



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

Updated 3/21/22

Slides Summary / Table of Contents

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

Beware the “Exempt” trap!

- Not Human Subjects Research != Exempt
- HHS pulled cruel jokes with certain IRB terms like “Exempt”
- Exempt has a specific meaning in the IRB world
 - All “Exempt” studies are human subjects research
- The IRB must review Exempt research prior to starting

Know who can be the PI!

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

Funding matters

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

Submitting to the IRB: Basics

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

CITI training

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

General IRB tips

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

IRB document pages; look under “IN THIS SECTION”

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](#)

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

INSTITUTIONAL REVIEW BOARD

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

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

IN THIS SECTION

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

Protocol and consent templates

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

Protocol and supplemental document tips

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

Chart review protocol template

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

Consent tips

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

Remote research considerations - Consent

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

Remote research considerations - Risks

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

ERA

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

ERA tips

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

External IRB Process: sIRB, WIRB, Advarra

Know the IRB of Record

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

Steps involved in relying on another IRB

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

IAAs (reliance agreements)

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

IAA constraints

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

How to submit in ERA when relying on another IRB

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

Local context review

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

Local context review (cont'd)

- Consent form:
 - PI and study team contact information
 - Injury statement is consistent with the contract
 - Reference to the separate HIPAA Authorization is included*
 - Temple IRB, Temple University, and Temple University Hospital System and its affiliates are listed as entities that have access to the study records
 - Compensation conforms w/ TU policies (e.g., ClinCard, cash exemptions, gift cards)
 - Are LAR signature blocks appropriate given what Temple is doing?
 - Is the Temple protocol number included?
- HIPAA Authorization
 - Are LAR signature blocks appropriate given what Temple is doing?
 - Are the additional signature blocks necessary given the protocol?
 - Are HIV status, substance abuse, or mental health records being accessed, even solely for exclusionary purposes?

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

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

Screenshot notes

- This is not a 1 slide, 1 click format. There are some gaps and some steps that are combined within 1 screenshot.
- Pop-up windows that are in the screenshot will not exist until a button (like “Add”) on the main page is clicked.
- The pop-ups may appear in a different part of the screen or not be fully visible as they are in the screenshots.
- Use the red arrows to denote the button/clicking sequence.

Finding an Existing Record or Study

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

InfoEd's eResearch Portal

era.temple.edu/EnableWeb/Portal/Home

SMART IRBIRB Form&SOPC & WTU RemoteEaster EggERA DevIREXERA TestConnexusBookmarks 4 Dum...Reading list

infoEdGLOBAL

v13 PortalModule AdminWelcome DAVID COMALLILogout

HomeMy ProfileLocate My RecordsLocate RecordsCalendarMessagesAssignments

29248

My Proposals and Awards

My Human Subjects

Laboratory Animals

My Conflict of Interests

Invention

TT System Overview

SPIN

Workflow Chart(s)

--Select--

[IRB All Submissions](#)Human Subjects Protocol

Portal Configurations

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

The screenshot displays the InfoEd's eResearch Portal interface. At the top, a browser window shows the URL `era.temple.edu/EnableWeb/Portal/Home`. Below the browser, a navigation bar includes the InfoEd logo, user information (`v13 Portal`, `Module Admin`, `Welcome DAVID COMALLI`, `Logout`), and a search bar with the text `Uknis`. A red arrow points to the search bar. The main content area features a sidebar with links: `My Proposals and Awards`, `My Human Subjects`, `Laboratory Animals`, `My Conflict of Interests`, `Invention`, `TT System Overview`, and `SPIN`. The central panel displays `Workflow Chart(s)` with a dropdown menu set to `--Select--` and two links: `IRB All Submissions` and `Human Subjects Protocol`. A `Portal Configurations` button is located in the bottom right corner.

