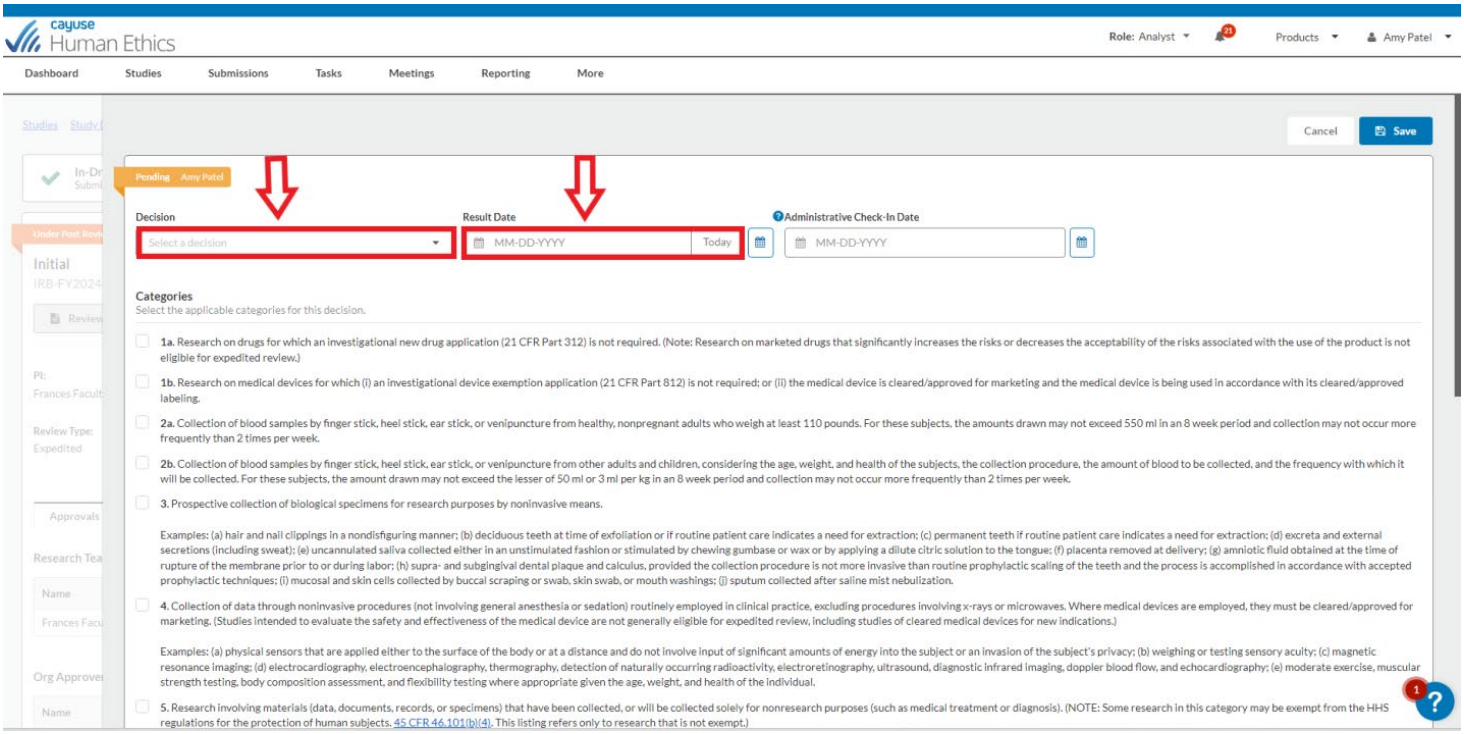
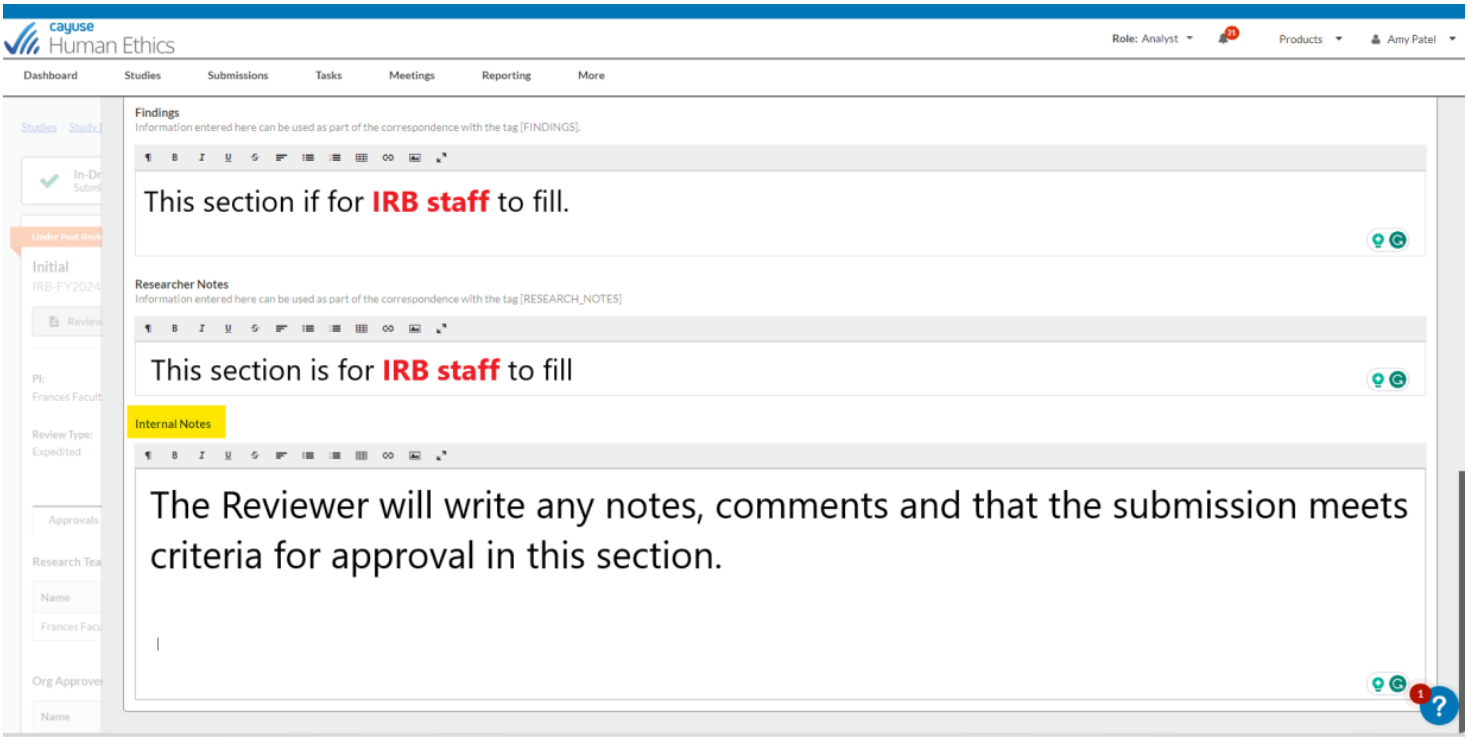
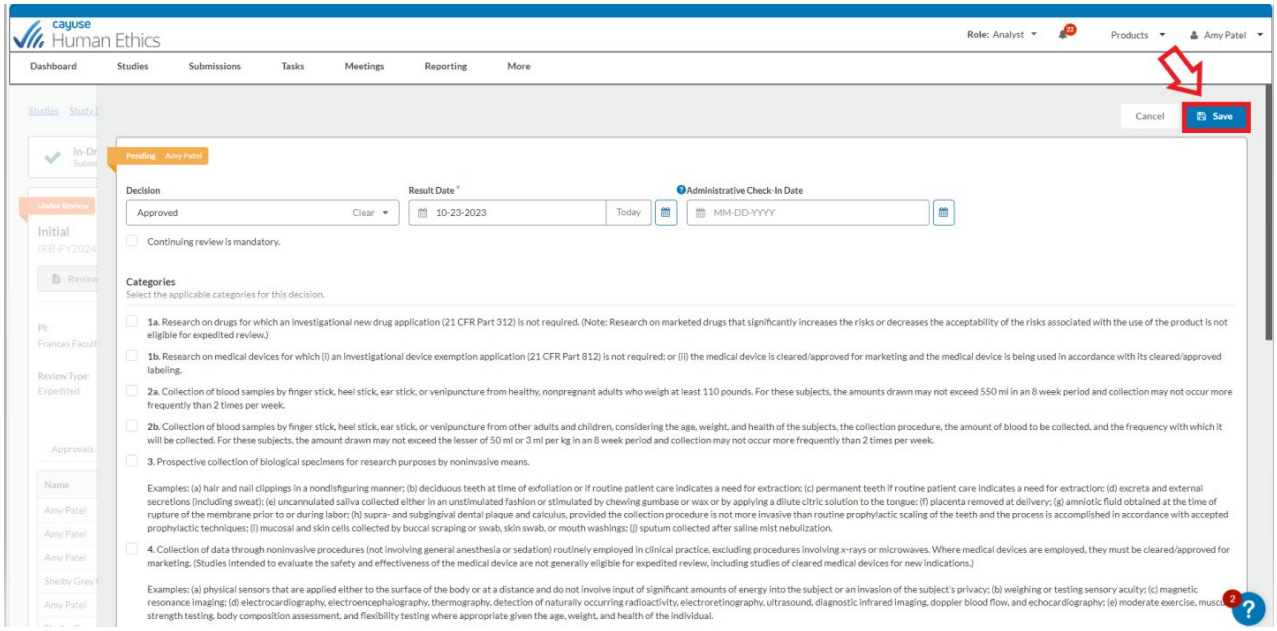
Reviewers – in the decision page you are to put all comments, notes and approval language in the 'Internal Notes' section.

