



# How to Submit Prospective and Retrospective Studies to the IRB

David Comalli  
IRB Assistant Director  
October 15, 2020

# Slides Summary / Table of Contents

- Introduction the IRB, define human subjects research, review categories (2-7)
- Retrospective and prospective studies (8-9)
- Specific notes and submission tips (10-21)
- ERA screenshots (22-75)
  - Initial Submission (23-42)
  - Approval Route (38-56)
  - Responding to Modifications Required to Secure Approval (57-61)
  - Retrieving stamped consents (62-69)
  - Creating a Modification / RNI / Continuing Review / Study Closure (70-75)

# What is the IRB?

An **Institutional Review Board (IRB)**, is a committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving human subjects.

- #1 Priority: Protect subjects from physical, psychological, or status/financial harm
  - Even retrospective chart reviews carry risks: invasion of privacy; confidentiality breach
- #2 Priority: Protect Temple's research program
  - Federal penalties, less funding, damage to Temple's image

# Human subjects research (HSR)

- A systematic investigation—designed to develop/contribute to generalizable knowledge—involving living individuals about whom an investigator conducting research obtains: 1. Identifiable private information or 2. Data through intervention or interaction with the individual.
- If a project is Human Subjects Research, it must be reviewed/approved by the IRB.

So your protocol is Human Subjects  
Research...



What's Next?

# Submit to the IRB to be reviewed as follows...

- Exempt: A designated reviewer determines that the research is exempt from certain rules and regulations.
  - The IRB **must** review the initial protocol and modifications that may change the category.
  - Use the **Minimal Risk** protocol and consent templates.
- Expedited: A designated reviewer approves the research initially, annually (in some cases), and any modifications.
  - Does not mean faster.
  - Use the **Minimal Risk** protocol and consent templates.
- Full Board: A fully convened IRB committee reviews the research initially, annually (at minimum), and any modifications.
  - For research that doesn't fit into the above categories or is greater than minimal risk.
  - Use the **Main** protocol and informed consent templates.

# Exempt, Expedited, and Full Board...

- Cannot begin before the IRB approves the research.
- The IRB will stamp the consent form(s), and those are the ones that should be used.
  - Stamped consents can be found in the Attachments tab for every approved submission in which a consent was submitted.
- Changes to the study (recruitment methods, data collection/storage, N, tasks, personnel, etc.) should be submitted as Modifications.
- Problems (over-enrollment, unsigned consent, protocol deviation, confidentiality breach, adverse event, etc.) need to be reported to the IRB.

# Exempt 4: Retrospective vs prospective chart reviews

- Retrospective = exists at the time that the IRB receives the submission.
  - Waiver of consent and HIPAA authorization is fairly simple.
  - Use the IRB's Chart Review Protocol Template.
- Prospective = exists after the time that the IRB receives the submission.
  - Waiver of consent or HIPAA authorization may not be granted.
  - Collecting patient follow-up data that extends beyond the date of submission introduces a prospective element to the study.
  - The Chart Review Protocol Template may still apply, but if waivers of consent and HIPAA aren't sought / granted, the Minimal Risk Protocol Template is preferred.



# Prospective studies that are not chart reviews

- Minimal Risk studies
  - Examples include blood draws, MRI, some behavioral interventions
- Greater than Minimal Risk studies
  - Examples include drug/device trials, experimental surgeries, surveys / interviews of incriminating behavior
- Randomized trial of two SOC procedures / drugs
  - Can still be greater than minimal risk

A couple of notes...

# 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, but will be submitted to the Temple IRB prior to WIRB review.
  - Must include the WIRB Initial Submission Form in the submission to the Temple IRB.

