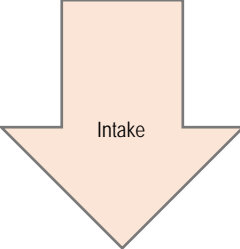
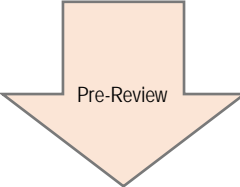
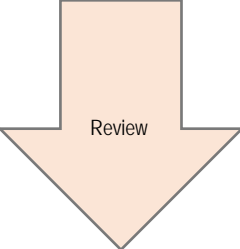

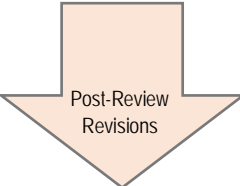


The Review Process

 <p>Intake</p>	<ul style="list-style-type: none"> • IRB receives notification from Wufoo Electronic Application Form(s) of protocol submission and protocol number is assigned. • IRB Coordinator creates a protocol record in Egnyte and downloads all submitted research materials. • IRB Coordinator review materials for completeness and submission requirements. • If protocol submission is incomplete or submission requirements are not met, IRB coordinator sends email to PI. • Once the protocol is complete, the protocol moves to Pre-Review.
 <p>Pre-Review</p>	<ul style="list-style-type: none"> • IRB coordinator reviews protocol materials to prepare for the appropriate type of review • If the IRB coordinator identifies changes necessary before further review can be conducted, a pre-review email is sent to the researcher outlining changes requested. • Researcher provides revised materials (with changes note in tracked changes) to the IRB. • IRB coordinator verifies review readiness, assesses level of review, and sends the protocol for review.
 <p>Review</p>	<ul style="list-style-type: none"> • NHSR Submission – protocols are routed for verification of NHSR eligibility. • FLEX Review – protocols are routed for verification of registration project eligibility. • Exempt & Exempt with Limited Review – protocols are routed for verification of exempt eligibility. • Expedited Review – protocols are routed to one or more IRB members for review to determine all regulatory approval criteria are satisfied. • Full Board Review – protocol are schedules for review at the next available fully convened IRB committee meeting.
 <p>Post-Review Communications</p>	<ul style="list-style-type: none"> • IRB Coordinator communicates review outcome. • IRB Coordinator and/or the IRB verifies the changes satisfy the reviewer's requests. • Once satisfied, approval or determination documentation is issued.
 <p>Post-Review Revisions</p>	<ul style="list-style-type: none"> • If changes and/or clarification are necessary to secure approval or a determination of NHSR, FLEX, Exempt and/or Exempt-Limited Review, the IRB Coordinator issues a required modifications letter outlining the modifications required. • Researcher provides revised materials (with changes noted in tracked changes) to the IRB. • The IRB Coordinator and/or the IRB verifies the required modifications satisfy the reviewer's requests. Once satisfied, approval or determination documentation is issued.