trained, and maintain proper oversight of the research. IRBs will require a current Curriculum Vitae and professional license for all CIs. In addition, many IRBs are requiring documentation of some type of human subject protection training.
What are additional considerations regarding the CIs and conduct of the research study at the investigative site?	The IRB will consider items such as: <ul style="list-style-type: none"> • Pending actions against CIs from the state licensing board or regulatory authorities. If applicable, be prepared to submit findings (eg, FDA-483) and corrective actions. • Properly trained and available investigative site <ul style="list-style-type: none"> ■ Adequate facilities and equipment ■ Access to adequate population
Is the site prepared to specify which types of consents are required, and do they have electronic versions available to submit?	The IRB must review and approve all Informed Consent documents, including separate Informed Consent documents for sub-studies, pharmacokinetic sampling, genetic testing, or other addendums.
How will the Health Insurance Portability and Accountability Act (HIPAA) authorization be submitted?	The IRB will want to know how the HIPAA authorization will be submitted, either as part of the Informed Consent or as a stand-alone document. Obtaining this authorization from each individual on the study is an investigator responsibility according to the “covered entity.”
Will translation of the documents such as the informed consent, patient questionnaires, diaries, or recruitment material be required? If so, into what languages?	IRB requirements regarding translated documents, certifications, and back-translations vary. Many IRBs do not accept pre-translated consents. This means that the IRB can have the document translated, once it has been approved by the board. A certification of translation is normally required.
Is assent of the subjects required?	The IRB will want to know at what age assent is required to be obtained. They may also ask whether legal guardians besides the subject’s parents may be used.

Preparing the Sites	Special Instructions/Notes
What type of recruitment material will be presented? Is it audiovisual or printed material?	The IRB must review and approve all recruitment material including audiovisual and printed material. Examples include: <ul style="list-style-type: none"> • Phone screening scripts • Questionnaires • Survey collections • Participant surveys • Patient incentives for recruitment • Research staff incentives for recruitment • Study diaries • Participant education material
What type of agreement or attestation is required of the CI by the IRB?	Some IRBs require the CI to agree or certify that the statements and information supplied to the IRB are a true and accurate representation of their commitment to follow the applicable FDA requirements and abide by IRB requirements.
What are the enrollment recruitment plans?	The IRB will require information regarding enrollment criteria concerning: <ul style="list-style-type: none"> • Approximate number of sites that will participate and anticipated number of participants per site • Expected enrollment start and completion dates • Anticipated length of study participation • Expected study completion date
How does the site protect the privacy of the research participants?	The IRB is looking for a plan to describe how research participant privacy and confidentiality will be protected during and after the study.
What is the population community from which participants are being recruited? Are participants from vulnerable populations being recruited?	The IRB will evaluate impact of the research upon participants and the affected community. Specifically, the IRB will be looking for populations that may be vulnerable to coercion or undue influence. The IRB is required to evaluate the equitable selection of participants from various populations and sub-populations to evaluate, whether including or excluding these subjects is fair and equitable. For example: <ul style="list-style-type: none"> • Research staff or their family members • Sponsor staff or family members • Homeless persons • Students • Restriction to recruitment of adult females or males • Adults with diminished cognitive ability • Nursing home patients • Children or children who are wards of the state • Patients who are unable to consent for themselves • Non-English speaking patients

In summary, using investigator sites that are competent and well informed about their obligations creates an open and honest environment for working together with the IRB and the sponsor or CRO to conduct research studies that follow the appropriate ethical standards and principles, are in compliance with applicable FDA regulations, ICH GCP guidelines, and provide for the best protection of the human research participants.

Acknowledgements: The author would like to acknowledge Kathy Bohannon, Director, Clinical Trial Management, Premier Research Group, Limited, and James Ottinger, Vice President, Global Compliance and Consulting, Premier Research Group, Limited, for their assistance in reviewing this article.

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