

How to submit to the Temple IRB, external IRBs, and navigate ERA

Updated 3/21/22

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Tips and Tricks for avoiding common pitfalls and navigating the submission process



Beware the "Exempt" trap!

Not Human Subjects Research =! Exempt

HHS pulled cruel jokes with certain IRB terms like "Exempt"

- Exempt has a specific meaning in the IRB world
 - All "Exempt" studies are human subjects research
- The IRB must review Exempt research prior to starting

Know who can be the PI!

- Only fulltime faculty members can be the PI, unless a special PI Exception form is signed by your dean and the Vice President for Research (Michele Masucci).
- If you are not fulltime faculty and don't have that form, make sure you are not listed as the PI.
 - Even if the study is your idea, and you're doing the vast majority of work.
- If you assign the wrong PI, reach out to the IRB.
 - Only the IRB staff can change the PI for a created study.



Funding matters

- Federally-funded studies:
 - May require Single IRB.
 - Require additional language in the consent.
 - Consult with the IRB prior to submitting the protocol (and grant if multi-site).
- Industry-initiated studies:
 - Must be reviewed by WIRB or Advarra, but will be submitted to the Temple IRB prior to external IRB review.



Submitting to the IRB: Basics

- CITI training
 - First time: research.temple.edu > Research Compliance > Institutional Review Board (IRB) > IRB Trainings and Resources
 - https://research.temple.edu/research-compliance/institutional-review-board-irb/irb-trainings-and-resources
 - Subsequent visits: citiprogram.org
- IRB template documents
 - research.temple.edu > Research Compliance > Institutional Review Board (IRB) > Investigator Quick Links
 - https://research.temple.edu/research-compliance/institutional-review-board-irb/investigator-quick-links
- ERA (the website that submissions to and communications from the IRB occur)
 - era.temple.edu
 - User guide at research.temple.edu > ERA > Training Tutorials & Documentation
 - https://atlas.ocis.temple.edu/research/researchadmin/era/era user guide.asp



CITI training

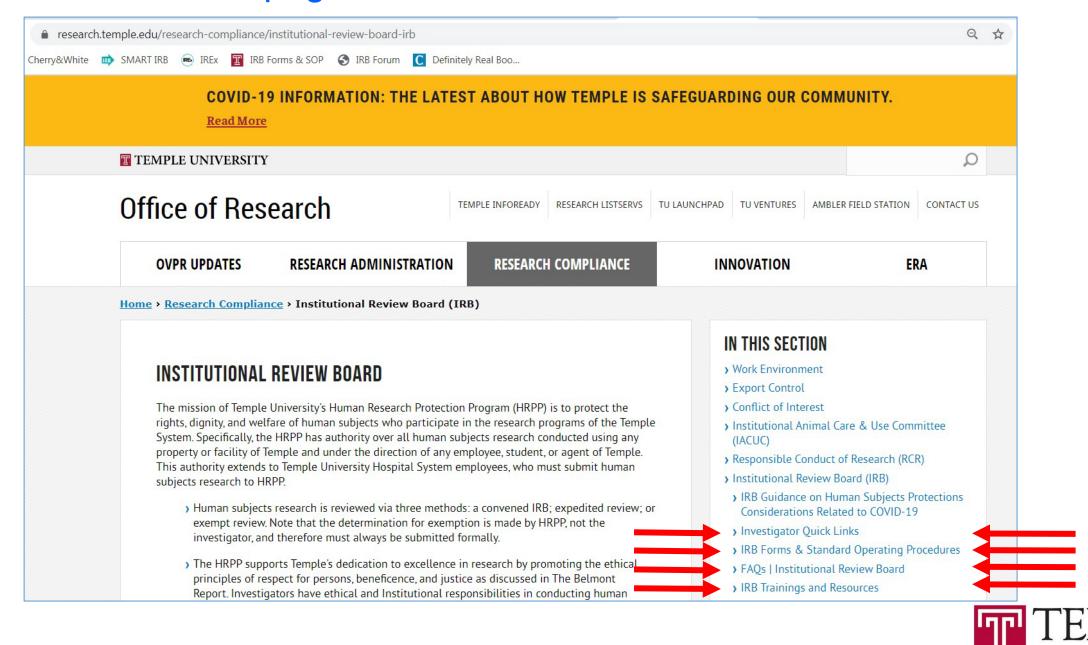
- Be sure to affiliate with Temple University, <u>not</u> Temple Hospital
 - Easiest way is signing in via the IRB Training and Resources webpage (https://research.temple.edu/research-compliance/institutional-review-board-irb/irb-trainings-and-resources)
- Two required courses:
 - Biomedical Research or Social/Behavioral Research takes ~1-4 hours
 - Practice Runs Training 1 module, takes ~5 minutes
 - GCP (Good Clinical Practice) Required if conducting a clinical trial that is NIH- or FDA regulated. – takes ~1-3 hours
- Does not need to be completed prior to submitting to the IRB but...
- Needs to be completed by everyone on the study before the IRB will approve the study

General IRB tips

- When planning, give at least 2 months for a submission to be approved.
 - The first review can take up to a month and there may be Mods Required.
 - Check in with a coordinator if you haven't heard from us after a month.
- Read HRP-070, -071, -802, and -803.
 - https://research.temple.edu/research-compliance/institutional-review-board-irb/irb-forms-standard-operating-procedures
- An hour of checking your work can save weeks in time-to-approval.
- The IRB stamps all non-Exempt consents forms and consent scripts.
- Use ERA as your repository for clean protocols, consents, and recruitment materials
 - That way you are always using / modifying the approved documents.
- If you have questions, reach out to a coordinator.
 - https://research.temple.edu/research-compliance/meet-our-staff#IRB



IRB document pages; look under "IN THIS SECTION"



UNIVERSITY

Protocol and consent templates

- Download the Word docs from the website.
- Don't leave in the instructional language.
- The IRB focuses on the abstract, title, investigator, and study design
 - Particularly: timing, inclusion/exclusion, what data will be accessed / collected, privacy & confidentiality, recruitment, study methods, and consent methods
- Make sure the IRB knows what you're doing, why you're doing it, and can grant a waiver of HIPAA authorization (consult HRP-428 for the requirements) if doing a retrospective chart review.



Protocol and supplemental document tips

- Don't leave in the instructional language
- Provide Word docs and tracked changes in Word (if a response)
- Be consistent across all study documents.
 - Participant duration, N, if identifiers are linked to data via a key, etc.
- Don't describe durations with dates, use months / weeks / years.
 - Bad: Recruitment completed by December 2019.
 - Good: Recruitment completed 3 months after IRB approval.
- Double-check you're using the approved document as the base for any Amendments.
- The IRB focuses on the abstract, title, investigator, and study design (particularly timing, inclusion/exclusion, what will be accessed, and privacy & confidentiality).



Chart review protocol template

- Don't leave in the instructional language
- When possible, use the methodology provided in the table (section 8d)
 - Be sure you can actually follow it if you plan to use it
- The IRB focuses on the abstract, title, investigator, and study design (particularly timing, inclusion/exclusion, what will be accessed, and privacy & confidentiality)
- Make sure the IRB knows what you're doing, why you're doing it, and can grant a waiver of HIPAA authorization (consult HRP-428 for the requirements)
- To the website! (https://research.temple.edu/research-compliance/institutional-review-board-irb/investigator-quick-links)

Consent tips

- If recording (video or audio), it must be in the consent.
- If using a contractor to transcribe, it must be in the consent.
- Minimal risk research usually does not require signed consent.
- Be clear about the potential for follow-up contacts (including member checks).
- Unless your study has an intervention, the Survey Interview and Focus Group Consent Template is the best bet.
- If using the Minimal Risk Consent Template:
 - Only include the consent summary if the study is federally funded <u>and</u> the consent body is longer than 4 pages.
- To the website! (https://research.temple.edu/research-compliance/institutional-review-board-irb/investigator-quick-links)



Remote research considerations - Consent

- Is a waiver of documentation of consent appropriate?
 - No for HIPAA-regulated research or greater than minimal risk research
- Ensure your protocol has a plan for how you know the person signing is the participant (e.g., video-conference or phone call while consenting)
- Use REDCap to acquire signatures when possible
- FDA-regulated research cannot have remote consent at this time



Remote research considerations - Risks

- Are there people in the background of the participant's video or phone call that should not be privy to the discussion or activity?
 - How about on your end?
- Is transmitted data securely?
 - HIPAA-compliant video calls
 - Survey responses encrypted?
- Are extra precautions necessary because an activity is occurring at someone's home?
 - Exercise interventions
 - At-home sample collection



ERA

- ERA is the portal through which Investigators and the IRB communicate (submissions and responses) officially.
- The IRB / ERA User Guide is helpful and has screen shots, but you will waste time and effort if you don't use the table of contents.
 - https://atlas.ocis.temple.edu/research/researchadmin/era/era user guide.asp
- era.temple.edu > sign in > My Human Subjects
- Before going to the website, some tips.



ERA tips

- Make sure that you're in My Human Subjects, not My Proposals.
- Only full-time faculty can be the PI.
 - The 3rd prompt will ask for the PI, but will automatically have your name in it. Change to the correct PI.
- Immediately add the Application for Human Research (see ERA User Guide pages 13-15).
- Immediately add yourself to the Application for Human Research (eForm).
 - If you don't you won't be able to access the record in the future.
- When all documents (minimum eForm and protocol) are uploaded, click submit, I agree, and continue.
 - Ensure it says "Electronic Submission Pending" on the Submissions page.
 - Emails are generally sent to your / your Pl's @temple.edu address.
- The Department Head needs to be in the approval route for initial subs.
 - If your PI is the DH, then add the Dean.
- Upload docs via "Add" button, Not the Attachments tab.



External IRB Process: sIRB, WIRB, Advarra



Know the IRB of Record

- IRB of Record provides approval for Initial & subsequent submissions.
- Temple will not always be the IRB of Record
- The federal government* mandated single IRB (sIRB) review for multisite, government-funded research
 - *Excluding the DOJ and FDA**
 - **Unless funded by a federal agency that is not the DOJ
- Industry-initiated studies must go to either WIRB or Advarra
- Another IRB can be the IRB of Record*, even if not required
 - *Depending on IAA constraints discussed later



Steps involved in relying on another IRB

- Determine who the IRB of Record will be, preferably in the grant stage.
- Collaborators at the institution whose IRB will review the study should talk with their IRB about their process.
- Contact the Temple IRB and discuss methods for facilitating the process.
- Start the IAA process.
- Submit in ERA so the Temple IRB can perform a local context review.
 - We will release the study to the other IRB after it passes our local requirements.

IAAs (reliance agreements)

- IAA = Institutional Authorization Agreement (i.e., a reliance agreement)
- IAAs are required in anytime Temple will not be the IRB of Record
 - Except if the study is being submitted to a WCG IRB (.e.g., WIRB) or Advarra
- IAAs are not a painless process and will likely result in slower approval to start research, so start early



IAA constraints

- The IRB of Record must be AAHRPP Accredited.
 - Ask their IRB or check https://www.aahrpp.org/learn/find-an-accredited-organization
- The SMART IRB agreement should be used unless the IRB of Record requires otherwise.
 - https://smartirb.org/reliance/
- Beware additional documents required by the IRB of Record!
 - Local context review forms
 - Letter of Intent or Indemnification
 - Letter of Acknowledgement
- The study cannot be Exempt.



How to submit in ERA when relying on another IRB

- Create a new study as you normally would, and include a <u>clearly labeled</u> memo stating who will be the IRB of Record and if the IAA will use SMART IRB.
- Include any documents associated with the IAA (e.g., local context forms, LOIs, LOAs, ancillary committee checklists, etc.).
 - Every IRB is unique in what other documents they require
- If submitting to WIRB, include the WIRB Initial Submission Form
- Once the submission passes local context requirements, we will provide a letter indicating that the study can be submitted to the other IRB.

Local context review

- Can the PI be a PI?
- Do research personnel have required CITI trainings and are in the route?
- Is there a known fCOI, and is the required language in the consent?
- Ancillary committee (e.g., MRC, IBC, etc.) notification or approval, as appropriate
- Are there any differences between the main protocol and how it will happen here?

Local context review (cont'd)

Consent form:

- PI and study team contact information
- Injury statement is consistent with the contract
- Reference to the separate HIPAAAuthorization is included*
- Temple IRB, Temple University, and Temple University Hospital System and its affiliates are listed as entities that have access to the study records
- Compensation conforms w/ TU policies (e.g., ClinCard, cash exemptions, gift cards)
- Are LAR signature blocks appropriate given what Temple is doing?
- Is the Temple protocol number included?

HIPAAAuthorization

- Are LAR signature blocks appropriate given what Temple is doing?
- Are the additional signature blocks necessary given the protocol?
 - Are HIV status, substance abuse, or mental health records being accessed, even solely for exclusionary purposes?

What needs to still be submitted to our IRB after the study is approved?

- Approval letter (unless approved by WIRB or Advarra)
- Reportable events
 - Serious or continuing noncompliance
 - Termination or suspension
 - Unanticipated problems involving risks to subjects or others
- Personnel changes
- Closure letter (unless WIRB or Advarra are the IRB of Record)



Screenshot notes

 This is not a 1 slide, 1 click format. There are some gaps and some steps that are combined within 1 screenshot.

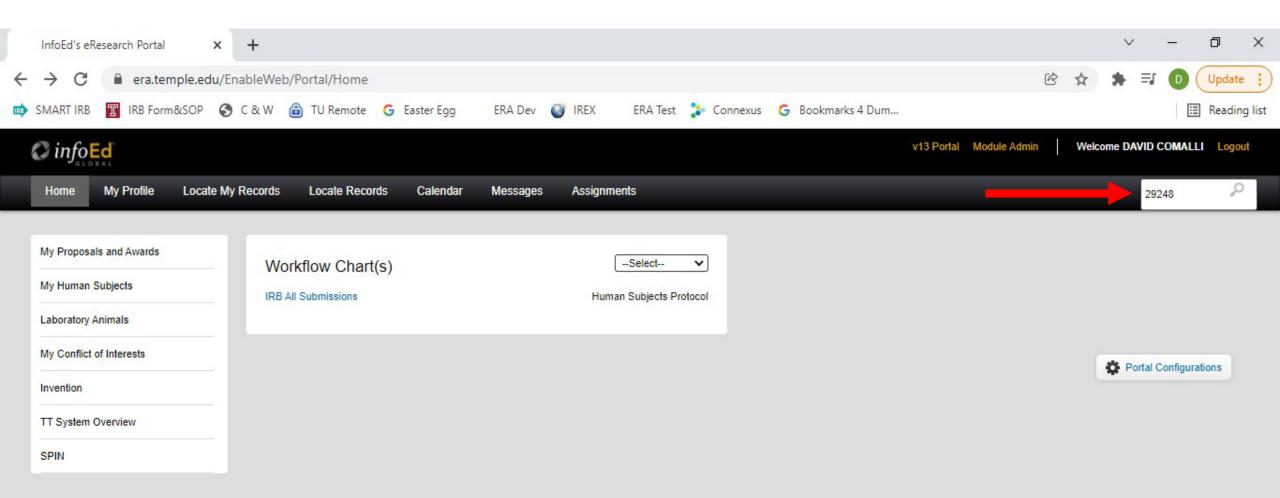
- Pop-up windows that are in the screenshot will not exist until a button (like "Add") on the main page is clicked.
- The pop-ups may appear in a different part of the screen or not be fully visible as they are in the screenshots.
- Use the red arrows to denote the button/clicking sequence.



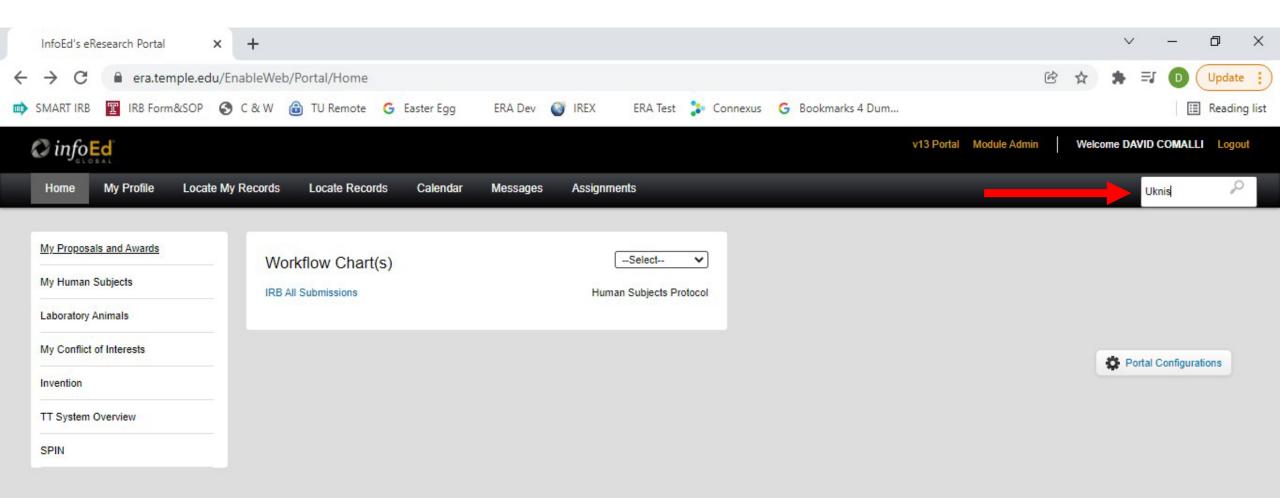
Finding an Existing Record or Study



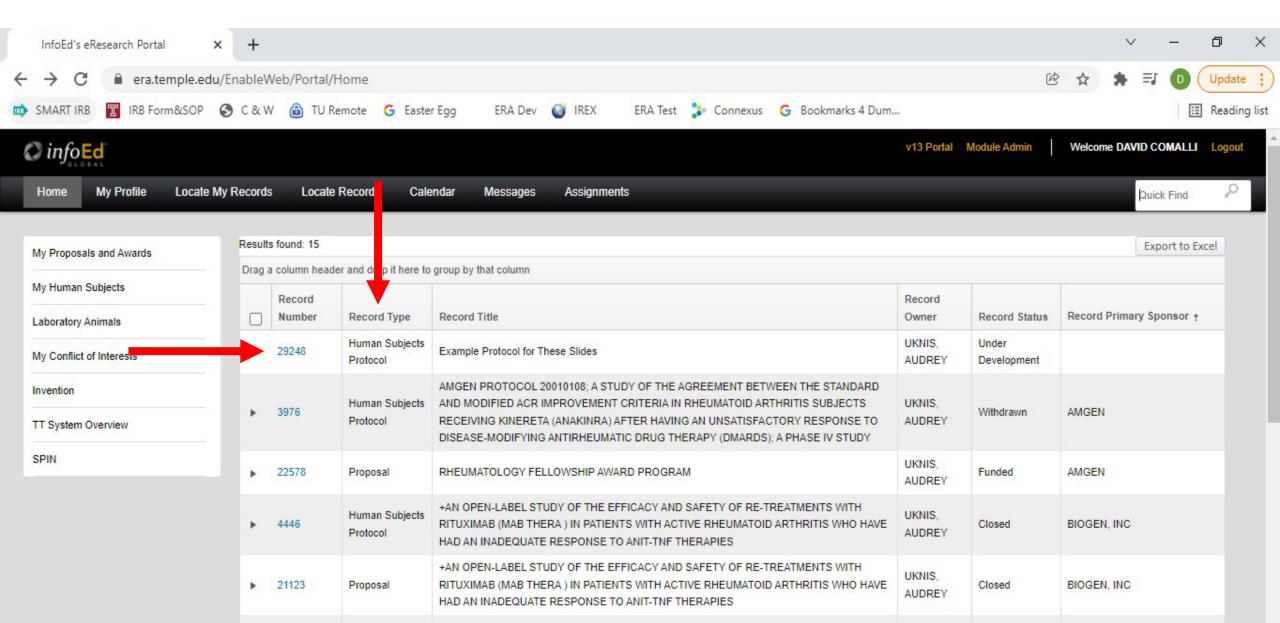
After signing in, type the Record # into the "Quick Find" search bar and hit Enter (or click the magnifying glass)



