



# Submitting to the IRB: Prospective and Retrospective Studies

David Comalli, Ph.D.  
IRB Program Coordinator  
November 14, 2019

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# 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 or psychological 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

# My job: Designated reviewer

I review minimal risk Human Subjects Research for:

- Regulatory compliance
  - HIPAA, FDA, consent, FERPA, etc.
- Temple's Policies
  - CITI training, approval routes, etc.



# 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.

# NHSR examples

- Case study – Not human subjects research > not “generalizable”
- Research on a de-identified (prior to being obtained) dataset – Not human subjects research > not “human subjects”
- QI / QA that is specific to Temple’s operations – Not human subjects research > not “generalizable”
- Unsure? Contact the IRB (email [IRB@temple.edu](mailto:IRB@temple.edu) or call a coordinator)
- A NHSR determination does not = bad project

# Common misconceptions

- Human subjects research must always involve direct intervention or interaction with individuals.

## **FALSE**

- Analyses of identifiable data sets.
- A project must be Human Subjects Research in order for results to be published.

## **FALSE**

- IRB considers whether or not a project is designed to contribute to “generalizable knowledge” not whether or not the results will be presented or published.
- IRB considers design – not intent.

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 Categories

- Exempt 1 - Research on educational practices
- Exempt 2 - Surveys, interviews, educational tests, or observation of public
  - No minors
- Exempt 3 - Benign (and short) behavioral intervention, collecting data solely via verbal or written responses or audiovisual recording
  - No minors
- Exempt 4 - Secondary data analysis of (at least) initially identifiable information
- Exempt 5 (Federal demonstration project), 6 (Taste and food testing), 7 (Collecting identifiable data for future research with Broad Consent), and 8 (Using data collected under 7) are either not relevant or not happening at Temple

# Expedited Categories

- Expedited 1 - Research on drugs or devices that don't need specific FDA approvals (INDs or IDEs)
- Expedited 2 - Collection of blood from healthy adults (<550 ml/8 wk; up to 2x/wk) or other adults and children (<50ml or 3 ml/kg/8 wk; up to 2x/wk)
- Expedited 3 - Noninvasive collection of biological specimens
- Expedited 4 - Noninvasive collection of data (e.g., MRI, EEG, hr, bp, etc.)
- Expedited 5 - Secondary analysis of identifiable data that isn't under HIPAA
- Expedited 6 - Data collected from video/audio recordings
- Expedited 7 – Surveys, interviews; research on cognition, perception, language, and other individual/group characteristics and behaviors

# 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.

A couple of notes...

# Retrospective vs prospective studies

- 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.

# 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.

# 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 a week 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
  - 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)

# 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 – 18 modules, 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

# 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>)

# 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.

# 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.

# 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

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**

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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

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Record Number  
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Done Save

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No Forms have been associated with this submission.

Add Components - Google Chrome

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

Upload

Upload Close

Upload new document

Name

Location  No file chosen

Category

Document ID

Document Version Number

Document Version Date

Add Initial Submission Components

Add

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

# Open the eForm

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

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

Buttons: Done, Save

Navigation: Submissions (3), Linkages, Summaries, Attachments (11), Communication

Breadcrumbs: Home > Submissions > Initial Submission > Submission

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

Initial Submission: Document/Form Add, Application for Human Research

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

Tools: Save, Table of Contents, Quest Hist, Form Hist, Print

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

Personnel - Review Add

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

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 data?  
\* Involved in the consent process?  Yes  No  
\* Does this person have a financial interest related to the research?

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

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...

Record Number  
26289

My example protocol for t  
DAVID COMALLI - RESEARC

Done Save

Submissions (3) Linkages Summaries Attachments (11) Communica

Home > Submissions > Initial Submission > Submission

Initial Submission

Document/Form Add  
Application for Human Research

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

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

Save  
Table of Contents  
Quest Hist  
Form Hist  
Print

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

Name  
COMALLI, DAVID

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

Certifications

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

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

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

Personnel Listing

Select Close

kendrick

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

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

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...

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

Initial Submission

Document/Form Add

Application for Human Research

Save

Table of Contents

Quest Hist

Form Hist

Print

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
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CITI - Students conducting minimal risk research	28-Aug-2018
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\* Interpersonal contact or communication with subjects, or acc

\* Involved in the consent process?  Yes  No

\* Does this person have a financial interest related to the resea

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

Human Subjects

Edit Mode

Change Project Info

Select value - Google Chrome

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

Personnel Listing

Select Close

kendrick,

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

The screenshot shows a web application interface for managing research submissions. The main window displays the 'Research Personnel' section for a submission titled 'My example protocol for DAVID COMALLI - RESEARCH'. A pop-up window titled 'Select value - Google Chrome' is open, showing a 'Personnel Listing' with a table of personnel. A red arrow points to the 'Select' button in the pop-up window.