InfoEd's eResearch Portal

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

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v13 Portal Module Admin | Welcome DAVID COMALLI Logout

Home My Profile Locate My Records Locate Records Calendar Messages Assignments

Uknis

My Proposals and Awards

My Human Subjects

Laboratory Animals

My Conflict of Interests

Invention

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Workflow Chart(s)

--Select--

IRB All Submissions

Human Subjects Protocol

Portal Configurations

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

InfoEd's eResearch Portal

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

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

My Proposals and Awards

My Human Subjects

Laboratory Animals

My Conflict of Interests

Invention

TT System Overview

SPIN

Results found: 15

Export to Excel

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

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

Hover over “Edit”

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

The screenshot shows the InfoEd's eResearch Portal interface. The browser address bar displays `era.temple.edu/EnableWeb/Portal/Home`. The top navigation bar includes links for SMART IRB, IRB Form&SOP, C & W, TU Remote, Easter Egg, ERA Dev, IREX, ERA Test, Connexus, and Bookmarks 4 Dum... A user profile for DAVID COMALLI is shown with a 'Logout' button. The main navigation bar contains links for Home, My Profile, Locate My Records, Locate Records, Calendar, Messages, and Assignments. A 'Quick Find' search bar is also present.

On the left sidebar, a list of menu items is shown: My Proposals and Awards, My Human Subjects, Laboratory Animals, My Conflict of Interests, Invention, TT System Overview, and SPIN. A red arrow points to the 'My Conflict of Interests' item.

The main content area displays a table of records. The table has columns for Record Number, Record Type, Record Title, Record Owner, Record Status, and Record Primary Sponsor. A context menu is open over the 'Edit' option for record 292. The menu options are: Edit, View, Create New, Info, Delete, and Bookmark Record.

Results found: 15

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

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

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The screenshot shows the InfoEd's eResearch Portal interface. The browser address bar displays `era.temple.edu/EnableWeb/Portal/Home`. The top navigation bar includes links for SMART IRB, IRB Form&SOP, C & W, TU Remote, Easter Egg, ERA Dev, IREX, ERA Test, Connexus, and Bookmarks 4 Dum... A user profile for DAVID COMALLI is shown with a Logout link. The main navigation bar contains links for Home, My Profile, Locate My Records, Locate Records, Calendar, Messages, and Assignments. A sidebar on the left lists various sections: My Proposals and Awards, My Human Subjects, Laboratory Animals, My Conflict of Interests, Invention, TT System Overview, and SPIN. A red arrow points to the 'Edit' option in a context menu that appears over the first record in the table. The table has columns for Record Number, Record Type, Record Title, Record Owner, Record Status, and Record Primary Sponsor. The first record has a Record Number of 292, Record Type of Human Subjects, and Record Title of Example Protocol for These Slides.

InfoEd's eResearch Portal

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

My Proposals and Awards

My Human Subjects

Laboratory Animals

My Conflict of Interests

Invention

TT System Overview

SPIN

Results found: 15

Export to Excel

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

	Record Number	Record Type	Record Title	Record Owner	Record Status	Record Primary Sponsor
<input type="checkbox"/>	292	Human Subjects	Example Protocol for These Slides	UKNIS, AUDREY	Under Development	
	397	Human Subjects		UKNIS, AUDREY	Withdrawn	
	225	Human Subjects		UKNIS, AUDREY	Funded	AMGEN
	4446	Human Subjects Protocol		UKNIS, AUDREY	Closed	
	21123	Proposal		UKNIS, AUDREY	Closed	

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

InfoEd's eResearch Portal

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

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My Proposals and Awards

My Human Subjects

Laboratory Animals

My Conflict of Interests

Invention

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	Record Number	Record Type	Record Title	Record Owner	Record Status	Record Primary Sponsor ↑
▶	292	Human Subjects		UKNIS, AUDREY	Under Development	
▶	397			UKNIS, AUDREY	Withdrawn	
▶	225			UKNIS, AUDREY	Funded	AMGEN
▶	4446	Human Sub Protocol		UKNIS, AUDREY	Closed	
▶	21123	Proposal	+AN OPEN-LABEL STUDY OF THE EFFICACY AND SAFETY OF RE-TREATMENTS WITH RITUXIMAB (MAB THERA) IN PATIENTS WITH ACTIVE RHEUMATOID ARTHRITIS WHO HAVE HAD AN INADEQUATE RESPONSE TO ANIT-TNF THERAPIES	UKNIS, AUDREY	Closed	BIOGEN, INC