You can also search by the PI's name, but this method is less specific

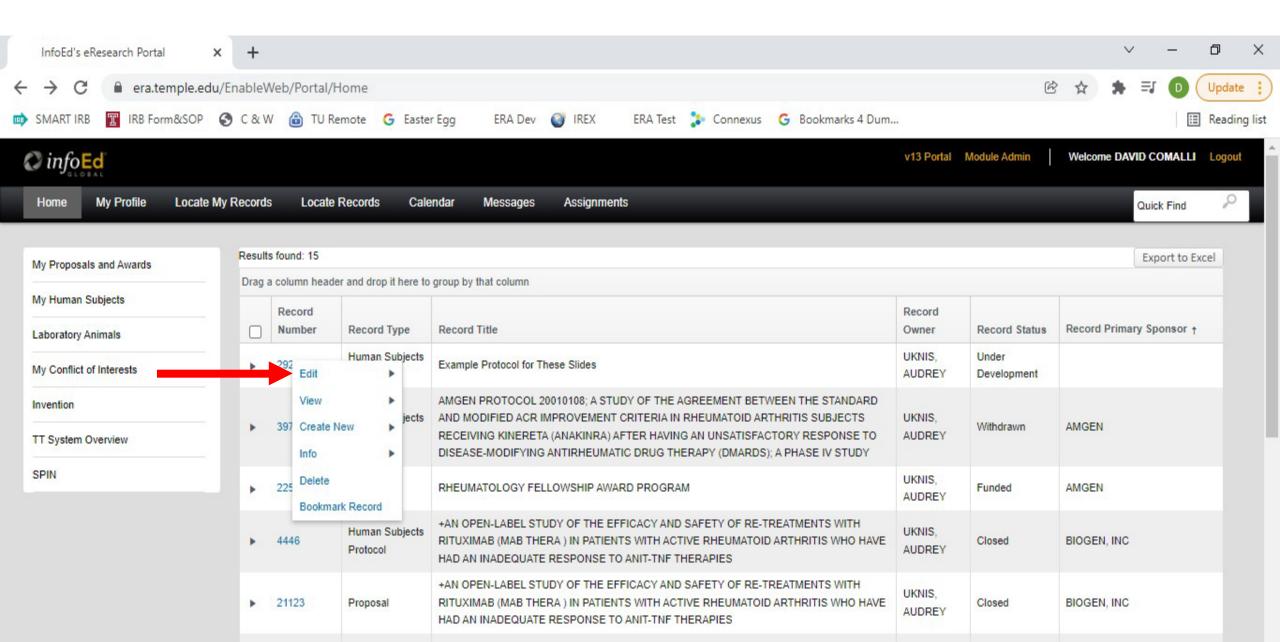


Make sure the "Record Type" is "Human Subjects Protocol" Then single click on the protocol number



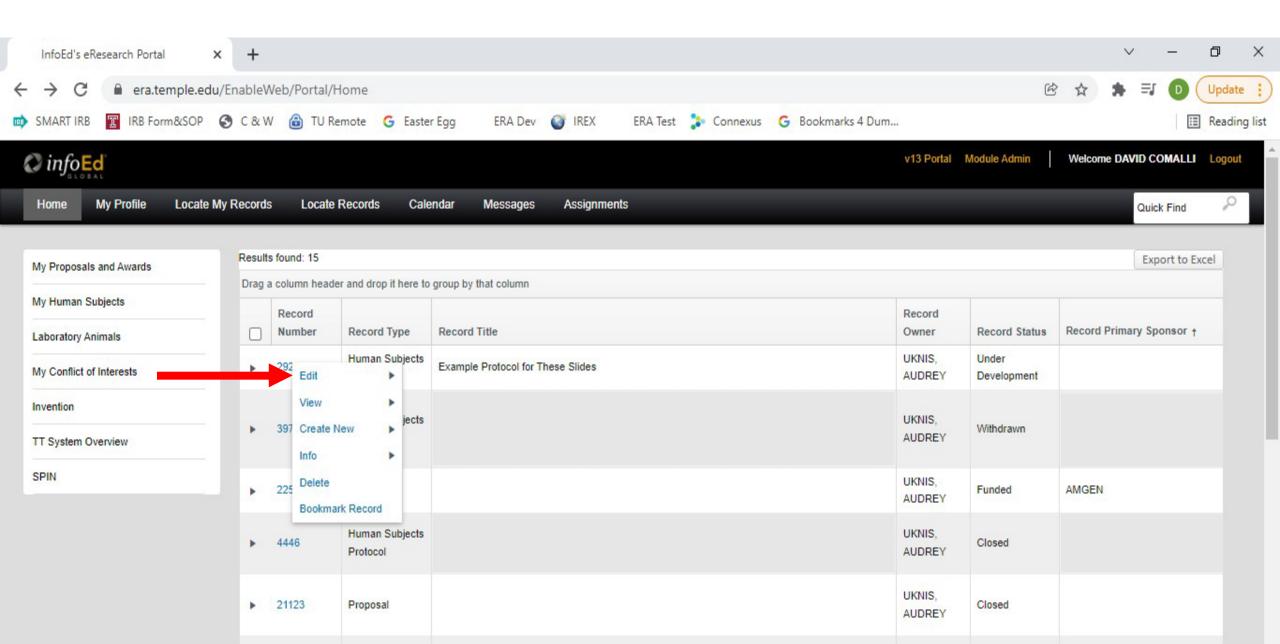
Hover over "Edit"

It is suggested to avoid the other options, unless you are an expert ERA user

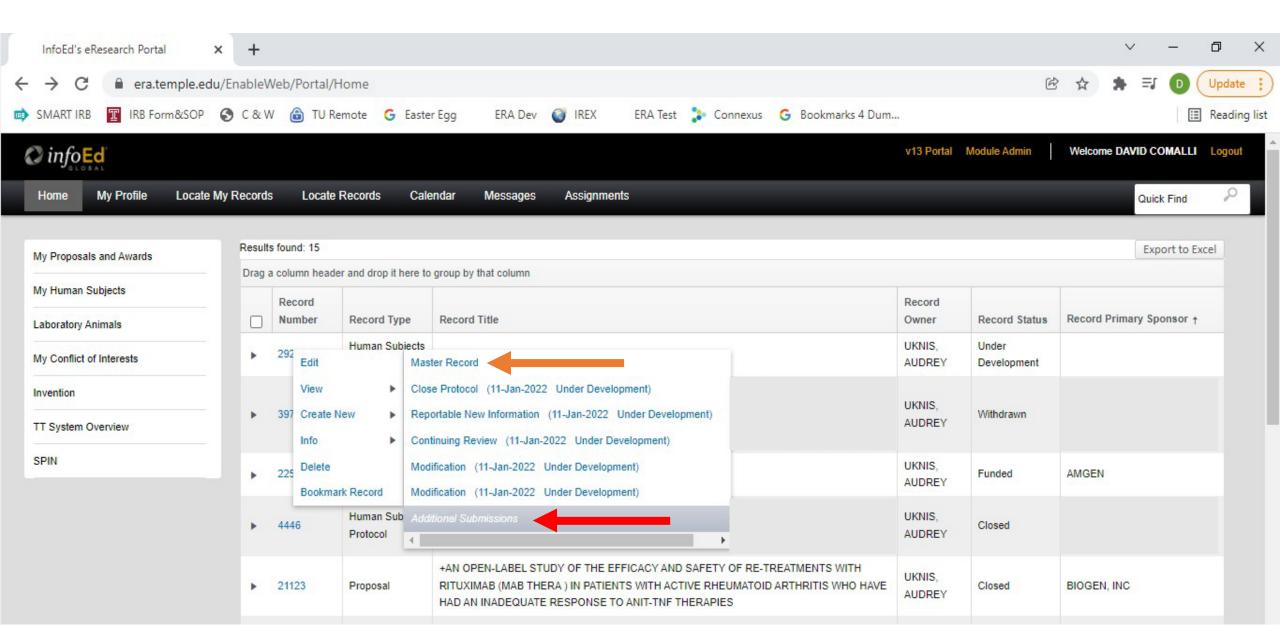


Hover over "Edit"

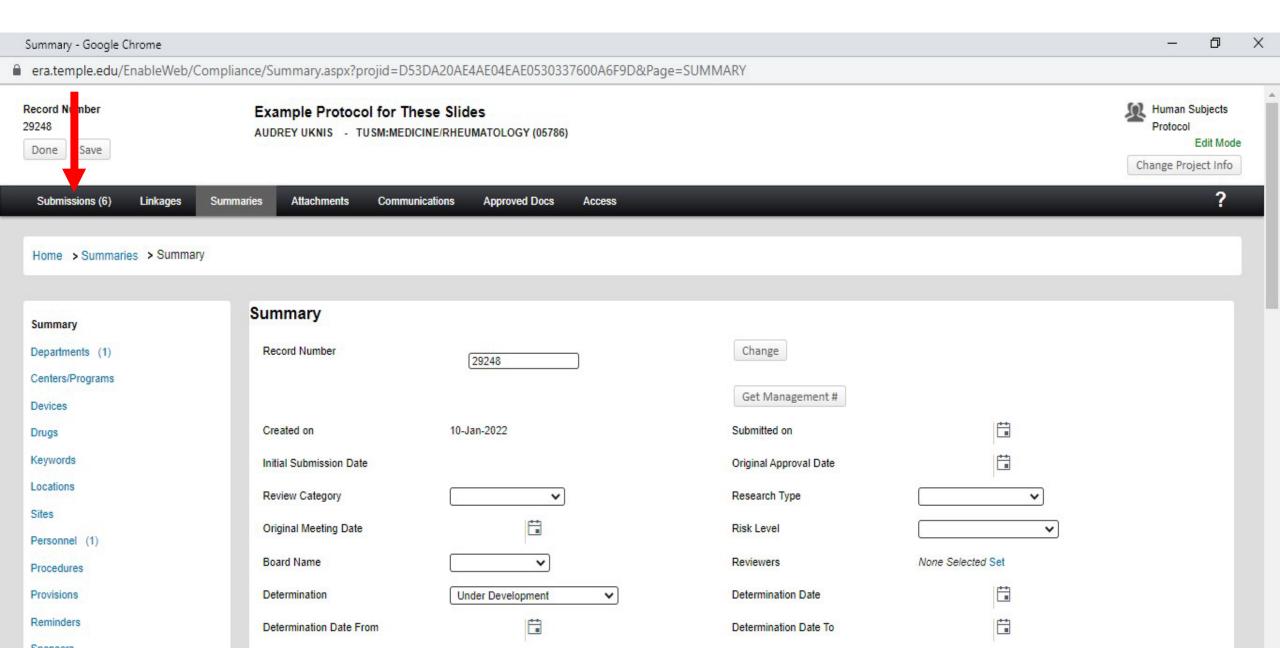
It is suggested to avoid the other options, unless you are an expert ERA user



Move mouse over to the right then click on "Additional Submissions" If that is not an option, click "Master Record"



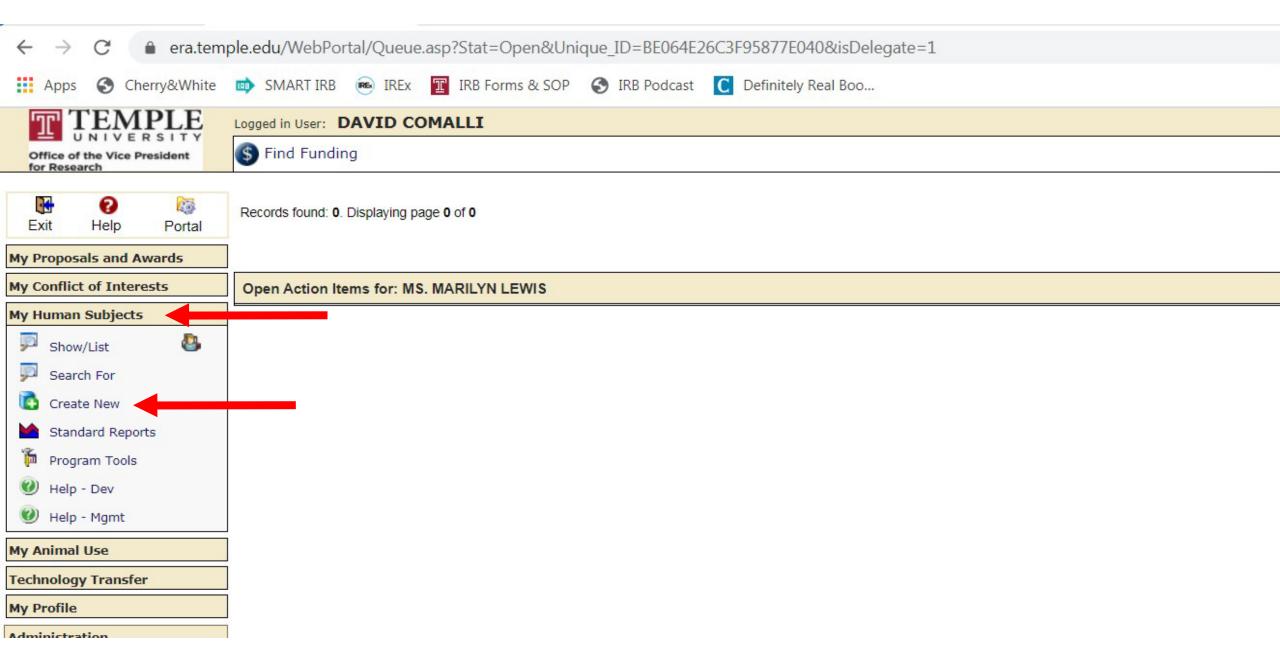
If you clicked "Master Record," click on Submissions to get to the Submissions page



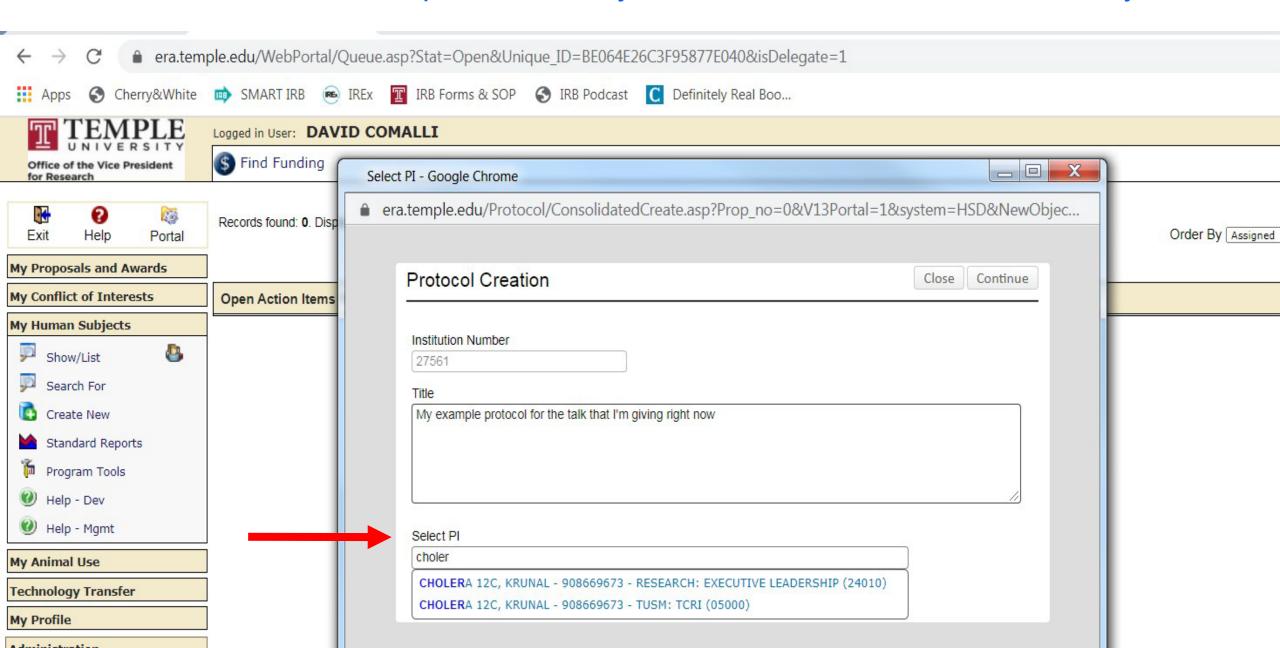
Creating & Submitting an Initial Submission



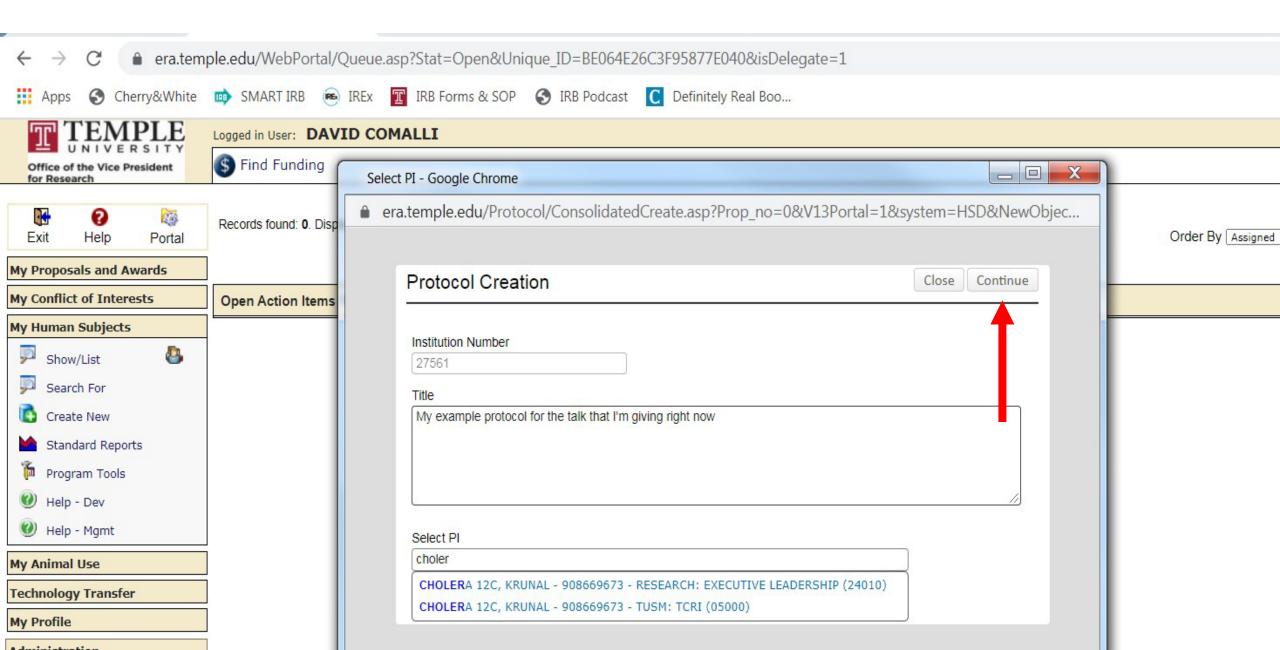
My Human Subjects > Create New



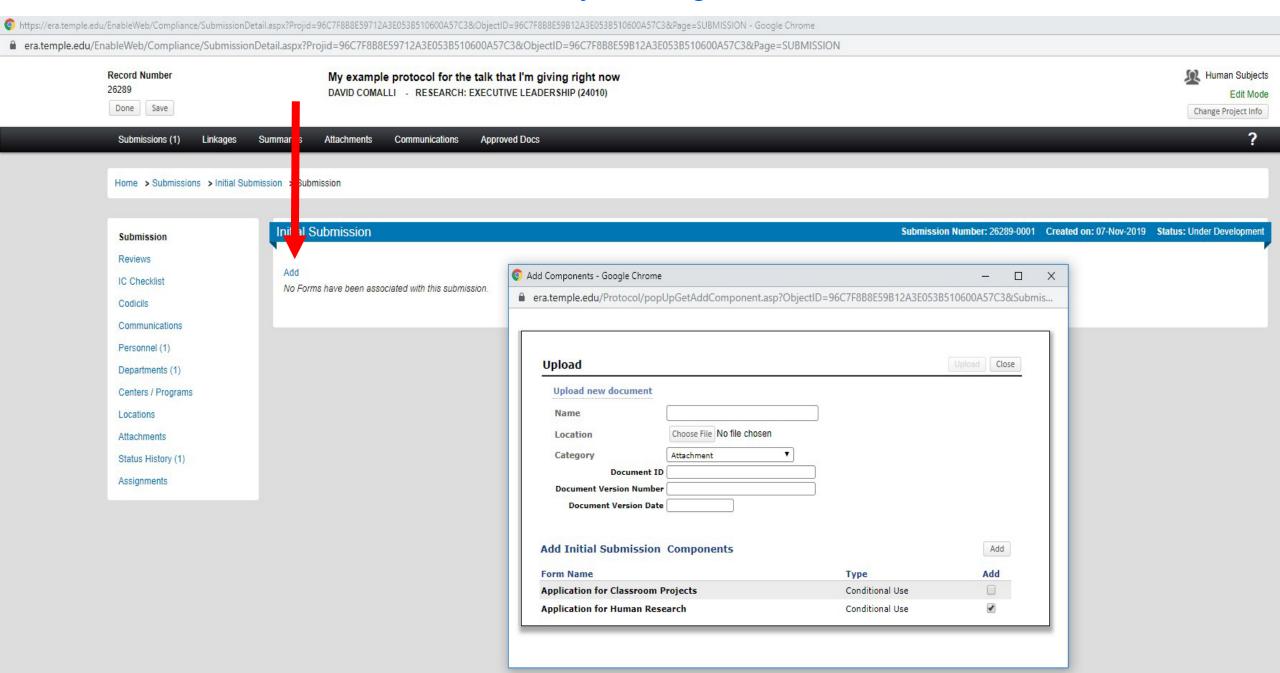
MAKE SURE TO SELECT THE RIGHT PI Your name will show up automatically, delete and search for PI if it's not you