**Main Window Information:**

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

**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
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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):

This Application for Human Research includes the following:

**Pop-up Window:**

Select value - Google Chrome

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

Personnel Listing

KENDRICK, ZEBULON - 901293793 - HSC PROVOST (27500)

Select Close

# 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

289-0001 Created on: 07-Nov-2019 Status: Under Development  
(Route History) Submit Remove

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

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

Upload Close

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

Upload new document

Name Flyer

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

Category Attachment

Document ID

Document Version Number

Document Version Date

Add Initial Submission Components Add

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

# Click "Choose File" and find the document

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

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

Record Number  
26289  
Done Save

My example protocol f  
DAVID COMALLI - RESEA

Human Subjects  
Edit Mode  
Change Project Info

Submissions (3) Linkages Summaries Attachments (11) Commu

Home > Submissions > Initial Submission > Submission

## Initial Submission

Document/Form Add  
Application for Human Research

### Submission

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

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"/>

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

(Route History)



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

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

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

**Record Number**  
26289  
[Done] [Save]

**My example protocol f**  
DAVID COMALLI - RESEA

Submissions (3) Linkages Summaries Attachments (11) Commu

Home > Submissions > Initial Submission > Submission

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

**Initial Submission**  
Document/Form Add  
Application for Human Research

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** Flyer

**Location** [Choose File] Poster for put...t places.docx

**Category** Attachment

**Document ID** [ ]

**Document Version Number** [ ]

**Document Version Date** [ ]

**Add Initial Submission Components** [Add]

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

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

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.asp?ObjectID=96C7F8B8E59B12A3E053B510600A57C3&Submis...

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

**Upload** Upload Close

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

Upload new document

Name

Location  Poster for put...t places.docx

Category

Document ID

Document Version Number

Document Version Date

**Add Initial Submission Components**

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

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

The screenshot shows a web application interface with a modal window for uploading documents. The modal is titled "Upload" and 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:


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

The background page shows a submission detail for "My example protocol" (DAVID COMALLI - RESEARCH) with a record number of 26289. It includes a sidebar with navigation options like "Submissions (3)", "Linkages", "Summaries", "Attachments (11)", and "Communi...". The top right corner has a user profile for "Human Subjects" with an "Edit Mode" button and a "Change Project Info" button.

# 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](#)

## Submission

[Reviews \(1\)](#)

[IC Checklist](#)

[Codicils](#)

[Communications](#)

[Personnel \(2\)](#)

[Departments \(1\)](#)

[Centers / Programs](#)

[Locations](#)

[Attachments \(13\)](#)

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

[Assignments](#)

## 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>



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

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

# 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 \(1\)](#)

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[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>

# 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](#)

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[Submissions \(5\)](#)

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[Summaries](#)

[Attachments \(20\)](#)

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[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>



# “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>

# 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

Change Project Info

Done Save

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

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Submission

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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	Submit
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	

No comments have been recorded yet

Development

Submit

Remove

Remove

Remove

Remove

Remove

Remove

Remove

# Open the Acknowledge email (from OFFICE\_OLD, IRB); click “Reviewer Dashboard”

An Initial Application For Your Review Σ Inbox x

**OFFICE\_OLD, IRB**

to me ▾

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

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

IRB #:26289

Principal Investigator: DAVID COMALLI

Department:RESEARCH: EXECUTIVE LEADERSHIP (24010)

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

Sponsor:NO EXTERNAL SPONSOR

Your approval is required for this submission.

Click [here](#) for a short version of instructions on how to review this submission.

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

To add your review, click here [Reviewer Dashboard](#)



To review the entire submission, click here [Open Submission Package](#)

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

# You may need to sign into ERA; Click the “Review” tab

aging/ReviewItem.asp?RoutedStepID=96D9139C670A3B60E053B510600A6296

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

HELP

REVIEW

ROUTE

## Human Subject Protocol - *Modifications Required to Secure Approval*

Number: [26289](#)

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

Sponsor: NO EXTERNAL SPONSOR

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

Form/Document	Document Type	Submitted	
<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

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>

### Add Comments:

To be shared with everyone

**B** *I* U **A** ▼

### Select a decision:

Acknowledge

PI Clarification

Close

### Comments I can see...

*No Comments have been recorded*

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 **A** ▼

#### Select a decision:

Acknowledge

PI Clarification



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

aging/ReviewItem.asp?RoutedStepID=96D9139C670A3B60E053B510600A6296

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

HELP

REVIEW

ROUTE

### Human Subject Protocol - *Modifications Required to Secure Approval*

Number: [26289](#)

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



# 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

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

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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	Log	Delete
<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


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Done

Save

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

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**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




# 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

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- [Attachments \(7\)](#)
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## 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	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

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## 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>

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

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**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

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

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## 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

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## 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)

Record Number  
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Attachments (9)

## Attachments

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

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

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

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

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Done Save

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

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Attachments (9)

## Attachments

Attachments

Print All Folder Maintenance Add Document Delete Selected

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

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

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Attachments (9)

## Attachments

Attachments

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

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

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

# 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

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**Submissions**

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



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

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


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

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## Submissions

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

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## Submissions

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

Codicils

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

Page 1



**Section I**

IRB Project #: 26289

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

Investigator: COMALLI, DAVID

\* Department: RESEARCH: EXECUTIVE LEADERSHIP (24010)

\* Physical Address: 3340 N. Broad St.

