Exception From Informed Consent (EFIC)
STUDY PROCESS FLOW CHART

Part 1
(Planning / Hold Community Engagement Meetings)
PI and Study team
- Review FDA guidance regarding EFIC studies (even if the study will not be under FDA oversight)
- Develop idea and basic protocol
- Contact IRBMED Staff for initial review and Q/A.
IRBMED Staff
- Consult with study team
- Analysis and confirmation of EFIC status
- Work with study team in preparing application
- Alert IRBMED Directors and Co-Chairs
- Assign to Full Board when ready for initial discussion
PI and Study team
- Complete and submit eResearch application
- Make any changes needed to basic protocol, including
  - Community Consultation (CC) Plan
  - Public Disclosure (PD) Plan
  - Status of FDA approval (if applicable)
IRBMED Staff
- Consult with study team
- Analysis and confirmation of EFIC status
- Work with study team in preparing application
- Alert IRBMED Directors and Co-Chairs
- Assign to Full Board when ready for initial discussion
Part 2
(Finalizing Study / Request full IRBMED Approval)
PI and Study team
Submit by ORIO the final results of the Community Consultation, and results to date of Public Disclosure activities.
PI and Study team
Amendment to revise the eResearch application as needed and provide the final protocol, consents, etc.
IRBMED Staff
Initial review of Amendment. Return to study team if changes needed Assign to Full Board
Community Engagement process begins after approval of plan by IRB Full Board.
PI and Study team
- Complete and submit eResearch application
- Make any changes needed to basic protocol, including
  - Community Consultation (CC) Plan
  - Public Disclosure (PD) Plan
  - Status of FDA approval (if applicable)
IRBMED Staff
- Consult with study team
- Analysis and confirmation of EFIC status
- Work with study team in preparing application
- Alert IRBMED Directors and Co-Chairs
- Assign to Full Board when ready for initial discussion
Study enrollment begins after full approval issued by IRBMED.

Part 3
(Starting / Ending Study)
PI and Study team
During study conduct, be alert to and submit:
- SCRs, and AMEs as appropriate
- AEs/ORIOs (especially FDA notifications)
Continue Public Disclosure activities
Enrollment continues until goal met or early termination rules are applied.
Continue Public Disclosure activities
Submit by ORIO final report on Public Disclosure activities.
After all publications are complete, submit Study Termination.
NOTE: there is a separate process for EFIC studies for which IRBMED cedes oversight to an external IRB
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