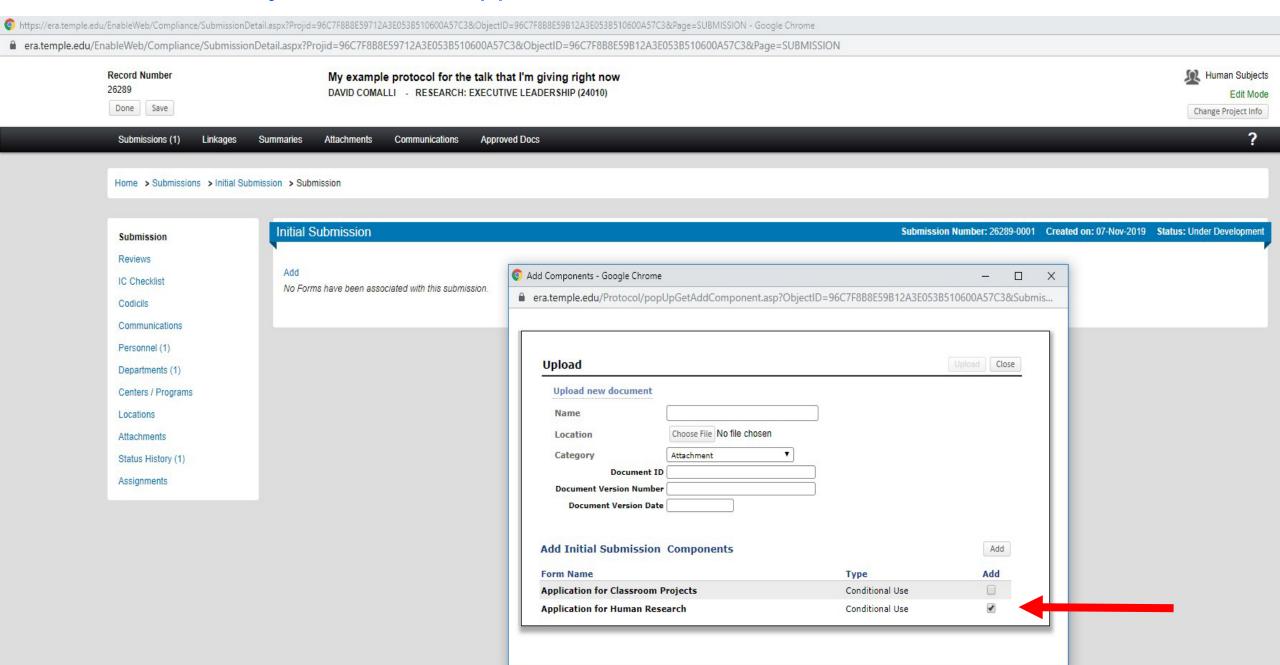
Click Continue and be directed to the Initial Submission



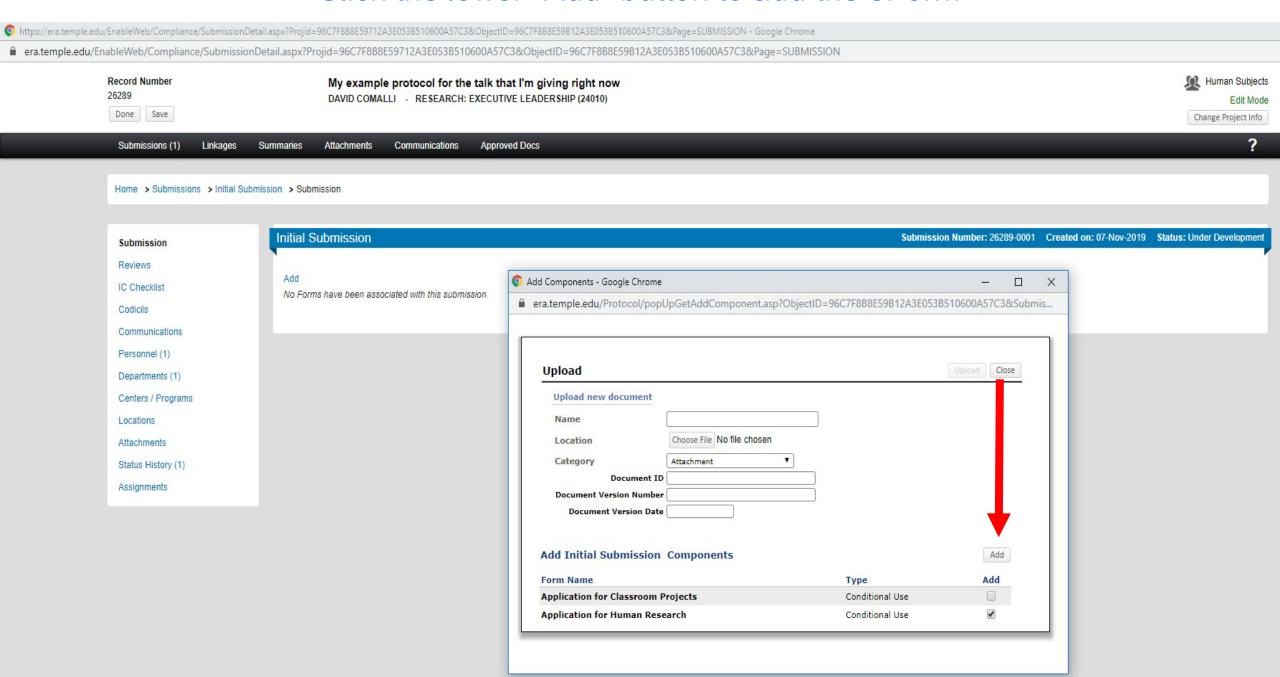
Add documents by clicking the "Add" button



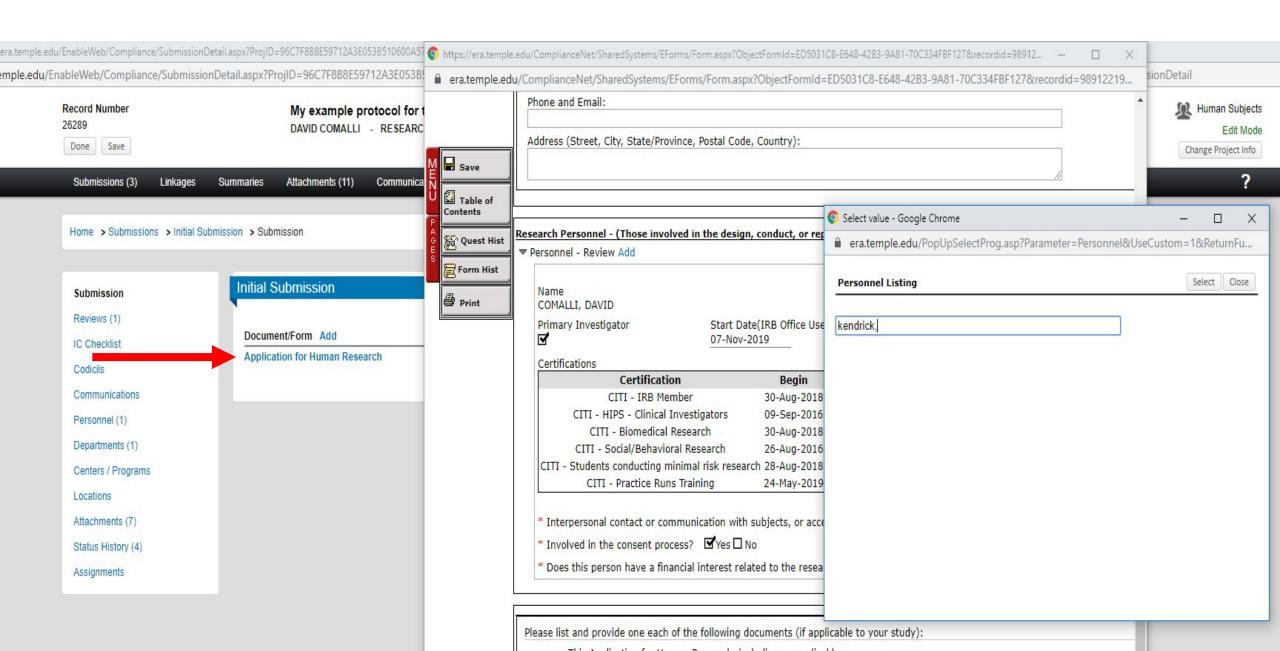
Always create the Application for Human Research eForm first



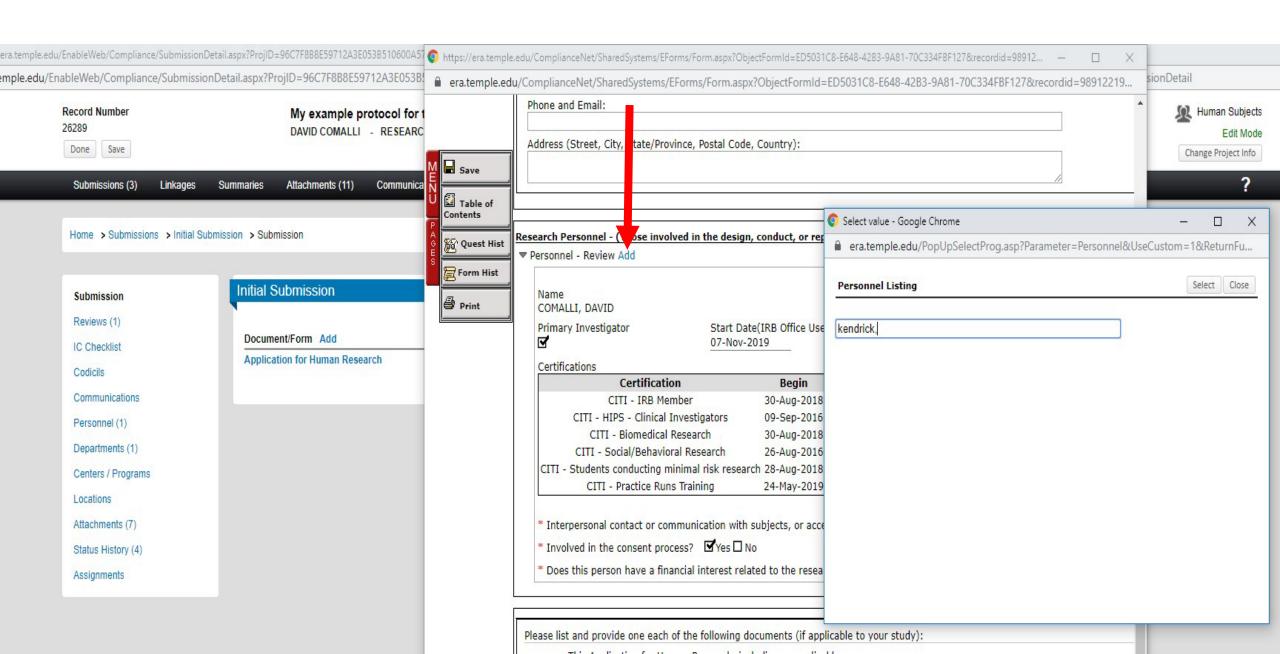
Click the lower "Add" button to add the eForm



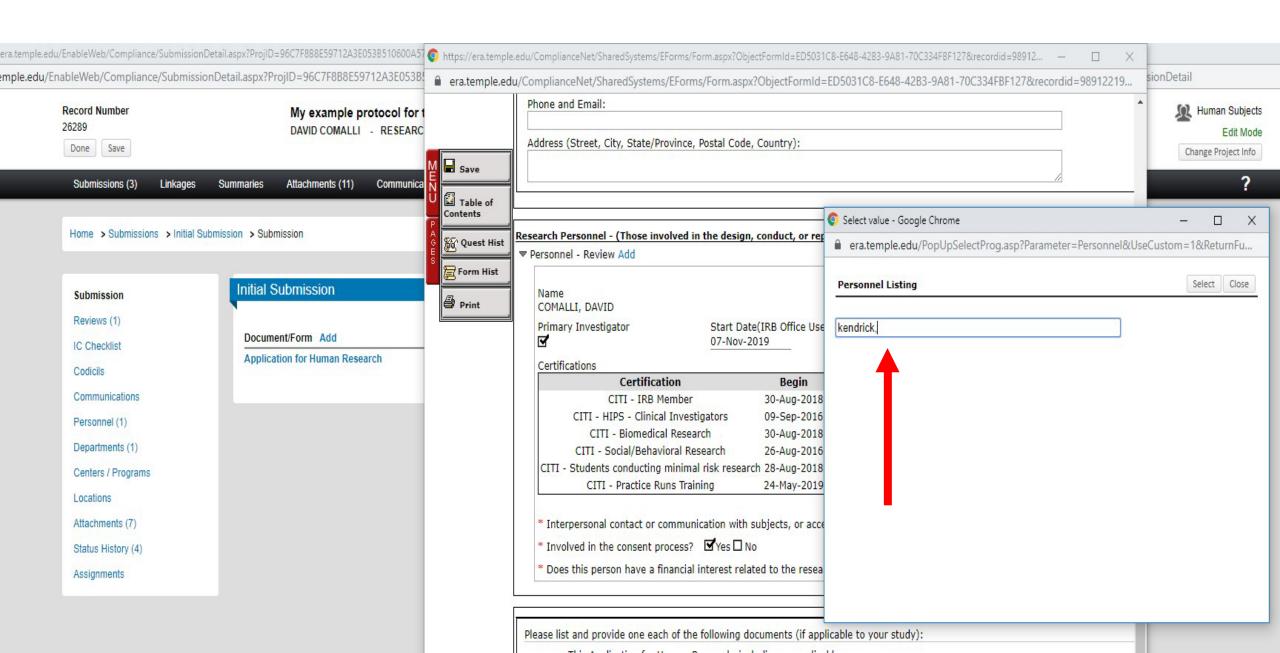
Open the eForm



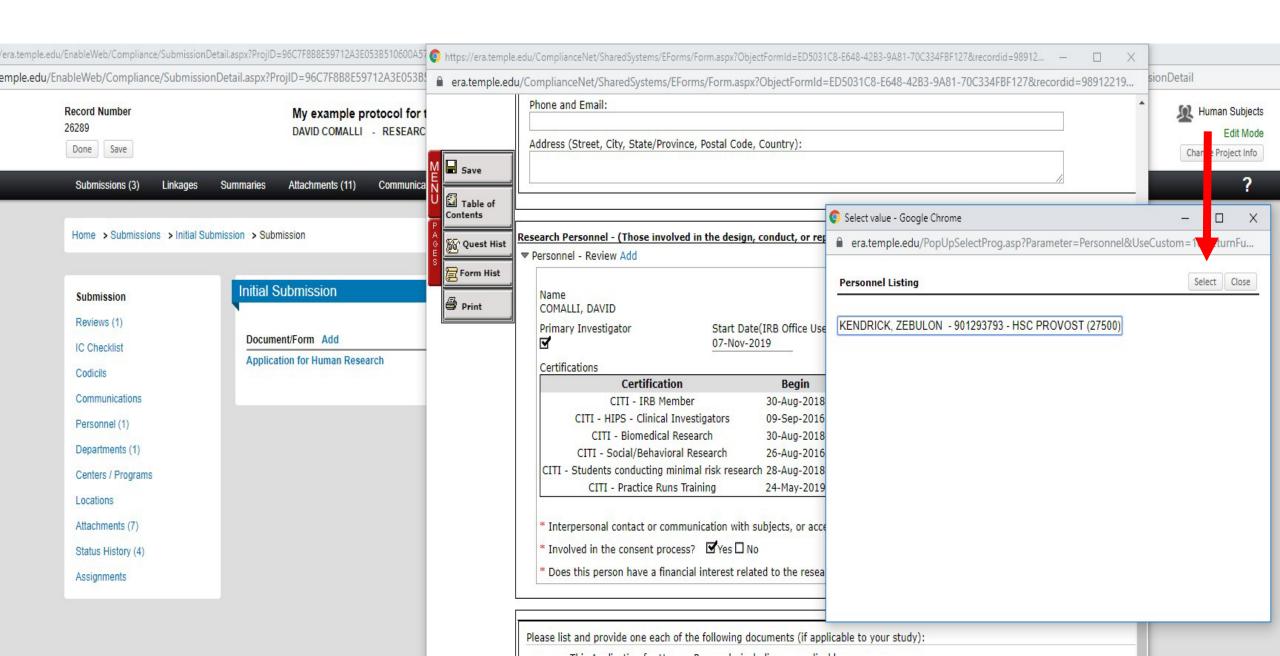
Add all research personnel, especially yourself (if you're not the PI)



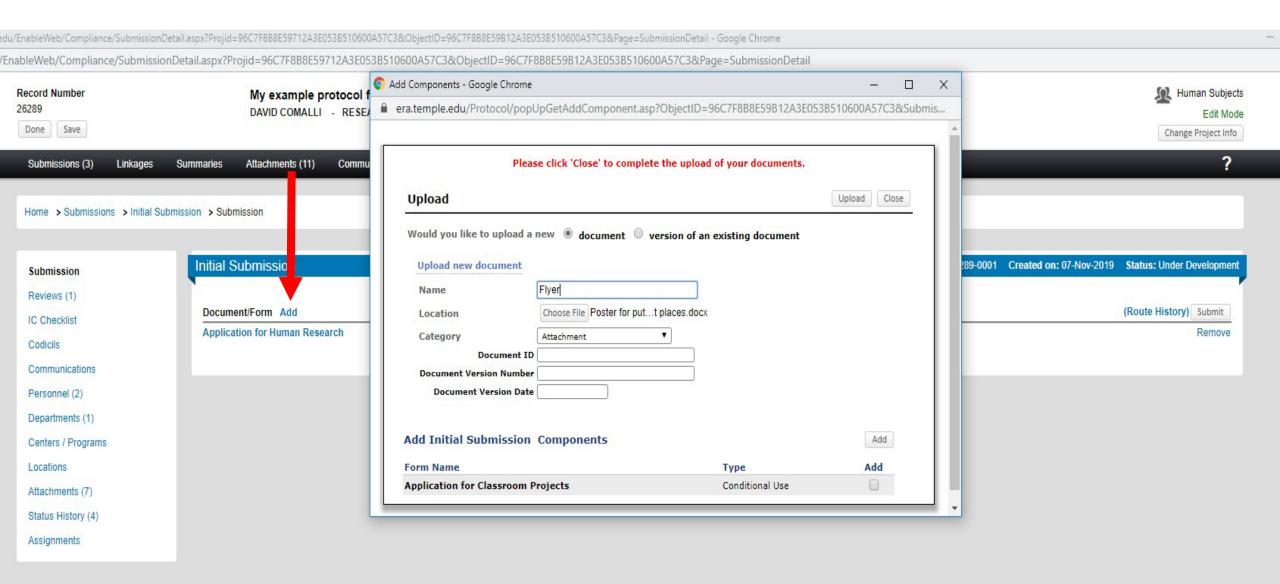
Start typing the last name of the person you're adding and click their name



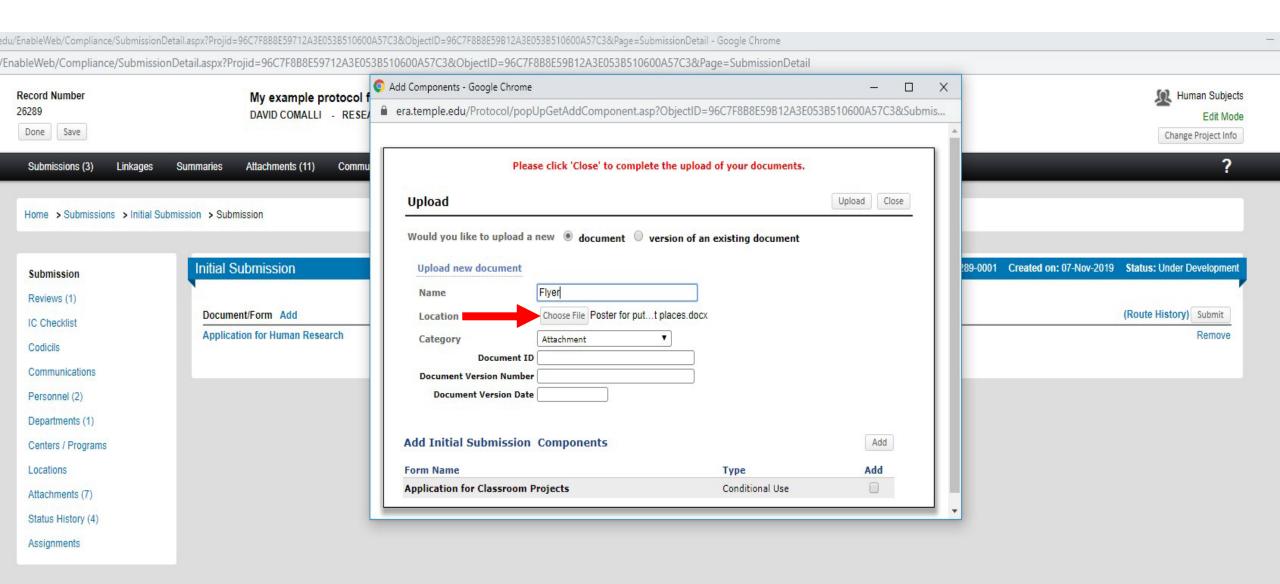
Click "Select" button; continue adding personnel and then complete the eForm