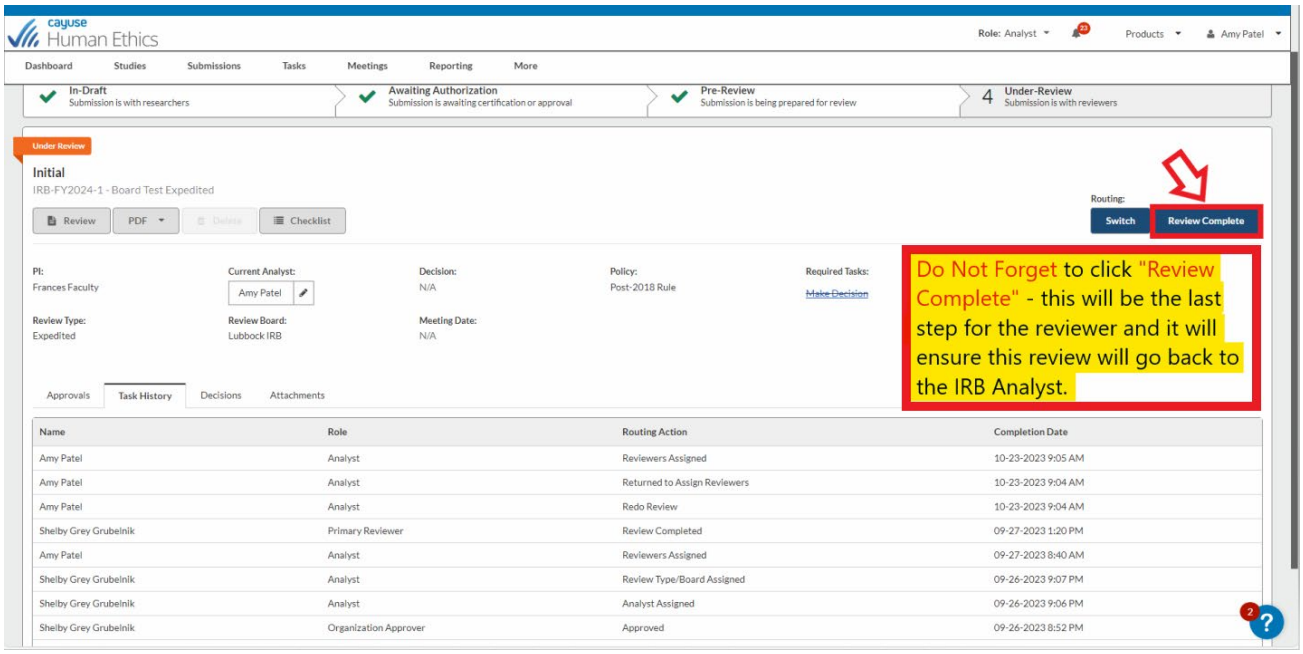
Please indicate whether the research continues to satisfy the requirements for approval in accordance with 45 CFR 46.111 [and 21 CFR 56.111, if FDA-regulated].

