



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

Updated 1/12/22

Slides Summary / Table of Contents

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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, **not** 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”

The screenshot shows the Temple University IRB website. At the top, there is a yellow banner for COVID-19 information. Below that is the Temple University logo and the text 'Office of Research'. A navigation bar includes links for 'TEMPLE INFOREADY', 'RESEARCH LISTSERVS', 'TU LAUNCHPAD', 'TU VENTURES', 'AMBLER FIELD STATION', and 'CONTACT US'. A secondary navigation bar highlights 'RESEARCH COMPLIANCE' among other options like 'OVPR UPDATES', 'RESEARCH ADMINISTRATION', 'INNOVATION', and 'ERA'. The main content area has a breadcrumb trail: 'Home > Research Compliance > Institutional Review Board (IRB)'. The left column is titled 'INSTITUTIONAL REVIEW BOARD' and contains a paragraph about the HRPP mission and a list of two bullet points. The right column is titled 'IN THIS SECTION' and contains a list of seven links. Red arrows point from the right side of the page to the links 'Investigator Quick Links', 'IRB Forms & Standard Operating Procedures', 'FAQs | Institutional Review Board', and 'IRB Trainings and Resources'. Another set of red arrows points from the left side of the page to the same four links.

research.temple.edu/research-compliance/institutional-review-board-irb

Cherry&White SMART IRB IREx IRB Forms & SOP IRB Forum Definitely Real Boo...

COVID-19 INFORMATION: THE LATEST ABOUT HOW TEMPLE IS SAFEGUARDING OUR COMMUNITY.
[Read More](#)

TEMPLE UNIVERSITY

Office of Research

TEMPLE INFOREADY | RESEARCH LISTSERVS | TU LAUNCHPAD | TU VENTURES | AMBLER FIELD STATION | CONTACT US

OVPR UPDATES | RESEARCH ADMINISTRATION | **RESEARCH COMPLIANCE** | INNOVATION | ERA

Home > [Research Compliance](#) > [Institutional Review Board \(IRB\)](#)

INSTITUTIONAL REVIEW BOARD

The mission of Temple University’s Human Research Protection Program (HRPP) is to protect the rights, dignity, and welfare of human subjects who participate in the research programs of the Temple System. Specifically, the HRPP has authority over all human subjects research conducted using any property or facility of Temple and under the direction of any employee, student, or agent of Temple. This authority extends to Temple University Hospital System employees, who must submit human subjects research to HRPP.

- › Human subjects research is reviewed via three methods: a convened IRB; expedited review; or exempt review. Note that the determination for exemption is made by HRPP, not the investigator, and therefore must always be submitted formally.
- › The HRPP supports Temple’s dedication to excellence in research by promoting the ethical principles of respect for persons, beneficence, and justice as discussed in The Belmont Report. Investigators have ethical and Institutional responsibilities in conducting human

IN THIS SECTION

- › [Work Environment](#)
- › [Export Control](#)
- › [Conflict of Interest](#)
- › [Institutional Animal Care & Use Committee \(IACUC\)](#)
- › [Responsible Conduct of Research \(RCR\)](#)
- › [Institutional Review Board \(IRB\)](#)
- › [IRB Guidance on Human Subjects Protections Considerations Related to COVID-19](#)
- › [Investigator Quick Links](#)
- › [IRB Forms & Standard Operating Procedures](#)
- › [FAQs | Institutional Review Board](#)
- › [IRB Trainings and Resources](#)

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 Modifications.
- 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 **and** 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 PI'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 clearly labeled 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 HIPAA Authorization 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?
- HIPAA Authorization
 - 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)

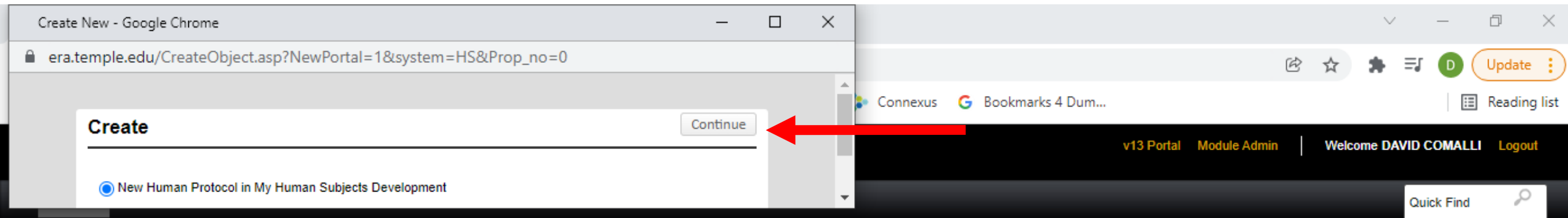
Screenshot notes

- 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.

Click “My Human Subjects” > Create New

The screenshot shows a web browser window with the URL `era.temple.edu/EnableWeb/Portal/Home#`. The browser's address bar and tabs are visible at the top. Below the browser, the InfoEd logo is on the left, and user information "v13 Portal Module Admin | Welcome DAVID COMALLI Logout" is on the right. A dark navigation bar contains links for Home, My Profile, Locate My Records, Locate Records, Calendar, Messages, and Assignments. On the right of this bar is a "Quick Find" search box. The main content area is divided into a left sidebar and a main panel. The sidebar lists: My Proposals and Awards, My Human Subjects (highlighted with a red arrow), Laboratory Animals, My Conflict of Interests, Invention, TT System Overview, and SPIN. The main panel is titled "My Human Subjects" and contains a "Create New" section with a button labeled "Create New Human Protocol" (highlighted with a red arrow). Below this is an "Accessing Records/Reporting" section with three buttons: "Locate records by using filters", "Show a listing of All my records", and "Pre-Defined Reports". A fourth button, "Reviews Management", is located below the first button in the "Accessing Records/Reporting" section.

Click Continue



The screenshot shows a Google Chrome browser window with the address bar displaying `era.temple.edu/CreateObject.asp?NewPortal=1&system=HS&Prop_no=0`. A modal dialog box titled "Create" is open, containing a radio button selected for "New Human Protocol in My Human Subjects Development" and a "Continue" button. A red arrow points to the "Continue" button. The browser's address bar includes navigation icons, a search icon, and an "Update" button. The top navigation bar of the application is visible, showing "v13 Portal", "Module Admin", "Welcome DAVID COMALLI", and "Logout". A "Quick Find" search box is located in the bottom right corner of the browser window.

My Proposals and Awards

My Human Subjects

Laboratory Animals

My Conflict of Interests

Invention

TT System Overview

SPIN

My Human Subjects

Create New

Create New Human Protocol

Accessing Records/Reporting

Locate records by using filters

Show a listing of *All* my records

Pre-Defined Reports

Reviews Management

MAKE SURE TO SELECT THE RIGHT PI

If you're not the PI, you must change the PI before moving forward

The image shows a web browser window with a dialog box titled "Protocol Creation" overlaid on a main page. The dialog box contains the following fields:

- Institution Number:** 29248
- Title:** (Empty text area)
- Select PI:** COMALLI, DAVID - RESEARCH: EXECUTIVE LEADERSHIP (24010) (A red arrow points to this dropdown menu)

The background page is a web application interface with a navigation bar containing "v13 Portal", "Module Admin", and "Welcome DAVID COMALLI Logout". A "Quick Find" search box is visible on the right side of the navigation bar. Below the navigation bar, there are buttons for "of All my records" and "Pre-Defined Reports".

Your name will show up automatically, **delete and search for PI if it's not you**
Then click the correct PI's name and then click "Continue"

Select PI - Google Chrome

era.temple.edu/Protocol/ConsolidatedCreate.asp?Prop_no=0&NewPortal=1&system=HSD&New...

Protocol Creation

Close Continue

Institution Number
29248

Title
Example Protocol for These Slides

Select PI
Uknol

BOUKNIGHT, BRITT H. -	- INFRASTRUCTURE, OPERATIONS & SECURI (77400)
BOUKNIGHT, BRITT H. -	- CLIENT SERVICES (77030)
UKNIS, AUDREY -	- TUSM:MEDICINE/RHEUMATOLOGY (05786)

ERA Test Connexus Bookmarks 4 Dum... Update

v13 Portal Module Admin Welcome DAVID COMALLI Logout

Quick Find

of All my records Pre-Defined Reports

Add documents by clicking the "Add" button

https://era.temple.edu/EnableWeb/Compliance/SubmissionDetail.aspx?Projid=96C7F888E59712A3E053B510600A57C3&ObjectID=96C7F888E59B12A3E053B510600A57C3&Page=SUBMISSION - Google Chrome
era.temple.edu/EnableWeb/Compliance/SubmissionDetail.aspx?Projid=96C7F888E59712A3E053B510600A57C3&ObjectID=96C7F888E59B12A3E053B510600A57C3&Page=SUBMISSION

Record Number
26289
Done Save

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

Human Subjects
Edit Mode
Change Project Info

Submissions (1) Linkages Summaries Attachments Communications Approved Docs

Home > Submissions > Initial Submission > Submission

Submission
Reviews
IC Checklist
Codicils
Communications
Personnel (1)
Departments (1)
Centers / Programs
Locations
Attachments
Status History (1)
Assignments

Initial Submission

Submission Number: 26289-0001 Created on: 07-Nov-2019 Status: Under Development

Add
No Forms have been associated with this submission.

Add Components - Google Chrome
era.temple.edu/Protocol/popUpGetAddComponent.asp?ObjectID=96C7F888E59B12A3E053B510600A57C3&Submis...

Upload

Upload Close

Upload new document

Name

Location No file chosen

Category

Document ID

Document Version Number

Document Version Date

Add Initial Submission Components

Form Name	Type	Add
Application for Classroom Projects	Conditional Use	<input type="checkbox"/>
Application for Human Research	Conditional Use	<input checked="" type="checkbox"/>

Always create the Application for Human Research eForm first

https://era.temple.edu/EnableWeb/Compliance/SubmissionDetail.aspx?Projid=96C7F888E59712A3E053B510600A57C3&ObjectID=96C7F888E59B12A3E053B510600A57C3&Page=SUBMISSION - Google Chrome
era.temple.edu/EnableWeb/Compliance/SubmissionDetail.aspx?Projid=96C7F888E59712A3E053B510600A57C3&ObjectID=96C7F888E59B12A3E053B510600A57C3&Page=SUBMISSION

Record Number
26289

Done Save

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

Human Subjects

Edit Mode

Change Project Info

Submissions (1) Linkages Summaries Attachments Communications Approved Docs ?

Home > Submissions > Initial Submission > Submission

Submission

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Initial Submission

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No Forms have been associated with this submission.

Add Components - Google Chrome

era.temple.edu/Protocol/popUpGetAddComponent.aspx?ObjectID=96C7F888E59B12A3E053B510600A57C3&Submis...

Upload

Upload Close

Upload new document

Name

Location No file chosen

Category

Document ID

Document Version Number

Document Version Date

Add Initial Submission Components

Add

Form Name	Type	Add
Application for Classroom Projects	Conditional Use	<input type="checkbox"/>
Application for Human Research	Conditional Use	<input checked="" type="checkbox"/>



Click the lower "Add" button to add the eForm

https://era.temple.edu/EnableWeb/Compliance/SubmissionDetail.aspx?Projid=96C7F888E59712A3E053B510600A57C3&ObjectID=96C7F888E59B12A3E053B510600A57C3&Page=SUBMISSION - Google Chrome
era.temple.edu/EnableWeb/Compliance/SubmissionDetail.aspx?Projid=96C7F888E59712A3E053B510600A57C3&ObjectID=96C7F888E59B12A3E053B510600A57C3&Page=SUBMISSION

Record Number
26289

Done Save

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

Human Subjects

Edit Mode

Change Project Info

Submissions (1) Linkages Summaries Attachments Communications Approved Docs ?

