INVESTIGATOR/STUDY TEAM CONCERNS

4/18/2021

In the course of conducting research with humans, a member of the DUHS research community, such as an investigator, study coordinator, member of the investigator's key personnel, or a colleague may have concerns or suggestions related to the DUHS human research protection program. These concerns and suggestions are welcomed by the HRPP leaders and staff since they provide a focused opportunity for improvement in the quality of our HRPP.

Members of the DUHS research community are encouraged to convey their concerns and suggestions to the Institutional Official (IO), Vice Dean for Clinical Research, Vice Dean for Scientific Integrity, the IRB Executive Director, the Lead IRB Chairperson, or another responsible individual as appropriate, such as the person's departmental chairperson or Clinical Research Unit (CRU) Director.

The recipient is expected to promptly acknowledge the contributor's concern or suggestion, and if it falls within the scope of the recipient's authority, to respond to it. If the concern or suggestion is within the scope of another person's authority, the recipient will forward the correspondence to that person, and inform the contributor.

When a concern or suggestion is sufficiently concerning or complex to require the input of several people, such as a problem requiring an interdisciplinary or interdepartmental solution, the IO and the Vice Deans will play a central role in resolving the concern or implementing the suggestion.

The CRU Director, IO, Vice Deans, IRB Executive Director, or an IRB Chair may request a formal audit, with defined scope, by Duke's Office of Audit, Risk and Compliance.

Previous Version Date(s): 11/12/2007, 6/7/2011, 3/1/2016