



March 4, 2026

## RE: CRISP Registry Version 3.3 Update – IRB Approval and Required Site Action

We are pleased to announce that **CRISP Registry Protocol Version 3.3** has been approved by the Memorial Health System (MHS), our Data Coordinating Center IRB.

This amendment reflects important structural refinements and the introduction of new modules to enhance the CRISP registry's real-world surveillance capabilities while maintaining its observational design.

---

### Summary of Key Updates (v3.2 → v3.3)

#### 1. Refinement of Existing Data Elements

- Minor additions and adjustments to data variables within Core Registry, ASD Module and PA Stent Modules

#### 2. CRF Structural Reorganization

- CRFs are now organized into:
  - **Core Registry (applicable to all cases)**
  - **Seven Procedure-Specific Modules**
- This structure improves clarity, usability, and module-based real-world surveillance design

#### 3. Introduction of New Modules

- The following modules have been formally introduced under Version 3.3:
  - **Premie PDA Closure Module**
  - **TPVI (Balloon-Expanding) Module**
  - **TPVI (Self-Expanding) Module**
  - **Aortic Stent Module**
- These modules are structured under the Core CRISP Registry and are designed to enhance **systematic real-world data collection** for transcatheter cardiac devices and procedures

---

### Required Next Steps

#### 1. For Currently Active Participating Sites

- We kindly request that each participating center:
  - Submit a **local IRB amendment** to update from Version 3.2 to Version 3.3.
  - Necessary documents for IRB revision will be distributed to each site shortly.

#### 2. For Prospective Sites in the Onboarding Process

- **If Version 3.2 has NOT yet been submitted to your local IRB:**
  - Please initiate your IRB application using **Version 3.3 documents**.
- **If Version 3.2 has already been submitted to your local IRB:**
  - Use of Version 3.2 documents is at the discretion of your local IRB process and timing.
  - However, all sites will ultimately need **local approval of Version 3.3**.

---

We sincerely appreciate your continued collaboration and commitment to improving real-world evidence in congenital cardiac catheterization through the CRISP registry.

### CRISP Registry Organizers