Home > Submissions > Initial Submission > Submission

Submission

Reviews

IC Checklist

Codicils

Communications

Personnel (1)

Departments (1)

Centers / Programs

Locations

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Status History (1)

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Initial Submission

Submission Number: 26289-0001 Created on: 07-Nov-2019 Status: Under Development

Add

No Forms have been associated with this submission.

Add Components - Google Chrome

era.temple.edu/Protocol/popUpGetAddComponent.asp?ObjectID=96C7F888E59B12A3E053B510600A57C3&Submis...

Upload

Upload Close

Upload new document

Name
Location No file chosen
Category
Document ID
Document Version Number
Document Version Date

Add Initial Submission Components

Add

Form Name	Type	Add
Application for Classroom Projects	Conditional Use	<input type="checkbox"/>
Application for Human Research	Conditional Use	<input checked="" type="checkbox"/>

Open the eForm

The screenshot displays the eForm system interface. The main page shows submission details for a protocol titled "My example protocol for t" by DAVID COMALLI. A red arrow points from the "IC Checklist" link in the left sidebar to the "Application for Human Research" link in the submission details area. A pop-up window titled "Personnel Listing" is open, showing a list of personnel with a search box containing "kendrick".

Record Number: 26289
My example protocol for t
DAVID COMALLI - RESEARCH

Submission Details: Submissions (3), Linkages, Summaries, Attachments (11), Communications

Submission: Initial Submission

Document/Form Add: Application for Human Research

Personnel Listing: kendrick

Certification	Begin
CITI - IRB Member	30-Aug-2018
CITI - HIPS - Clinical Investigators	09-Sep-2016
CITI - Biomedical Research	30-Aug-2018
CITI - Social/Behavioral Research	26-Aug-2016
CITI - Students conducting minimal risk research	28-Aug-2018
CITI - Practice Runs Training	24-May-2019

Research Personnel - (Those involved in the design, conduct, or review)

Personnel - Review Add

Name: COMALLI, DAVID
Primary Investigator:
Start Date (IRB Office Use): 07-Nov-2019

* Interpersonal contact or communication with subjects, or access to identifiable information? Yes No
* Involved in the consent process? Yes No
* Does this person have a financial interest related to the research? Yes No

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

era.temple.edu/EnableWeb/Compliance/SubmissionDetail.aspx?ProjID=96C7F888E59712A3E053B510600A57

era.temple.edu/EnableWeb/Compliance/SubmissionDetail.aspx?ProjID=96C7F888E59712A3E053B510600A57

era.temple.edu/ComplianceNet/SharedSystems/EForms/Form.aspx?ObjectFormId=ED5031C8-E648-42B3-9A81-70C334FBF127&recordid=9891219...

era.temple.edu/ComplianceNet/SharedSystems/EForms/Form.aspx?ObjectFormId=ED5031C8-E648-42B3-9A81-70C334FBF127&recordid=98912219...

Record Number
26289

My example protocol for t
DAVID COMALLI - RESEARC

Done Save

Submissions (3) Linkages Summaries Attachments (11) Communica

Home > Submissions > Initial Submission > Submission

Initial Submission

Document/Form Add
Application for Human Research

Submission
Reviews (1)
IC Checklist
Codicils
Communications
Personnel (1)
Departments (1)
Centers / Programs
Locations
Attachments (7)
Status History (4)
Assignments

Save
Table of Contents
Quest Hist
Form Hist
Print

Phone and Email:
Address (Street, City, State/Province, Postal Code, Country):

Research Personnel - (Use involved in the design, conduct, or rep
Personnel - Review Add

Name
COMALLI, DAVID

Primary Investigator Start Date(IRB Office Use
07-Nov-2019

Certifications

Certification	Begin
CITI - IRB Member	30-Aug-2018
CITI - HIPS - Clinical Investigators	09-Sep-2016
CITI - Biomedical Research	30-Aug-2018
CITI - Social/Behavioral Research	26-Aug-2016
CITI - Students conducting minimal risk research	28-Aug-2018
CITI - Practice Runs Training	24-May-2019

* Interpersonal contact or communication with subjects, or acc
* Involved in the consent process? Yes No
* Does this person have a financial interest related to the resea

Please list and provide one each of the following documents (if applicable to your study):

Personnel Listing

Select Close

kendrick

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

Record Number: 26289
My example protocol for t
DAVID COMALLI - RESEARC

Done Save

Submissions (3) Linkages Summaries Attachments (11) Communica

Home > Submissions > Initial Submission > Submission

Submission
Reviews (1)
IC Checklist
Codicils
Communications
Personnel (1)
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Attachments (7)
Status History (4)
Assignments

Initial Submission
Document/Form Add
Application for Human Research

Phone and Email:
Address (Street, City, State/Province, Postal Code, Country):

Save
Table of Contents
Quest Hist
Form Hist
Print

Research Personnel - (Those involved in the design, conduct, or rep
Personnel - Review Add

Name: COMALLI, DAVID
Primary Investigator:
Start Date(IRB Office Use): 07-Nov-2019

Certifications

Certification	Begin
CITI - IRB Member	30-Aug-2018
CITI - HIPS - Clinical Investigators	09-Sep-2016
CITI - Biomedical Research	30-Aug-2018
CITI - Social/Behavioral Research	26-Aug-2016
CITI - Students conducting minimal risk research	28-Aug-2018
CITI - Practice Runs Training	24-May-2019

* Interpersonal contact or communication with subjects, or acc
* Involved in the consent process? Yes No
* Does this person have a financial interest related to the resea

Please list and provide one each of the following documents (if applicable to your study):

Human Subjects
Edit Mode
Change Project Info

Select value - Google Chrome
era.temple.edu/PopUpSelectProg.asp?Parameter=Personnel&UseCustom=1&ReturnFu...
Personnel Listing
Select Close
kendrick,
↑

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

The screenshot shows a web application interface for adding research personnel. The main window displays a form for "My example protocol for DAVID COMALLI - RESEARCH". The form includes fields for "Phone and Email:" and "Address (Street, City, State/Province, Postal Code, Country):". A sidebar menu on the left contains options like "Submissions (3)", "Linkages", "Summaries", "Attachments (11)", and "Communications". A "MENU" sidebar on the right includes "Save", "Table of Contents", "Quest Hist", "Form Hist", and "Print".

A pop-up window titled "Select value - Google Chrome" is open, showing a "Personnel Listing" table. A red arrow points to the "Select" button in the pop-up window. The listing includes the following entries:

Certification	Begin
CITI - IRB Member	30-Aug-2018
CITI - HIPS - Clinical Investigators	09-Sep-2016
CITI - Biomedical Research	30-Aug-2018
CITI - Social/Behavioral Research	26-Aug-2016
CITI - Students conducting minimal risk research	28-Aug-2018
CITI - Practice Runs Training	24-May-2019

The pop-up window also shows a search result for "KENDRICK, ZEBULON - 901293793 - HSC PROVOST (27500)".

Below the personnel listing, there are checkboxes for "Involved in the consent process?" (Yes/No) and "Does this person have a financial interest related to the research?".

Add additional study documents by clicking the “Add” button

era.temple.edu/EnableWeb/Compliance/SubmissionDetail.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&ObjectID=96C7F8B8E59B12A3E053B510600A57C3&Page=SubmissionDetail - Google Chrome

era.temple.edu/EnableWeb/Compliance/SubmissionDetail.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&ObjectID=96C7F8B8E59B12A3E053B510600A57C3&Page=SubmissionDetail

Record Number
26289

Done Save

My example protocol f
DAVID COMALLI - RESEA

Submissions (3) Linkages Summaries Attachments (11) Commu

Home > Submissions > Initial Submission > Submission

Submission

Reviews (1)

IC Checklist

Codicils

Communications

Personnel (2)

Departments (1)

Centers / Programs

Locations

Attachments (7)

Status History (4)

Assignments

Initial Submission

Document/Form Add

Application for Human Research

Add Components - Google Chrome

era.temple.edu/Protocol/popUpGetAddComponent.asp?ObjectID=96C7F8B8E59B12A3E053B510600A57C3&Submis...

Please click 'Close' to complete the upload of your documents.

Upload

Upload Close

Would you like to upload a new document version of an existing document

Upload new document

Name

Location Poster for put...t places.docx

Category

Document ID

Document Version Number

Document Version Date

Add Initial Submission Components

Form Name	Type	Add
Application for Classroom Projects	Conditional Use	<input type="checkbox"/>

Human Subjects

Edit Mode

Change Project Info

?

89-0001 Created on: 07-Nov-2019 Status: Under Development

(Route History)

Remove

Click "Choose File" and find the document

era.temple.edu/EnableWeb/Compliance/SubmissionDetail.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&ObjectID=96C7F8B8E59B12A3E053B510600A57C3&Page=SubmissionDetail - Google Chrome

era.temple.edu/EnableWeb/Compliance/SubmissionDetail.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&ObjectID=96C7F8B8E59B12A3E053B510600A57C3&Page=SubmissionDetail

Record Number
26289

My example protocol f
DAVID COMALLI - RESEA

Done Save

Submissions (3) Linkages Summaries Attachments (11) Commu

Home > Submissions > Initial Submission > Submission

Submission

Reviews (1)

IC Checklist

Codicils

Communications

Personnel (2)

Departments (1)

Centers / Programs

Locations

Attachments (7)

Status History (4)

Assignments

Initial Submission

Document/Form Add

Application for Human Research

Human Subjects

Edit Mode

Change Project Info

?

89-0001 Created on: 07-Nov-2019 Status: Under Development

(Route History) Submit

Remove

Add Components - Google Chrome

era.temple.edu/Protocol/popUpGetAddComponent.aspx?ObjectID=96C7F8B8E59B12A3E053B510600A57C3&Submis...

Please click 'Close' to complete the upload of your documents.


Upload

Upload Close

Would you like to upload a new document version of an existing document

Upload new document

Name

Location  Poster for put...t places.docx

Category

Document ID

Document Version Number

Document Version Date

Add Initial Submission Components

Form Name	Type	Add
Application for Classroom Projects	Conditional Use	<input type="checkbox"/>

“Name” should be succinct and informative; It’s what the IRB will see

era.temple.edu/EnableWeb/Compliance/SubmissionDetail.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&ObjectID=96C7F8B8E59B12A3E053B510600A57C3&Page=SubmissionDetail - Google Chrome

era.temple.edu/EnableWeb/Compliance/SubmissionDetail.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&ObjectID=96C7F8B8E59B12A3E053B510600A57C3&Page=SubmissionDetail

Record Number
26289
Done Save

My example protocol f
DAVID COMALLI - RESEA

Submissions (3) Linkages Summaries Attachments (11) Commu

Home > Submissions > Initial Submission > Submission

Submission
Reviews (1)
IC Checklist
Codicils
Communications
Personnel (2)
Departments (1)
Centers / Programs
Locations
Attachments (7)
Status History (4)
Assignments

Initial Submission

Document/Form Add
Application for Human Research

Human Subjects
Edit Mode
Change Project Info

89-0001 Created on: 07-Nov-2019 Status: Under Development
(Route History) Submit
Remove

Add Components - Google Chrome
era.temple.edu/Protocol/popUpGetAddComponent.aspx?ObjectID=96C7F8B8E59B12A3E053B510600A57C3&Submis...

Please click 'Close' to complete the upload of your documents.

Upload Close

Would you like to upload a new document version of an existing document

Upload new document

Name Flyer|

Location Choose File Poster for put...t places.docx

Category Attachment

Document ID

Document Version Number

Document Version Date

Add Initial Submission Components Add

Form Name	Type	Add
Application for Classroom Projects	Conditional Use	<input type="checkbox"/>

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

edu/EnableWeb/Compliance/SubmissionDetail.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&ObjectID=96C7F8B8E59B12A3E053B510600A57C3&Page=SubmissionDetail - Google Chrome

EnableWeb/Compliance/SubmissionDetail.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&ObjectID=96C7F8B8E59B12A3E053B510600A57C3&Page=SubmissionDetail

Record Number
26289

Done Save

My example protocol f
DAVID COMALLI - RESEA

Submissions (3) Linkages Summaries Attachments (11) Commu

Home > Submissions > Initial Submission > Submission

Submission

Reviews (1)

IC Checklist

Codicils

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Status History (4)

Assignments

Initial Submission

Document/Form Add

Application for Human Research

Human Subjects

Edit Mode

Change Project Info

?

