

HARVARD
UNIVERSITY



Brief Project History and Intro to Click
The background of ESTR

Topics

- IRB System Project Initiative
- System Selection Process
- What is Click?
- What is Click 7.0?
- Workflow Examples



IRB System Project Initiative

- The Harvard Human Research Protection Coordinating Committee (HRPCC) began developing a uniform set of IRB policies and procedures for human subjects research across the three Institutional Review Boards (IRBs), in preparation to become accredited under one Human Research Protection Program (HRPP).
 - HRPCC: Comprised of the Institutional Officials for each IRB office and the Provost's office.
- To support this goal, in October 2011, the technology team began the selection process, which included conversations with peer organizations, and in March 2012, demonstrating system functionality for faculty and staff feedback, prior to selection.
 - Technology Team: Comprised of individuals from each of the three IRB offices, the Provosts office, Financial Systems Solutions and HU-Information Technology



System Selection Process

- Participants from the selection team attended five 3-hour onsite vendor demonstrations
 - Vendors were required to follow business scenario prescribed “scripts”
 - IRB participants completed vendor scorecards
 - Select IRB participants completed more detailed vendor requirements scorecards
- Conducted reference calls with institutions provided by vendors; continue to reach out to peer institutions per Harvard guidance
- Conducted faculty demonstrations across the University for feedback prior to vendor selection.
- In May 2012, Click 7.0 (Alameda) was selected as the new IRB submission system.



What is Click?

- Click has been providing enterprise web-based solutions since 1996
 - Focused on software solutions for research administration and compliance since 2002.
 - Well-documented track record of successful implementation of projects of significant scale and complexity within leading academic medical centers and hospitals.
 - Leader in large-scale deployments.
 - Client list includes many of the largest National Institutes of Health (NIH)-funded research institutions.
- Click® Portal is designed to unify multiple research-related business processes into an integrated, comprehensive electronic solution.



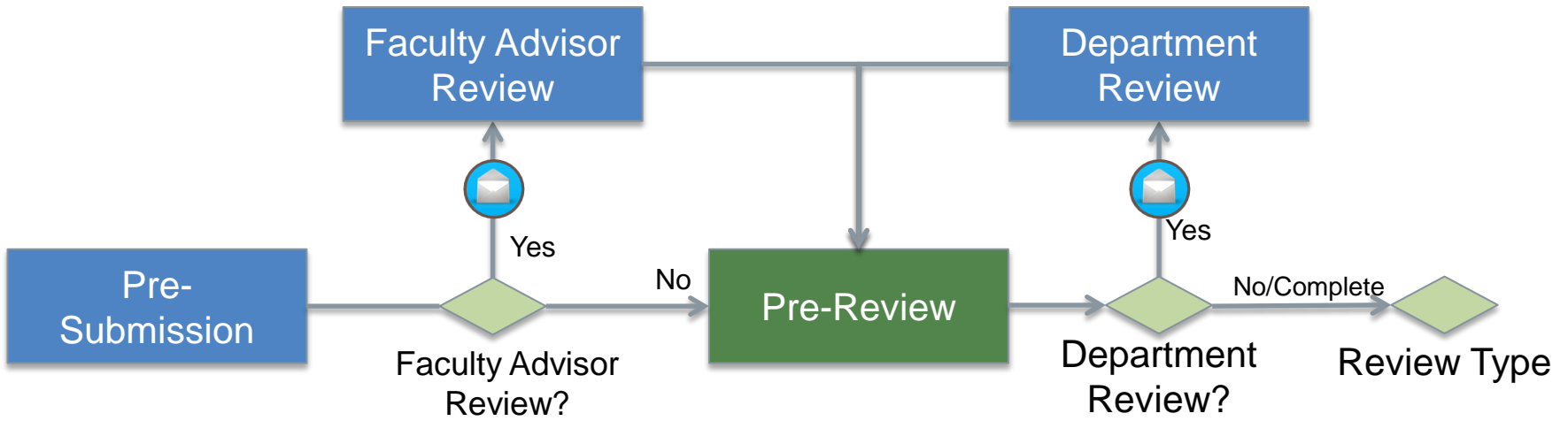
What is Click® IRB 7.0?

- **Click® IRB 7.0 Features**

- Huron's Industry-leading HRPP toolkit, SOPs, checklists, and worksheets.
- Support for initial submissions, modifications, continuing reviews.
- Comprehensive form sets with validations and document attachments.
- Electronic workflow routing and review.
- Integrated meeting management facility.
- Automated reminders.
- Correspondence generation.
- Stamping, watermarking of approved documents.
- Electronic document management.
- Integrated online help and comprehensive user documentation.
- Designed to meet AAHRPP accreditation standards.
- Eliminates paper processes and shortens turnaround times.
- Manages the audit trail for all document versions.



Workflow – Pre-Submission / Pre-Review



Workflow – IRB Review