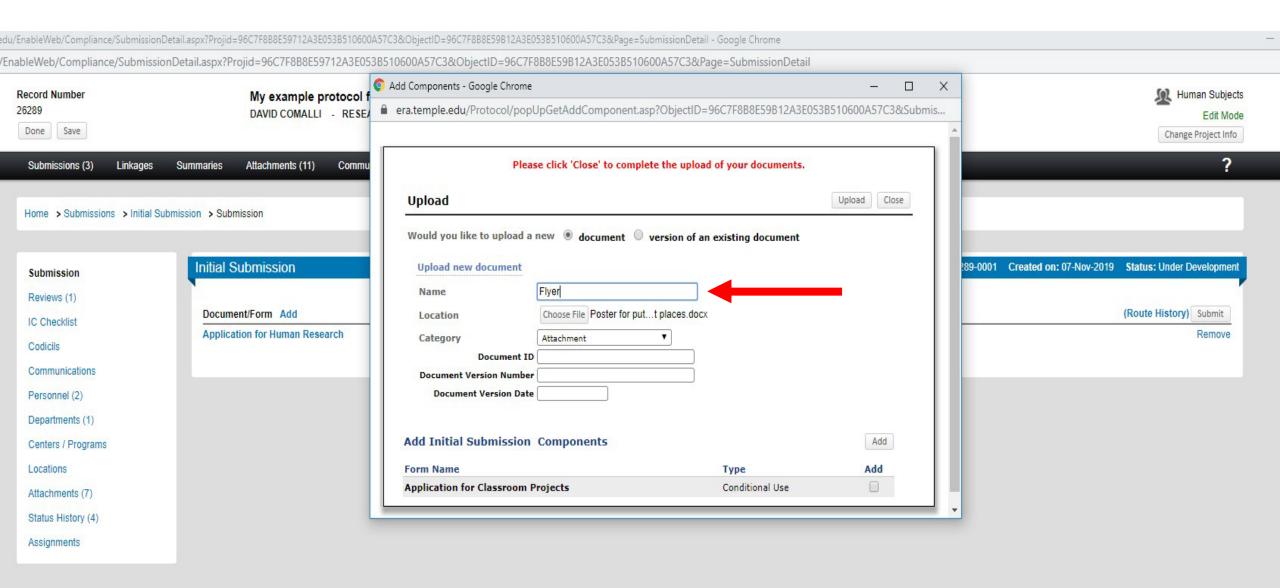
Add additional study documents by clicking the "Add" button



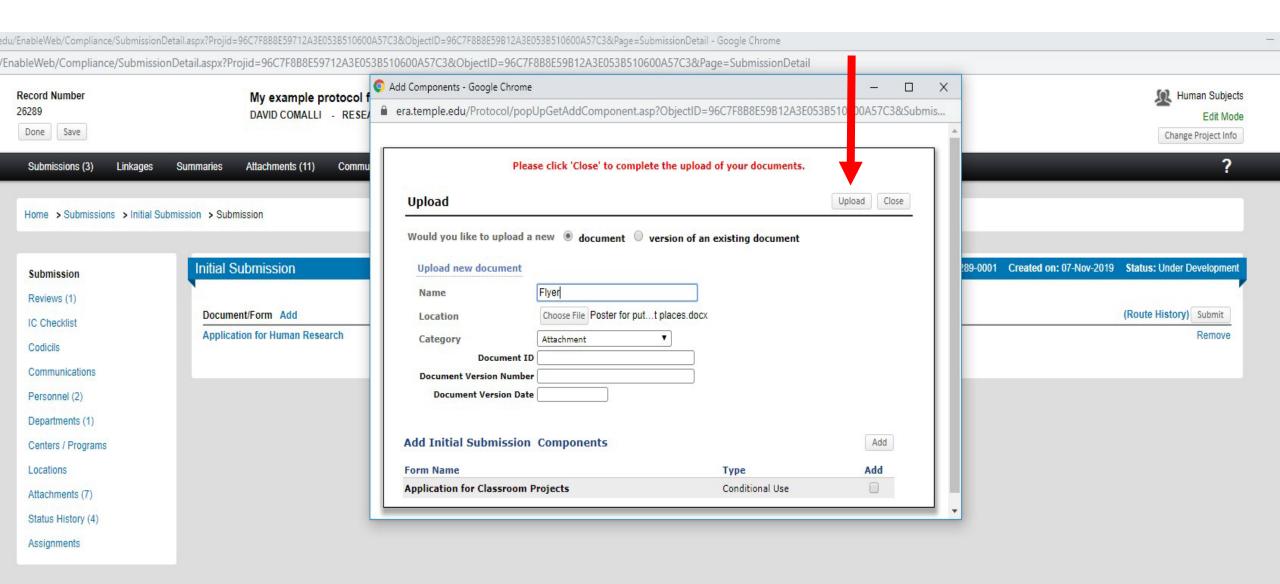
Click "Choose File" and find the document



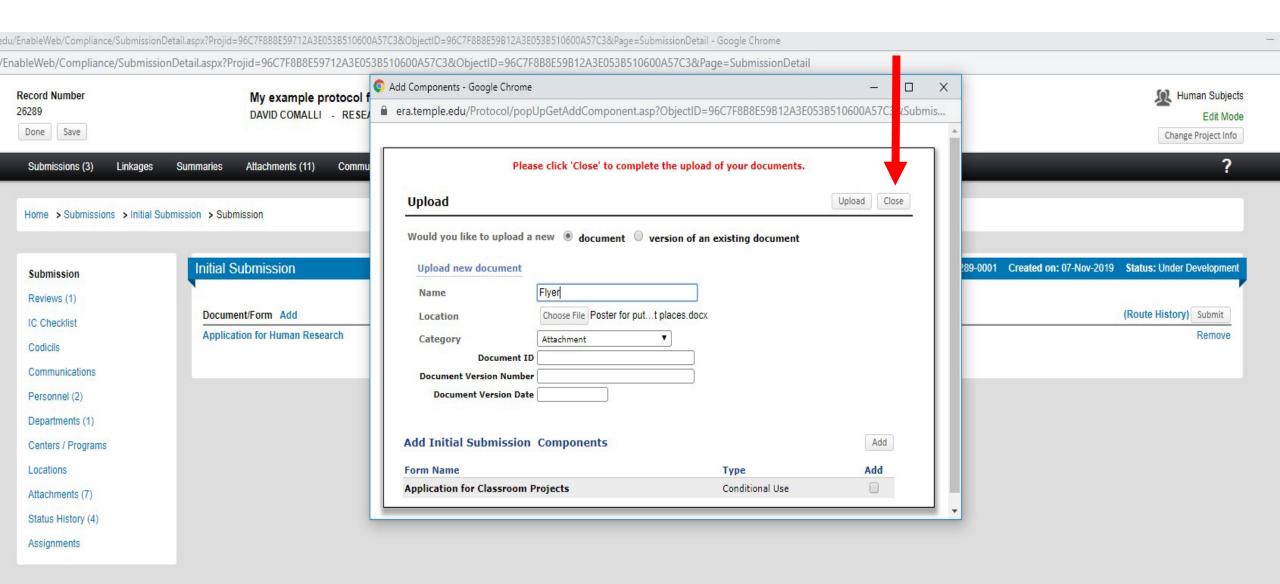
"Name" should be succinct and informative; It's what the IRB will see



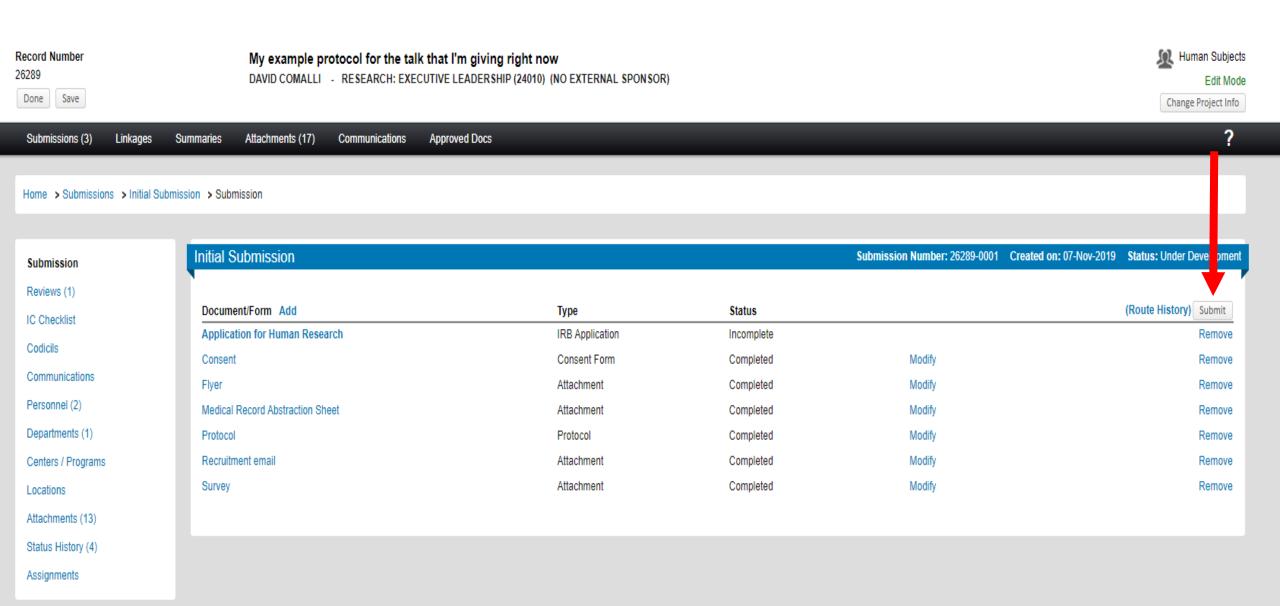
Click "Upload"; See pop-up window refresh; repeat



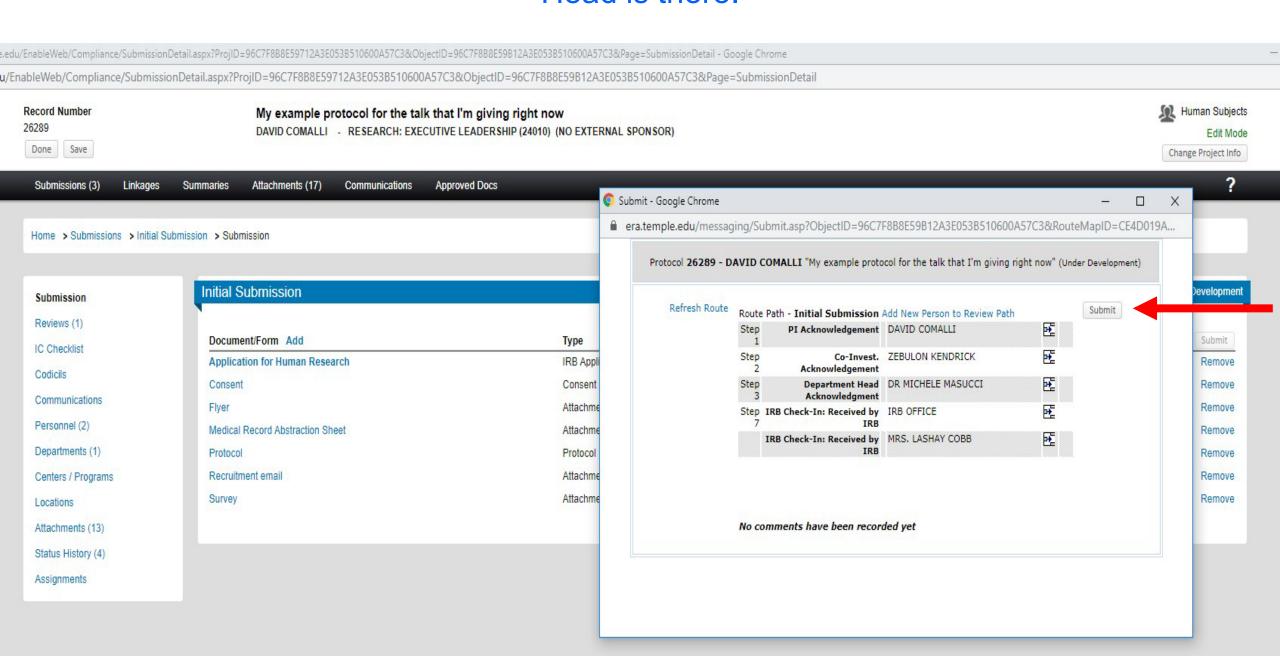
Clicking "Close" will refresh the main page and show all uploaded documents



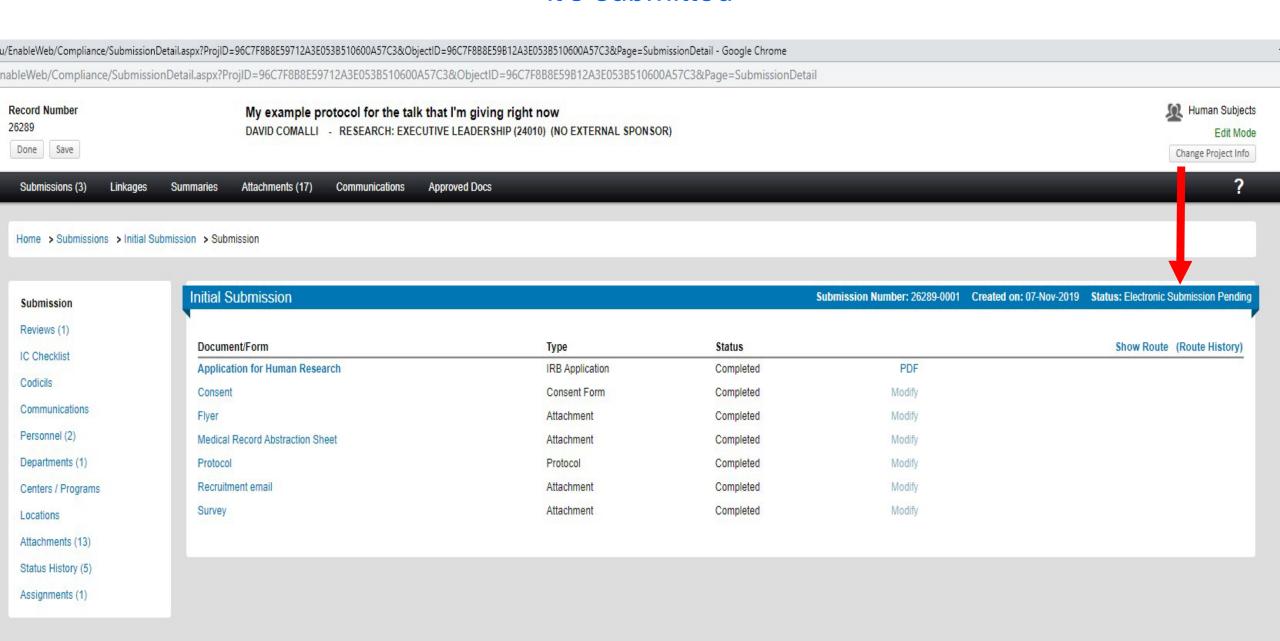
Click "Submit" when all documents are uploaded; Note it's not actually submitted yet



After the attestation, inspect the approval route and click submit; Make sure the Dept. Head is there.



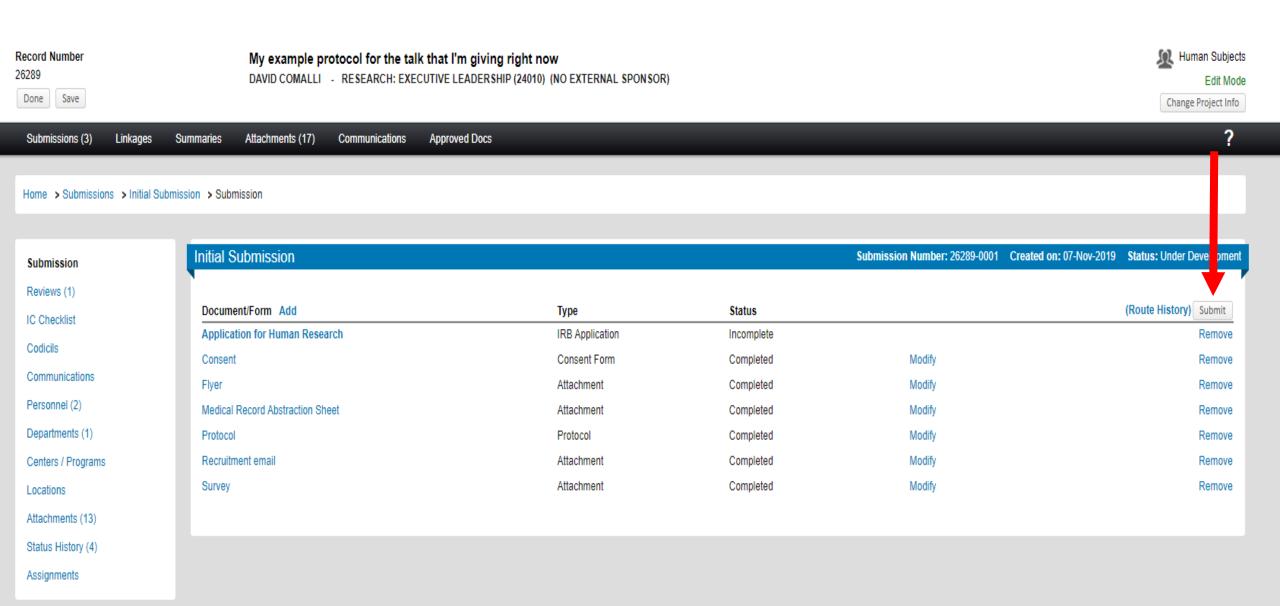
Status will change from "Under Development" to "Electronic Submission Pending" once it's submitted



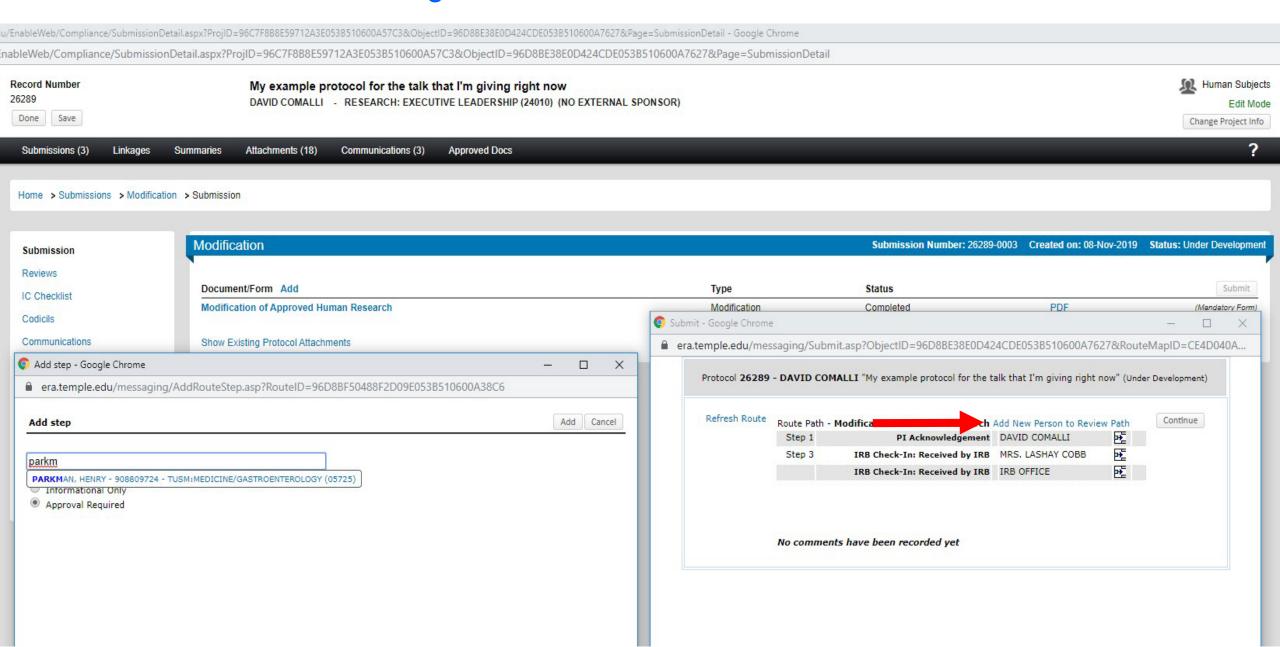
Approval Route Adding Personnel



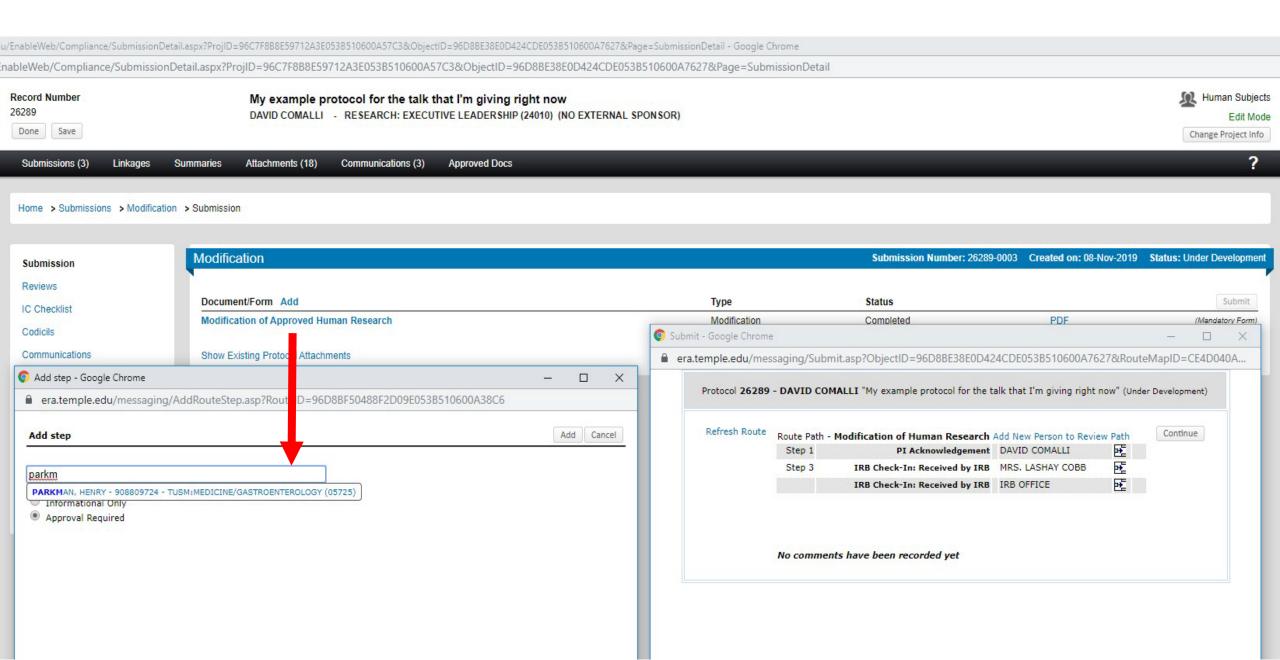
Click "Submit" when all documents are uploaded; Note it's not actually submitted yet