89-0001 Created on: 07-Nov-2019 Status: Under Development

(Route History) Submit

Remove

Add Components - Google Chrome

era.temple.edu/Protocol/popUpGetAddComponent.asp?ObjectID=96C7F8B8E59B12A3E053B510600A57C3&Submis...

Please click 'Close' to complete the upload of your documents.

Upload Upload Close

Would you like to upload a new document version of an existing document

Upload new document

Name

Location Poster for put...t places.docx

Category

Document ID

Document Version Number

Document Version Date

Add Initial Submission Components

Form Name	Type	Add
Application for Classroom Projects	Conditional Use	<input type="checkbox"/>

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

The screenshot shows a web application interface for managing submissions. The main page displays details for a submission with Record Number 26289, titled "My example protocol for DAVID COMALLI - RESEARCH". The submission is in the "Initial Submission" stage. A modal window titled "Add Components" is open, prompting the user to upload a document. The modal contains a form with the following fields:

- Name:** Flyer
- Location:** Choose File Poster for put...t places.docx
- Category:** Attachment
- Document ID:** (empty)
- Document Version Number:** (empty)
- Document Version Date:** (empty)

The modal also includes an "Upload" button and a "Close" button. A red arrow points to the "Close" button. Below the form, there is a section for "Add Initial Submission Components" with a table:

Form Name	Type	Add
Application for Classroom Projects	Conditional Use	<input type="checkbox"/>


The background page shows a navigation menu on the left with options like "Submissions (3)", "Linkages", "Summaries", "Attachments (11)", and "Commu...". On the right, there is a user profile for "Human Subjects" with an "Edit Mode" button and a "Change Project Info" button. The submission status is "Under Development" and was created on 07-Nov-2019.

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

Record Number
26289

My example protocol for the talk that I'm giving right now

DAVID COMALLI - RESEARCH: EXECUTIVE LEADERSHIP (24010) (NO EXTERNAL SPONSOR)

 Human Subjects

[Edit Mode](#)

[Done](#) [Save](#)

[Change Project Info](#)

[Submissions \(3\)](#) [Linkages](#) [Summaries](#) [Attachments \(17\)](#) [Communications](#) [Approved Docs](#)



[Home](#) > [Submissions](#) > [Initial Submission](#) > [Submission](#)

Initial Submission

Submission Number: 26289-0001 Created on: 07-Nov-2019 Status: Under Development

Document/Form Add	Type	Status	(Route History)	Submit
Application for Human Research	IRB Application	Incomplete		Remove
Consent	Consent Form	Completed	Modify	Remove
Flyer	Attachment	Completed	Modify	Remove
Medical Record Abstraction Sheet	Attachment	Completed	Modify	Remove
Protocol	Protocol	Completed	Modify	Remove
Recruitment email	Attachment	Completed	Modify	Remove
Survey	Attachment	Completed	Modify	Remove

Submission

[Reviews \(1\)](#)

[IC Checklist](#)

[Codicils](#)

[Communications](#)

[Personnel \(2\)](#)

[Departments \(1\)](#)

[Centers / Programs](#)

[Locations](#)

[Attachments \(13\)](#)

[Status History \(4\)](#)

[Assignments](#)

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

Record Number: 26289

My example protocol for the talk that I'm giving right now

DAVID COMALLI - RESEARCH: EXECUTIVE LEADERSHIP (24010) (NO EXTERNAL SPONSOR)

Human Subjects

Edit Mode

Change Project Info

Submissions (3) | Linkages | Summaries | Attachments (17) | Communications | Approved Docs

Home > Submissions > Initial Submission > Submission

Initial Submission

Document/Form	Add	Type
Application for Human Research		IRB Appli
Consent		Consent
Flyer		Attachme
Medical Record Abstraction Sheet		Attachme
Protocol		Protocol
Recruitment email		Attachme
Survey		Attachme

Submission

- Reviews (1)
- IC Checklist
- Codicils
- Communications
- Personnel (2)
- Departments (1)
- Centers / Programs
- Locations
- Attachments (13)
- Status History (4)
- Assignments

Submit - Google Chrome

era.temple.edu/messaging/Submit.asp?ObjectID=96C7F8B8E59B12A3E053B510600A57C3&RouteMapID=CE4D019A...

Protocol 26289 - DAVID COMALLI "My example protocol for the talk that I'm giving right now" (Under Development)

Refresh Route

Step	Route Path - Initial Submission	Add New Person to Review Path	Submit
1	PI Acknowledgement	DAVID COMALLI	<input type="checkbox"/>
2	Co-Invest. Acknowledgement	ZEBULON KENDRICK	<input type="checkbox"/>
3	Department Head Acknowledgement	DR MICHELE MASUCCI	<input type="checkbox"/>
7	IRB Check-In: Received by IRB	IRB OFFICE	<input type="checkbox"/>
	IRB Check-In: Received by IRB	MRS. LASHAY COBB	<input type="checkbox"/>

No comments have been recorded yet

Development

Submit

Remove

Remove

Remove

Remove

Remove

Remove

Remove

Status will change from “Under Development” to “Electronic Submission Pending” once it’s submitted

u/EnableWeb/Compliance/SubmissionDetail.aspx?ProjID=96C7F8B8E59712A3E053B510600A57C3&ObjectID=96C7F8B8E59B12A3E053B510600A57C3&Page=SubmissionDetail - Google Chrome


nableWeb/Compliance/SubmissionDetail.aspx?ProjID=96C7F8B8E59712A3E053B510600A57C3&ObjectID=96C7F8B8E59B12A3E053B510600A57C3&Page=SubmissionDetail

Record Number

26289

My example protocol for the talk that I'm giving right now

DAVID COMALLI - RESEARCH: EXECUTIVE LEADERSHIP (24010) (NO EXTERNAL SPONSOR)

 Human Subjects

[Edit Mode](#)

[Change Project Info](#)

[Done](#) [Save](#)

[Submissions \(3\)](#) [Linkages](#) [Summaries](#) [Attachments \(17\)](#) [Communications](#) [Approved Docs](#) [?](#)

[Home](#) > [Submissions](#) > [Initial Submission](#) > [Submission](#)

Submission

[Reviews \(1\)](#)

[IC Checklist](#)

[Codicils](#)

[Communications](#)

[Personnel \(2\)](#)

[Departments \(1\)](#)

[Centers / Programs](#)

[Locations](#)

[Attachments \(13\)](#)

[Status History \(5\)](#)

[Assignments \(1\)](#)

Initial Submission

Submission Number: 26289-0001 Created on: 07-Nov-2019 Status: Electronic Submission Pending

Document/Form	Type	Status	Show Route (Route History)
Application for Human Research	IRB Application	Completed	PDF
Consent	Consent Form	Completed	Modify
Flyer	Attachment	Completed	Modify
Medical Record Abstraction Sheet	Attachment	Completed	Modify
Protocol	Protocol	Completed	Modify
Recruitment email	Attachment	Completed	Modify
Survey	Attachment	Completed	Modify

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

u/EnableWeb/Compliance/SubmissionDetail.aspx?ProjID=96C7F8B8E59712A3E053B510600A57C3&ObjectID=96D8BE38E0D424CDE053B510600A7627&Page=SubmissionDetail - Google Chrome

nableWeb/Compliance/SubmissionDetail.aspx?ProjID=96C7F8B8E59712A3E053B510600A57C3&ObjectID=96D8BE38E0D424CDE053B510600A7627&Page=SubmissionDetail

Record Number

26289

My example protocol for the talk that I'm giving right now

DAVID COMALLI - RESEARCH: EXECUTIVE LEADERSHIP (24010) (NO EXTERNAL SPONSOR)

Human Subjects

Edit Mode

Change Project Info

Done Save

Submissions (3) Linkages Summaries Attachments (18) Communications (3) Approved Docs



Home > Submissions > Modification > Submission

Submission

Reviews

IC Checklist

Codicils

Communications

Modification

Submission Number: 26289-0003 Created on: 08-Nov-2019 Status: Under Development

Document/Form Add

Modification of Approved Human Research

Show Existing Protocol Attachments

Type

Status

Submit

Modification

Completed

PDF

(Mandatory Form)

Submit - Google Chrome

era.temple.edu/messaging/Submit.asp?ObjectID=96D8BE38E0D424CDE053B510600A7627&RouteMapID=CE4D040A...

Protocol 26289 - DAVID COMALLI "My example protocol for the talk that I'm giving right now" (Under Development)

Refresh Route

Route Path - Modification  Add New Person to Review Path

Continue

Step 1	PI Acknowledgement	DAVID COMALLI	
Step 3	IRB Check-In: Received by IRB	MRS. LASHAY COBB	
	IRB Check-In: Received by IRB	IRB OFFICE	

No comments have been recorded yet

Add step - Google Chrome

era.temple.edu/messaging/AddRouteStep.asp?RouteID=96D8BF50488F2D09E053B510600A38C6

Add step

Add Cancel

parkm

PARKMAN, HENRY - 908809724 - TUSM:MEDICINE/GASTROENTEROLOGY (05725)

Informational Only

Approval Required

Type the last name and select the person

u/EnableWeb/Compliance/SubmissionDetail.aspx?ProjID=96C7F8B8E59712A3E053B510600A57C3&ObjectID=96D8BE38E0D424CDE053B510600A7627&Page=SubmissionDetail - Google Chrome


nableWeb/Compliance/SubmissionDetail.aspx?ProjID=96C7F8B8E59712A3E053B510600A57C3&ObjectID=96D8BE38E0D424CDE053B510600A7627&Page=SubmissionDetail

Record Number

26289

My example protocol for the talk that I'm giving right now

DAVID COMALLI - RESEARCH: EXECUTIVE LEADERSHIP (24010) (NO EXTERNAL SPONSOR)

 Human Subjects

[Edit Mode](#)

[Change Project Info](#)

[Done](#)

[Save](#)

[Submissions \(3\)](#)

[Linkages](#)

[Summaries](#)

[Attachments \(18\)](#)

[Communications \(3\)](#)

[Approved Docs](#)



[Home](#) > [Submissions](#) > [Modification](#) > [Submission](#)

Submission

[Reviews](#)

[IC Checklist](#)

[Codicils](#)

[Communications](#)

Modification

Submission Number: 26289-0003 Created on: 08-Nov-2019 Status: Under Development

[Document/Form](#) [Add](#)

[Modification of Approved Human Research](#)

[Show Existing Protocol Attachments](#)

Type

Status

[Submit](#)

Modification

Completed

PDF

(Mandatory Form)


Submit - Google Chrome


era.temple.edu/messaging/Submit.asp?ObjectID=96D8BE38E0D424CDE053B510600A7627&RouteMapID=CE4D040A...