Context menu for record 292:

- Edit
- View
- Create New
- Info
- Delete
- Bookmark Record

Context menu for record 4446:

- Master Record
- Close Protocol (11-Jan-2022 Under Development)
- Reportable New Information (11-Jan-2022 Under Development)
- Continuing Review (11-Jan-2022 Under Development)
- Modification (11-Jan-2022 Under Development)
- Modification (11-Jan-2022 Under Development)
- Additional Submissions

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

Summary - Google Chrome

era.temple.edu/EnableWeb/Compliance/Summary.aspx?projid=D53DA20AE4AE04EAE0530337600A6F9D&Page=SUMMARY

Record Number
29248

Done Save

Example Protocol for These Slides
AUDREY UKNIS - TUSM:MEDICINE/RHEUMATOLOGY (05786)

Human Subjects Protocol
Edit Mode
Change Project Info

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

Home > Summaries > Summary

Summary

Record Number 29248 Change

Created on 10-Jan-2022 Submitted on [Calendar Icon]

Initial Submission Date [Calendar Icon] Original Approval Date [Calendar Icon]

Review Category [Dropdown] Research Type [Dropdown]

Original Meeting Date [Calendar Icon] Risk Level [Dropdown]

Board Name [Dropdown] Reviewers None Selected Set

Determination Under Development [Dropdown] Determination Date [Calendar Icon]

Determination Date From [Calendar Icon] Determination Date To [Calendar Icon]








Summary


- Departments (1)
- Centers/Programs
- Devices
- Drugs
- Keywords
- Locations
- Sites
- Personnel (1)
- Procedures
- Provisions
- Reminders
- Sponsors

Creating & Submitting an Initial Submission


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...

 **TEMPLE**
UNIVERSITY
Office of the Vice President
for Research

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

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

Open Action Items for: MS. MARILYN LEWIS

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 the ERA Temple University web portal. The browser address bar displays the URL: `era.temple.edu/WebPortal/Queue.asp?Stat=Open&Unique_ID=BE064E26C3F95877E040&isDelegate=1`. The portal header includes the Temple University logo, the text "Office of the Vice President for Research", and the user login information: "Logged in User: DAVID COMALLI". A navigation bar contains links for "Find Funding", "Exit", "Help", and "Portal". The left sidebar lists various menu items: "My Proposals and Awards", "My Conflict of Interests", "My Human Subjects" (with sub-links: Show/List, Search For, Create New, Standard Reports, Program Tools, Help - Dev, Help - Mgmt), "My Animal Use", "Technology Transfer", and "My Profile". The main content area shows "Records found: 0. Display" and "Open Action Items". A modal window titled "Select PI - Google Chrome" is open, displaying the "Protocol Creation" form. The form includes fields for "Institution Number" (27561), "Title" (My example protocol for the talk that I'm giving right now), and "Select PI" (choler). A red arrow points to the "Select PI" dropdown menu. Below the dropdown, two search results are listed: "CHOLERA 12C, KRUNAL - 908669673 - RESEARCH: EXECUTIVE LEADERSHIP (24010)" and "CHOLERA 12C, KRUNAL - 908669673 - TUSM: TCRI (05000)". The modal window also features "Close" and "Continue" buttons.

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...

TEMPLE UNIVERSITY
Office of the Vice President for Research

Logged in User: **DAVID COMALLI**

Find Funding

Records found: 0. Display

Exit Help Portal

My Proposals and Awards

My Conflict of Interests

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

Open Action Items

Order By Assigned

Select PI - Google Chrome

era.temple.edu/Protocol/ConsolidatedCreate.asp?Prop_no=0&V13Portal=1&system=HSD&NewObjec...

