JHM Single IRB Review Step 1 Step 4 Step 5 Step 6(a) 🕌 Lead Site Investigators Lead Site/ Coordinating Center Lead Site/ IRB review concerns provides JHM IRB **Coordinating Center** Lead Site PI submits are addressed; Lead reliance team with revises the protocol IRB application Site PI submits protocol and and template response template consent consent form form Have the IRB review Steps 6(b) Is the application concerns been adequately ready for IRB review? addressed? IRB Review JHM IRB Step 8 Step 9 JHM IRB review is Reliance team complete; A local Approval letter and performs a pre-Reliance team drafts IRB Staff prepares context study documents are screen of the a summary of Is the application documents for questionnaire [LCQ] issued to the Lead protocol and comments and ready for IRB is created, including Site / Coordinating approval template consent recommendations approval? Center any Board-specific form local context issues Step 7 Step 3 Step 2