Protocol **26289** - **DAVID COMALLI** "My example protocol for the talk that I'm giving right now" (Under Development)

[Refresh Route](#)

Route Path - **Modification of Human Research** [Add New Person to Review Path](#) [Continue](#)

Step 1 **PI Acknowledgement** DAVID COMALLI 

Step 3 **IRB Check-In: Received by IRB** MRS. LASHAY COBB 

IRB Check-In: Received by IRB IRB OFFICE 

No comments have been recorded yet

Add step - Google Chrome

era.temple.edu/messaging/AddRouteStep.asp?RouteID=96D8BF50488F2D09E053B510600A38C6

Add step

[Add](#)

[Cancel](#)

parkm

PARKMAN, HENRY - 908809724 - TUSM:MEDICINE/GASTROENTEROLOGY (05725)

Informational Only

Approval Required

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

u/EnableWeb/Compliance/SubmissionDetail.aspx?ProjID=96C7F8B8E59712A3E053B510600A57C3&ObjectID=96D8BE38E0D424CDE053B510600A7627&Page=SubmissionDetail - Google Chrome

nableWeb/Compliance/SubmissionDetail.aspx?ProjID=96C7F8B8E59712A3E053B510600A57C3&ObjectID=96D8BE38E0D424CDE053B510600A7627&Page=SubmissionDetail

Record Number
26289

My example protocol for the talk that I'm giving right now
DAVID COMALLI - RESEARCH: EXECUTIVE LEADERSHIP (24010) (NO EXTERNAL SPONSOR)

Human Subjects
[Edit Mode](#)
[Change Project Info](#)

[Done](#) [Save](#)

[Submissions \(3\)](#) [Linkages](#) [Summaries](#) [Attachments \(18\)](#) [Communications \(3\)](#) [Approved Docs](#)

[Home](#) > [Submissions](#) > [Modification](#) > [Submission](#)

- Submission
- Reviews
- IC Checklist
- Codicils
- Communications

Modification Submission Number: 26289-0003 Created on: 08-Nov-2019 Status: Under Development

Document/Form [Add](#)
[Modification of Approved Human Research](#)
[Show Existing Protocol Attachments](#)

Add step - Google Chrome
era.temple.edu/messaging/AddRouteStep.asp?RouteID=96D8BF50488F2D09E053B510600A38C6

Add step

[PARKMAN, HENRY - 908809724 - TUSM:MEDICINE/GASTROENTEROLOGY \(05725\)](#)

Informational Only
 Approval Required

[Add](#) [Cancel](#)



Submit - Google Chrome
era.temple.edu/messaging/Submit.asp?ObjectID=96D8BE38E0D424CDE053B510600A7627&RouteMapID=CE4D040A...

Type	Status	
Modification	Completed	PDF (Mandatory Form)

Protocol **26289 - DAVID COMALLI** "My example protocol for the talk that I'm giving right now" (Under Development)

[Refresh Route](#) [Add New Person to Review Path](#) [Continue](#)

Step	Route Path	Personnel	Action
Step 1	PI Acknowledgement	DAVID COMALLI	
Step 3	IRB Check-In: Received by IRB	MRS. LASHAY COBB	
	IRB Check-In: Received by IRB	IRB OFFICE	

No comments have been recorded yet

Look at the approval route and click "Continue"

u/EnableWeb/Compliance/SubmissionDetail.aspx?ProjID=96C7F8B8E59712A3E053B510600A57C3&ObjectID=96D8BE38E0D424CDE053B510600A7627&Page=SubmissionDetail - Google Chrome

nableWeb/Compliance/SubmissionDetail.aspx?ProjID=96C7F8B8E59712A3E053B510600A57C3&ObjectID=96D8BE38E0D424CDE053B510600A7627&Page=SubmissionDetail

Record Number

26289

My example protocol for the talk that I'm giving right now

DAVID COMALLI - RESEARCH: EXECUTIVE LEADERSHIP (24010) (NO EXTERNAL SPONSOR)

Human Subjects

Edit Mode

Change Project Info

Done Save

Submissions (3) Linkages Summaries Attachments (18) Communications (3) Approved Docs



Home > Submissions > Modification > Submission

Modification

Submission Number: 26289-0003 Created on: 08-Nov-2019 Status: Under Development

Document/Form Add

Modification of Approved Human Research

Show Existing Protocol Attachments

Submission

Reviews

IC Checklist

Codicils

Communications

Add step - Google Chrome

era.temple.edu/messaging/AddRouteStep.asp?RouteID=96D8BF50488F2D09E053B510600A38C6

Add step

Add Cancel

parkm

PARKMAN, HENRY - 908809724 - TUSM:MEDICINE/GASTROENTEROLOGY (05725)

Informational Only

Approval Required

Type

Status

Modification

Completed

PDF

(Mandatory Form)

Submit - Google Chrome

era.temple.edu/messaging/Submit.asp?ObjectID=96D8BE38E0D424CDE053B510600A7627&RouteMapID=CE4D040A...

Protocol 26289 - DAVID COMALLI "My example protocol for the talk that I'm giving right now" (Under Development)

Refresh Route

Route Path - Modification of Human Research Add New Person to Review Path

Continue

Step 1	PI Acknowledgement	DAVID COMALLI	
Step 3	IRB Check-In: Received by IRB	MRS. LASHAY COBB	
	IRB Check-In: Received by IRB	IRB OFFICE	

No comments have been recorded yet



You will get an email after the person ahead of you (as indicated in the previous approval route pop-up) has acknowledged the submission

era.edu/EnableWeb/Compliance/SubmissionDetail.aspx?ProjID=96C7F8B8E59712A3E053B510600A57C3&ObjectID=96C7F8B8E59B12A3E053B510600A57C3&Page=SubmissionDetail - Google Chrome

u/EnableWeb/Compliance/SubmissionDetail.aspx?ProjID=96C7F8B8E59712A3E053B510600A57C3&ObjectID=96C7F8B8E59B12A3E053B510600A57C3&Page=SubmissionDetail

Record Number
26289

My example protocol for the talk that I'm giving right now

DAVID COMALLI - RESEARCH: EXECUTIVE LEADERSHIP (24010) (NO EXTERNAL SPONSOR)

Human Subjects

Edit Mode

Done Save

Change Project Info

Submissions (3) Linkages Summaries Attachments (17) Communications Approved Docs

Home > Submissions > Initial Submission > Submission

Submission

Reviews (1)

IC Checklist

Codicals

Communications

Personnel (2)

Departments (1)

Centers / Programs

Locations

Attachments (13)

Status History (4)

Assignments

Initial Submission

Document/Form Add

Type

Application for Human Research

IRB Appli

Consent

Consent

Flyer

Attachme

Medical Record Abstraction Sheet

Attachme

Protocol

Protocol

Recruitment email

Attachme

Survey

Attachme

Submit - Google Chrome

era.temple.edu/messaging/Submit.asp?ObjectID=96C7F8B8E59B12A3E053B510600A57C3&RouteMapID=CE4D019A...

Protocol 26289 - DAVID COMALLI "My example protocol for the talk that I'm giving right now" (Under Development)

Refresh Route

Step	Route Path - Initial Submission	Add New Person to Review Path	
1	PI Acknowledgement	DAVID COMALLI	
2	Co-Invest. Acknowledgement	ZEBULON KENDRICK	
3	Department Head Acknowledgment	DR MICHELE MASUCCI	
7	IRB Check-In: Received by IRB	IRB OFFICE	
	IRB Check-In: Received by IRB	MRS. LASHAY COBB	

Submit

No comments have been recorded yet

Development

Submit

Remove

Remove

Remove

Remove

Remove

Remove

Remove

Open the Acknowledge email (from OFFICE_OLD, IRB); click “Reviewer Dashboard”

An Initial Application For Your Review Σ 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 DASHBOARD!!!!!!

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

aging/ReviewItem.asp?RoutedStepID=96D9139C670A3B60E053B510600A6296

C&W IBX health reward International WIRB Form ERA Test ERA Dev WHO Training FDA Custom Device Exe...

HELP

REVIEW

ROUTE

Human Subject Protocol - *Modifications Required to Secure Approval*

Number: [26289](#)

Title: My example protocol for the talk that I'm giving right now

Sponsor: NO EXTERNAL SPONSOR

Submitted: 08-Nov-2019 11:15:10 AM

Form/Document	Document Type	Submitted	
Application for Human Research	IRB Application	08-Nov-2019 11:15:10 AM	PDF
Consent Clean 11.11.19	Attachment	08-Nov-2019 11:15:09 AM	Modify
Consent Tracked 11.11.19	Attachment	08-Nov-2019 11:15:09 AM	Modify
Flyer	Attachment	08-Nov-2019 11:15:09 AM	Modify
Medical Record Abstraction Sheet	Attachment	08-Nov-2019 11:15:09 AM	Modify
Protocol	Protocol	08-Nov-2019 11:15:09 AM	Modify
Recruitment email	Attachment	08-Nov-2019 11:15:09 AM	Modify
Survey	Attachment	08-Nov-2019 11:15:09 AM	Modify

Add Comments:

To be shared with everyone

B *I* U **A** ▼

Select a decision:

Acknowledge

PI Clarification

Close

Comments I can see...

No Comments have been recorded




Review documents by clicking on them

- HELP
- REVIEW
- ROUTE

Human Subject Protocol - *Modifications Required to Secure Approval*

Number: [26289](#)
Title: My example protocol for the talk that I'm giving right now
Sponsor: NO EXTERNAL SPONSOR
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Form/Document	Document Type	Submitted	
Application for Human Research	IRB Application	08-Nov-2019 11:15:10 AM	PDF
Consent Clean 11.11.19	Attachment	08-Nov-2019 11:15:09 AM	Modify
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Flyer	Attachment	08-Nov-2019 11:15:09 AM	Modify
Medical Record Abstraction Sheet	Attachment	08-Nov-2019 11:15:09 AM	Modify
Protocol	Protocol	08-Nov-2019 11:15:09 AM	Modify
Recruitment email	Attachment	08-Nov-2019 11:15:09 AM	Modify
Survey	Attachment	08-Nov-2019 11:15:09 AM	Modify

Close

Comments I can see...
No Comments have been recorded

Add Comments:
To be shared with everyone

B **I** **U** **A** ▼

Select a decision:

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)

aging/ReviewItem.asp?RoutedStepID=96D9139C670A3B60E053B510600A6296

C&W IBX health reward International WIRB Form ERA Test ERA Dev WHO Training FDA Custom Device Exe...

HELP

REVIEW

ROUTE

Human Subject Protocol - *Modifications Required to Secure Approval*

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Form/Document	Document Type	Submitted	
Application for Human Research	IRB Application	08-Nov-2019 11:15:10 AM	PDF
Consent Clean 11.11.19	Attachment	08-Nov-2019 11:15:09 AM	Modify
Consent Tracked 11.11.19	Attachment	08-Nov-2019 11:15:09 AM	Modify
Flyer	Attachment	08-Nov-2019 11:15:09 AM	Modify
Medical Record Abstraction Sheet	Attachment	08-Nov-2019 11:15:09 AM	Modify
Protocol	Protocol	08-Nov-2019 11:15:09 AM	Modify
Recruitment email	Attachment	08-Nov-2019 11:15:09 AM	Modify
Survey	Attachment	08-Nov-2019 11:15:09 AM	Modify

Close

Comments I can see...

No Comments have been recorded

Add Comments:

To be shared with everyone

B *I* U **A** ▼

Select a decision:

Acknowledge

PI Clarification



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

aging/ReviewItem.asp?RoutedStepID=96D9139C670A3B60E053B510600A6296

C&W IBX health reward International WIRB Form ERA Test ERA Dev WHO Training FDA Custom Device Exe...

HELP

REVIEW

ROUTE

Human Subject Protocol - *Modifications Required to Secure Approval*

Number: [26289](#)

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Submitted: 08-Nov-2019 11:15:10 AM

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Recruitment email	Attachment	08-Nov-2019 11:15:09 AM	Modify
Survey	Attachment	08-Nov-2019 11:15:09 AM	Modify

Close

Comments I can see...

