Device & IDE Study Path

PI Submits

Pre-submission

PBC Review (if required)

PI Re-Submits

Ancillary Committee(s) Review

MCRU Review (if required)

IRB Review

IRB Approval with contingency

CRAO begins Review and uses activity “Issue Ancillary Conditional Approval” in order to move study forward in the process--IF MAC part A/B approval letters are needed. For CED studies, Final approval will be released.

CRAO confirms documentation is appropriate at Leadership Review Meeting

Study Team provides documentation device is under CED policy and uploads into eRPM.

Study Activity Begins

IRB completes review and issues approval

CRAO completes review and issues approval

Study team submits Amendment and uploads MAC part A/B approval letters

Approved by: CRAO Director
Date: 11.15.2012

Revised: 11.15.2012

Calendar Review Analysis Office
Device Study Procedure Flow

Blue = eRPM Project Status
Green = PI Activities
Pink = CRAO/IRB (eRPM) Activities