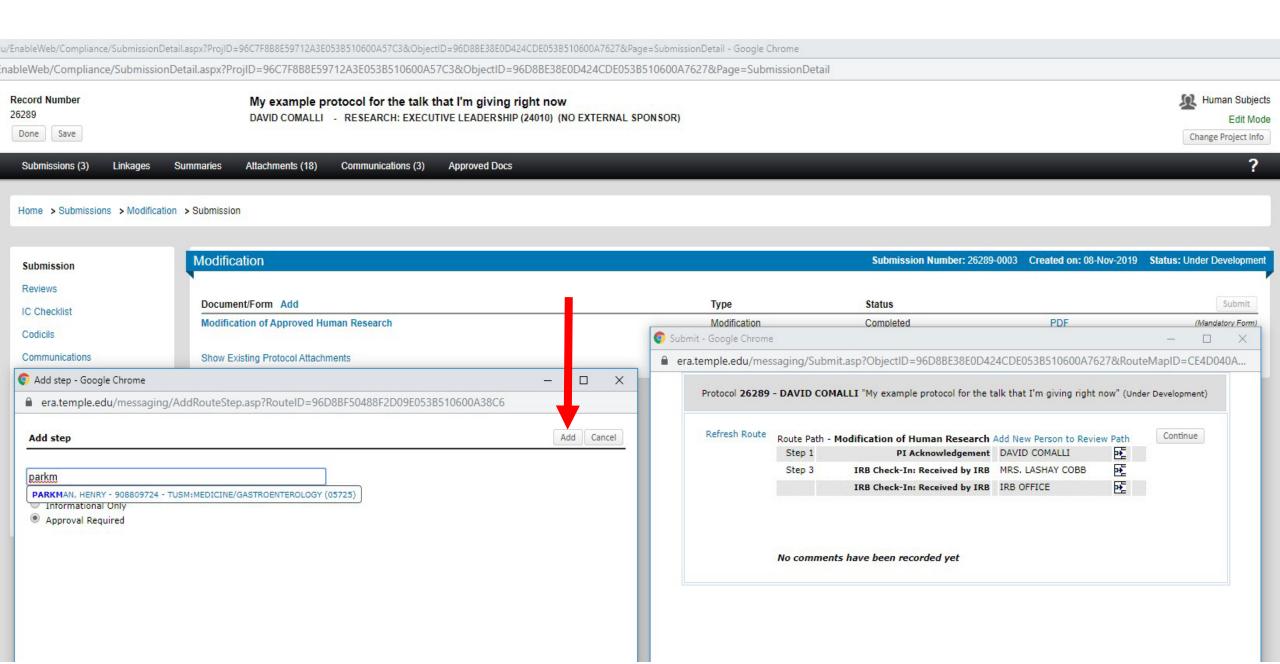
If adding Temple (Hospital or University) personnel, add them to the approval route by clicking "Add New Person to Review Path"



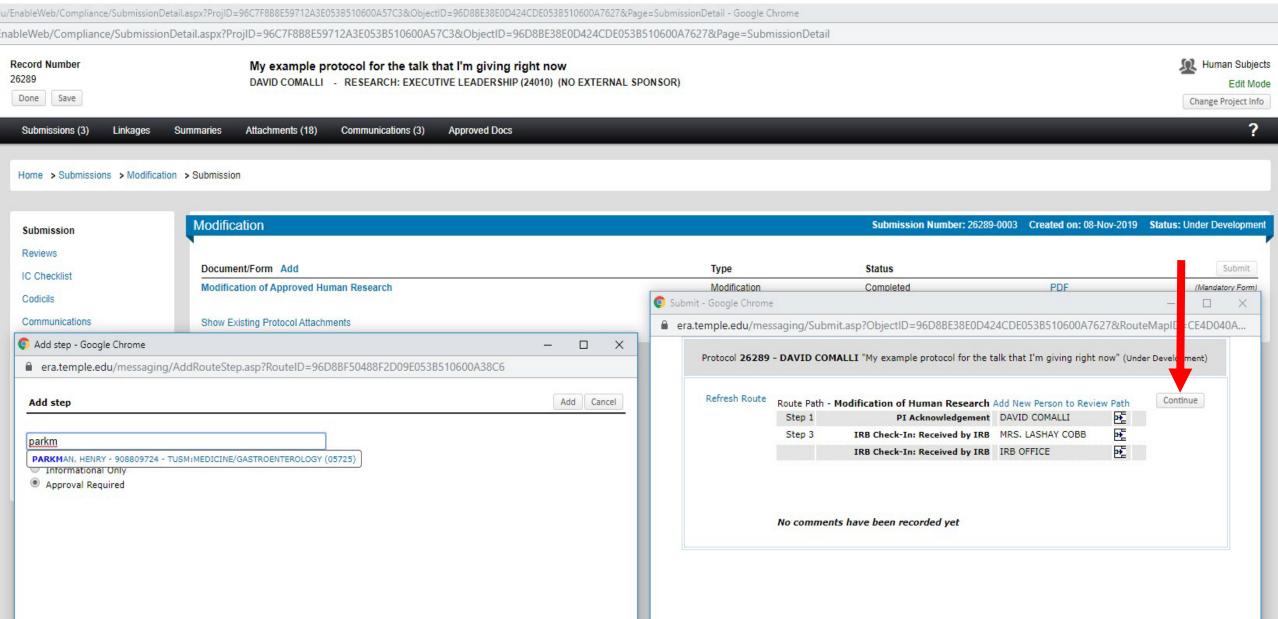
Type the last name and select the person



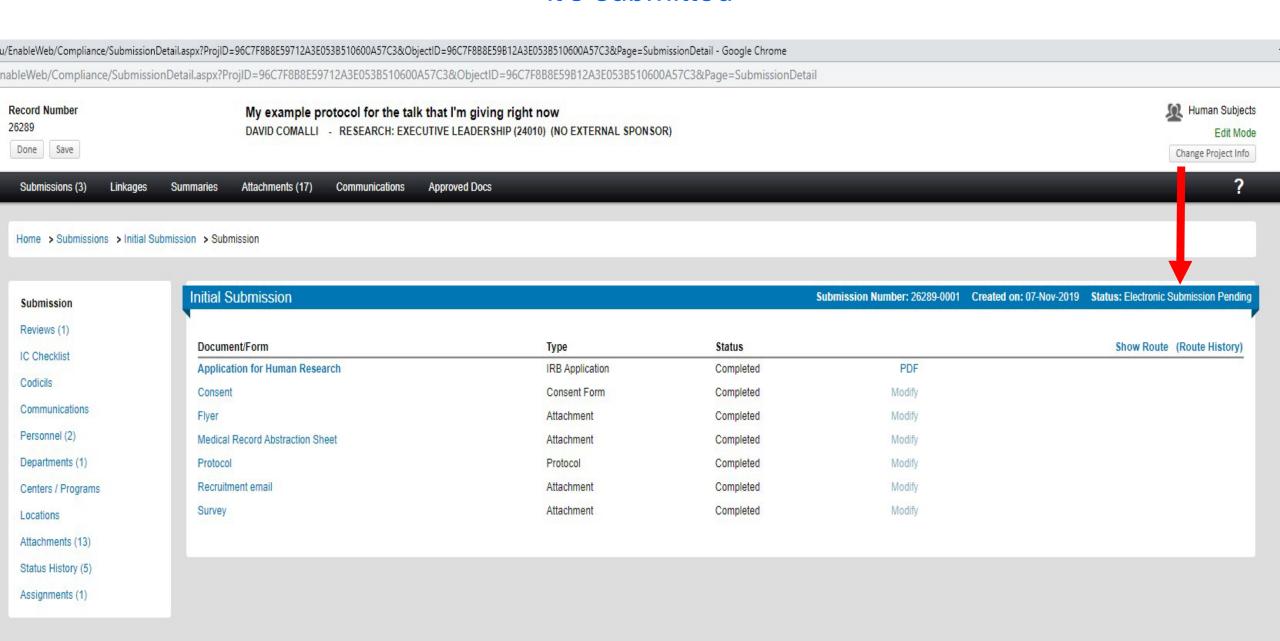
Click "Add" and repeat until all new personnel are added



Look at the approval route and click "Continue" You will get an email after the person ahead of you acknowledged the submission



Status will change from "Under Development" to "Electronic Submission Pending" once it's submitted



Approval Route: Acknowledging a Submission



Once it is your turn to acknowledge the submission, you'll receive an email. Open the Acknowledge email (from OFFICE OLD, IRB); click "Reviewer Dashboard"

An Initial Application For Your Review D Inbox x

OFFICE_OLD, IRB

to me -

An Initial Application has been submitted to the Institutional Review Board. Your Approval is required for this submission.

Please click the link below to review and comment on the following application

IRB #:26289

Principal Investigator: DAVID COMALLI

Department:RESEARCH: EXECUTIVE LEADERSHIP (24010) Title:My example protocol for the talk that I'm giving right now

Sponsor: NO EXTERNAL SPONSOR

Your approval is required for this submission.

Click here for a short version of instructions on how to review this submission.

REMEMBER TO SAVE YOUR WORK BY CLICKING ON "SAVE" IN THE UPPER RIGHT-HAND SIDE OF THE REVIEWER'S DASHBOARDIIII

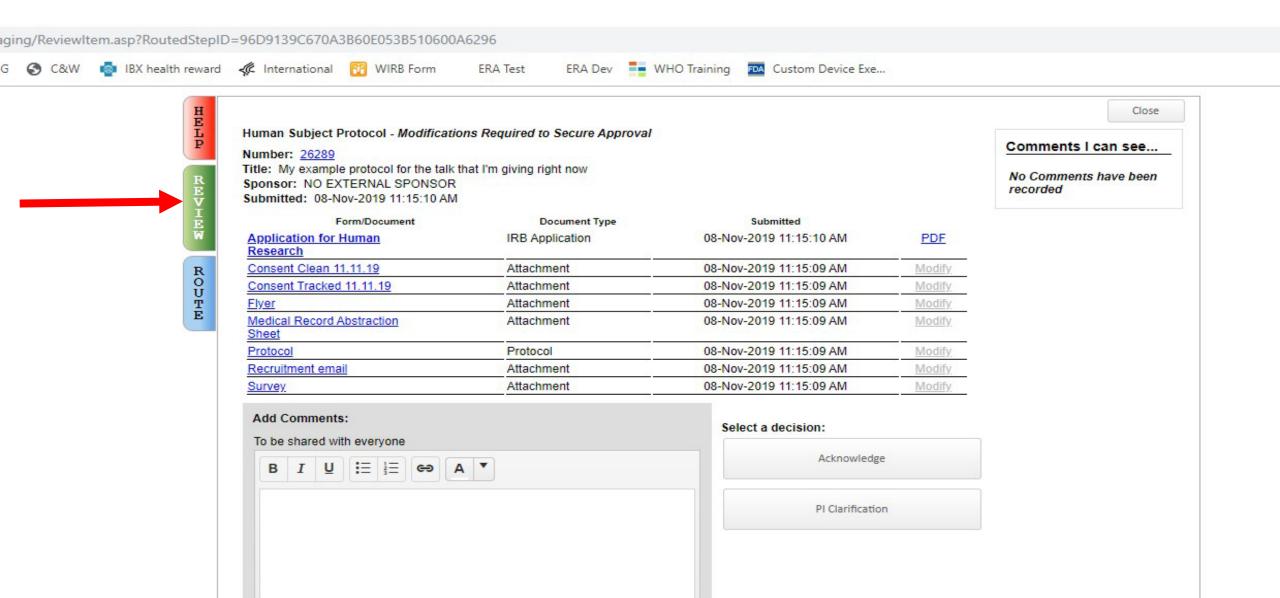
To add your review, click here Reviewer Dashboard



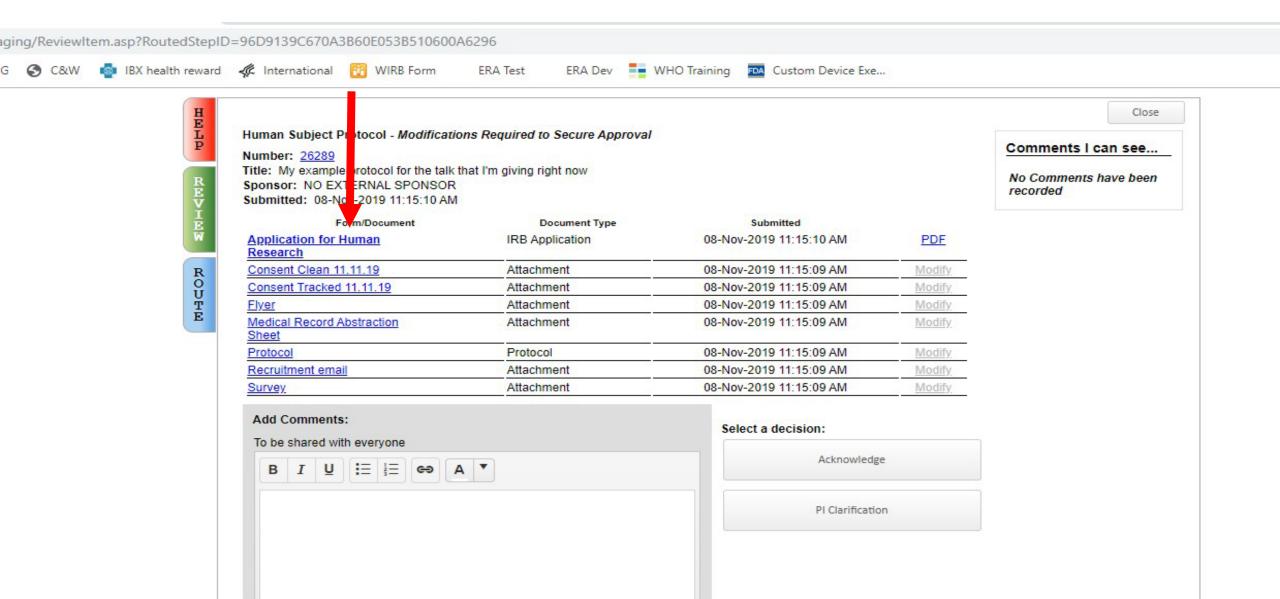
To review the entire submission, click here Open Submission Package

If you have questions about the approval process, please contact the IRB Office at (215) 707-3390.

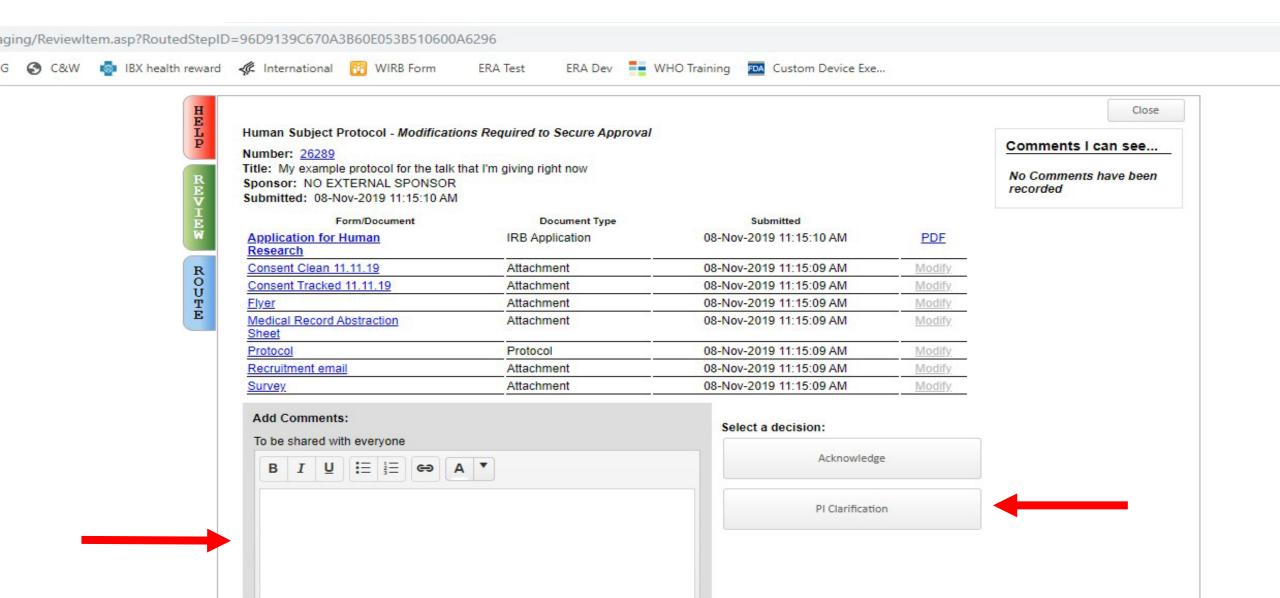
You may need to sign into ERA; Click the "Review" tab



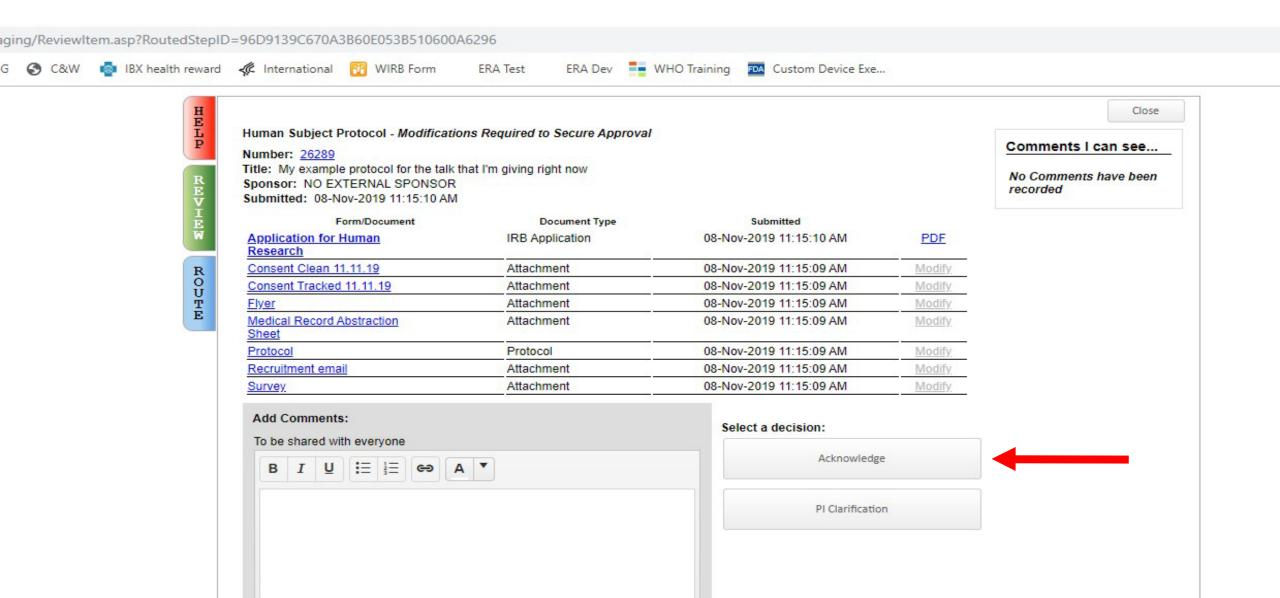
Review documents by clicking on them



If you notice an error, you can stop the approval route (so the error can be fixed) by adding a Comment and clicking "PI Clarification"; Re-submit after fix(es)



