Irb guidance

Health & Medicine

Drug research and development are an essential part of the medical and pharmaceutical company today and therefore each step has to be taken cautiously to keep the process flawless and thereby maintain the efficiency of the system.

The system is rendered useless if there are fingers being pointed at the preciseness and the authenticity of the outcome of the research. Issues may crop up related to the research due to a difference in the interest of the scientists and the financial interests of researchers in the study, thereby making it theresponsibilityof the staff or the pollster to make others aware of the underlying rift in the interests of the two.

The function of thefoodand drug administration (FDA) is to gauge the researches that are requirements of the law needed for the development of new medicines and other similar products and to apply for re-categorizing medical instruments and gadgets, together with upgrading the image of these products.

Moreover it minutely scrutinizes each and every detail of the data put forth so as to be sure that the research had been done with the required steps so that the study is neutral.

The other duty of the FDA is to remain fully aware of the benefit of the sponsors and the clinical investigators, and the reason why the study is being carried out, and therefore analyze if both are appropriate to each other or not. It even keeps a check by visiting the sites to be sure about the authenticity of the results. (Source: Good Clinical Practice Regulations)

The secretary of the US department of theHealthand Human services, Tommy G Thompson has stated that the best way to preserve the efficiency of the research is by maintaining the ethics in the study, and the preeminent way to do this is by keeping nothing hidden from all the elements involved in the research, Therefore, shielding all the subjects in the study.

There is a report by the name of " Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection" which is followed by the HHS and FDA in all the researches that they undertake, aimed at providing a written guidance about the rights of all the human subjects that are a part of the study. (Source: HHS Provides Guidance on Financial Relationships and Interests in Research Involving Human Subjects)

The other issue that comes forth is the imbursement to the people taking part in the study. It has been known that the subjects have been paid, but on what grounds, that still is questionable as any written proof on this subject matter has yet not been found.

Even the federal and the experts of the field (being researched) do not see eye to eye on this matter. This is where the Institutional Review Boards step in.

These agencies are aimed at ensuring that no harm what so ever is caused to the subjects of the research and that they were not brain washed or coerced to be a part of the study and that it was solely their decision to participate. (Source: National practices regarding payment to research subjects for participating in pediatric research)

There are however certain rules that have to be abided by when it comes to paying the subjects. Firstly that the payments should be made in bits as the study progresses, however if any of the subjects back off before the completion of the research in that case the payment should be made at the time that had been promised to them had they not backed out.

Moreover a check should be made that incase if an additional benefit is to be given to the subject, then it should not be a handsome amount so that it holds the subject back to remain in the research out of greed who would have otherwise not been a part of any longer therefore every monetary dealing should also be documented and written in the approval. (Source: National practices regarding payment to research subjects for participating in pediatric research)

References

US Food and Drug Adinistration (2006). Good Clinical Practice Regulations. Read the sections in part 312 related to financial disclosure (part 54). Retrieved on July 24, 2008 from http://www. accessdata. fda. gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch. cfm? CFRPart= 54

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