# 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.

# CITI training

- Be sure to affiliate with Temple University, **not** Temple Hospital
  - Easiest way is signing in via the IRB website linked on previous slide
- Two required courses:
  - Biomedical Research or Social/Behavioral Research – takes ~1-4 hours
  - Practice Runs Training – 1 module, takes ~5 minutes
- 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 approves and stamps all 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>

# 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](http://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://www.temple.edu/research/researchadmin/era/era\\_login.asp](https://www.temple.edu/research/researchadmin/era/era_login.asp)

# 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.
- To the website! (<https://research.temple.edu/research-compliance/institutional-review-board-irb/investigator-quick-links>)



# 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 main heading is 'INSTITUTIONAL REVIEW BOARD', followed by a paragraph about the HRPP mission. Below this is a list of two items: 'Human subjects research is reviewed via three methods...' and 'The HRPP supports Temple's dedication to excellence in research...'. To the right, an 'IN THIS SECTION' menu lists several links. Red arrows point from the text in the main content area to the corresponding links in the menu.

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 tips

- 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.
- If recording (video or audio), it must be in the consent.
- Minimal risk research usually does not require signed consent.
  - If you need signed consent (research with minors, HIPAA, etc.), the signature blocks are in the Main Informed Consent Template.
- Only include the consent summary if the study is federally funded **and** the consent body is longer than 4 pages.
- Double-check you're using the approved document as the base for any Modifications.
- Unless you are accessing medical records, you do not need HIPAA Authorization.

# Chart review protocol template

- Don't leave in the instructional language
- When possible, use the methodology provided in the table (section 8d)
- 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>)

# 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://www.temple.edu/research/researchadmin/era/era\\_login.asp](https://www.temple.edu/research/researchadmin/era/era_login.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 3<sup>rd</sup> 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 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.

# 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.

# My Human Subjects > Create New

era.temple.edu/WebPortal/Queue.asp?Stat=Open&Unique\_ID=BE064E26C3F95877E040&isDelegate=1

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



Logged in User: **DAVID COMALLI**

Find Funding

Exit Help Portal

Records found: 0. Displaying page 0 of 0

My Proposals and Awards

My Conflict of Interests

Open Action Items for: MS. MARILYN LEWIS

My Human Subjects

- Show/List
- Search For
- Create New
- Standard Reports
- Program Tools
- Help - Dev
- Help - Mgmt

My Animal Use

Technology Transfer

My Profile

Administration

# MAKE SURE TO SELECT THE RIGHT PI

Your name will show up automatically, delete and search for PI if it's not you

The screenshot shows a web browser window with the URL `era.temple.edu/WebPortal/Queue.asp?Stat=Open&Unique_ID=BE064E26C3F95877E040&isDelegate=1`. The browser's address bar and tabs are visible. The main content area shows the Temple University logo and the text "Logged in User: DAVID COMALLI". A "Find Funding" button is present. Below this, there are navigation links for "Exit", "Help", and "Portal". A sidebar on the left contains several menu items: "My Proposals and Awards", "My Conflict of Interests", "My Human Subjects" (with sub-items: Show/List, Search For, Create New, Standard Reports, Program Tools, Help - Dev, Help - Mgmt), "My Animal Use", "Technology Transfer", and "My Profile".

Overlaid on the page is a "Select PI - Google Chrome" dialog box. The dialog box has a title bar and standard window controls. The URL in the dialog is `era.temple.edu/Protocol/ConsolidatedCreate.asp?Prop_no=0&V13Portal=1&system=HSD&NewObjec...`. The dialog contains a "Protocol Creation" form with the following fields:

- Institution Number:** 27561
- Title:** My example protocol for the talk that I'm giving right now
- Select PI:** cholera

Below the "Select PI" dropdown, two search results are displayed:

- CHOLERA 12C, KRUNAL - 908669673 - RESEARCH: EXECUTIVE LEADERSHIP (24010)
- CHOLERA 12C, KRUNAL - 908669673 - TUSM: TCRI (05000)

A red arrow points to the "Select PI" dropdown menu.



# Click Continue and be directed to the Initial Submission

The screenshot shows a web browser window with the URL `era.temple.edu/WebPortal/Queue.asp?Stat=Open&Unique_ID=BE064E26C3F95877E040&isDelegate=1`. The browser's address bar and tabs are visible at the top. The main content area displays the Temple University logo and navigation options. A modal dialog box titled "Protocol Creation" is open, containing the following fields:

- Institution Number:** 27561
- Title:** My example protocol for the talk that I'm giving right now
- Select PI:** cholera

Below the "Select PI" field, two options are listed:

- [CHOLERA 12C, KRUNAL - 908669673 - RESEARCH: EXECUTIVE LEADERSHIP \(24010\)](#)
- [CHOLERA 12C, KRUNAL - 908669673 - TUSM: TCRI \(05000\)](#)

The dialog box has "Close" and "Continue" buttons at the top right. A red arrow points to the "Continue" button. The background page shows a sidebar with navigation links like "My Proposals and Awards", "My Conflict of Interests", and "My Human Subjects".