No Comments have been recorded

Add Comments:

To be shared with everyone

B *I* U **A** ▼

Select a decision:

Acknowledge

PI Clarification



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

u/EnableWeb/Compliance/Submissions.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&Page=Submissions - Google Chrome


u/EnableWeb/Compliance/Submissions.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&Page=Submissions

Record Number

26289

My example protocol for the talk that I'm giving right now

DAVID COMALLI - RESEARCH: EXECUTIVE LEADERSHIP (24010) (NO EXTERNAL SPONSOR)

 Human Subjects

[Edit Mode](#)

Done

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Submissions

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Type	Submission Number	Investigator Submitted On Date	Management Submitted On Date	Internal ID	Determination	Determination Date	Date From	Date To	Access Log	
Close Protocol	26289-0005	08-Nov-2019	08-Nov-2019	N/A	Electronic Submission Pending	N/A	N/A	N/A	Log	Delete
Modification	26289-0003	08-Nov-2019	08-Nov-2019	N/A	Workflow Step 2 (Prep for Review)	N/A	N/A	N/A	Log	Delete
Initial Submission	26289-0001	08-Nov-2019	08-Nov-2019	N/A	Modifications Required to Secure Approval	09-Nov-2019	N/A	N/A	Log	Delete
Modifications Required to Secure Approval	26289-0002	N/A	N/A	N/A	Approved	12-Nov-2019	N/A	N/A	Log	Delete
Reportable New Information	26289-0004	N/A	N/A	N/A	Under Development		N/A	N/A	Log	Delete

If something is “Electronic Submission Pending,” Then it’s been submitted to—but not brought into—the IRB

u/EnableWeb/Compliance/Submissions.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&Page=Submissions - Google Chrome


u/EnableWeb/Compliance/Submissions.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&Page=Submissions

Record Number

26289

My example protocol for the talk that I'm giving right now

DAVID COMALLI - RESEARCH: EXECUTIVE LEADERSHIP (24010) (NO EXTERNAL SPONSOR)

 Human Subjects

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Submissions

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Modification	26289-0003	08-Nov-2019	08-Nov-2019	N/A	Workflow Step 2 (Prep for Review)	N/A	N/A	N/A	Log	Delete
Initial Submission	26289-0001	08-Nov-2019	08-Nov-2019	N/A	Modifications Required to Secure Approval	09-Nov-2019	N/A	N/A	Log	Delete
Modifications Required to Secure Approval	26289-0002	N/A	N/A	N/A	Approved	12-Nov-2019	N/A	N/A	Log	Delete
Reportable New Information	26289-0004	N/A	N/A	N/A	Under Development	N/A	N/A	N/A	Log	Delete

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

Done Save

Change Project Info

Submissions (14) Linkages Summaries Attachments (68) Communications (40) Approved Docs ?

Home > Submissions > Modification > Submission

Modification

Submission Number: 23074-0004 Created on: 30-Sep-2019 Status: Electronic Submission Pending

Document/Form	Type	Status		Show Route (Route History)
Modification of Approved Human Research	Modification	Completed	PDF	(Mandatory Form)



Submission

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IC Checklist

Codicils

Communications

Personnel (5)

Departments (1)

Centers / Programs

Locations

Attachments (1)

Status History (2)

Assignments (1)

https://era.temple.edu/messaging/showroute.asp?RouteID=93C916A70BFBB422E053B510600A36B1&Title=Off&boIM...
Temple University [US] | era.temple.edu/messaging/showroute.asp?RouteID=93C916A70BFBB422E053B510600A36B1...

Active Routing Progress

[Open Full](#)

23074 - DR. RYAN TIERNEY "Effect of Fatigue on Concussion Ocular-Motor Screening Assessments"
Submitted by DAVID COMALLI on behalf of DR. RYAN TIERNEY

Route Name	Route Type	Step Number/Name	Who	Notified	Decision	Insert	Remove
Modification of Human Research	Final Review	Step 0 - Inserted Step	DAVID COMALLI	30-Sep-2019 12:54:41 PM	Acknowledge - Acknowledge		
Modification of Human Research	Final Review	Step 1 - Inserted Step	DAVID COMALLI	01-Oct-2019 4:40:32 PM			
Modification of Human Research	Final Review	Step 1 - PI Acknowledgement	DR. RYAN TIERNEY				
Modification of Human Research	Final Review	Step 3 - IRB Check-In: Received by IRB	MRS. LASHAY COBB				
Modification of Human Research	Final Review		IRB OFFICE				

No comments have been recorded yet

The date under “Notified” only reflects when a person was notified

Done Save

Change Project Info

Submissions (14) Linkages Summaries Attachments (68) Communications (40) Approved Docs ?

Home > Submissions > Modification > Submission

Submission

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Personnel (5)

Departments (1)

Centers / Programs

Locations

Attachments (1)

Status History (2)

Assignments (1)

Modification

Submission Number: 23074-0004 Created on: 30-Sep-2019 Status: Electronic Submission Pending

Document/Form	Type	Status	Show Route (Route History)
Modification of Approved Human Research	Modification	Completed	PDF (Mandatory Form)

https://era.temple.edu/messaging/showroute.asp?RouteID=93C916A70BFBB422E053B510600A36B1&Title=Off&boIM...
Temple University [US] | era.temple.edu/messaging/showroute.asp?RouteID=93C916A70BFBB422E053B510600A36B1...

Active Routing Progress

[Open Full](#)

23074 - DR. RYAN TIERNEY "Effect of Fatigue on Concussion Ocular Motor Screening Assessments"
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Modification of Human Research	Final Review	Step 3 - IRB Check-In: Received by IRB	MRS. LASHAY COBB				
Modification of Human Research	Final Review		IRB OFFICE				

No comments have been recorded yet

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

Home > Submissions > Modification > Submission

- Submission
- Reviews
- IC Checklist
- Codicils
- Communications
- Personnel (5)
- Departments (1)
- Centers / Programs
- Locations
- Attachments (1)
- Status History (2)
- Assignments (1)

Modification Submission Number: 23074-0004 Created on: 30-Sep-2019 Status: Electronic Submission Pending

Document/Form	Type	Status	Show Route (Route History)
Modification of Approved Human Research	Modification	Completed	PDF <small>(Mandatory Form)</small>

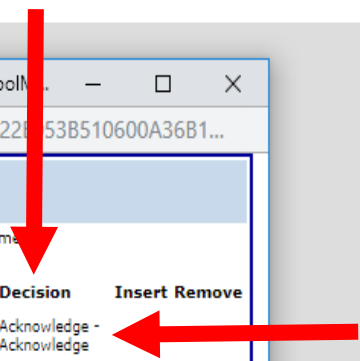
https://era.temple.edu/messaging/showroute.asp?RouteID=93C916A70BFBB422E053B510600A36B1&Title=Off&bolM...
Temple University [US] | era.temple.edu/messaging/showroute.asp?RouteID=93C916A70BFBB422E053B510600A36B1...

Active Routing Progress
[Open Full](#)

23074 - DR. RYAN TIERNEY "Effect of Fatigue on Concussion Ocular-Motor Screening Assessment"
Submitted by DAVID COMALLI on behalf of DR. RYAN TIERNEY

Route Name	Route Type	Step Number/Name	Who	Notified	Decision	Insert	Remove
Modification of Human Research	Final Review	Step 0 - Inserted Step	DAVID COMALLI	30-Sep-2019 12:54:41 PM	Acknowledge - Acknowledge		
Modification of Human Research	Final Review	Step 1 - Inserted Step	DAVID COMALLI	01-Oct-2019 4:40:32 PM			
Modification of Human Research	Final Review	Step 1 - PI Acknowledgement	DR. RYAN TIERNEY				
Modification of Human Research	Final Review	Step 3 - IRB Check-In: Received by IRB	MRS. LASHAY COBB				
Modification of Human Research	Final Review		IRB OFFICE				

No comments have been recorded yet



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

u/EnableWeb/Compliance/Submissions.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&Page=Submissions - Google Chrome


u/EnableWeb/Compliance/Submissions.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&Page=Submissions

Record Number

26289

My example protocol for the talk that I'm giving right now

DAVID COMALLI - RESEARCH: EXECUTIVE LEADERSHIP (24010) (NO EXTERNAL SPONSOR)

 Human Subjects

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Type	Submission Number	Investigator Submitted On Date	Management Submitted On Date	Internal ID	Determination	Determination Date	Date From	Date To	Access Log	
Close Protocol	26289-0005	08-Nov-2019	08-Nov-2019	N/A	Electronic Submission Pending	N/A	N/A	N/A	Log	Delete
Modification	26289-0003	08-Nov-2019	08-Nov-2019	N/A	Workflow Step 2 (Prep for Review)	N/A	N/A	N/A	Log	Delete
Initial Submission	26289-0001	08-Nov-2019	08-Nov-2019	N/A	Modifications Required to Secure Approval	09-Nov-2019	N/A	N/A	Log	Delete
Modifications Required to Secure Approval	26289-0002	N/A	N/A	N/A	Approved	12-Nov-2019	N/A	N/A	Log	Delete
Reportable New Information	26289-0004	N/A	N/A	N/A	Under Development	N/A	N/A	N/A	Log	Delete


Respond to “Modifications Required to Secure Approval” by clicking the “Respond...” link; Don’t create a “Modification” to respond to requested changes

era.temple.edu/EnableWeb/Compliance/Submissions.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&Page=Submissions - Google Chrome

era.temple.edu/EnableWeb/Compliance/Submissions.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&Page=Submissions

Record Number
26289

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DAVID COMALLI - RESEARCH: EXECUTIVE LEADERSHIP (24010) (NO EXTERNAL SPONSOR)

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Type	Submission Number	Investigator Submitted On Date	Management Submitted On Date	Internal ID	Determination	Determination Date	Date From	Date To	Access Log	
Initial Submission	26289-0001	08-Nov-2019	08-Nov-2019	N/A	Modifications Required to Secure Approval	09-Nov-2019	N/A	N/A	Log	Delete
Respond to Modifications Requested										



Select a Submission - Google Chrome

era.temple.edu/protocol/administration/reviews/popUpSubmissionType.asp?system=HS&proji...

Select Submission

Submission


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

era.temple.edu/EnableWeb/Compliance/Submissions.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&Page=Submissions - Google Chrome

era.temple.edu/EnableWeb/Compliance/Submissions.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&Page=Submissions

Record Number
26289

My example protocol for the talk that I'm giving right now
DAVID COMALLI - RESEARCH: EXECUTIVE LEADERSHIP (24010) (NO EXTERNAL SPONSOR)

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Type	Submission Number	Investigator Submitted On Date	Management Submitted On Date	Internal ID	Determination	Determination Date	Date From	Date To	Access Log	
Initial Submission	26289-0001	08-Nov-2019	08-Nov-2019	N/A	Modifications Required to Secure Approval	09-Nov-2019	N/A	N/A	Log	Delete
Respond to Modifications Requested										

Select a Submission - Google Chrome

era.temple.edu/protocol/administration/reviews/popUpSubmissionType.asp?system=HS&proji...

Select Submission

Submission



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


du/EnableWeb/Compliance/SubmissionDetail.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&ObjectID=96D84568D867134AE053B510600AC3CF&Page=SubmissionDetail - Google Chrome

EnableWeb/Compliance/SubmissionDetail.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&ObjectID=96D84568D867134AE053B510600AC3CF&Page=SubmissionDetail

Record Number
26289

My example protocol for the talk that I'm giving right now

DAVID COMALLI - RESEARCH: EXECUTIVE LEADERSHIP (24010) (NO EXTERNAL SPONSOR)

 Human Subjects

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[Submissions \(2\)](#) [Linkages](#) [Summaries](#) [Attachments \(14\)](#) [Communications \(3\)](#) [Approved Docs](#)



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Modifications Required to Secure Approval

Submission Number: 26289-0002 Created on: 08-Nov-2019 Status: Under Development

Submission

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[Locations](#)

[Attachments \(7\)](#)

[Status History \(1\)](#)

[Assignments](#)

Document/Form Add	Type	Status		Submit
Application for Human Research	IRB Application	Completed	PDF	Remove
Consent	Consent Form	Completed	PDF	Remove
Flyer	Attachment	Completed	Modify	Remove
Medical Record Abstraction Sheet	Attachment	Completed	Modify	Remove
Protocol	Protocol	Completed	Modify	Remove
Recruitment email	Attachment	Completed	Modify	Remove
Survey	Attachment	Completed	Modify	Remove

[Show Existing Protocol Attachments](#)


Add the new (Tracked Changes and Clean versions) documents

du/EnableWeb/Compliance/SubmissionDetail.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&ObjectID=96D84568D867134AE053B510600AC3CF&Page=SubmissionDetail - Google Chrome

EnableWeb/Compliance/SubmissionDetail.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&ObjectID=96D84568D867134AE053B510600AC3CF&Page=SubmissionDetail