\* Phone Number: 215-707-7792

**Section II**

\* Summarize the modification:

Adding Dr. Henry Parkman as a Co-Investigator.

**Section III**

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

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

Yes  No  \* Investigator Protocol

Yes  No  \* Research tools

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

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

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


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

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

Record Number  
26289

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

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

 Human Subjects

[Edit Mode](#)

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

[Change Project Info](#)

[Submissions \(5\)](#) [Linkages](#) [Summaries](#) [Attachments \(20\)](#) [Communications \(6\)](#) [Approved Docs](#)



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### 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)

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Summaries

Attachments (18)

Communications (3)

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?

Home > Submissions > Modification > Submission

Modification

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

Document/Form Add

Modification of Approved Human Research

Show Existing Protocol Attachments

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


# 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](#)



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Modification

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

Document/Form [Add](#)

[Modification of Approved Human Research](#)

[Show Existing Protocol Attachments](#)

Type

Status

[Submit](#)

Modification

Completed

PDF

(Mandatory Form)

Submit - Google Chrome

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

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

Refresh Route

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

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

*No comments have been recorded yet*

Add step - Google Chrome

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

Add step

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

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

Informational Only

Approval Required



# Type the last name and select the person

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

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)

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Modification

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

Document/Form Add

Modification of Approved Human Research

Show Existing Protocol Attachments

Type

Status

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Modification

Completed

PDF

(Mandatory Form)

Add step - Google Chrome

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

Add step

Add

Cancel

parkm

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

Informational Only

Approval Required

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

# 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

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26289

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

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

Document/Form Add  
Modification of Approved Human Research  
Show Existing Protocol Attachments

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

**Add step**

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

Informational Only  
 Approval Required

Add Cancel



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

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

Refresh Route

Type	Status		
Modification	Completed	PDF	(Mandatory Form)

Route Path	- Modification of Human Research	Add New Person to Review Path	
Step 1	PI Acknowledgement	DAVID COMALLI	
Step 3	IRB Check-In: Received by IRB	MRS. LASHAY COBB	
	IRB Check-In: Received by IRB	IRB OFFICE	

No comments have been recorded yet

# Look at the approval route and click "Continue"

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

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

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

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

Human Subjects

Edit Mode

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Done

Save

Submissions (3)

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## Modification

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

Document/Form Add

Modification of Approved Human Research

Show Existing Protocol Attachments

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Add step - Google Chrome

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

Add step

Add

Cancel

parkm

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

Informational Only

Approval Required

Type

Status

Modification

Completed

PDF

(Mandatory Form)

Submit - Google Chrome

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

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

Refresh Route

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

Continue

Step 1 PI Acknowledgement DAVID COMALLI

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

IRB Check-In: Received by IRB IRB OFFICE

No comments have been recorded yet

# 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

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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	 <a href="#">Show Route</a> <a href="#">(Route History)</a> <small>(Mandatory Form)</small>

https://era.temple.edu/messaging/showroute.asp?RouteID=93C916A70BFBB422E053B510600A36B1&Title=Off&boIM...





Temple University [US] | era.temple.edu/messaging/showroute.asp?RouteID=93C916A70BFBB422E053B510600A36B1...

### Active Routing Progress

[Open Full](#)

**23074 - DR. RYAN TIERNEY "Effect of Fatigue on Concussion Ocular-Motor Screening Assessments"**

*Submitted by DAVID COMALLI on behalf of DR. RYAN TIERNEY*

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

*No comments have been recorded yet*

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

Done Save

Change Project Info

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



Home > Submissions > Modification > Submission

## Submission

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Status History (2)

Assignments (1)

## Modification

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

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

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

### Active Routing Progress

[Open Full](#)

**23074 - DR. RYAN TIERNEY "Effect of Fatigue on Concussion Ocular Motor Screening Assessments"**  
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	Show Route (Route History)
Modification of Approved Human Research	Modification	Completed	PDF <small>(Mandatory Form)</small>

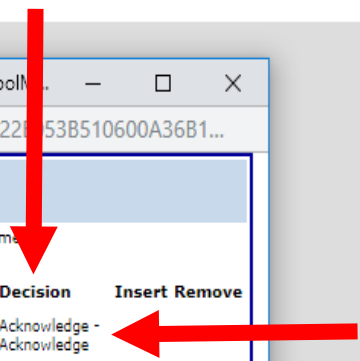
https://era.temple.edu/messaging/showroute.asp?RouteID=93C916A70BFBB422E053B510600A36B1&Title=Off&bolM...  
Temple University [US] | era.temple.edu/messaging/showroute.asp?RouteID=93C916A70BFBB422E053B510600A36B1...

**Active Routing Progress**  
[Open Full](#)

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

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

*No comments have been recorded yet*



# 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	
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**Effect of Fatigue on Concussion Ocular-Motor Screening Assessments**  
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Attachments (68)

## Attachments

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<a href="#">HIPAA</a>	Attachment	ROOT	Submission Package	Initial Submission	1	18-Jun-2015 11:21:45 AM	
<a href="#">Consent Form</a>	Attachment	ROOT	Submission Package	Initial Submission	1	18-Jun-2015 11:30:19 AM	





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