# 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

Add

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

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.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

Codicals

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.aspx?ObjectID=96C7F888E59B12A3E053B510600A57C3&Submis...

Upload

Upload Close

Upload new document

Name

Location

Choose File No file chosen

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

Application for Human Research

Conditional Use



# Open the eForm

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

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

Codicals

Communications

Personnel (1)

Departments (1)

Centers / Programs

Locations

Attachments (7)

Status History (4)

Assignments

Initial Submission

Document/Form Add

Application for Human Research

CZMS

- Save
- Table of Contents
- Quest Hist
- Form Hist
- Print

https://era.temple.edu/ComplianceNet/SharedSystems/EForms/Form.aspx?ObjectFormId=ED5031C8-E648-42B3-9A81-70C334FBF127&recordid=98912...  
era.temple.edu/ComplianceNet/SharedSystems/EForms/Form.aspx?ObjectFormId=ED5031C8-E648-42B3-9A81-70C334FBF127&recordid=98912219...

Phone and Email:

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

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

Select value - Google Chrome

era.temple.edu/PopUpSelectProg.asp?Parameter=Personnel&UseCustom=1&ReturnFu...

Personnel Listing

kendrick,

Select Close

Human Subjects

Edit Mode

Change Project Info



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

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

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

Record Number  
26289

My example protocol for  
DAVID COMALLI - RESEARCH

Done Save

Submissions (3) Linkages Summaries Attachments (11) Communication

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

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...

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 review of the research)  
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 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

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

Personnel Listing

Select Close

era.temple.edu/PopUpSelectProg.asp?Parameter=Personnel&UseCustom=1&ReturnFu...

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
- Codicals
- Communications
- Personnel (1)
- Departments (1)
- Centers / Programs
- Locations
- Attachments (7)
- Status History (4)
- Assignments

Initial Submission

Document/Form Add  
Application for Human Research

Save  
Table of Contents  
Quest Hist  
Form Hist  
Print

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

**Research Personnel - (Those involved in the design, conduct, or re**  
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):

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

Human Subjects  
Edit Mode  
Change Project Info

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

The screenshot shows a web application interface for managing research submissions. The main window displays a form for adding personnel, with a pop-up window titled "Select value - Google Chrome" open. The pop-up window shows a list of personnel, with "KENDRICK, ZEBULON - 901293793 - HSC PROVOST (27500)" selected. A red arrow points to the "Select" button in the pop-up window.

**Main Window:**

- Record Number: 26289
- My example protocol for DAVID COMALLI - RESEARCH
- Buttons: Done, Save
- Navigation: Submissions (3), Linkages, Summaries, Attachments (11), Communications
- Breadcrumbs: Home > Submissions > Initial Submission > Submission
- Submission: Initial Submission
- Document/Form Add: Application for Human Research
- Left Menu: Submission, Reviews (1), IC Checklist, Codicils, Communications, Personnel (1), Departments (1), Centers / Programs, Locations, Attachments (7), Status History (4), Assignments
- Vertical Menu: Save, Table of Contents, Quest Hist, Form Hist, Print

**Pop-up Window: Personnel Listing**

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 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 additional study documents by clicking the “Add” button

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

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

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

Upload Close

Upload

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"/>

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

(Route History) Submit Remove

# Click "Choose File" and find the document

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

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**  
DAVID COMALLI - RESEARCH

Submissions (3) | Linkages | Summaries | Attachments (11) | Communications

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

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** 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

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 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 document management. A modal window titled "Add Components" is open, displaying a form for uploading a document. The modal contains the following elements:

- A red message: "Please click 'Close' to complete the upload of your documents." with a red arrow pointing to the "Close" button.
- Buttons: "Upload" and "Close".
- Radio buttons: "document" (selected) and "version of an existing document".
- Section: "Upload new document" with fields for:
  - Name: "Flyer"
  - Location: "Choose File" button, "Poster for put...t places.docx"
  - Category: "Attachment" (dropdown)
  - Document ID: (text input)
  - Document Version Number: (text input)
  - Document Version Date: (text input)
- Section: "Add Initial Submission Components" with an "Add" button.
- Table with columns: "Form Name", "Type", and "Add".


