Role Of Sub investigators In A Clinical Trial Team

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Sub investigator

Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform clinical trial related procedures and/or to make important trial related decisions

Usually two in each trial who share equal responsibility
The term sub-investigator is more vague than the term PI

This term is commonly used to refer to any member of the study team other than the principal investigator.

In general, sub-investigators are members of the study team who assist the investigator with the study and can make decisions about the clinical research.
sub-investigator term should be limited to people who can make study-related decisions regarding the diagnosis and treatment of the disease or condition under investigation.

However

Medical professionals who provide service to research subjects during a study, but who do not make study-related medical decisions under the protocol should not be identified as sub-investigators.
In other words, the Sub-investigator is the responsible person who assists the investigator to conduct the study and make decisions about the research.
As an example, consider a study of a new immunosuppressant medication that requires baseline and end-of-study chest x-rays of all research subjects.

The chest x-rays required by the protocol are standard two-view films. According to the study protocol, the radiologist who reviews the films and dictates reports does not make study-related medical decisions. In fact, the radiologist is not likely to know that the films are even related to a research study.
In this case, the radiologist’s role would be only that of radiologist.

Such persons would not be named as sub-investigators because they will not make study-related decisions under the protocol.
Who can be a Co-PI?

Persons eligible for designation as PI are also eligible to be designated as Co-PIs.
No undergraduate or graduate students may be designated as Co-PIs.
Persons who are located at other universities and University may not be designated as Co-PIs
General Qualifications

- An appropriately qualified person (MD, PhD)
- Trained and experienced in clinical research
- Familiar with the background of the study drug and requirements of the study
- Have high ethical standards and professional honesty
Job Description

He/she Acts as the secondary physician in medical and clinical issues, as requested or required.

He Works with the Principal Investigator to evaluate clinical trials and ensure that all study-related procedures are completed.
Responsibilities

• Screen and recruit patients
• Obtain informed consent from potential study subjects
• Confirm eligibility of study subjects
• Sign prescriptions
• Clinical examinations,
• Evaluate laboratory and other medical reports.
• Supervise administration of study drug
Maintain accurate accountability for all clinical supplies received by site

Observe, measure and record effects of drug

Evaluate, manage and report all adverse events

keep and make study documentation available for data verification purposes
There are 3 types of subinvestigators:

1. The first type is a “junior sub investigator”:

   This type of sub investigator may serve as the PI’s second in deciding, or have responsibility for a subset of subjects

   but under the PI’s supervision.
The second type is a "specialist investigator" who performs technical tasks, such as medical procedures, tests and assessments that require special experience.

The PI may or may not have the same expertise. If not, the presence of the sub investigator completes the set of qualifications that the study needs to be conducted. For example, an medical oncologist may be qualified to be a PI on a pain study, provided a neurologist is a sub investigator.
The third type of sub investigator is a “backup investigator”

This type of investigator fills in when the PI is unavailable, e.g., busy with clinical patients or attending a meeting.

Most studies should have at least one such sub investigator as a backup to the PI. However, backup sub investigators cannot solve the (PUZZLE of study)
Thank you !!!