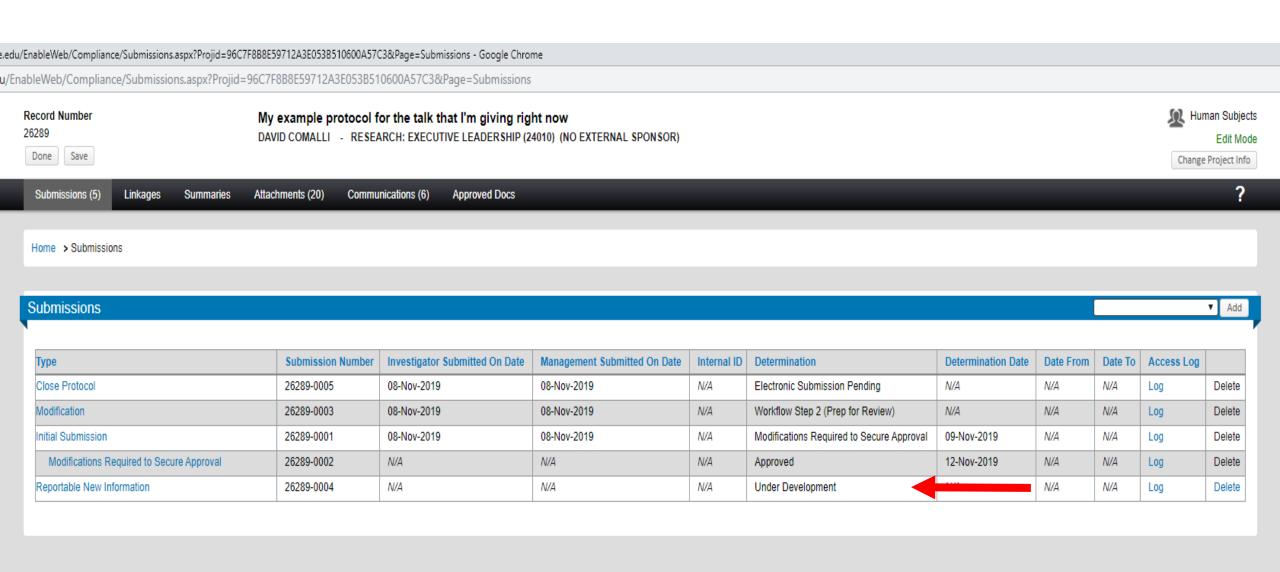
If the contents are acceptable, click "Acknowledge" and agree to the subsequent attestation



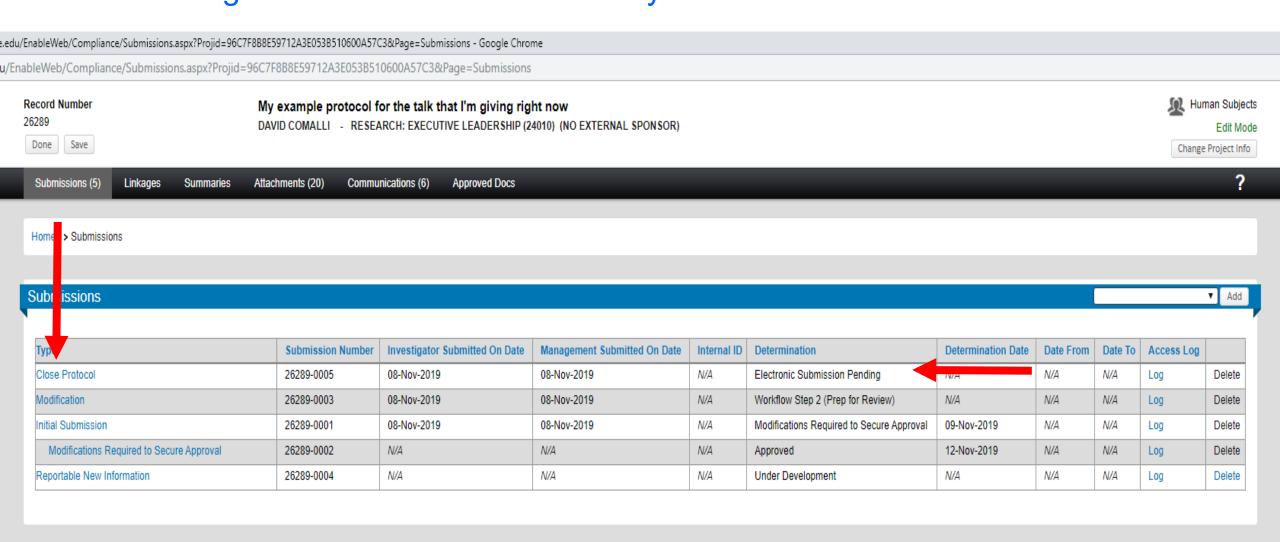
Approval Route: Checking where the Submission is in the Route



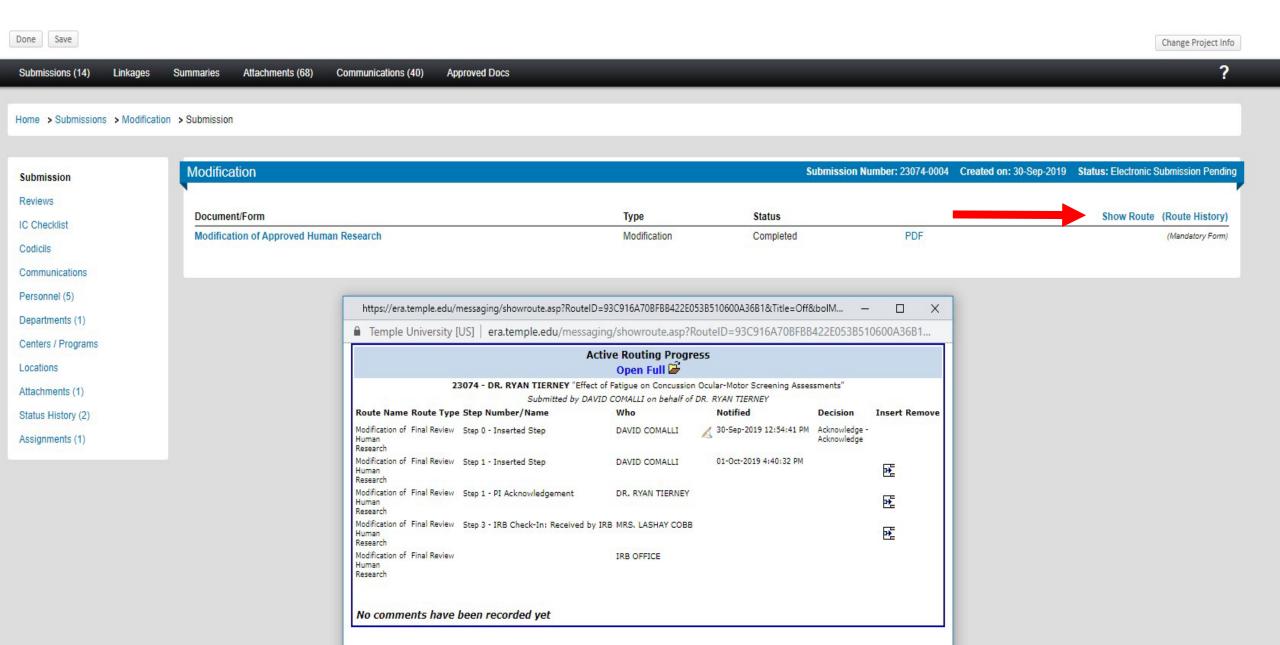
Status can be viewed on the "Submissions" page as well; "Under Development" means not submitted



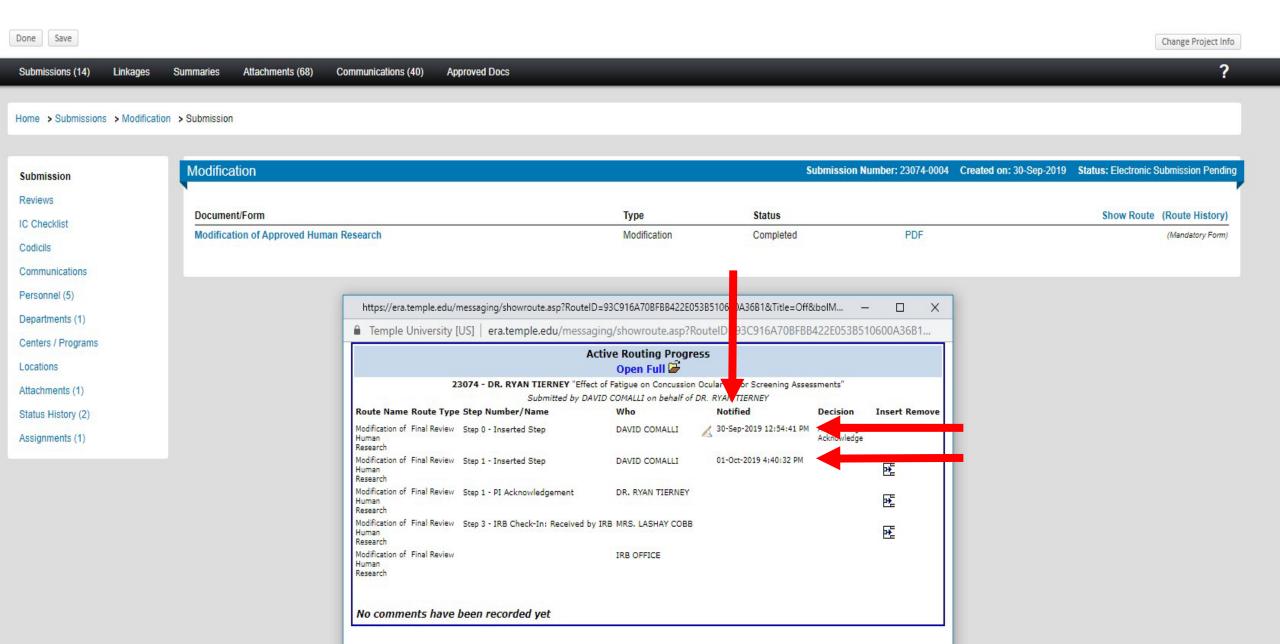
If something is "Electronic Submission Pending," Then it's been submitted to—but not brought into—the IRB. Clicking the submission itself can let you see who the submission is with.



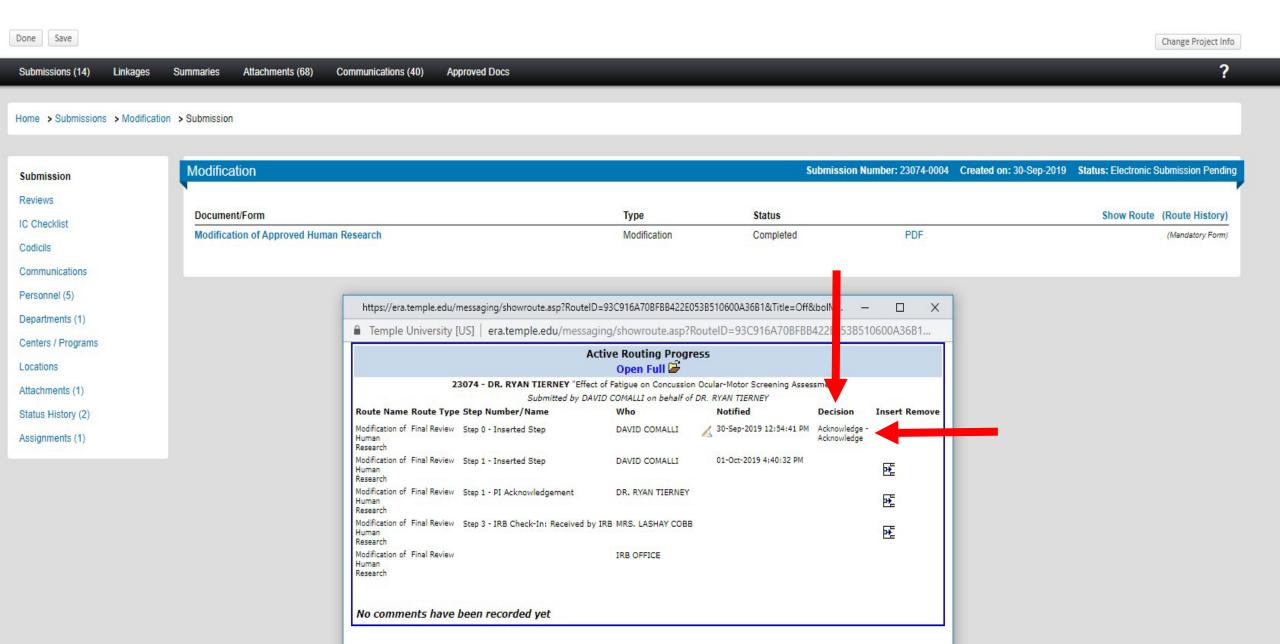
At any time, click "Show Route" to see who has Acknowledged and been notified



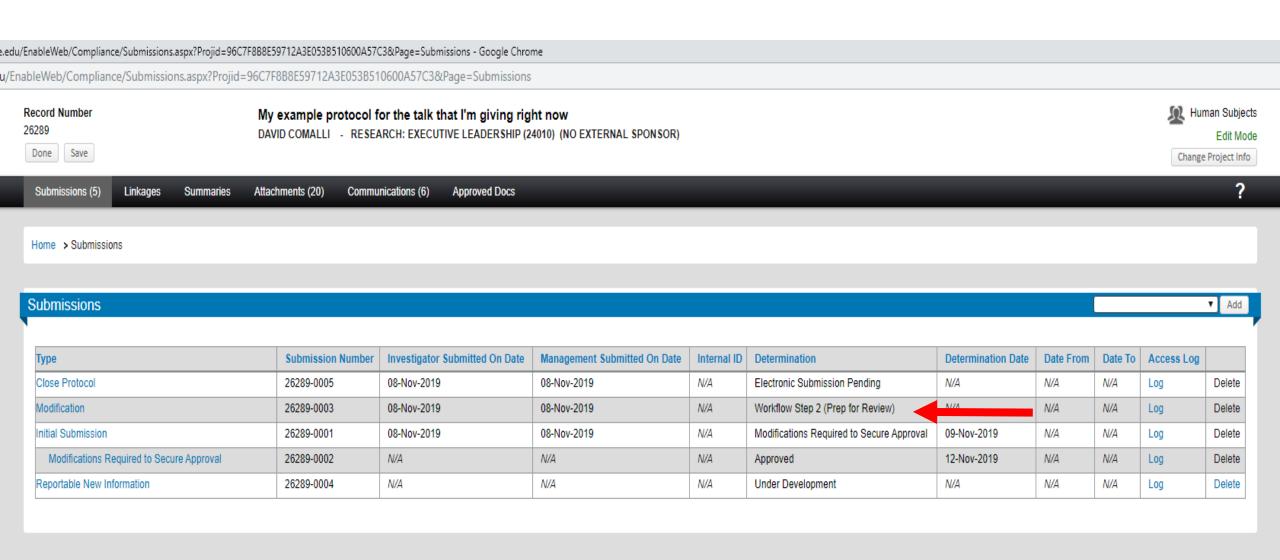
The date under "Notified" only reflects when a person was notified



They haven't acknowledged without the "Acknowledge - Acknowledge" under "Decision"; Hover over Ack – Ack to see (left hand, top corner) when the person Acknowledged



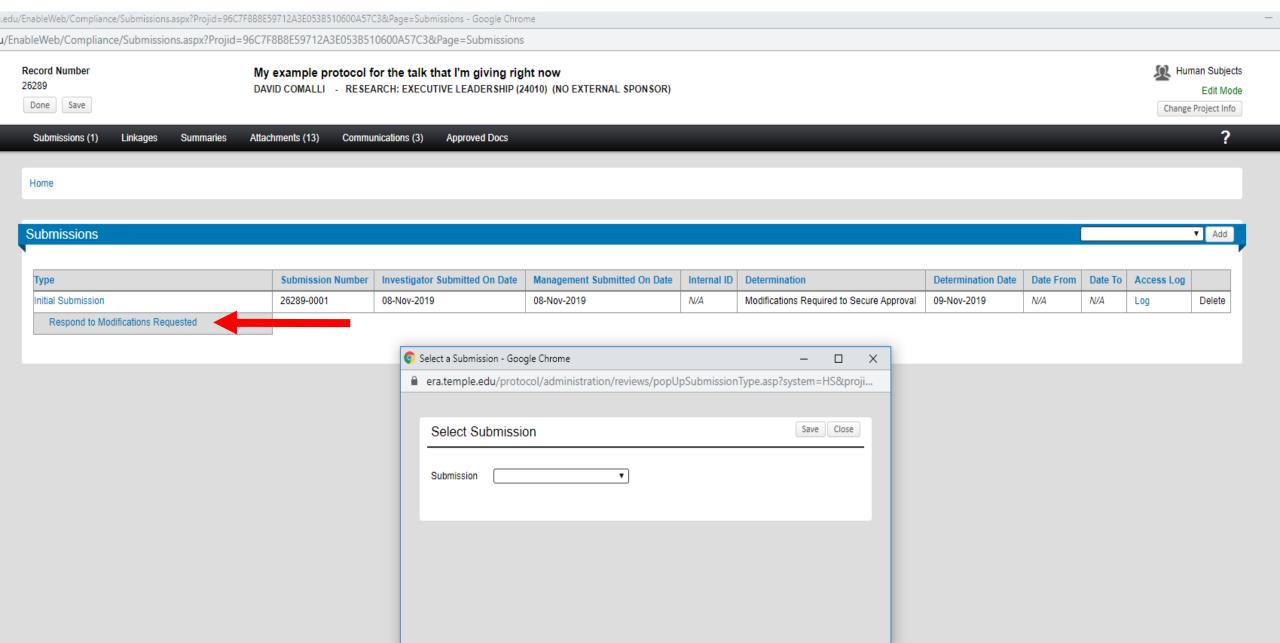
"Workflow Step 2" reflects that the IRB has the submission, but has yet to review it



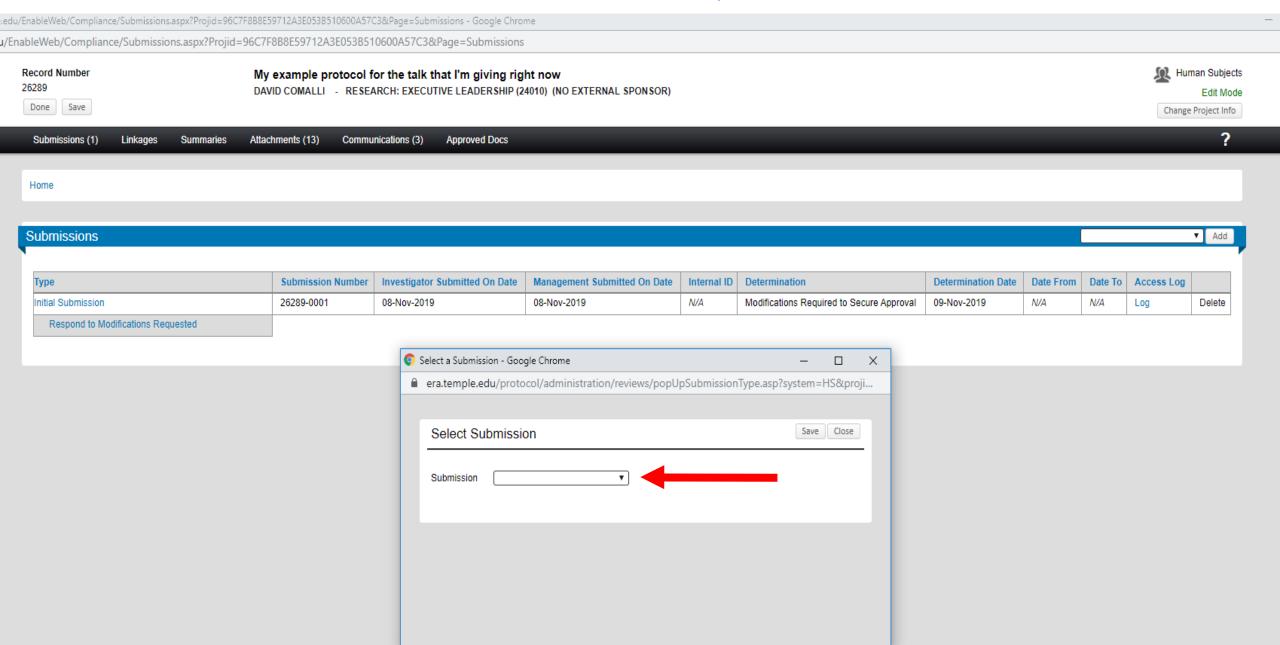
Responding to Modifications Requested



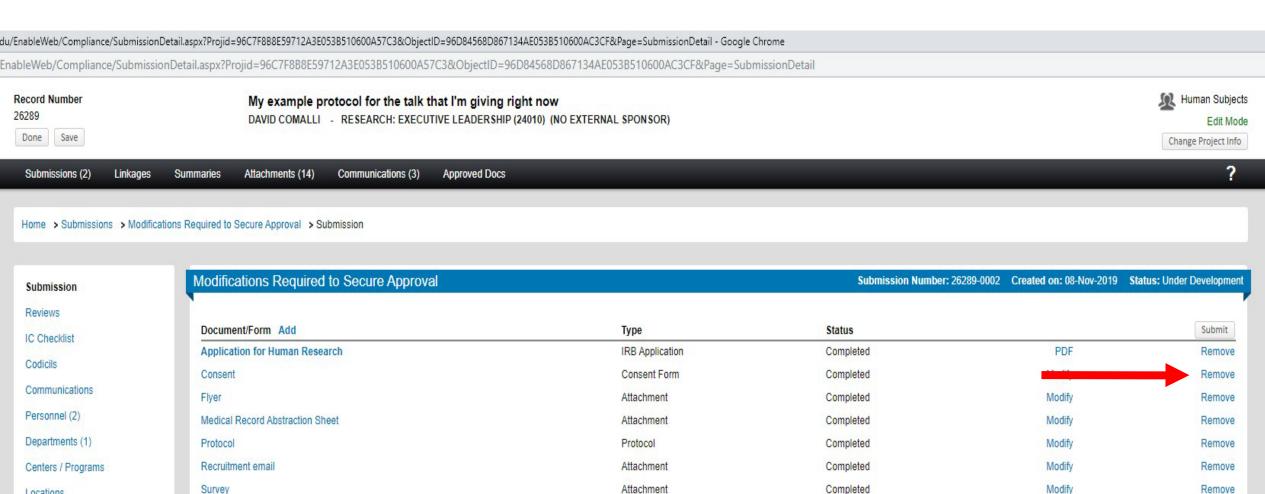
Respond to "Modifications Required to Secure Approval" by clicking the "Respond..." link; Don't create an "Amendment" to respond to requested changes