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

The background page shows a submission detail for "My example protocol f" by "DAVID COMALLI". It includes a sidebar with navigation options like "Submissions (3)", "Linkages", "Summaries", "Attachments (11)", and "Commu...". The top right corner has a user profile for "Human Subjects" with "Edit Mode" and "Change Project Info" buttons.

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 <a href="#">Add</a>	Type	Status	(Route History)	<a href="#">Submit</a>
<a href="#">Application for Human Research</a>	IRB Application	Incomplete		<a href="#">Remove</a>
<a href="#">Consent</a>	Consent Form	Completed	<a href="#">Modify</a>	<a href="#">Remove</a>
<a href="#">Flyer</a>	Attachment	Completed	<a href="#">Modify</a>	<a href="#">Remove</a>
<a href="#">Medical Record Abstraction Sheet</a>	Attachment	Completed	<a href="#">Modify</a>	<a href="#">Remove</a>
<a href="#">Protocol</a>	Protocol	Completed	<a href="#">Modify</a>	<a href="#">Remove</a>
<a href="#">Recruitment email</a>	Attachment	Completed	<a href="#">Modify</a>	<a href="#">Remove</a>
<a href="#">Survey</a>	Attachment	Completed	<a href="#">Modify</a>	<a href="#">Remove</a>

#### 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.

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  
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 (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

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

# 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)
<a href="#">Application for Human Research</a>	IRB Application	Completed	<a href="#">PDF</a>
Consent	Consent Form	Completed	<a href="#">Modify</a>
Flyer	Attachment	Completed	<a href="#">Modify</a>
Medical Record Abstraction Sheet	Attachment	Completed	<a href="#">Modify</a>
Protocol	Protocol	Completed	<a href="#">Modify</a>
Recruitment email	Attachment	Completed	<a href="#">Modify</a>
Survey	Attachment	Completed	<a href="#">Modify</a>



# 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

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  
[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	
Modification	Completed	PDF (Mandatory Form)

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

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

Route Path	Step	Action	Personnel	Details
Modification	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*

# Type the last name and select the person

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


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

[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.aspx?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.aspx?RouteID=96D8BF50488F2D09E053B510600A38C6

**Add step**

[Add](#)

[Cancel](#)

**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

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

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

# 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

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

Modification

Completed

PDF

(Mandatory Form)

Submit

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

# 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

Codicils

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

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	
<a href="#">Application for Human Research</a>	IRB Application	08-Nov-2019 11:15:10 AM	<a href="#">PDF</a>
<a href="#">Consent Clean 11.11.19</a>	Attachment	08-Nov-2019 11:15:09 AM	<a href="#">Modify</a>
<a href="#">Consent Tracked 11.11.19</a>	Attachment	08-Nov-2019 11:15:09 AM	<a href="#">Modify</a>
<a href="#">Flyer</a>	Attachment	08-Nov-2019 11:15:09 AM	<a href="#">Modify</a>
<a href="#">Medical Record Abstraction Sheet</a>	Attachment	08-Nov-2019 11:15:09 AM	<a href="#">Modify</a>
<a href="#">Protocol</a>	Protocol	08-Nov-2019 11:15:09 AM	<a href="#">Modify</a>
<a href="#">Recruitment email</a>	Attachment	08-Nov-2019 11:15:09 AM	<a href="#">Modify</a>
<a href="#">Survey</a>	Attachment	08-Nov-2019 11:15:09 AM	<a href="#">Modify</a>