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 Human Subjects

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[Departments \(1\)](#)

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[Attachments \(7\)](#)

[Status History \(1\)](#)

[Assignments](#)

Modifications Required to Secure Approval

Submission Number: 26289-0002 Created on: 08-Nov-2019 Status: Under Development

Document/Form Add	Type	Status		Submit
Application for Human Research	IRB Application	Completed	PDF	Remove
Consent	Consent Form	Completed	Modify	Remove
Flyer	Attachment	Completed	Modify	Remove
Medical Record Abstraction Sheet	Attachment	Completed	Modify	Remove
Protocol	Protocol	Completed	Modify	Remove
Recruitment email	Attachment	Completed	Modify	Remove
Survey	Attachment	Completed	Modify	Remove

[Show Existing Protocol Attachments](#)


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

Record Number

26289

My example protocol for the talk that I'm giving right now

DAVID COMALLI - RESEARCH: EXECUTIVE LEADERSHIP (24010) (NO EXTERNAL SPONSOR)

 Human Subjects

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Submission

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[IC Checklist](#)

[Codicils](#)

[Communications](#)

[Personnel \(2\)](#)

[Departments \(1\)](#)

[Centers / Programs](#)

[Locations](#)

[Attachments \(8\)](#)

[Status History \(1\)](#)

[Assignments](#)

Modifications Required to Secure Approval

Submission Number: 26289-0002 Created on: 08-Nov-2019 Status: Under Development

Document/Form Add	Type	Status		<input type="button" value="Submit"/>
Application for Human Research	IRB Application	Completed	PDF	Remove
Consent Clean 11.11.19	Attachment	Completed	Modify	Remove
Consent Tracked 11.11.19	Attachment	Completed	Modify	Remove
Flyer	Attachment	Completed	Modify	Remove
Medical Record Abstraction Sheet	Attachment	Completed	Modify	Remove
Protocol	Protocol	Completed	Modify	Remove
Recruitment email	Attachment	Completed	Modify	Remove
Survey	Attachment	Completed	Modify	Remove

[Show Existing Protocol Attachments](#)

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

u/EnableWeb/Compliance/Submissions.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&Page=Submissions - Google Chrome


u/EnableWeb/Compliance/Submissions.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&Page=Submissions

Record Number

26289

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DAVID COMALLI - RESEARCH: EXECUTIVE LEADERSHIP (24010) (NO EXTERNAL SPONSOR)

 Human Subjects

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Submissions

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Close Protocol	26289-0005	08-Nov-2019	08-Nov-2019	N/A	Electronic Submission Pending	N/A	N/A	N/A	Log	Delete
Modification	26289-0003	08-Nov-2019	08-Nov-2019	N/A	Workflow Step 2 (Prep for Review)	N/A	N/A	N/A	Log	Delete
Initial Submission	26289-0001	08-Nov-2019	08-Nov-2019	N/A	Modifications Required to Secure Approval	09-Nov-2019	N/A	N/A	Log	Delete
Modifications Required to Secure Approval	26289-0002	08-Nov-2019	08-Nov-2019	N/A	Approved	12-Nov-2019	N/A	N/A	Log	Delete
Reportable New Information	26289-0004	N/A	N/A	N/A	Under Development	N/A	N/A	N/A	Log	Delete


Click on the "Attachments" link within the submission

u/EnableWeb/Compliance/SubmissionDetail.aspx?ProjID=96C7F8B8E59712A3E053B510600A57C3&ObjectID=96D84568D867134AE053B510600AC3CF&Page=SubmissionDetail - Google Chrome

EnableWeb/Compliance/SubmissionDetail.aspx?ProjID=96C7F8B8E59712A3E053B510600A57C3&ObjectID=96D84568D867134AE053B510600AC3CF&Page=SubmissionDetail

Record Number
26289

My example protocol for the talk that I'm giving right now
DAVID COMALLI - RESEARCH: EXECUTIVE LEADERSHIP (24010) (NO EXTERNAL SPONSOR)

 Human Subjects

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[Assignments](#)

Modifications Required to Secure Approval

Submission Number: 26289-0002 Created on: 08-Nov-2019 Status: Approved

Document/Form	Type	Status	
Application for Human Research	IRB Application	Completed	PDF
Consent Clean 11.11.19	Attachment	Completed	Modify
Consent Tracked 11.11.19	Attachment	Completed	Modify
Flyer	Attachment	Completed	Modify
Medical Record Abstraction Sheet	Attachment	Completed	Modify
Protocol	Protocol	Completed	Modify
Recruitment email	Attachment	Completed	Modify
Survey	Attachment	Completed	Modify
Show Existing Protocol Attachments			

Find the IRB Approved and Stamped consent(s)

Record Number
26289

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[Submissions \(2\)](#) [Linkages](#) [Summaries](#) [Attachments \(17\)](#) [Communications \(3\)](#) [Approved Docs](#) [?](#)

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Attachments (9)

Attachments

Attachments [Print All](#) [Folder Maintenance](#) [Add Document](#) [Delete Selected](#)

Drag a column header and drop it here to group by that column

Name	Category	Folder	Managed by	Submission	Versions	Last Updated	Select
Protocol	Protocol	ROOT	Submission Package	Modifications Required to Secure Approval	2	08-Nov-2019 9:59:58 AM	<input type="checkbox"/>
Flyer	Attachment	ROOT	Submission Package	Modifications Required to Secure Approval	2	08-Nov-2019 10:01:57 AM	<input type="checkbox"/>
Recruitment email	Attachment	ROOT	Submission Package	Modifications Required to Secure Approval	2	08-Nov-2019 10:03:26 AM	<input type="checkbox"/>
Medical Record Abstraction Sheet	Attachment	ROOT	Submission Package	Modifications Required to Secure Approval	2	08-Nov-2019 10:03:50 AM	<input type="checkbox"/>
Survey	Attachment	ROOT	Submission Package	Modifications Required to Secure Approval	2	08-Nov-2019 10:04:13 AM	<input type="checkbox"/>
Consent Tracked 11.11.19	Attachment	ROOT	Submission Package	Modifications Required to Secure Approval	1	08-Nov-2019 10:21:33 AM	<input type="checkbox"/>
Consent Clean 11.11.19	Attachment	ROOT	Submission Package	Modifications Required to Secure Approval	1	08-Nov-2019 10:21:53 AM	<input type="checkbox"/>
IRB Approved and Stamped Consent	Stamped Consent	ROOT	Record	Modifications Required to Secure Approval	1	08-Nov-2019 10:24:21 AM	<input type="checkbox"/>
Application for Human Research	IRB Application	ROOT	Submission Package	Modifications Required to Secure Approval	1	08-Nov-2019 10:17:52 AM	<input type="checkbox"/>



They should be sortable by “Category,” labeled as “ Stamped Consent ”

EnableWeb/Compliance/Attachments.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&ObjectID=96D84568D867134AE053B510600AC3CF&ProjAttachFolderId=ROOT&Page=SubAttachments - Google Chrome

EnableWeb/Compliance/Attachments.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&ObjectID=96D84568D867134AE053B510600AC3CF&ProjAttachFolderId=ROOT&Page=SubAttachments

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26289

My example protocol for the talk that I'm giving right now

DAVID COMALLI - RESEARCH: EXECUTIVE LEADERSHIP (24010) (NO EXTERNAL SPONSOR)

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Home > Submissions > Modifications Required to Secure Approval > Attachments

Attachments (9)

Attachments

Attachments

Print All Folder Maintenance Add Document Delete Selected

Drag a column header and drop it here to group by that column

Name	Category	Folder	Managed by	Submission	Versions	Last Updated	Select
Protocol	Protocol	ROOT	Submission Package	Modifications Required to Secure Approval	2	08-Nov-2019 9:59:58 AM	<input type="checkbox"/>
Flyer	Attachment	ROOT	Submission Package	Modifications Required to Secure Approval	2	08-Nov-2019 10:01:57 AM	<input type="checkbox"/>
Recruitment email	Attachment	ROOT	Submission Package	Modifications Required to Secure Approval	2	08-Nov-2019 10:03:26 AM	<input type="checkbox"/>
Medical Record Abstraction Sheet	Attachment	ROOT	Submission Package	Modifications Required to Secure Approval	2	08-Nov-2019 10:03:50 AM	<input type="checkbox"/>
Survey	Attachment	ROOT	Submission Package	Modifications Required to Secure Approval	2	08-Nov-2019 10:04:13 AM	<input type="checkbox"/>
Consent Tracked 11.11.19	Attachment	ROOT	Submission Package	Modifications Required to Secure Approval	1	08-Nov-2019 10:21:33 AM	<input type="checkbox"/>
Consent Clean 11.11.19	Attachment	ROOT	Submission Package	Modifications Required to Secure Approval	1	08-Nov-2019 10:21:53 AM	<input type="checkbox"/>
IRB Approved and Stamped Consent	Stamped Consent	ROOT	Record	Modifications Required to Secure Approval	1	08-Nov-2019 10:24:21 AM	<input type="checkbox"/>
Application for Human Research	IRB Application	ROOT	Submission Package	Modifications Required to Secure Approval	1	08-Nov-2019 10:17:52 AM	<input type="checkbox"/>

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

EnableWeb/Compliance/Attachments.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&ObjectID=96D84568D867134AE053B510600AC3CF&ProjAttachFolderId=ROOT&Page=SubAttachments - Google Chrome

EnableWeb/Compliance/Attachments.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&ObjectID=96D84568D867134AE053B510600AC3CF&ProjAttachFolderId=ROOT&Page=SubAttachments

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My example protocol for the talk that I'm giving right now

DAVID COMALLI - RESEARCH: EXECUTIVE LEADERSHIP (24010) (NO EXTERNAL SPONSOR)

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Done Save

Submissions (2) Linkages Summaries Attachments (17) Communications (3) Approved Docs



Home > Submissions > Modifications Required to Secure Approval > Attachments

Attachments (9)

Attachments

Attachments

Print All Folder Maintenance Add Document Delete Selected

Drag a column header and drop it here to group by that column

Name	Category	Folder	Managed by	Submission	Versions	Last Updated	Select
Protocol	Protocol	ROOT	Submission Package	Modifications Required to Secure Approval	2	08-Nov-2019 9:59:58 AM	<input type="checkbox"/>
Flyer	Attachment	ROOT	Submission Package	Modifications Required to Secure Approval	2	08-Nov-2019 10:01:57 AM	<input type="checkbox"/>
Recruitment email	Attachment	ROOT	Submission Package	Modifications Required to Secure Approval	2	08-Nov-2019 10:03:26 AM	<input type="checkbox"/>
Medical Record Abstraction Sheet	Attachment	ROOT	Submission Package	Modifications Required to Secure Approval	2	08-Nov-2019 10:03:50 AM	<input type="checkbox"/>
Survey	Attachment	ROOT	Submission Package	Modifications Required to Secure Approval	2	08-Nov-2019 10:04:13 AM	<input type="checkbox"/>
Consent Tracked 11.11.19	Attachment	ROOT	Submission Package	Modifications Required to Secure Approval	1	08-Nov-2019 10:21:33 AM	<input type="checkbox"/>
Consent Clean 11.11.19	Attachment	ROOT	Submission Package	Modifications Required to Secure Approval	1	08-Nov-2019 10:21:53 AM	<input type="checkbox"/>
IRB Approved and Stamped Consent	Stamped Consent	ROOT	Record	Modifications Required to Secure Approval	1	08-Nov-2019 10:24:21 AM	<input type="checkbox"/>
Application for Human Research	IRB Application	ROOT	Submission Package	Modifications Required to Secure Approval	1	08-Nov-2019 10:17:52 AM	<input type="checkbox"/>

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

/EnableWeb/Compliance/Submissions.aspx?Projid=04EB30272885126CE053B510600A8005&Page=Submissions - Google Chrome


[US] | era.temple.edu/EnableWeb/Compliance/Submissions.aspx?Projid=04EB30272885126CE053B510600A8005&Page=Submissions