Select "Modifications Required to Secure Approval" from the dropdown (or "Deferred" if appropriate)



Remove documents that are requested to be changed; Don't remove the eForm; Don't use the Modify feature



Locations

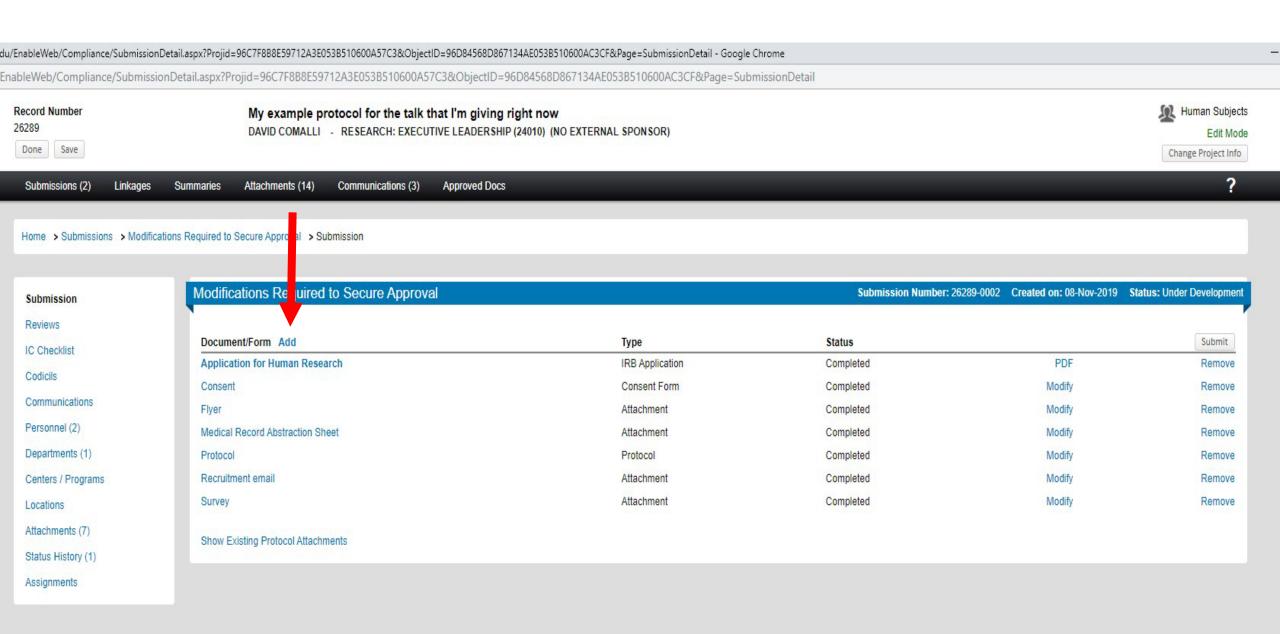
Attachments (7)

Status History (1)

Assignments

Show Existing Protocol Attachments

Add the new (Tracked Changes and Clean versions) documents



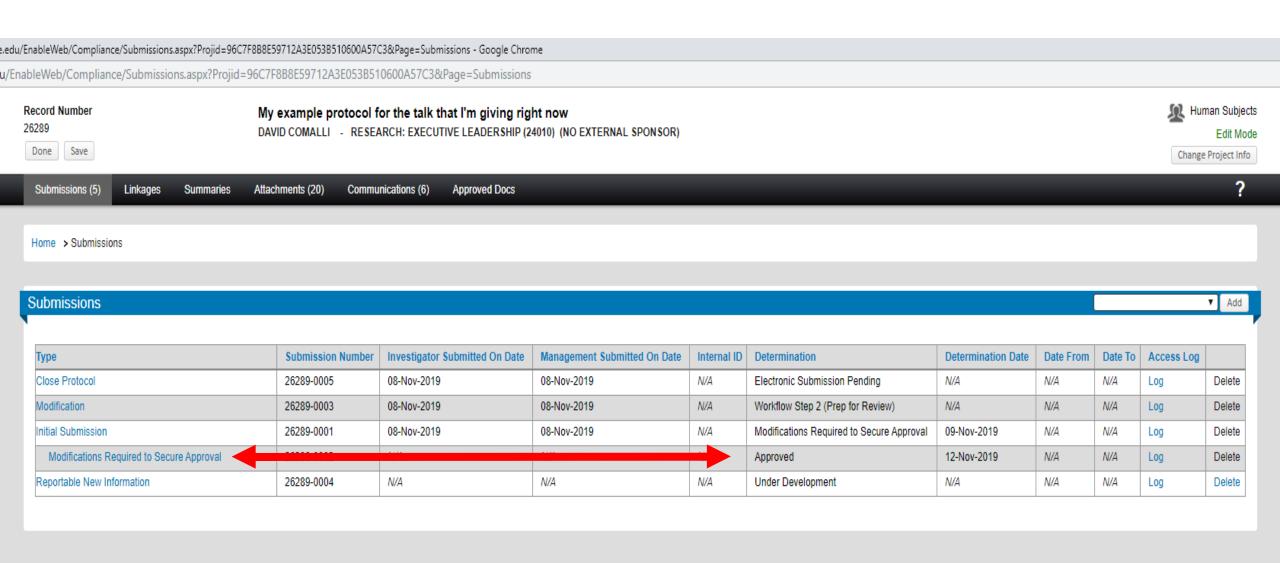
Click "Submit" once all updated documents are submitted; **Don't remove unchanged documents**

du/EnableWeb/Compliance/SubmissionDetail.aspx?ProjlD=96C7F8B8E59712A3E053B510600A57C3&mark=3283227&WFTablD=16&rand=0.16045401324682573&Mode=EDIT&ObjectlD=96D84568D867134AE053B510600AC3CF&Page=SubmissionDetail - Google Chrome EnableWeb/Compliance/SubmissionDetail.aspx?ProjID=96C7F8B8E59712A3E053B510600A57C3&mark=3283227&WFTabID=16&rand=0.16045401324682573&Mode=EDIT&ObjectID=96D84568D867134AE053B510600AC3CF&Page=SubmissionDetail Record Number Human Subjects My example protocol for the talk that I'm giving right now 26289 DAVID COMALLI - RESEARCH: EXECUTIVE LEADERSHIP (24010) (NO EXTERNAL SPONSOR) Edit Mode Done Save Change Project Info Submissions (2) Linkages Attachments (16) Communications (3) Approved Docs Home > Submissions > Modifications Required to Secure Approval > Submission Modifications Required to Secure Approval Submission Number: 26289-0002 Created on: 08-Nov-2019 Status: Under Develo Submission Reviews Document/Form Add Type Submit Status IC Checklist Application for Human Research IRB Application Completed PDF Remove Codicils Consent Clean 11.11.19 Attachment Completed Modify Remove Communications Consent Tracked 11.11.19 Modify Attachment Completed Remove Personnel (2) Flyer Attachment Completed Modify Remove Departments (1) Medical Record Abstraction Sheet Attachment Completed Modify Remove Centers / Programs Protocol Protocol Completed Modify Remove Recruitment email Attachment Completed Modify Remove Locations Survey Attachment Completed Modify Remove Attachments (8) Status History (1) Show Existing Protocol Attachments Assignments

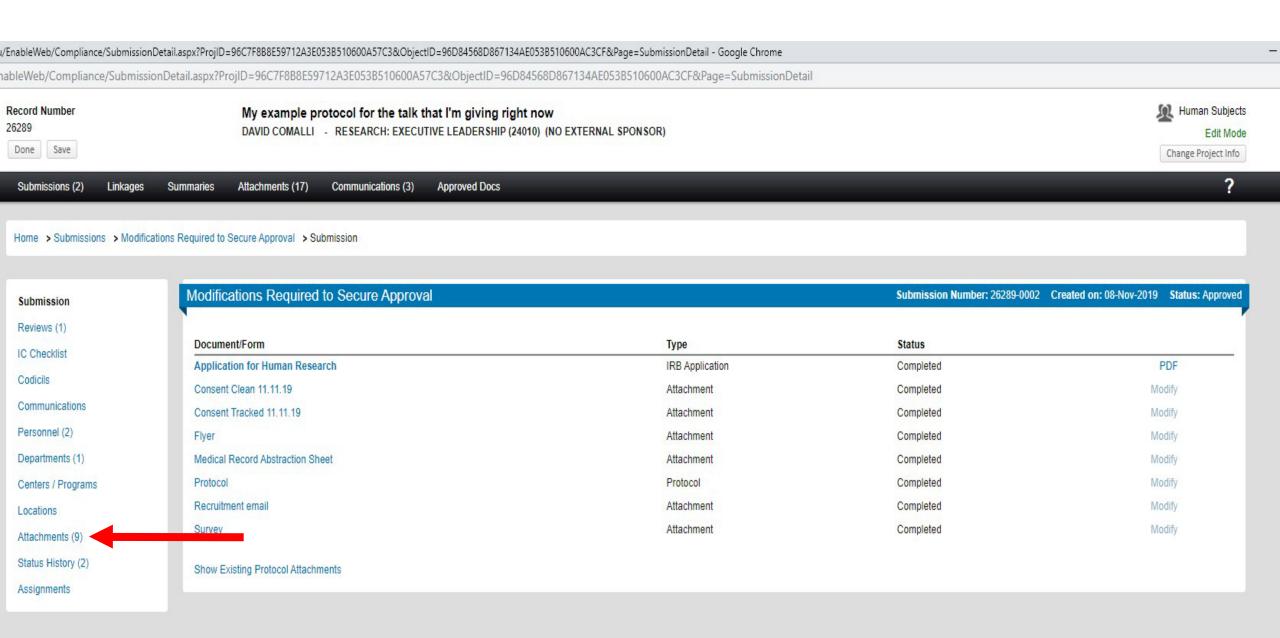
Finding the stamped consents (Expedited and Full Board research only)



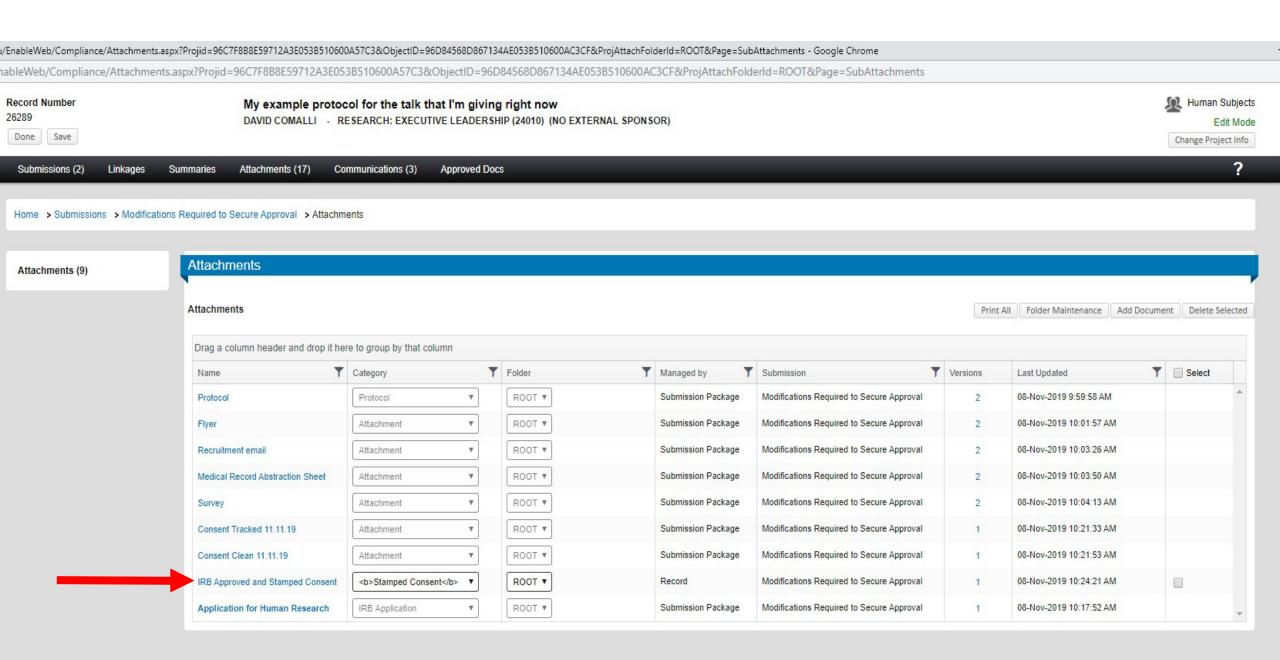
After the submission is approved, retrieve stamped consent forms by going to the "Approved" submission



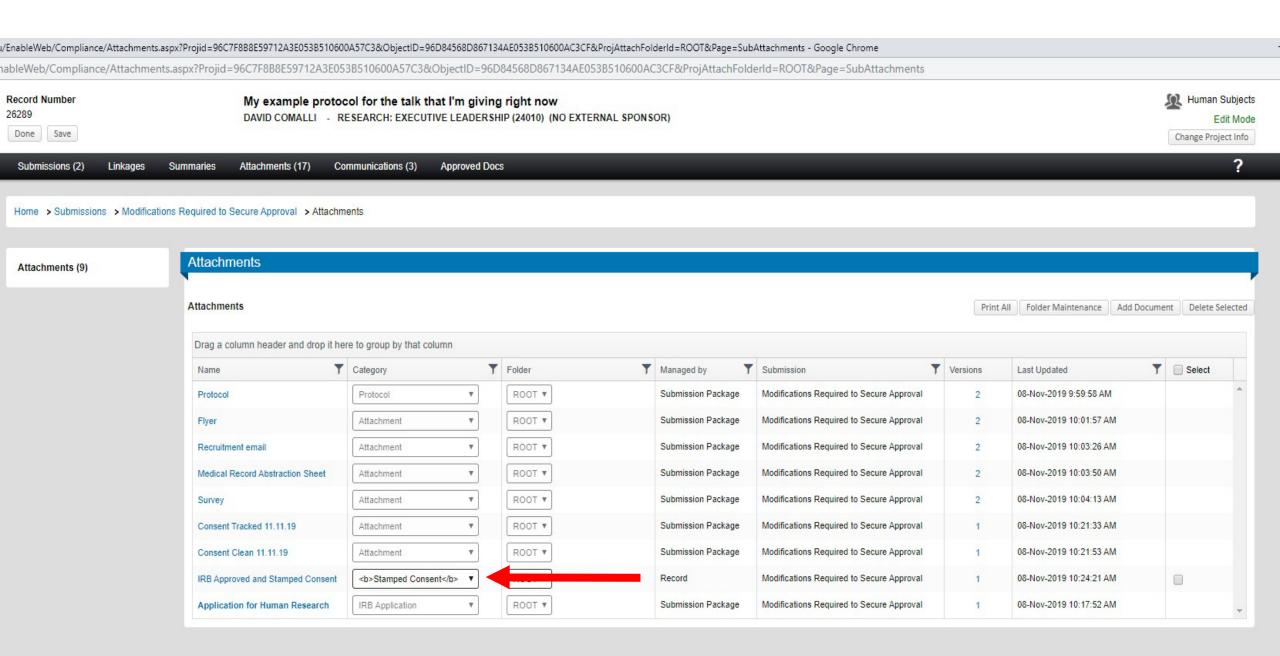
Click on the "Attachments" link within the submission



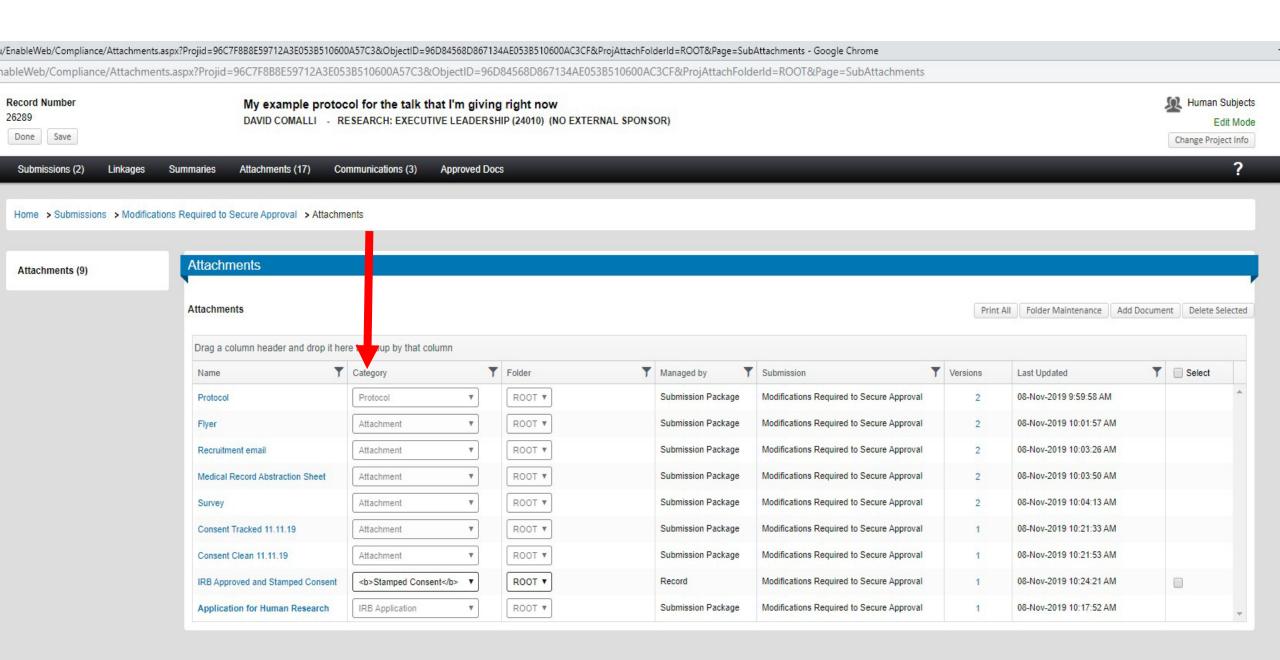
Find the IRB Approved and Stamped consent(s)



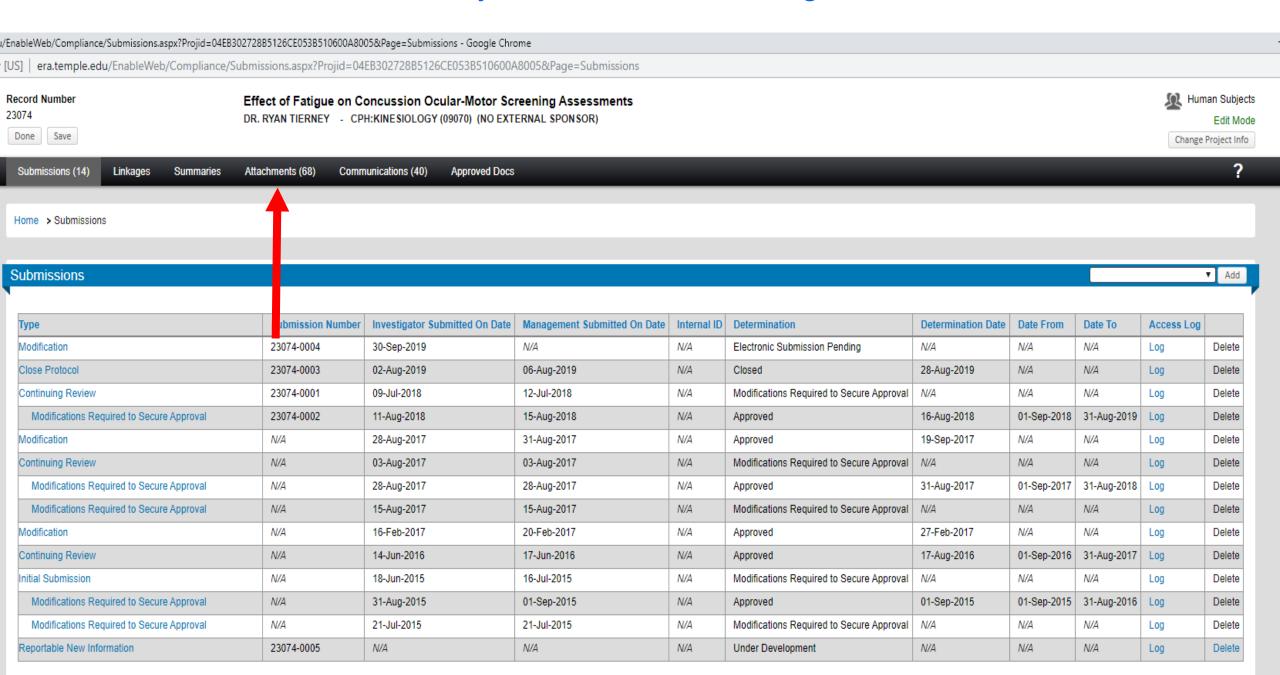
They should be sortable by "Category," labeled as " Stamped Consent "



