VOLUME 9 | FEBRUARY 11, 2022

THE IAC BULLETIN

Updates from the Office of Internal Controls and Audit Compliance

What is the IRB?

The Maryland Department of Health's (MDH) Institutional Review (IRB) Board was established in 1977 to protect the rights, welfare and dignity of human research subjects recruited to participate in research activities conducted within MDH and local health departments. The MDH IRB, which is part of the MDH Office of Internal Controls and Audit Compliance (IAC), is composed of nine full Board members and (currently) three alternate members who are all appointed by the Maryland Secretary of Health.

In accordance with several federal regulations, the IRB reviews all proposed human subject research projects involving MDH funds, patients, clients, data, or specimens, as well as projects involving a researcher who is employed by or a student of a residency program MDH. Additionally, the IRB is charged with the responsibility of determining if a project activity qualifies as "not research" or "exempt research," which does not need to adhere to federal regulations.

Relevant Federal Regulations

The IRB reviews and makes determinations in accordance with federal regulations which include 45 CFR 46; 21 CFR 50; and 21 CFR 56 as well as the MDH IRB Policy and Maryland law, HG §13-2001 et seq. The IRB also considers other federal regulations such as HIPAA regulations (45 CFR 164) when reviewing research applications.

SUBMIT YOUR 2022 IRB APPLICATION

The 2022 IRB application is available on our website, https://health.maryland.gov/iac/IRB/. Click on Forms, Policies, and Resources.

Questions?

Gay Hutchen
IRB Administrator
Phone: 410-767-5314
mdh.iac@maryland.gov

The Approval Process

IRB approval must be obtained before initiating any proposed human subject research projects connected to MDH. The Board reviews applications at monthly convened meetings or through an expedited process. Staff of the IRB will conduct a pre-review of applications for completeness prior to Board review for determination.

Maryland
DEPARTMENT OF HEALTH