Below is guidance as to why the MCW HRPP does not require/embed the MCW research HIPAA language "aka Section E" into its Expanded Access consent form templates (Treatment Use/Emergency use.)

Why is a HIPAA research authorization not required for Expanded Access (EA)?

Expanded Access is clinical treatment, not research. Under FDA policy, EA (sometimes called "compassionate use") allows use of an investigational drug, biologic, or device **for treatment outside of a clinical trial** when specific criteria are met (e.g., serious or life-threatening condition, no satisfactory alternatives, trial enrollment not possible). This activity is primarily undertaken to treat an individual patient or group of patients—not to generate generalizable knowledge—and therefore is **not research**. [fda.gov], [irbo.nih.gov]

Because EA is undertaken as clinical care, covered entities may use and disclose PHI under the HIPAA Privacy Rule's **Treatment, Payment, and Health Care Operations (TPO)** provisions. Specifically, **45 CFR §164.506** permits use and disclosure of PHI for treatment purposes without patient authorization (subject to the Rule's other safeguards). HHS guidance likewise states that PHI may be used/disclosed for treatment, payment, and operations to avoid unnecessary barriers to care. [ecfr.gov], [hhs.gov]

Therefore, because HIPAA authorization for research is not required in the EA context, the MCW HRPP does not include its standard research HIPAA authorization language ("Section E") in EA consent templates.