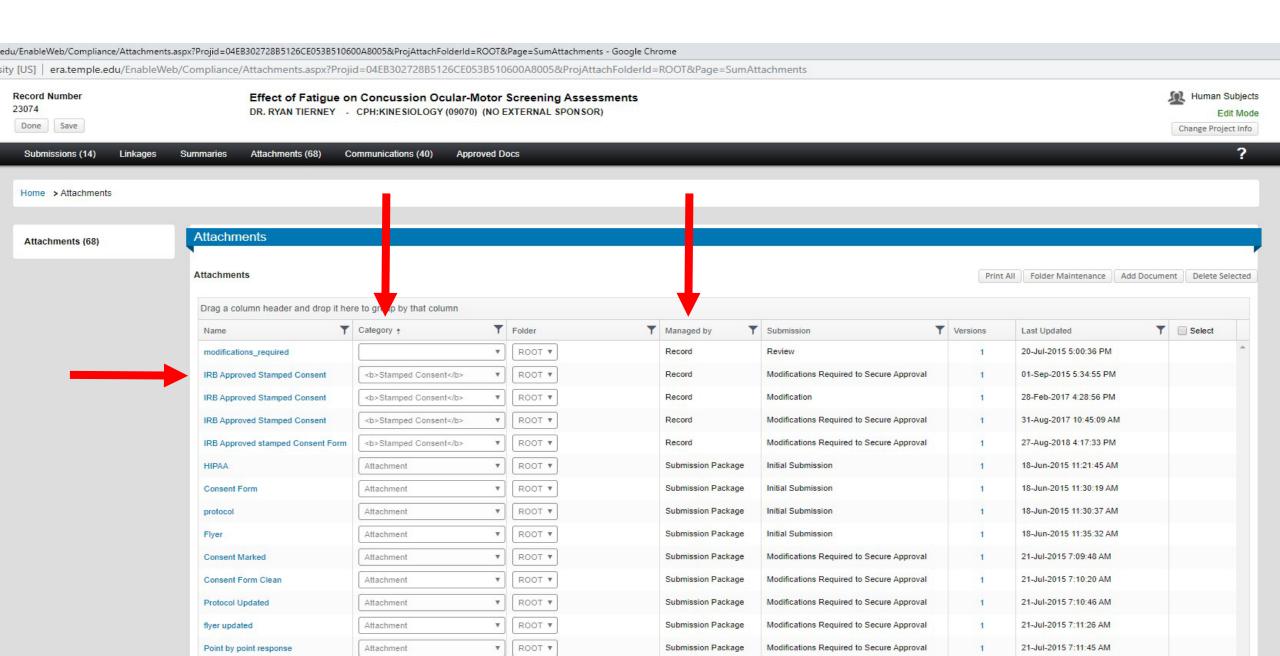
Clicking "Category" will sort alphabetically; Clicking again sorts in the opposite direction



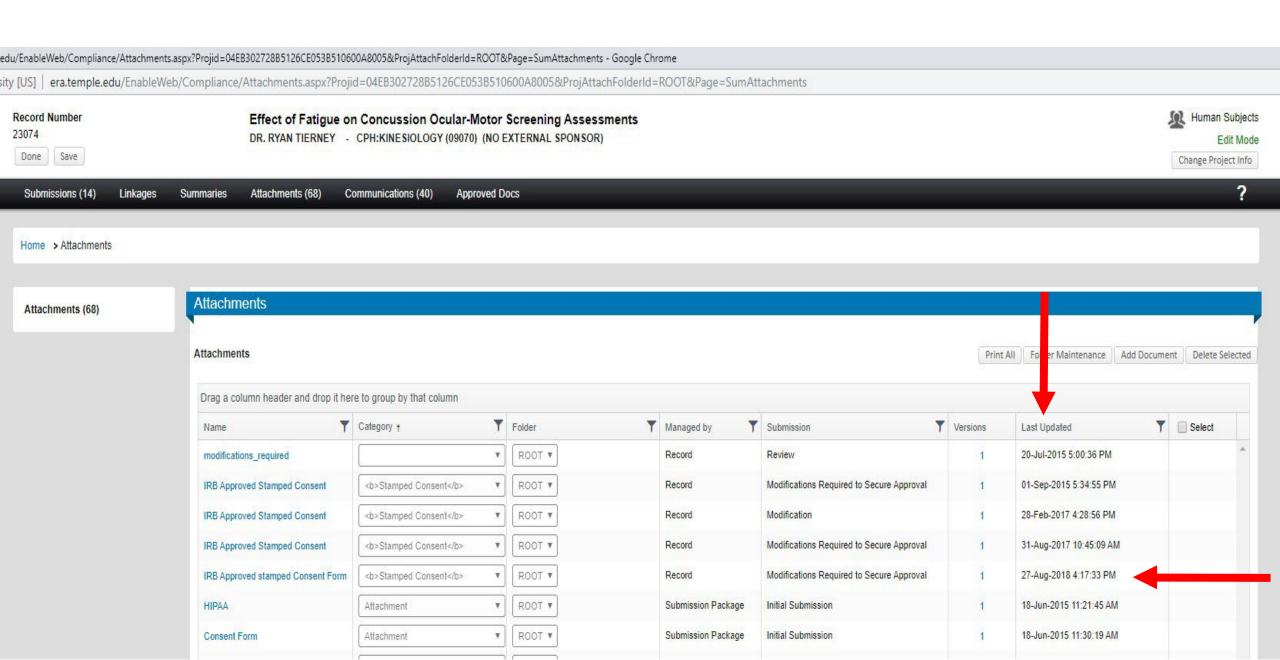
All documents for the study can be viewed in the general "Attachments" tab



Sort "Category" or "Managed by" to bring Stamped Consents to top (generally)



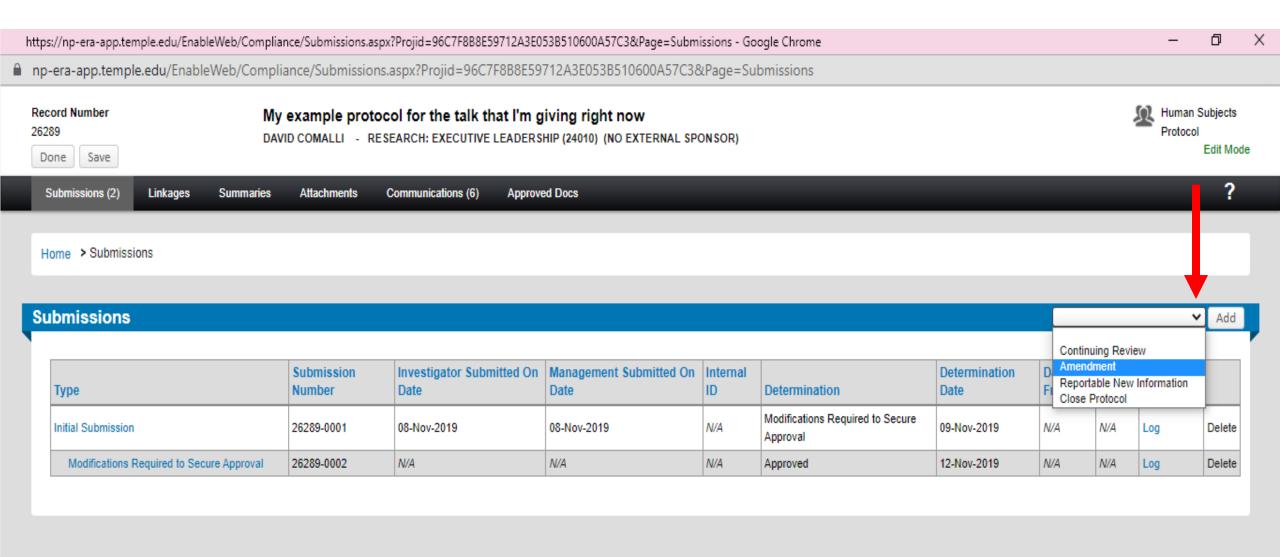
Mind "Last Updated" to ensure the correct version is being downloaded



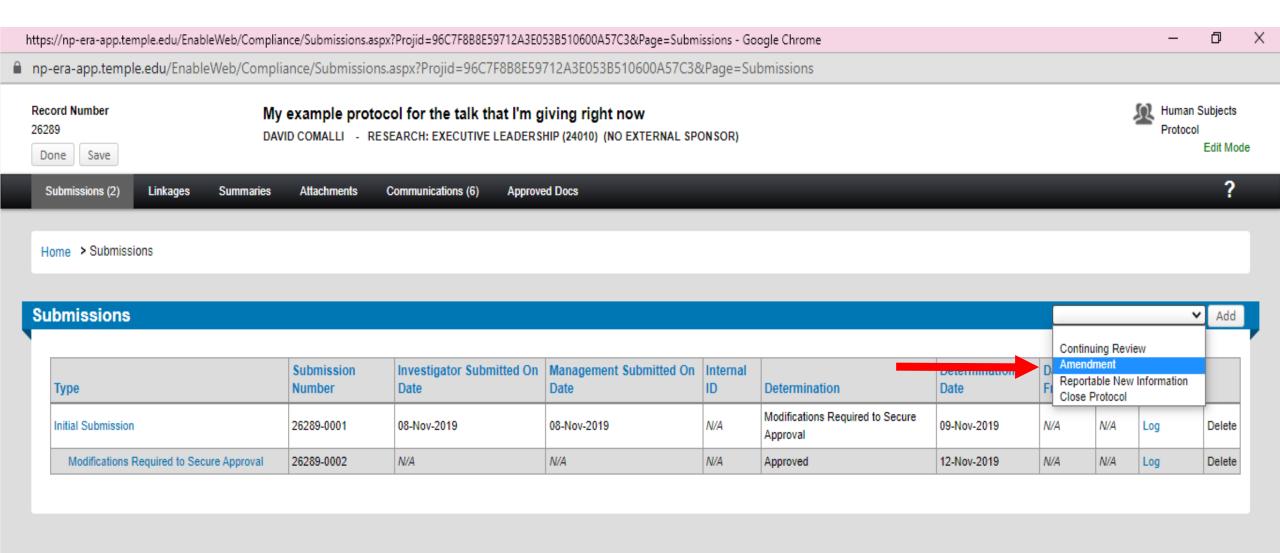
Creating Another Submission for an Already Approved Study (Amendment is shown; steps are the same for other submission types)



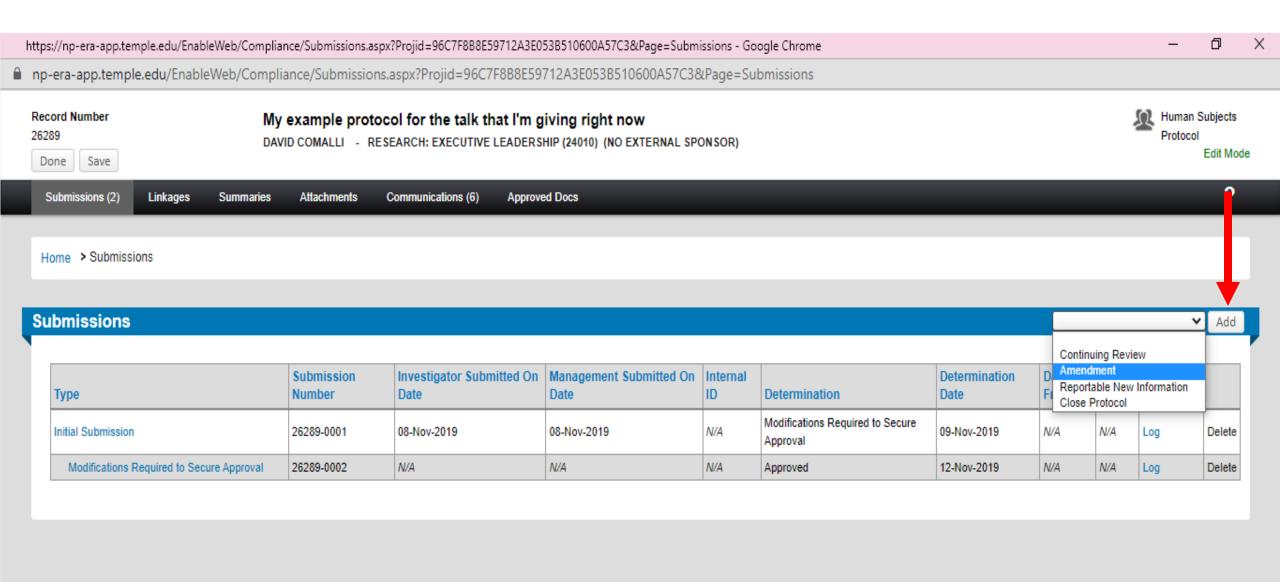
Create another submission by clicking the dropdown menu on the "Submissions" page



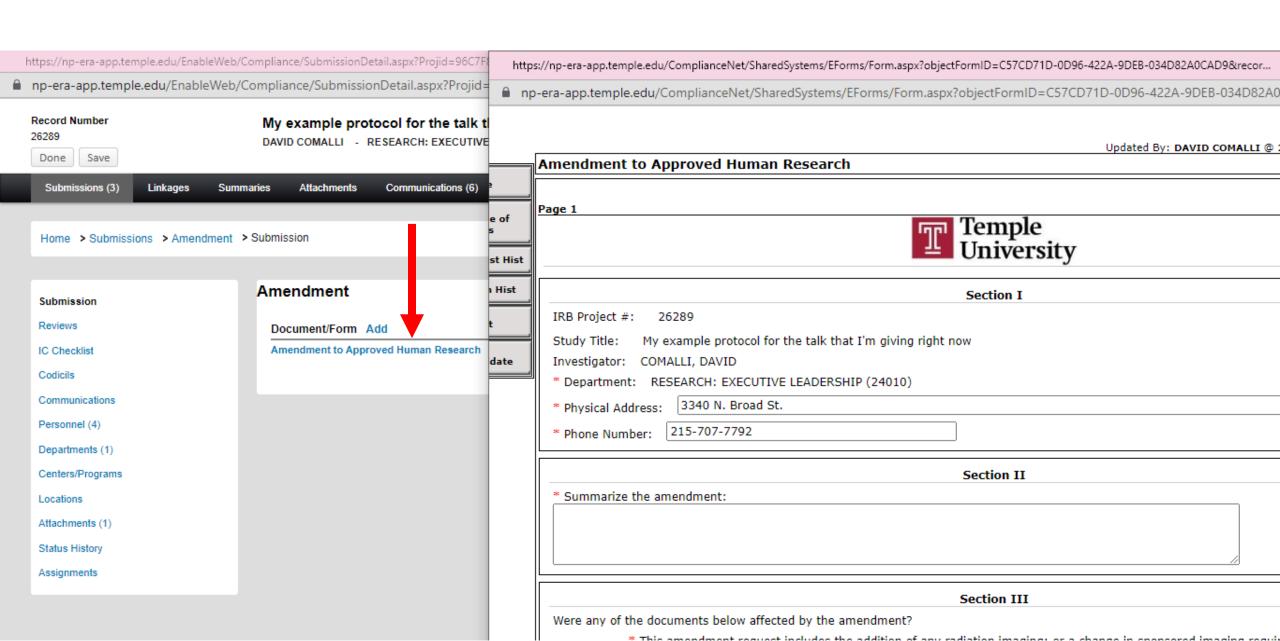
Select the desired submission type; This example is creating a "Amendment"



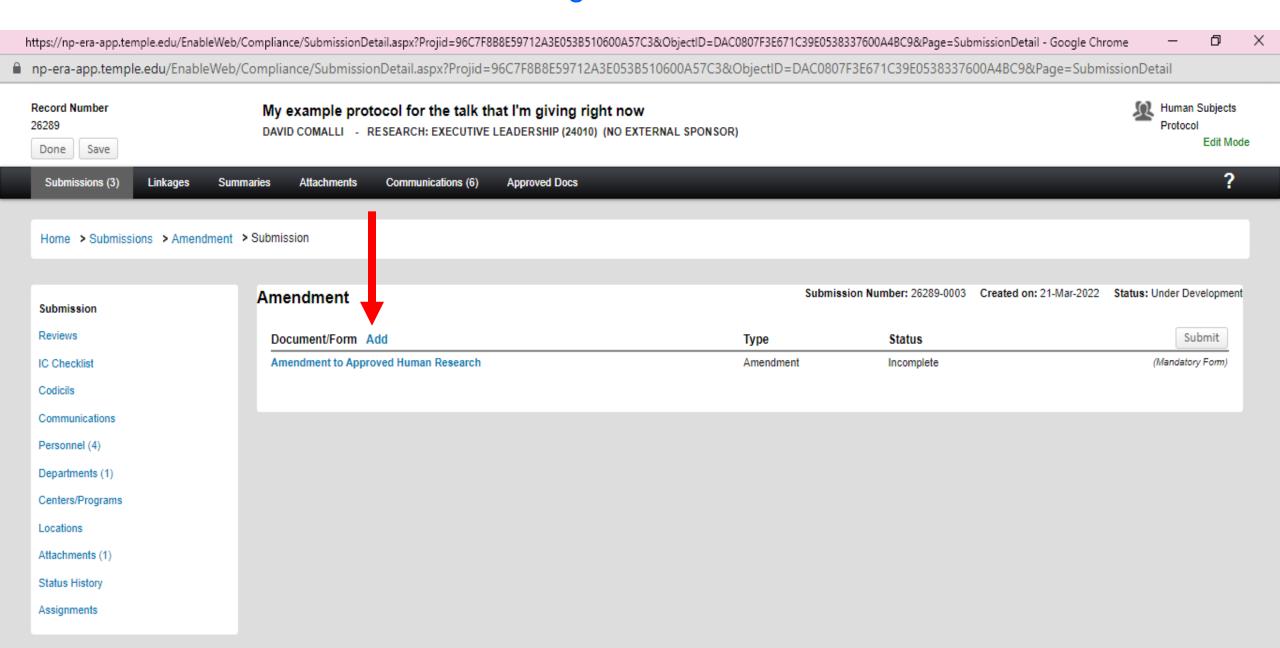
Click "Add"



Click and then complete the "Amendment to Approved Human Research" eForm



Click "Add" to add any additional documents; If changing approved documents, include tracked changes and clean versions



When ready, click "Submit" and get to the approval route; then click "Continue" (be sure to add new personnel before clicking Continue)

https://np-era-app.temple.edu/EnableWeb/Compliance/SubmissionDetail.aspx?Projid=96C7F888E59712A3E053B510600A57C3&ObjectID=DAC0807F3E671C39E0538337600A4BC9&Page=SubmissionDetail - Google Chrome np-era-app.temple.edu/EnableWeb/Compliance/SubmissionDetail.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&ObjectID=DAC0807F3E671C39E0538337600A4BC9&Page=SubmissionDetail Record Number My example protocol for the talk that I'm giving right now Human Subjects 26289 Protocol DAVID COMALLI - RESEARCH: EXECUTIVE LEADERSHIP (24010) (NO EXTERNAL SPONSOR) Edit Mode Save Done Submissions (3) Linkages Attachments Communications (6) Approved Docs Summaries Home > Submissions > Amendment > Submission Submission Number: 26289-0003 Created on: 21-Mar-2022 Status: Under Dev Amendment Submission Reviews Submit Document/Form Add Type Status Amendment to Approved Human Research Amendment Completed PDF (Mandatory Form) IC Checklist Submit - Google Chrome × Codicils Communications np-era-app.temple.edu/messaging/Submit.asp?ObjectID=DAC0807F3E671C39E0538337600A4BC Personnel (4) Protocol 26289 - DAVID COMALLI "My example protocol for the talk that I'm giving right now" (Under Departments (1) Development) Centers/Programs Locations Refresh Route Path - Modification of Human Research Add New Person to Review Path Continue Route Attachments (1) **3** PI FYI DAVID COMALLI Step 2 IRB Check-In: Received by IRB IRB OFFICE Status History Step 4 Assignments No comments have been recorded yet



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https://research.temple.edu/research-compliance/faqs-research-compliance

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