Exception From Informed Consent (EFIC) STUDY PROCESS FLOW CHART

PI and Study team PI and Study team **IRBMED Staff Community Engagement** Part 1 Consult with study team • Complete and submit process begins after approval • Review FDA guidance Analysis and confirmation eResearch application regarding EFIC studies of plan by IRB Full Board. (Planning / of EFIC status Make any changes (even if the study will • Work with study team in needed to basic protocol, not be under FDA Hold preparing application including oversight) Report on the progress of Community Alert IRBMED Directors and Community Consultation Develop idea and basic CC/PD activities by Co-Chairs (CC) Plan protocol **Engagement** submitting ORIOs (one or Assign to Full Board when • Public Disclosure (PD) **Contact IRBMED Staff** ready for initial discussion Plan more). Meetings) for initial review and • Status of FDA approval (if Q/A. Part 2 PI and Study team **IRBMED Staff** PI and Study team Initial review of (Finalizing Study Submit by ORIO the final Study enrollment beains Amendment. Amendment to revise the / Request full results of the Community after full approval Return to study team if eResearch application as Consultation, and results to **IRBMED** issued by IRBMED. needed and provide the changes needed date of Public Disclosure final protocol, consents, etc. Approval) Assign to Full Board activities. PI and Study team Enrollment During study conduct, be alert continues until goal to and submit: met or early Part 3 Submit by ORIO final After all publications are • SCRs. and AMEs as termination rules are report on Public complete, submit Study (Starting / appropriate applied. Disclosure activities. Termination. • AEs/ORIOs (especially FDA **Ending Study**) notifications) Continue Public Continue Public Disclosure Disclosure activities activities