Record Number

23074

Effect of Fatigue on Concussion Ocular-Motor Screening Assessments

DR. RYAN TIERNEY - CPH:KINESIOLOGY (09070) (NO EXTERNAL SPONSOR)

 Human Subjects

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Submissions

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Type	Submission Number	Investigator Submitted On Date	Management Submitted On Date	Internal ID	Determination	Determination Date	Date From	Date To	Access Log	
Modification	23074-0004	30-Sep-2019	N/A	N/A	Electronic Submission Pending	N/A	N/A	N/A	Log	Delete
Close Protocol	23074-0003	02-Aug-2019	06-Aug-2019	N/A	Closed	28-Aug-2019	N/A	N/A	Log	Delete
Continuing Review	23074-0001	09-Jul-2018	12-Jul-2018	N/A	Modifications Required to Secure Approval	N/A	N/A	N/A	Log	Delete
Modifications Required to Secure Approval	23074-0002	11-Aug-2018	15-Aug-2018	N/A	Approved	16-Aug-2018	01-Sep-2018	31-Aug-2019	Log	Delete
Modification	N/A	28-Aug-2017	31-Aug-2017	N/A	Approved	19-Sep-2017	N/A	N/A	Log	Delete
Continuing Review	N/A	03-Aug-2017	03-Aug-2017	N/A	Modifications Required to Secure Approval	N/A	N/A	N/A	Log	Delete
Modifications Required to Secure Approval	N/A	28-Aug-2017	28-Aug-2017	N/A	Approved	31-Aug-2017	01-Sep-2017	31-Aug-2018	Log	Delete
Modifications Required to Secure Approval	N/A	15-Aug-2017	15-Aug-2017	N/A	Modifications Required to Secure Approval	N/A	N/A	N/A	Log	Delete
Modification	N/A	16-Feb-2017	20-Feb-2017	N/A	Approved	27-Feb-2017	N/A	N/A	Log	Delete
Continuing Review	N/A	14-Jun-2016	17-Jun-2016	N/A	Approved	17-Aug-2016	01-Sep-2016	31-Aug-2017	Log	Delete
Initial Submission	N/A	18-Jun-2015	16-Jul-2015	N/A	Modifications Required to Secure Approval	N/A	N/A	N/A	Log	Delete
Modifications Required to Secure Approval	N/A	31-Aug-2015	01-Sep-2015	N/A	Approved	01-Sep-2015	01-Sep-2015	31-Aug-2016	Log	Delete
Modifications Required to Secure Approval	N/A	21-Jul-2015	21-Jul-2015	N/A	Modifications Required to Secure Approval	N/A	N/A	N/A	Log	Delete
Reportable New Information	23074-0005	N/A	N/A	N/A	Under Development	N/A	N/A	N/A	Log	Delete

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

Record Number
23074

Done Save

Effect of Fatigue on Concussion Ocular-Motor Screening Assessments
DR. RYAN TIERNEY - CPH:KINESIOLOGY (09070) (NO EXTERNAL SPONSOR)

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Attachments (68)

Attachments

Print All Folder Maintenance Add Document Delete Selected

Drag a column header and drop it here to group by that column

Name	Category	Folder	Managed by	Submission	Versions	Last Updated	Select
modifications_required		ROOT	Record	Review	1	20-Jul-2015 5:00:36 PM	
IRB Approved Stamped Consent	Stamped Consent	ROOT	Record	Modifications Required to Secure Approval	1	01-Sep-2015 5:34:55 PM	
IRB Approved Stamped Consent	Stamped Consent	ROOT	Record	Modification	1	28-Feb-2017 4:28:56 PM	
IRB Approved Stamped Consent	Stamped Consent	ROOT	Record	Modifications Required to Secure Approval	1	31-Aug-2017 10:45:09 AM	
IRB Approved stamped Consent Form	Stamped Consent	ROOT	Record	Modifications Required to Secure Approval	1	27-Aug-2018 4:17:33 PM	
HIPAA	Attachment	ROOT	Submission Package	Initial Submission	1	18-Jun-2015 11:21:45 AM	
Consent Form	Attachment	ROOT	Submission Package	Initial Submission	1	18-Jun-2015 11:30:19 AM	
protocol	Attachment	ROOT	Submission Package	Initial Submission	1	18-Jun-2015 11:30:37 AM	
Flyer	Attachment	ROOT	Submission Package	Initial Submission	1	18-Jun-2015 11:35:32 AM	
Consent Marked	Attachment	ROOT	Submission Package	Modifications Required to Secure Approval	1	21-Jul-2015 7:09:48 AM	
Consent Form Clean	Attachment	ROOT	Submission Package	Modifications Required to Secure Approval	1	21-Jul-2015 7:10:20 AM	
Protocol Updated	Attachment	ROOT	Submission Package	Modifications Required to Secure Approval	1	21-Jul-2015 7:10:46 AM	
flyer updated	Attachment	ROOT	Submission Package	Modifications Required to Secure Approval	1	21-Jul-2015 7:11:26 AM	
Point by point response	Attachment	ROOT	Submission Package	Modifications Required to Secure Approval	1	21-Jul-2015 7:11:45 AM	



Mind “Last Updated” to ensure the correct version is being downloaded

Record Number
23074

Effect of Fatigue on Concussion Ocular-Motor Screening Assessments
DR. RYAN TIERNEY - CPH:KINESIOLOGY (09070) (NO EXTERNAL SPONSOR)

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Attachments (68)

Attachments

Attachments

[Print All](#) [Folder Maintenance](#) [Add Document](#) [Delete Selected](#)

Drag a column header and drop it here to group by that column

Name	Category	Folder	Managed by	Submission	Versions	Last Updated	Select
modifications_required		ROOT	Record	Review	1	20-Jul-2015 5:00:36 PM	
IRB Approved Stamped Consent	Stamped Consent	ROOT	Record	Modifications Required to Secure Approval	1	01-Sep-2015 5:34:55 PM	
IRB Approved Stamped Consent	Stamped Consent	ROOT	Record	Modification	1	28-Feb-2017 4:28:56 PM	
IRB Approved Stamped Consent	Stamped Consent	ROOT	Record	Modifications Required to Secure Approval	1	31-Aug-2017 10:45:09 AM	
IRB Approved stamped Consent Form	Stamped Consent	ROOT	Record	Modifications Required to Secure Approval	1	27-Aug-2018 4:17:33 PM	
HIPAA	Attachment	ROOT	Submission Package	Initial Submission	1	18-Jun-2015 11:21:45 AM	
Consent Form	Attachment	ROOT	Submission Package	Initial Submission	1	18-Jun-2015 11:30:19 AM	



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

u/EnableWeb/Compliance/Submissions.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&Page=Submissions - Google Chrome


nableWeb/Compliance/Submissions.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&Page=Submissions

Record Number

26289

My example protocol for the talk that I'm giving right now

DAVID COMALLI - RESEARCH: EXECUTIVE LEADERSHIP (24010) (NO EXTERNAL SPONSOR)

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Submissions

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- Continuing Review
- Modification**
- Reportable New Information
- Close Protocol Expired

Type	Submission Number	Investigator Submitted On Date	Management Submitted On Date	Internal ID	Determination	Determination Date	Date From			
Initial Submission	26289-0001	08-Nov-2019	08-Nov-2019	N/A	Modifications Required to Secure Approval	09-Nov-2019	N/A			Delete
Modifications Required to Secure Approval	26289-0002	N/A	N/A	N/A	Approved	12-Nov-2019	N/A	N/A	Log	Delete

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

u/EnableWeb/Compliance/Submissions.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&Page=Submissions - Google Chrome


nableWeb/Compliance/Submissions.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&Page=Submissions

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Type	Submission Number	Investigator Submitted On Date	Management Submitted On Date	Internal ID	Determination	Determination Date	Date From			
Initial Submission	26289-0001	08-Nov-2019	08-Nov-2019	N/A	Modifications Required to Secure Approval	09-Nov-2019	N/A			Delete
Modifications Required to Secure Approval	26289-0002	N/A	N/A	N/A	Approved	12-Nov-2019	N/A	N/A	Log	Delete

- Continuing Review
- Modification**
- Reportable New Information
- Close Protocol Expired

Click "Add"

u/EnableWeb/Compliance/Submissions.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&Page=Submissions - Google Chrome


nableWeb/Compliance/Submissions.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&Page=Submissions

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My example protocol for the talk that I'm giving right now

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Submissions

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Type	Submission Number	Investigator Submitted On Date	Management Submitted On Date	Internal ID	Determination	Determination Date	Date From			
Initial Submission	26289-0001	08-Nov-2019	08-Nov-2019	N/A	Modifications Required to Secure Approval	09-Nov-2019	N/A			Delete
Modifications Required to Secure Approval	26289-0002	N/A	N/A	N/A	Approved	12-Nov-2019	N/A	N/A	Log	Delete

- Continuing Review
- Modification**
- Reportable New Information
- Close Protocol Expired

Click and then complete the “Modification of Approved Human Research” eForm

du/EnableWeb/Compliance/SubmissionDetail.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&ObjectID=96D88E38E0D424CDE053B510600A7627&Page=SubmissionDetail - Google Chrome

era temple.edu/ComplianceNet/SharedSystems/EForms/Form.aspx?ObjectFormId=75CF7E18-E049-478B-A0E1-8651C6A4AD08&recordid=8186908&system=HS&COIUnique_...

Record Number 26289

My example protocol for the talk
DAVID COMALLI - RESEARCH: EXEC

Done Save

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IC Checklist

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Personnel (1)

Departments (1)

Centers / Programs

Locations

Attachments (1)

Status History (1)

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Modification

Document/Form Add


Modification of Approved Human Research

Show Existing Protocol Attachments

Updated By: DAVID COMALLI @ 08-Nov-2019 10:52:17 AM

Modification of Approved Human Research

Page 1



Section I

IRB Project #: 26289

Study Title: My example protocol for the talk that I'm giving right now

Investigator: COMALLI, DAVID

* Department: RESEARCH: EXECUTIVE LEADERSHIP (24010)

* Physical Address: 3340 N. Broad St.

* Phone Number: 215-707-7792

Section II

* Summarize the modification:

Adding Dr. Henry Parkman as a Co-Investigator.

Section III

Were any of the documents below affected by the modification(s)?

Yes No * This modification request includes the addition of any radiation imaging; or a change in sponsored imaging requirements; or a change in number of radiation imaging or radiation therapies; or a change in type of radiation; or a change where the radiation is going to be administered.

Yes No * Investigator Protocol

Yes No * Research tools

Yes No * Data collection instruments (questionnaires, etc.; do not submit case report forms).

All written materials to be provided to or meant to be seen or heard by subjects, including:

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


...e.edu/EnableWeb/Compliance/SubmissionDetail.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&ObjectID=96D8BE38E0D424CDE053B510600A7627&Page=SubmissionDetail - Google Chrome

...u/EnableWeb/Compliance/SubmissionDetail.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&ObjectID=96D8BE38E0D424CDE053B510600A7627&Page=SubmissionDetail

Record Number
26289

My example protocol for the talk that I'm giving right now

DAVID COMALLI - RESEARCH: EXECUTIVE LEADERSHIP (24010) (NO EXTERNAL SPONSOR)

 Human Subjects

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[Done](#) [Save](#)

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[Attachments \(1\)](#)

[Status History \(5\)](#)

[Assignments](#)

Modification

Submission Number: 26289-0003 Created on: 08-Nov-2019 Status: Under Development

Document/Form	Add	Type	Status	Show Route	(Route History)
Modification of Approved Human Research		Modification	Completed	PDF	(Mandatory Form)

When ready, click "Submit" and get to the approval route

u/EnableWeb/Compliance/SubmissionDetail.aspx?ProjID=96C7F8B8E59712A3E053B510600A57C3&ObjectID=96D8BE38E0D424CDE053B510600A7627&Page=SubmissionDetail - Google Chrome


nableWeb/Compliance/SubmissionDetail.aspx?ProjID=96C7F8B8E59712A3E053B510600A57C3&ObjectID=96D8BE38E0D424CDE053B510600A7627&Page=SubmissionDetail

Record Number

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My example protocol for the talk that I'm giving right now

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Modification

Submission Number: 26289-0003 Created on: 08-Nov-2019 Status: Under Development

Document/Form Add

[Modification of Approved Human Research](#)

[Show Existing Protocol Attachments](#)

[Submit](#)

Type

Status

Modification

Completed

PDF

(Mandatory Form)

Submit - Google Chrome

era.temple.edu/messaging/Submit.asp?ObjectID=96D8BE38E0D424CDE053B510600A7627&RouteMapID=CE4D040A...