Protocol Creation

Close Continue

Institution Number

27561

Title

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

Select PI

choler

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

CHOLERA 12C, KRUNAL - 908669673 - TUSM: TCRI (05000)

Click Continue and be directed to the Initial Submission

← → ↻ 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...

TEMPLE UNIVERSITY
Office of the Vice President for Research

Logged in User: **DAVID COMALLI**

Find Funding

Records found: 0. Display

Exit Help Portal

My Proposals and Awards

My Conflict of Interests

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

Order By Assigned

Select PI - Google Chrome

era.temple.edu/Protocol/ConsolidatedCreate.asp?Prop_no=0&V13Portal=1&system=HSD&NewObjec...


Protocol Creation Close Continue

Institution Number
27561

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

Select PI
choler

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



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

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

[Add](#)
No Forms have been associated with this submission.

Upload [Upload](#) [Close](#)

Upload new document

Name

Location [Choose File](#) 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
DAVID COMALLI - RESEARCH: EXECUTIVE LEADERSHIP (24010)

Human Subjects
Edit Mode
Change Project Info

Submissions (1) Linkages Summaries Attachments Communications Approved Docs

Home > Submissions > Initial Submission > Submission

Submission

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IC Checklist

Codicils

Communications

Personnel (1)

Departments (1)

Centers / Programs

Locations

Attachments

Status History (1)

Assignments

Initial Submission

Add

No Forms have been associated with this submission.

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

Add Components - Google Chrome

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

Upload

Upload Close

Upload new document

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

Add Initial Submission Components

Add

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



Click the lower “Add” button to add the eForm

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

Record Number
26289

Done Save

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

Human Subjects
Edit Mode
Change Project Info

Submissions (1) Linkages Summaries Attachments Communications Approved Docs

Home > Submissions > Initial Submission > Submission

Submission

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

Initial Submission

Add

No Forms have been associated with this submission.

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

Add Components - Google Chrome

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

Upload

Upload Close

Upload new document

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

Add Initial Submission Components

Add

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

Open the eForm

era.temple.edu/EnableWeb/Compliance/SubmissionDetail.aspx?ProjID=96C7F8B8E59712A3E053B510600A57

Record Number
26289

Done Save

My example protocol for t
DAVID COMALLI - RESEAR

Submissions (3) Linkages Summaries Attachments (11) Communica

Home > Submissions > Initial Submission > Submission

Submission

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Codicals

Communications

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Departments (1)

Centers / Programs

Locations

Attachments (7)

Status History (4)

Assignments

Initial Submission

Document/Form Add

Application for Human Research

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

Phone and Email:

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

Save

Table of Contents

Quest Hist

Form Hist

Print

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

Personnel - Review Add

Name
COMALLI, DAVID

Primary Investigator ☒

Start Date (IRB Office Use)
07-Nov-2019

Certifications

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

* Interpersonal contact or communication with subjects, or acc

* Involved in the consent process? ☒ Yes ☐ No

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

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

Human Subjects

Edit Mode

Change Project Info

Select value - Google Chrome

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

Personnel Listing

Select Close

kendrick.

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

The screenshot displays the ERA ComplianceNet interface. The main window shows the 'Research Personnel' form for 'COMALLI, DAVID'. A red arrow points to the 'Add' link in the 'Personnel - Review' section. A pop-up window titled 'Personnel Listing' is open, showing a table of personnel with a search bar containing 'kendrick'.

