

## Investigator Qualifications and Provision of Medical Oversight

As part of its review, the IRB considers the qualifications and overall staffing adequacy of the research as described by the Principal Investigator (PI) in the IRB application and the Signature Assurance signed by the Department Chair or Faculty Advisor. Unless a study submitted to the Medical IRB is non-interventional, (e.g., survey, record review, or purely outcomes research), some form of medical oversight may be necessary. However, the degree and level of expertise needed can vary depending on risk level, condition, study population, applicable regulations, and external oversight (e.g., sponsor monitor; mentor). For greater than minimal risk protocols involving potential medical determinations someone with appropriate level of medical expertise would need to assume the responsibility for medical oversight.

### What are the UK IRB's expectations regarding qualifications and provision of medical oversight?

The following excerpt from the [University of Kentucky \(UK\) IRB PI Responsibility Guidance \(D9\)](#) outlines qualifications and oversight expectations:

*Investigators must be qualified by education, training and experience to assume responsibility for the proper conduct of human subject research.*

1. *Investigators are responsible for being able to provide evidence of such qualifications through up-to-date curriculum vitae and/or other relevant documentation requested by the IRB, funding agencies, and/or regulatory agencies.*
5. *Qualified physicians (or dentists, when appropriate) who are investigators or subinvestigators are responsible for all research-related medical (or dental) decisions.*

The following excerpt from the [UK Internal Prompt Reporting Form](#) provides assurance of review by a qualified physician:

***For Clinical Studies where the Principal Investigator (PI) is not a physician:***

*If this report is for a clinical study and the Principal Investigator (PI) is not a physician, a sub-investigator who is licensed to recognize, diagnose, and treat adverse events (e.g., MD or DMD) must review this report, and you, the PI, must confirm that an MD/DMD sub-investigator has reviewed and acknowledges the contents of this report:*

### What are the FDA's expectations regarding qualifications and provision of medical oversight?

The [Good Clinical Practice \(GCP\) Guidelines](#) state that each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).

The FDA regulations do not require that the investigator be a physician. Investigators must be qualified by training and experience as appropriate experts to investigate the drug (21 CFR 312.53(a)). In the event the clinical investigator is a non-physician, a qualified physician (or dentist, when appropriate) should be listed as a sub-investigator for the trial and should be responsible for all trial-related medical (or dental) decisions.

### What are FDA's expectations for IRB review of Investigator Qualifications?

Expectations are outlined in the FDA Guidance, [Guidance for IRBs, Clinical Investigators, and Sponsors IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed](#).

In regard to IRB review, the guidance states:

*Although FDA's regulations place responsibility on the sponsor to select clinical investigators who are "qualified by training and experience as appropriate experts" to investigate the test article, IRBs also have a role in reviewing an investigator's qualifications. In assessing investigator qualifications, the IRB may consider credentials, licensure, training, expertise, experience, and/or inspection history.*

The PI answers questions regarding study personnel qualifications and experience relative to an FDA regulated product in the Drug and Device section of the UK IRB application.

In regard to third-party assurance, the guidance states:

*The IRB may be able to obtain a statement regarding the investigator's qualifications from the chair of the investigator's department.*

By reviewing the IRB application and signing the Assurance statement, a UK Department Chairperson has assumed certain responsibilities, one of which is research and study personnel qualifications:

*Qualifications The Chair has ensured that the researcher(s) has sufficient time to conduct and complete the research and that persons listed as study personnel on the research protocol have the proper expertise and training necessary to carry out the research being proposed. The Chair has also ensured that the investigator must also have an appropriate number of qualified staff that are adequately informed about the protocol and their research related duties and functions. When an investigator assumes a sponsor function, the Chair ensures that the investigator is knowledgeable of the additional regulatory requirements of the sponsor and can comply with them.*

In cases where the UK IRB will serve as the relied-upon IRB for oversight, non-UK personnel qualifications and medical oversight will be addressed in the applicable agreement. The non-UK institution may attest to, or provide verification of adequacy to execute the protocol requirements. See the [UK Off-Site Research](#) website for details.

## What are FDA's expectations regarding delegation of procedures?

The FDA Guidance, [Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects](#) defines expectations regarding appropriate task delegation. The investigator should ensure that any individual to whom a task is delegated is **qualified by education, training, and experience** (and state licensure where relevant) to perform the delegated task (per FDA Investigator Guidance 2009). In addition, the investigator would need to ensure that the delegation is consistent with any specifications in the research protocol or stipulations by the IRB.

The PI may consider:

- if the task is within the scope of that person's professional licensure, if the task requires a license;
- whether the protocol specifies who should conduct a specific procedure; and
- if the IRB has additional stipulations based on any variable, including its knowledge of investigator history.

A PI, for example, may delegate physical exams to a nurse practitioner, advanced practice nurse, or Physician's Assistant (PA) if task is within his/her scope of practice in that state, the protocol does not specify and the IRB does not stipulate who performs the task.

In all cases, a qualified physician (or dentist) should be responsible for all trial-related medical (or dental) decisions and care. Therefore, a PI could not delegate investigator tasks involving such medical

determinations (i.e., unanticipated problem or adverse event assessment; inclusion/exclusion determination; taking subject off investigational product).



## Resources for state license validation and UK Provider Directories

- ◆ Validation of Kentucky Board of Medical Licensure:  
<http://web1.ky.gov/GenSearch/LicenseSearch.aspx?AGY=5>
- ◆ Other Kentucky license validation (P.A., Surgical Assistant):  
<http://kbml.ky.gov/Pages/index.aspx>
- ◆ UK Healthcare Provider Directory:  
<http://ukhealthcare.uky.edu/doctors/>
- ◆ UK Advanced Practice Provider Directory;  
[Advanced Practice Provider Directory | UK Healthcare \(uky.edu\)](#)