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

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



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

Close

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

**Add Comments:**  
To be shared with everyone

**B I U** [List Icon] [List Icon] [Link Icon] **A** [Dropdown Arrow]

**Select a decision:**

Acknowledge

PI Clarification



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*

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	
<a href="#">Application for Human Research</a>	IRB Application	08-Nov-2019 11:15:10 AM	<a href="#">PDF</a>
<a href="#">Consent Clean 11.11.19</a>	Attachment	08-Nov-2019 11:15:09 AM	<a href="#">Modify</a>
<a href="#">Consent Tracked 11.11.19</a>	Attachment	08-Nov-2019 11:15:09 AM	<a href="#">Modify</a>
<a href="#">Flyer</a>	Attachment	08-Nov-2019 11:15:09 AM	<a href="#">Modify</a>
<a href="#">Medical Record Abstraction Sheet</a>	Attachment	08-Nov-2019 11:15:09 AM	<a href="#">Modify</a>
<a href="#">Protocol</a>	Protocol	08-Nov-2019 11:15:09 AM	<a href="#">Modify</a>
<a href="#">Recruitment email</a>	Attachment	08-Nov-2019 11:15:09 AM	<a href="#">Modify</a>
<a href="#">Survey</a>	Attachment	08-Nov-2019 11:15:09 AM	<a href="#">Modify</a>

Close

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

#### Add Comments:

To be shared with everyone

**B** *I* U [List Icons] [Link Icon] **A** ▼

[Text input area for comments]

#### 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](#)

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	
<a href="#">Application for Human Research</a>	IRB Application	08-Nov-2019 11:15:10 AM	<a href="#">PDF</a>
<a href="#">Consent Clean 11.11.19</a>	Attachment	08-Nov-2019 11:15:09 AM	<a href="#">Modify</a>
<a href="#">Consent Tracked 11.11.19</a>	Attachment	08-Nov-2019 11:15:09 AM	<a href="#">Modify</a>
<a href="#">Flyer</a>	Attachment	08-Nov-2019 11:15:09 AM	<a href="#">Modify</a>
<a href="#">Medical Record Abstraction Sheet</a>	Attachment	08-Nov-2019 11:15:09 AM	<a href="#">Modify</a>
<a href="#">Protocol</a>	Protocol	08-Nov-2019 11:15:09 AM	<a href="#">Modify</a>
<a href="#">Recruitment email</a>	Attachment	08-Nov-2019 11:15:09 AM	<a href="#">Modify</a>
<a href="#">Survey</a>	Attachment	08-Nov-2019 11:15:09 AM	<a href="#">Modify</a>

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](#)

[Save](#)

[Change Project Info](#)

[Submissions \(5\)](#)

[Linkages](#)

[Summaries](#)

[Attachments \(20\)](#)

[Communications \(6\)](#)

[Approved Docs](#)



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

## Submissions

[Add](#)

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

# 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

[Edit Mode](#)

[Done](#)

[Save](#)

[Change Project Info](#)

[Submissions \(5\)](#)

[Linkages](#)

[Summaries](#)

[Attachments \(20\)](#)

[Communications \(6\)](#)

[Approved Docs](#)



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

## Submissions

[Add](#)

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

# 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

## 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)
<a href="#">Modification of Approved Human Research</a>	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"**  
*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

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)
<a href="#">Modification of Approved Human Research</a>	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"**  
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		
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*

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	PDF	Show Route (Route History)
Modification of Approved Human Research	Modification	Completed	PDF	(Mandatory Form)

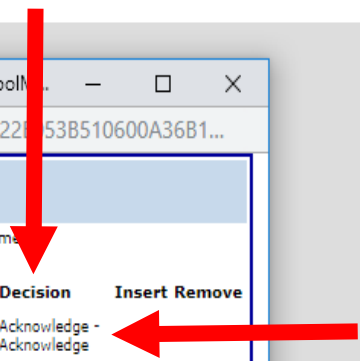
https://era.temple.edu/messaging/showroute.asp?RouteID=93C916A70BFBB422E053B510600A36B1&Title=Off&bolM...  
Temple University [US] | era.temple.edu/messaging/showroute.asp?RouteID=93C916A70BFBB422E053B510600A36B1...

