



Oct. 19, 2021

## **Statement on notification of compliance with FDA regulations**

In 2019, the FDA inspected the research records of certain clinical research studies. The four studies inspected were originally undertaken to contribute to evidence-based medicine in the emergency care setting and ultimately to improve the emergency care provided to patients. These studies were no longer active at the time of the FDA inspection and they have been closed for several years.

At the end of the inspections, the FDA shared their observations and Hennepin Healthcare and the researchers provided responses to the FDA (2019). Since then, Hennepin Healthcare and researchers have taken many remedial steps to address the FDA's observations.

Earlier this year (2021), the FDA notified the researchers that the prior research under FDA review did not adhere to statutory and regulatory requirements governing the conduct of clinical trials. The researchers provided responses to the FDA and outlined the remedial efforts they've taken as well as the measures taken by Hennepin Healthcare to strengthen the clinical research program across the institution. Recently, the FDA has communicated that the measures taken result in compliance with FDA regulations.

Since the studies ended, Hennepin Healthcare System and the Hennepin Healthcare Research Institute have continued to strengthen the clinical research program institution-wide to ensure a culture of compliance and engagement in research-related community outreach, including:

- reviewed and strengthened the use of standardized protocol templates for all investigator-initiated clinical studies to ensure accurate and complete submissions to the Institutional Review Board (IRB)
- required institutional pre-review of all IRB submissions that involve investigator-initiated clinical studies
- re-educated IRB members, hospital staff, and clinical researchers on the proper and compliant conduct of clinical research
- instituted additional mandatory clinical research, human subjects protections, and Good Clinical Practice education for all new research staff
- added required training on cultural competency and implicit bias for all research staff;
- instituted the use of new checklists and guidance documents for the IRB and investigators to help ensure compliance, and updated the IRB's written procedures accordingly
- implemented an electronic IRB management system to facilitate compliant IRB review and processes
- established community advisory boards comprised of members who come from diverse personal, professional and community backgrounds, with a goal to improve community listening and engagement specific to under-represented populations
- developed in-hospital and online information mechanisms to notify patients and others in the community about the research being conducted by hospital physicians and researchers

Together with our community, Hennepin Healthcare is focused on relationship building and learning in order to continue to improve the health and wellbeing of those we serve through equitable and aligned policies, practices, and procedures.