Record Number: 26289

My example protocol for
DAVID COMALLI - RESEARCH

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

Initial Submission

Document/Form Add
Application for Human Research

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

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 data:** ☒ Yes ☐ No

*** Involved in the consent process?** ☒ Yes ☐ No

*** Does this person have a financial interest related to the research?**

Personnel Listing

Search: kendrick

Select Close

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

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

era.temple.edu/EnableWeb/Compliance/SubmissionDetail.aspx?ProjID=96C7F8B8E59712A3E053B510600A57

Record Number
26289

My example protocol for t
DAVID COMALLI - RESEAR

Done Save

Submissions (3) Linkages Summaries Attachments (11) Communica

Home > Submissions > Initial Submission > Submission

Submission

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Initial Submission

Document/Form Add

Application for Human Research

Save

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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 rep

Personnel - Review Add

Name
COMALLI, DAVID

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

Certifications

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

* Interpersonal contact or communication with subjects, or acc

* Involved in the consent process? ☒ Yes ☐ No

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

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

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

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 displays the ERA eForm system interface. The main window shows the 'Research Personnel' section, which includes fields for Name, Primary Investigator, Start Date, and Certifications. A pop-up window titled 'Select value - Google Chrome' is open, showing a list of personnel with the entry 'KENDRICK, ZEBULON - 901293793 - HSC PROVOST (27500)' selected. A red arrow points to the 'Select' button in the pop-up window.

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

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

Initial Submission

Submission

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

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 data? ☒ Yes ☐ No

* 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):

Personnel Listing

KENDRICK, ZEBULON - 901293793 - HSC PROVOST (27500)

Select **Close**

Add additional study documents by clicking the “Add” button

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

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Home > Submissions > Initial Submission > Submission

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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 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"/>

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 - RESE

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Human Subjects

Edit Mode

Change Project Info

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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"/>

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

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 - RESE

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(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

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"/>

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

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

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

Record Number
26289

Done Save

My example protocol f
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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 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"/>

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

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 - RESE

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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

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

☐

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

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](#)

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[Summaries](#)

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[Communications](#)

[Approved Docs](#)

?

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[Departments \(1\)](#)

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[Locations](#)

[Attachments \(13\)](#)

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

[Assignments](#)

Initial Submission

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

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

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

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

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Locations

Attachments (13)

Status History (4)

Assignments

Initial Submission

Document/FormAdd

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

Route Path - Initial SubmissionAdd New Person to Review Path

Step 1

PI Acknowledgement

DAVID COMALLI

Submit

Step 2

Co-Invest. Acknowledgement

ZEBULON KENDRICK

Submit

Step 3

Department Head Acknowledgment

DR MICHELE MASUCCI

Submit

Step 7

IRB Check-In: Received by IRB

IRB OFFICE

Submit

IRB Check-In: Received by IRB

MRS. LASHAY COBB

Submit

No comments have been recorded yet

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)

Done

Save

Human Subjects

Edit Mode

Change Project Info

Submissions (3)

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?

Home > Submissions > Initial Submission > Submission

Submission

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IC Checklist

Codicils

Communications

Personnel (2)

Departments (1)

Centers / Programs

Locations

Attachments (13)

Status History (5)

Assignments (1)

Initial Submission

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

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

Approval Route Adding Personnel

Click “Submit” when all documents are uploaded; Note it’s not actually submitted yet

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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[Change Project Info](#)

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?

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[Personnel \(2\)](#)

[Departments \(1\)](#)

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[Locations](#)

[Attachments \(13\)](#)

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

[Assignments](#)

Initial Submission

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

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

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

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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Codicils

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Modification

Document/Form Add

Modification of Approved Human Research

Show Existing Protocol Attachments

Submission Number: 26289-0003

Created on: 08-Nov-2019

Status: Under Development

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

PI

Step 3

IRB Check-In: Received by IRB

MRS. LASHAY COBB

PI

IRB Check-In: Received by IRB

IRB OFFICE

PI

No comments have been recorded yet

Add step - Google Chrome

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

Add step

Add Cancel

parkm

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

Informational Only

Approval Required

Type the last name and select the person


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

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](#)

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)

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Home > Submissions > Modification > Submission