**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

[Edit Mode](#)

[Done](#)

[Save](#)

[Change Project Info](#)

[Submissions \(5\)](#)

[Linkages](#)

[Summaries](#)

[Attachments \(20\)](#)

[Communications \(6\)](#)

[Approved Docs](#)



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

## Submissions

[Add](#)

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




# 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

**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 \(1\)](#) [Linkages](#) [Summaries](#) [Attachments \(13\)](#) [Communications \(3\)](#) [Approved Docs](#)

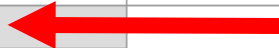


[Home](#)

Submissions

[Add](#)

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	<a href="#">Log</a>	<a href="#">Delete</a>
<a href="#">Respond to Modifications Requested</a>										



Select a Submission - Google Chrome

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

Select Submission [Save](#) [Close](#)

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)

 Human Subjects  
[Edit Mode](#)

[Submissions \(1\)](#) [Linkages](#) [Summaries](#) [Attachments \(13\)](#) [Communications \(3\)](#) [Approved Docs](#)



[Home](#)

## Submissions


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	<a href="#">Log</a>	<a href="#">Delete</a>
<a href="#">Respond to Modifications Requested</a>										

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

[Edit Mode](#)

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

[Change Project Info](#)

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




[Home](#) > [Submissions](#) > [Modifications Required to Secure Approval](#) > [Submission](#)

## Modifications Required to Secure Approval

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

### Submission

- [Reviews](#)
- [IC Checklist](#)
- [Codicils](#)
- [Communications](#)
- [Personnel \(2\)](#)
- [Departments \(1\)](#)
- [Centers / Programs](#)
- [Locations](#)
- [Attachments \(7\)](#)
- [Status History \(1\)](#)
- [Assignments](#)

Document/Form <a href="#">Add</a>	Type	Status		<a href="#">Submit</a>
<a href="#">Application for Human Research</a>	IRB Application	Completed	PDF	<a href="#">Remove</a>
<a href="#">Consent</a>	Consent Form	Completed		<a href="#">Remove</a>
<a href="#">Flyer</a>	Attachment	Completed	<a href="#">Modify</a>	<a href="#">Remove</a>
<a href="#">Medical Record Abstraction Sheet</a>	Attachment	Completed	<a href="#">Modify</a>	<a href="#">Remove</a>
<a href="#">Protocol</a>	Protocol	Completed	<a href="#">Modify</a>	<a href="#">Remove</a>
<a href="#">Recruitment email</a>	Attachment	Completed	<a href="#">Modify</a>	<a href="#">Remove</a>
<a href="#">Survey</a>	Attachment	Completed	<a href="#">Modify</a>	<a href="#">Remove</a>

[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

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



[Home](#) > [Submissions](#) > [Modifications Required to Secure Approval](#) > [Submission](#)

**Submission**

[Reviews](#)

[IC Checklist](#)

[Codicils](#)

[Communications](#)

[Personnel \(2\)](#)

[Departments \(1\)](#)

[Centers / Programs](#)

[Locations](#)

[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 <a href="#">Add</a>	Type	Status		<a href="#">Submit</a>
<a href="#">Application for Human Research</a>	IRB Application	Completed	<a href="#">PDF</a>	<a href="#">Remove</a>
<a href="#">Consent</a>	Consent Form	Completed	<a href="#">Modify</a>	<a href="#">Remove</a>
<a href="#">Flyer</a>	Attachment	Completed	<a href="#">Modify</a>	<a href="#">Remove</a>
<a href="#">Medical Record Abstraction Sheet</a>	Attachment	Completed	<a href="#">Modify</a>	<a href="#">Remove</a>
<a href="#">Protocol</a>	Protocol	Completed	<a href="#">Modify</a>	<a href="#">Remove</a>
<a href="#">Recruitment email</a>	Attachment	Completed	<a href="#">Modify</a>	<a href="#">Remove</a>
<a href="#">Survey</a>	Attachment	Completed	<a href="#">Modify</a>	<a href="#">Remove</a>

[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

[Edit Mode](#)

[Submissions \(2\)](#) [Linkages](#) [Summaries](#) [Attachments \(16\)](#) [Communications \(3\)](#) [Approved Docs](#)