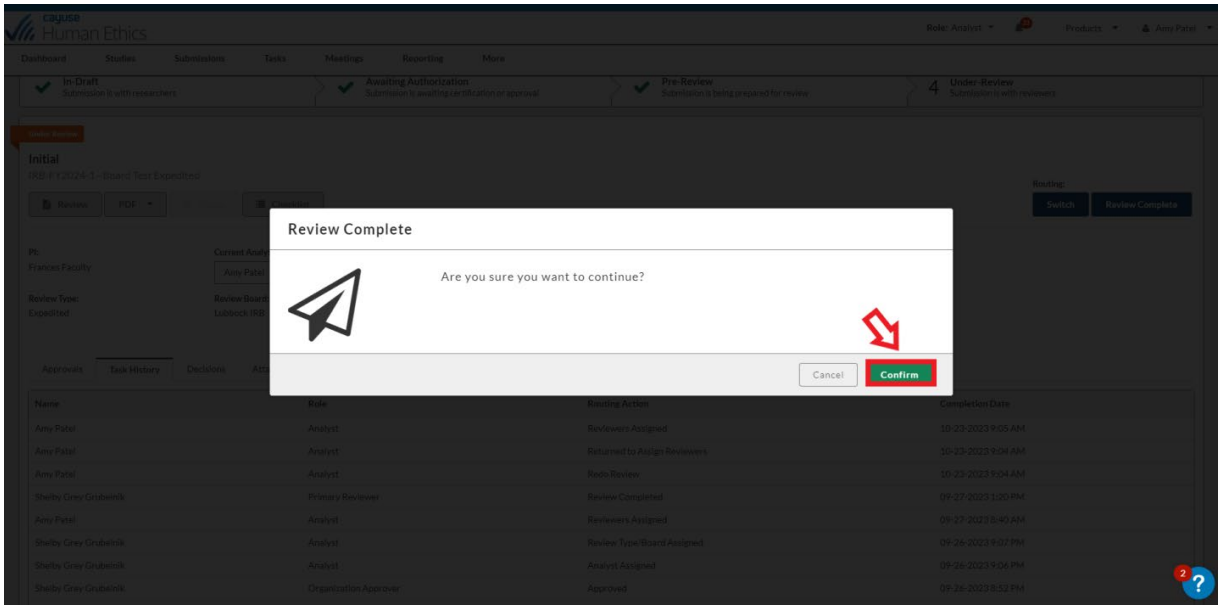
*Note – If you send back your review with stipulations, once the response comes in, you will have to put in your approval citing the regulations in the internal notes section again. It will come back as a new submission/review with the decision page cleared.






cayuse
Human Ethics
Role: Analyst
Products
Amy Patel
Dashboard
Studies
Submissions
Tasks
Meetings
Reporting
More
Cancel
Save
Pending Amy Patel
Decision
Approved
Clear
Result Date *
10-23-2023
Today
Administrative Check-In Date
MM-DD-YYYY
Continuing review is mandatory.
Categories
Select the applicable categories for this decision.
1a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
1b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2a. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week.
2b. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
3. Prospective collection of biological specimens for research purposes by noninvasive means.
Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscle strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.


cayuse
Human Ethics
Role: Analyst
Products
Amy Patel
Dashboard
Studies
Submissions
Tasks
Meetings
Reporting
More
In-Draft
Submission is with researchers
Awaiting Authorization
Submission is awaiting certification or approval
Pre-Review
Submission is being prepared for review
4 Under-Review
Submission is with reviewers
Under Review
Initial
IRB-FY2024-1 - Board Test Expedited
Review
PDF
Delete
Checklist
Routing:
Switch
Review Complete
PI:
Frances Faculty
Current Analyst:
Amy Patel
Decision:
N/A
Policy:
Post-2018 Rule
Required Tasks:
Make Decision
Review Type:
Expedited
Review Board:
Lubbock IRB
Meeting Date:
N/A
Do Not Forget to click "Review Complete" - this will be the last step for the reviewer and it will ensure this review will go back to the IRB Analyst.
Approvals
Task History
Decisions
Attachments
Name
Role
Routing Action
Completion Date
Amy Patel
Analyst
Reviewers Assigned
10-23-2023 9:05 AM
Amy Patel
Analyst
Returned to Assign Reviewers
10-23-2023 9:04 AM
Amy Patel
Analyst
Redo Review
10-23-2023 9:04 AM
Shelby Grey Grubelnik
Primary Reviewer
Review Completed
09-27-2023 1:20 PM
Amy Patel
Analyst
Reviewers Assigned
09-27-2023 8:40 AM
Shelby Grey Grubelnik
Analyst
Review Type/Board Assigned
09-26-2023 9:07 PM
Shelby Grey Grubelnik
Analyst
Analyst Assigned
09-26-2023 9:06 PM
Shelby Grey Grubelnik
Organization Approver
Approved
09-26-2023 8:52 PM


Review Complete
Are you sure you want to continue?
Cancel
Confirm