

IRBs Under Fire: The Rising Number of Clinical Research Studies Means More Risks

IRBs, independent review board, are the lynchpin in our system of medical research. They facilitate and oversee paid clinical trials and every type of [medical study](#) for an enormous variety of pharmaceutical companies, as well as device managers, institutions and physicians. The health care industry as a whole has been growing rapidly during the past years, necessitating ever increasing numbers of clinical research studies, [human drug trials](#) and medical research trials. IRBs are under ever greater pressure to meet the oversight needs for the growth in medical research.

Furthermore, with the specific growth in biotechnology and its attendant clinical research, IRBs are squeezed harder on two opposing sides. First, pharmaceutical companies and other parties wishing to conduct medical research need ever larger numbers of human trials, which they want to have overseen in as timely and efficient a manner as possible. On the other side, IRBs need to be ever more vigilant in their protection of human subjects for those trials. Allegations of failure to fully obtain consent from human subjects, of failure to fully protect those participants in studies such as human drug trials from unreasonable harm, and of conflicts of interest are on the rise.

Let's take a look at each of those allegations, one by one. First, IRBs must consistently make sure that every single participant in human trials for all types of clinical research grants truly informed consent. The first place to insure the protection of human subjects is by making sure that they are aware of all known potential risks. Furthermore, IRBs must verify that the participants have given their informed consent after fully comprehending what was explained to them—that they were educated in language they understood, not technical jargon.

Moving on to the allegation of failing to protect participants from unreasonable harm—one of the most important functions for an IRB is to use its expertise to vet potential clinical research studies so that protection of human subjects is paramount and the protocols are in place to effect it. As the workload for IRBs increases, it's vital that the quality of their oversight in no way diminishes. The initial review of clinical research studies must be thorough and ongoing reviews should be performed conscientiously.

Finally, in response to the increasing questions as to whether IRBs are suffering from ever greater conflicts of interest, IRBs must be vigilant in the application of their protocols to determine potential conflicts of interest in all the clinical research studies they oversee: both the personal type of conflict of interest, such as when a member of the IRB has a connection to an academic institution performing human trials, and potential financial conflicts of interest. As the health care industry grows, the possibility of financial conflicts of interest grows alongside it. IRBs need to be vigilant not only of conflicts of interest that might exist among those performing the research, but also potential conflicts of interest for members of the IRB itself.

If the oversight of medical research falters or breaks down, the very foundation of our health care system will crumble. It is crucial that the oversight IRBs provide to medical research trials, at this time of greater growth and bigger risks, is sound.