[Home](#) > [Submissions](#) > [Modifications Required to Secure Approval](#) > [Submission](#)

**Submission**

[Reviews](#)

[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	<a href="#">Remove</a>
Consent Clean 11.11.19	Attachment	Completed	<a href="#">Modify</a>	<a href="#">Remove</a>
Consent Tracked 11.11.19	Attachment	Completed	<a href="#">Modify</a>	<a href="#">Remove</a>
Flyer	Attachment	Completed	<a href="#">Modify</a>	<a href="#">Remove</a>
Medical Record Abstraction Sheet	Attachment	Completed	<a href="#">Modify</a>	<a href="#">Remove</a>
Protocol	Protocol	Completed	<a href="#">Modify</a>	<a href="#">Remove</a>
Recruitment email	Attachment	Completed	<a href="#">Modify</a>	<a href="#">Remove</a>
Survey	Attachment	Completed	<a href="#">Modify</a>	<a href="#">Remove</a>

[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

**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 \(5\)](#)

[Linkages](#)

[Summaries](#)

[Attachments \(20\)](#)

[Communications \(6\)](#)

[Approved Docs](#)



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

## Submissions

[Add](#)

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

# 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

[Edit Mode](#)

[Change Project Info](#)

[Done](#)

[Save](#)

[Submissions \(2\)](#)

[Linkages](#)

[Summaries](#)

[Attachments \(17\)](#)

[Communications \(3\)](#)

[Approved Docs](#)



[Home](#) > [Submissions](#) > [Modifications Required to Secure Approval](#) > [Submission](#)

**Submission**

[Reviews \(1\)](#)

[IC Checklist](#)

[Codicils](#)

[Communications](#)

[Personnel \(2\)](#)

[Departments \(1\)](#)

[Centers / Programs](#)

[Locations](#)

[Attachments \(9\)](#)

[Status History \(2\)](#)

[Assignments](#)

## Modifications Required to Secure Approval

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

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

# Find the IRB Approved and Stamped consent(s)

/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

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 \(2\)](#) [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	<b>Stamped Consent</b>	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 “<b> Stamped Consent </b>”

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

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

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 (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	<b>Stamped Consent</b>	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

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 (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	<b>Stamped Consent</b>	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

[Edit Mode](#)

[Change Project Info](#)

[Submissions \(14\)](#) | [Linkages](#) | [Summaries](#) | [Attachments \(68\)](#) | [Communications \(40\)](#) | [Approved Docs](#)



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

### Submissions

[Add](#)

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	<a href="#">Log</a>	<a href="#">Delete</a>
Close Protocol	23074-0003	02-Aug-2019	06-Aug-2019	N/A	Closed	28-Aug-2019	N/A	N/A	<a href="#">Log</a>	<a href="#">Delete</a>
Continuing Review	23074-0001	09-Jul-2018	12-Jul-2018	N/A	Modifications Required to Secure Approval	N/A	N/A	N/A	<a href="#">Log</a>	<a href="#">Delete</a>
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	<a href="#">Log</a>	<a href="#">Delete</a>
Modification	N/A	28-Aug-2017	31-Aug-2017	N/A	Approved	19-Sep-2017	N/A	N/A	<a href="#">Log</a>	<a href="#">Delete</a>
Continuing Review	N/A	03-Aug-2017	03-Aug-2017	N/A	Modifications Required to Secure Approval	N/A	N/A	N/A	<a href="#">Log</a>	<a href="#">Delete</a>
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	<a href="#">Log</a>	<a href="#">Delete</a>
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	<a href="#">Log</a>	<a href="#">Delete</a>
Modification	N/A	16-Feb-2017	20-Feb-2017	N/A	Approved	27-Feb-2017	N/A	N/A	<a href="#">Log</a>	<a href="#">Delete</a>
Continuing Review	N/A	14-Jun-2016	17-Jun-2016	N/A	Approved	17-Aug-2016	01-Sep-2016	31-Aug-2017	<a href="#">Log</a>	<a href="#">Delete</a>
Initial Submission	N/A	18-Jun-2015	16-Jul-2015	N/A	Modifications Required to Secure Approval	N/A	N/A	N/A	<a href="#">Log</a>	<a href="#">Delete</a>
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	<a href="#">Log</a>	<a href="#">Delete</a>
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	<a href="#">Log</a>	<a href="#">Delete</a>
Reportable New Information	23074-0005	N/A	N/A	N/A	Under Development	N/A	N/A	N/A	<a href="#">Log</a>	<a href="#">Delete</a>

