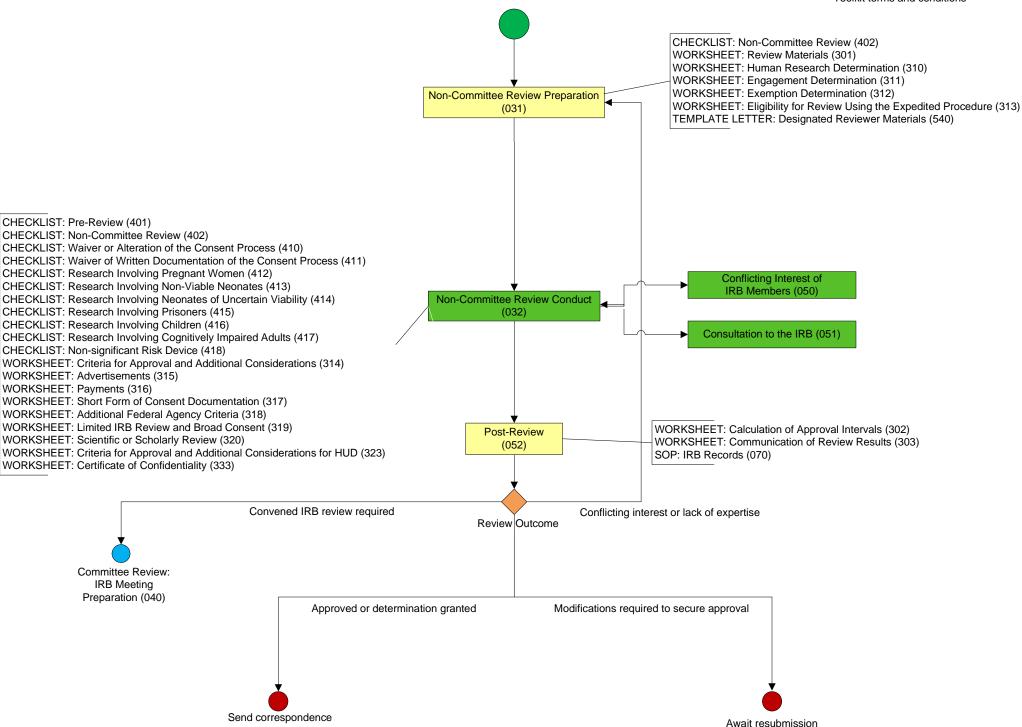
Incoming Items (Intake) **Huron HRPP Toolkit 4.1** ©2009-2018 Huron Consulting Services, LLC. Use subject to Huron's HRPP Toolkit terms and conditions Incoming Item SOP: IRB Records (070) CHECKLIST: Pre-Review (401) Incoming Items Directed to the IRB Non-Committee reviews are all WORKSHEET: Drugs (306) WORKSHEET: Devices (307) reviews that do not require WORKSHEET: Pre-Review (308) review by a convened IRB: Determinations that an activity is not human research Type of Information **Exemption determinations** Pre-Review (021) Review using the expedited **Approval or Determination** Level of Review Needed procedure This pathway is for all reviews that involve approval or a determination: Determination that an activity is not human research Exemption determination Legend Initial review Committee Review: Study Closure: Non-Committee Review: Continuing review IRB Meeting Post-Review (052) Non-Committee Review Review of modifications Preparation (040) Preparation (031) Intermediate connector Study closure Serve as sIRB-send for Establishing Authorization Agreements (801) Pre-Review (021) **Establishing Reliance** Decision point Reliance Request This pathway includes: WORKBOOK: Institutional Profiles (861) Confirmed/Denied Requests to serve as the IRB of record for another institution WORKSHEET: Communication and IRB member or Requests to rely on an external IRB Responsibilities (830) committee SOP IRB Staff SOP All Emergency Use, Compassionate Use (Device WORKSHEET: Emergency Use of a Test Article (322) Only) and IRB Waiver for Individual Patient WORKSHEET: Device Compassionate Use (325) **Emergency Use Notification** Expanded Access (Drug Only) Review (023) Emergency Use of a Test Article in a Life TEMPLATE LETTERS Emergency Use (570-573) Threatening Situation Post-Review (027) Await 5 day report or protocol submission This is for suspensions or terminations by someone other than the convened IRB WORKSHEET: Review of Information Items (321) TEMPLATE LETTER: External Report (520) SOP: IRB Records (070) Suspension or Termination Issued Outside of the New Information (024) Convened IRB (026) Other Information This includes: Complaints Notifications Committee Review: Review Outcome Reports IRB Meeting Preparation (040) Non-compliance issues Adverse events Investigations (025) No findings or Finding that requires non-serious/non-continuing convened IRB review non-compliance Unanticipated problem involving risks to participants or others Serious or continuing non-compliance Suspension or termination of IRB approval Send correspondence Committee Review: IRB Meeting Preparation (040)

Non-Committee Review

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Convened IRB Review

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