

QA Monitoring

QA Monitoring reviews both research and IRB management of studies to promote high quality, ethical research by facilitating the identification and resolution of compliance concerns and by identifying, disseminating, and promoting best practices.

Why Was My Study Chosen?

Receiving notification that a study has been selected for a monitoring visit does not imply that wrongdoing is suspected. Any research involving human subjects may be audited. Quality assurance and improvement activities are applied to all university researchers, departments, and units engaged in Institutional Review Board (IRB) approved human subjects research, including those whose research is conducted at non-university sites.

The following criteria increase the likelihood that a study will be reviewed:

- FDA regulated investigator-initiated studies
- Studies with more than minimal risk to participants
- Vulnerable participant populations (e.g., children)
- Investigators who are new to research
- No other monitoring in place
- High number of protocol deviations or unanticipated adverse events

The principal investigator will be notified of study selection by email once the monitoring visit is scheduled a letter will follow with details of the visit.

For additional information on Quality Assurance Activities, please contact:

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