# 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)

Human Subjects  
Edit Mode  
Change Project Info

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

Home > Attachments

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	<b>Stamped Consent</b>	ROOT	Record	Modifications Required to Secure Approval	1	01-Sep-2015 5:34:55 PM	
IRB Approved Stamped Consent	<b>Stamped Consent</b>	ROOT	Record	Modification	1	28-Feb-2017 4:28:56 PM	
IRB Approved Stamped Consent	<b>Stamped Consent</b>	ROOT	Record	Modifications Required to Secure Approval	1	31-Aug-2017 10:45:09 AM	
IRB Approved stamped Consent Form	<b>Stamped Consent</b>	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)

Human Subjects

Edit Mode

Change Project Info

Done Save

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



Home > Attachments

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	<b>Stamped Consent</b>	ROOT	Record	Modifications Required to Secure Approval	1	01-Sep-2015 5:34:55 PM	
IRB Approved Stamped Consent	<b>Stamped Consent</b>	ROOT	Record	Modification	1	28-Feb-2017 4:28:56 PM	
IRB Approved Stamped Consent	<b>Stamped Consent</b>	ROOT	Record	Modifications Required to Secure Approval	1	31-Aug-2017 10:45:09 AM	
IRB Approved stamped Consent Form	<b>Stamped Consent</b>	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)

 Human Subjects

[Edit Mode](#)

[Change Project Info](#)

[Done](#)

[Save](#)

[Submissions \(2\)](#)

[Linkages](#)

[Summaries](#)

[Attachments \(17\)](#)

[Communications \(3\)](#)

[Approved Docs](#)

?

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

**Submissions**

[Add](#)

- 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			<a href="#">Delete</a>
Modifications Required to Secure Approval	26289-0002	N/A	N/A	N/A	Approved	12-Nov-2019	N/A	N/A	<a href="#">Log</a>	<a href="#">Delete</a>

# 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

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 \(2\)](#)

[Linkages](#)

[Summaries](#)

[Attachments \(17\)](#)

[Communications \(3\)](#)

[Approved Docs](#)



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

## Submissions

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			<a href="#">Delete</a>
Modifications Required to Secure Approval	26289-0002	N/A	N/A	N/A	Approved	12-Nov-2019	N/A	N/A	<a href="#">Log</a>	<a href="#">Delete</a>

- 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

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 \(2\)](#)

[Linkages](#)

[Summaries](#)

[Attachments \(17\)](#)

[Communications \(3\)](#)

[Approved Docs](#)



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

## Submissions

[Add](#)

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			<a href="#">Delete</a>
Modifications Required to Secure Approval	26289-0002	N/A	N/A	N/A	Approved	12-Nov-2019	N/A	N/A	<a href="#">Log</a>	<a href="#">Delete</a>



# 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

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

Home > Submissions > Modification > Submission

Submission

Reviews

IC Checklist

Codicals

Communications

Personnel (1)

Departments (1)

Centers / Programs

Locations

Attachments (1)

Status History (1)

Assignments

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  Complete

Page 1

 **TEMPLE**  
UNIVERSITY®

**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:

\* Phone Number:

**Section II**

\* Summarize the modification:

**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

u/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

Done

Save

**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 \(5\)](#)

[Linkages](#)

[Summaries](#)

[Attachments \(20\)](#)

[Communications \(6\)](#)

[Approved Docs](#)

?

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

**Submission**

[Reviews \(1\)](#)

[IC Checklist](#)

[Codicils](#)

[Communications \(3\)](#)

[Personnel \(1\)](#)

[Departments \(1\)](#)

[Centers / Programs](#)

[Locations](#)

[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

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

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

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

parkm

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

Informational Only

Approval Required



[IRB@temple.edu](mailto:IRB@temple.edu)

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

215-707-3390