University of Maryland Baltimore

Human Research Protections Program (HRPP)
Tip of the Month

August 2026

BESH and Consent Form Posting Requirements

What is BESH?

Basic Experimental Studies Involving Humans (BESH) are studies designed to improve understanding of fundamental biological or behavioral processes without a direct clinical application.

New OHRP Clarification (August 10, 2026)

The Office for Human Research Protections (OHRP) has clarified that BESH studies are generally **not considered clinical trials** under 45 CFR 46.102(b) and therefore are **not subject to the informed consent form posting requirement** at 45 CFR 46.116(h).

Why?

The Common Rule definition of a clinical trial requires prospective assignment to an intervention to evaluate **health-related biomedical or behavioral outcomes**. OHRP considers studies evaluating outcomes with the potential for a direct effect on health to be clinical trials. Studies that generate only fundamental knowledge about biological systems or human behavior generally do not meet this definition.

Key Takeaway for Investigators

If your NIH-funded or HHS-supported BESH study is not a clinical trial under the Common Rule definition at 45 CFR 46.102(b), it generally is not subject to the informed consent form posting requirement at 45 CFR 46.116(h).

Important Reminder

BESH remains human subjects research and must continue to comply with all applicable human research protection requirements, including IRB review, informed consent, and other federal, institutional, and sponsor policies

Source: OHRP FAQ, issued August 10, 2026; NIH Guide Notice NOT-OD-26-032.