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Modification

Document/Form Add

Modification of Approved Human Research

Show Existing Protocol Attachments

Submission Number: 26289-0003

Created on: 08-Nov-2019

Status: Under Development

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

PDF

Step 3

IRB Check-In: Received by IRB

MRS. LASHAY COBB

PDF

IRB Check-In: Received by IRB

IRB OFFICE

PDF

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”

You will get an email after the person ahead of you acknowledged the submission

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

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 (3)

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Modification

Document/Form Add

Modification of Approved Human Research

Show Existing Protocol Attachments

Submission Number: 26289-0003

Created on: 08-Nov-2019

Status: Under Development

Submit

Type	Status	
Modification	Completed	PDF

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

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

No comments have been recorded yet

Continue

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

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)

Done

Save

Human Subjects

Edit Mode

Change Project Info

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?

Home > Submissions > Initial Submission > Submission

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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)
Application for Human Research	IRB Application	Completed	PDF
Consent	Consent Form	Completed	Modify
Flyer	Attachment	Completed	Modify
Medical Record Abstraction Sheet	Attachment	Completed	Modify
Protocol	Protocol	Completed	Modify
Recruitment email	Attachment	Completed	Modify
Survey	Attachment	Completed	Modify

Approval Route: Acknowledging a Submission

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

An Initial Application For Your Review 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

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

HELP

REVIEW

ROUTE

Human Subject Protocol - *Modifications Required to Secure Approval*

Number: [26289](#)

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

Sponsor: NO EXTERNAL SPONSOR

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

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


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

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

HELP

REVIEW

ROUTE

Human Subject Protocol - *Modifications Required to Secure Approval*

Number: [26289](#)

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

Sponsor: NO EXTERNAL SPONSOR

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

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

Add Comments:

To be shared with everyone

B *I* U    **A** ▼

Select a decision:

Acknowledge

PI Clarification

Close

Comments I can see...

No Comments have been recorded

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

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

HELP

REVIEW

ROUTE

Human Subject Protocol - *Modifications Required to Secure Approval*

Number: [26289](#)

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

Sponsor: NO EXTERNAL SPONSOR

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

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

Add Comments:

To be shared with everyone

B *I* U    **A** ▼

Select a decision:

Acknowledge

PI Clarification

Close

Comments I can see...

No Comments have been recorded



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

aging/ReviewItem.asp?RoutedStepID=96D9139C670A3B60E053B510600A6296

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

HELP

REVIEW

ROUTE

Human Subject Protocol - *Modifications Required to Secure Approval*

Number: [26289](#)

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

Sponsor: NO EXTERNAL SPONSOR

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

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

Add Comments:

To be shared with everyone

B *I* U    **A** ▼

Select a decision:

Acknowledge

PI Clarification

Close

Comments I can see...

No Comments have been recorded



Approval Route: Checking where the Submission is in the Route

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

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

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


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

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

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

DoneSave

Change Project Info

Submissions (14)LinkagesSummariesAttachments (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: 23074-0004Created on: 30-Sep-2019Status: 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 - 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

DoneSave

Change Project Info

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Departments (1)

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Status History (2)

Assignments (1)

Modification

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

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- Centers / Programs
- Locations
- Attachments (1)
- Status History (2)
- Assignments (1)

Modification

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

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

https://era.temple.edu/messaging/showroute.asp?RouteID=93C916A70BFBB422E053B510600A36B1&Title=Off&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			
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Modification of Human Research	Final Review	Step 3 - IRB Check-In: Received by IRB	MRS. LASHAY COBB				
Modification of Human Research	Final Review		IRB OFFICE				

No comments have been recorded yet

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

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


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

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 Human Subjects

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

Responding to Modifications Requested

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

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

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

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

Select a Submission - Google Chrome

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

Select Submission

SaveClose

Submission

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

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

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

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Done Save

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

Select a Submission - Google Chrome

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

Select Submission

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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Modifications Required to Secure Approval