Protocol **26289** - **DAVID COMALLI** "My example protocol for the talk that I'm giving right now" (Under Development)

[Refresh Route](#)

Route Path - **Modification of Human Research** [Add New Person to Review Path](#)

[Continue](#)

Step 1	PI Acknowledgement	DAVID COMALLI	
Step 3	IRB Check-In: Received by IRB	MRS. LASHAY COBB	
	IRB Check-In: Received by IRB	IRB OFFICE	

No comments have been recorded yet

Add step - Google Chrome

era.temple.edu/messaging/AddRouteStep.asp?RouteID=96D8BF50488F2D09E053B510600A38C6

Add step

[Add](#)

[Cancel](#)

PARKMAN, HENRY - 908809724 - TUSM:MEDICINE/GASTROENTEROLOGY (05725)

Informational Only

Approval Required

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

InfoEd's eResearch Portal x +

era.temple.edu/EnableWeb/Portal/Home

SMART IRB IRB Form&SOP C & W TU Remote Easter Egg ERA Dev IREX ERA Test Connexus Bookmarks 4 Dum... Reading list

infoEd GLOBAL v13 Portal Module Admin Welcome DAVID COMALLI Logout

Home My Profile Locate My Records Locate Records Calendar Messages Assignments

29248

- My Proposals and Awards
- My Human Subjects
- Laboratory Animals
- My Conflict of Interests
- Invention
- TT System Overview
- SPIN

Workflow Chart(s) --Select--

[IRB All Submissions](#) Human Subjects Protocol

Portal Configurations

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

The screenshot shows a web browser window with the address bar displaying `era.temple.edu/EnableWeb/Portal/Home`. The browser's address bar and toolbar are visible at the top. Below the browser, the portal's header includes the **infoEd GLOBAL** logo on the left and user information on the right: **v13 Portal**, **Module Admin**, **Welcome DAVID COMALLI**, and **Logout**. A dark navigation bar contains several menu items: **Home**, **My Profile**, **Locate My Records**, **Locate Records**, **Calendar**, **Messages**, and **Assignments**. On the right side of this navigation bar is a search bar containing the text "Uknis" and a magnifying glass icon. A red arrow points from the right towards this search bar. Below the navigation bar, the main content area features a sidebar on the left with links for **My Proposals and Awards**, **My Human Subjects**, **Laboratory Animals**, **My Conflict of Interests**, **Invention**, **TT System Overview**, and **SPIN**. The central content area displays a **Workflow Chart(s)** section with a dropdown menu set to "--Select--". Below this, there are two links: **IRB All Submissions** and **Human Subjects Protocol**. In the bottom right corner, there is a **Portal Configurations** button with a gear icon.

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

InfoEd's eResearch Portal

era.temple.edu/EnableWeb/Portal/Home

SMART IRB IRB Form&SOP C & W TU Remote Easter Egg ERA Dev IREX ERA Test Connexus Bookmarks 4 Dum... Reading list

infoEd GLOBAL v13 Portal Module Admin Welcome DAVID COMALLI Logout

Home My Profile Locate My Records **Locate Record** Calendar Messages Assignments Quick Find

My Proposals and Awards
My Human Subjects
Laboratory Animals
My Conflict of Interests
Invention
TT System Overview
SPIN

Results found: 15 Export to Excel

Drag a column header and drop it here to group by that column

<input type="checkbox"/>	Record Number	Record Type	Record Title	Record Owner	Record Status	Record Primary Sponsor ↑
	29248	Human Subjects Protocol	Example Protocol for These Slides	UKNIS, AUDREY	Under Development	
▶	3976	Human Subjects Protocol	AMGEN PROTOCOL 20010108; A STUDY OF THE AGREEMENT BETWEEN THE STANDARD AND MODIFIED ACR IMPROVEMENT CRITERIA IN RHEUMATOID ARTHRITIS SUBJECTS RECEIVING KINERETA (ANAKINRA) AFTER HAVING AN UNSATISFACTORY RESPONSE TO DISEASE-MODIFYING ANTIRHEUMATIC DRUG THERAPY (DMARDS); A PHASE IV STUDY	UKNIS, AUDREY	Withdrawn	AMGEN
▶	22578	Proposal	RHEUMATOLOGY FELLOWSHIP AWARD PROGRAM	UKNIS, AUDREY	Funded	AMGEN
▶	4446	Human Subjects Protocol	+AN OPEN-LABEL STUDY OF THE EFFICACY AND SAFETY OF RE-TREATMENTS WITH RITUXIMAB (MAB THERA) IN PATIENTS WITH ACTIVE RHEUMATOID ARTHRITIS WHO HAVE HAD AN INADEQUATE RESPONSE TO ANIT-TNF THERAPIES	UKNIS, AUDREY	Closed	BIOGEN, INC
▶	21123	Proposal	+AN OPEN-LABEL STUDY OF THE EFFICACY AND SAFETY OF RE-TREATMENTS WITH RITUXIMAB (MAB THERA) IN PATIENTS WITH ACTIVE RHEUMATOID ARTHRITIS WHO HAVE HAD AN INADEQUATE RESPONSE TO ANIT-TNF THERAPIES	UKNIS, AUDREY	Closed	BIOGEN, INC

Hover over "Edit"

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

The screenshot shows the InfoEd's eResearch Portal interface. The browser address bar displays `era.temple.edu/EnableWeb/Portal/Home`. The page header includes the InfoEd logo, user information "Welcome DAVID COMALLI", and a "Logout" link. A navigation bar contains links for Home, My Profile, Locate My Records, Locate Records, Calendar, Messages, and Assignments. A search bar labeled "Quick Find" is also present.

The main content area displays a table of records with the following columns: Record Number, Record Type, Record Title, Record Owner, Record Status, and Record Primary Sponsor. A context menu is open over the "Edit" option for record 292. A red arrow points to the "Edit" option.

Record Number	Record Type	Record Title	Record Owner	Record Status	Record Primary Sponsor
292	Human Subjects	Example Protocol for These Slides	UKNIS, AUDREY	Under Development	
397	jects	AMGEN PROTOCOL 20010108; A STUDY OF THE AGREEMENT BETWEEN THE STANDARD AND MODIFIED ACR IMPROVEMENT CRITERIA IN RHEUMATOID ARTHRITIS SUBJECTS RECEIVING KINERETA (ANAKINRA) AFTER HAVING AN UNSATISFACTORY RESPONSE TO DISEASE-MODIFYING ANTIRHEUMATIC DRUG THERAPY (DMARDS); A PHASE IV STUDY	UKNIS, AUDREY	Withdrawn	AMGEN
225		RHEUMATOLOGY FELLOWSHIP AWARD PROGRAM	UKNIS, AUDREY	Funded	AMGEN
4446	Human Subjects Protocol	+AN OPEN-LABEL STUDY OF THE EFFICACY AND SAFETY OF RE-TREATMENTS WITH RITUXIMAB (MAB THERA) IN PATIENTS WITH ACTIVE RHEUMATOID ARTHRITIS WHO HAVE HAD AN INADEQUATE RESPONSE TO ANIT-TNF THERAPIES	UKNIS, AUDREY	Closed	BIOGEN, INC
21123	Proposal	+AN OPEN-LABEL STUDY OF THE EFFICACY AND SAFETY OF RE-TREATMENTS WITH RITUXIMAB (MAB THERA) IN PATIENTS WITH ACTIVE RHEUMATOID ARTHRITIS WHO HAVE HAD AN INADEQUATE RESPONSE TO ANIT-TNF THERAPIES	UKNIS, AUDREY	Closed	BIOGEN, INC

Hover over "Edit"

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

The screenshot shows the InfoEd's eResearch Portal interface. The browser address bar displays `era.temple.edu/EnableWeb/Portal/Home`. The page header includes the InfoEd logo, navigation links (Home, My Profile, Locate My Records, etc.), and a user welcome message for DAVID COMALLI. A sidebar on the left lists various menu items, with a red arrow pointing to the 'Edit' option in a dropdown menu for record 292. The main content area shows a table of 15 records found, with columns for Record Number, Record Type, Record Title, Record Owner, Record Status, and Record Primary Sponsor.

Record Number	Record Type	Record Title	Record Owner	Record Status	Record Primary Sponsor
292	Human Subjects	Example Protocol for These Slides	UKNIS, AUDREY	Under Development	
397	Human Subjects		UKNIS, AUDREY	Withdrawn	
225			UKNIS, AUDREY	Funded	
4446	Human Subjects Protocol		UKNIS, AUDREY	Closed	
21123	Proposal		UKNIS, AUDREY	Closed	

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

InfoEd's eResearch Portal x +

era.temple.edu/EnableWeb/Portal/Home

SMART IRB IRB Form&SOP C & W TU Remote Easter Egg ERA Dev IREX ERA Test Connexus Bookmarks 4 Dum... Reading list

infoEd GLOBAL v13 Portal Module Admin Welcome DAVID COMALLI Logout

Home My Profile Locate My Records Locate Records Calendar Messages Assignments Quick Find

My Proposals and Awards

My Human Subjects

Laboratory Animals

My Conflict of Interests

Invention

TT System Overview

SPIN

Results found: 15 Export to Excel

Drag a column header and drop it here to group by that column

<input type="checkbox"/>	Record Number	Record Type	Record Title	Record Owner	Record Status	Record Primary Sponsor ↑
▶	292	Human Subjects		UKNIS, AUDREY	Under Development	
▶ Edit Master Record ←						
▶ View ▶ Close Protocol (11-Jan-2022 Under Development)						
▶	397	Create New	▶ Reportable New Information (11-Jan-2022 Under Development)	UKNIS, AUDREY	Withdrawn	
▶ Info ▶ Continuing Review (11-Jan-2022 Under Development)						
▶	225	Delete	Modification (11-Jan-2022 Under Development)	UKNIS, AUDREY	Funded	AMGEN
▶ Bookmark Record Modification (11-Jan-2022 Under Development)						
▶	4446	Human Sub Protocol	Additional Submissions ←	UKNIS, AUDREY	Closed	
▶	21123	Proposal	+AN OPEN-LABEL STUDY OF THE EFFICACY AND SAFETY OF RE-TREATMENTS WITH RITUXIMAB (MAB THERA) IN PATIENTS WITH ACTIVE RHEUMATOID ARTHRITIS WHO HAVE HAD AN INADEQUATE RESPONSE TO ANIT-TNF THERAPIES	UKNIS, AUDREY	Closed	BIOGEN, INC

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

Record Number
29248

Done Save

Example Protocol for These Slides

AUDREY UKNIS - TUSM:MEDICINE/RHEUMATOLOGY (05786)

Human Subjects
Protocol

Edit Mode

Change Project Info

Submissions (6) Linkages Summaries Attachments Communications Approved Docs Access ?

Home > Summaries > Summary

Summary

Departments (1)

Centers/Programs

Devices

Drugs

Keywords

Locations

Sites

Personnel (1)

Procedures

Provisions

Reminders

Sponsors

Summary

Record Number

29248

Change

Get Management #

Created on

10-Jan-2022

Submitted on



Initial Submission Date

Original Approval Date



Review Category

Research Type

Original Meeting Date



Risk Level

Board Name

Reviewers

None Selected Set

Determination

Under Development

Determination Date



Determination Date From



Determination Date To





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

215-707-3390