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

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

[Show Existing Protocol Attachments](#)


Add the new (Tracked Changes and Clean versions) documents

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

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

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Modifications Required to Secure Approval				Submission Number: 26289-0002 Created on: 08-Nov-2019 Status: Under Development	
Document/Form	Add	Type	Status	Submit	
Application for Human Research		IRB Application	Completed	PDF	Remove
Consent		Consent Form	Completed	Modify	Remove
Flyer		Attachment	Completed	Modify	Remove
Medical Record Abstraction Sheet		Attachment	Completed	Modify	Remove
Protocol		Protocol	Completed	Modify	Remove
Recruitment email		Attachment	Completed	Modify	Remove
Survey		Attachment	Completed	Modify	Remove
Show Existing Protocol Attachments					

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

du/EnableWeb/Compliance/SubmissionDetail.aspx?ProjID=96C7F8B8E59712A3E053B510600A57C3&mark=3283227&WFTabID=16&rand=0.16045401324682573&Mode=EDIT&ObjectID=96D84568D867134AE053B510600AC3CF&Page=SubmissionDetail - Google Chrome


EnableWeb/Compliance/SubmissionDetail.aspx?ProjID=96C7F8B8E59712A3E053B510600A57C3&mark=3283227&WFTabID=16&rand=0.16045401324682573&Mode=EDIT&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 Add	Type	Status		Submit
Application for Human Research	IRB Application	Completed	PDF	Remove
Consent Clean 11.11.19	Attachment	Completed	Modify	Remove
Consent Tracked 11.11.19	Attachment	Completed	Modify	Remove
Flyer	Attachment	Completed	Modify	Remove
Medical Record Abstraction Sheet	Attachment	Completed	Modify	Remove
Protocol	Protocol	Completed	Modify	Remove
Recruitment email	Attachment	Completed	Modify	Remove
Survey	Attachment	Completed	Modify	Remove

[Show Existing Protocol Attachments](#)

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

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

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


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

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


Click on the “Attachments” link within the submission

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

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Modifications Required to Secure Approval

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

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

Find the IRB Approved and Stamped consent(s)

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


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

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

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

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

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

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

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

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

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

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

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

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

/EnableWeb/Compliance/Submissions.aspx?Projid=04EB302728B5126CE053B510600A8005&Page=Submissions - Google Chrome


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Record Number

23074

Effect of Fatigue on Concussion Ocular-Motor Screening Assessments

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

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[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	Log	Delete
Close Protocol	23074-0003	02-Aug-2019	06-Aug-2019	N/A	Closed	28-Aug-2019	N/A	N/A	Log	Delete
Continuing Review	23074-0001	09-Jul-2018	12-Jul-2018	N/A	Modifications Required to Secure Approval	N/A	N/A	N/A	Log	Delete
Modifications Required to Secure Approval	23074-0002	11-Aug-2018	15-Aug-2018	N/A	Approved	16-Aug-2018	01-Sep-2018	31-Aug-2019	Log	Delete
Modification	N/A	28-Aug-2017	31-Aug-2017	N/A	Approved	19-Sep-2017	N/A	N/A	Log	Delete
Continuing Review	N/A	03-Aug-2017	03-Aug-2017	N/A	Modifications Required to Secure Approval	N/A	N/A	N/A	Log	Delete
Modifications Required to Secure Approval	N/A	28-Aug-2017	28-Aug-2017	N/A	Approved	31-Aug-2017	01-Sep-2017	31-Aug-2018	Log	Delete
Modifications Required to Secure Approval	N/A	15-Aug-2017	15-Aug-2017	N/A	Modifications Required to Secure Approval	N/A	N/A	N/A	Log	Delete
Modification	N/A	16-Feb-2017	20-Feb-2017	N/A	Approved	27-Feb-2017	N/A	N/A	Log	Delete
Continuing Review	N/A	14-Jun-2016	17-Jun-2016	N/A	Approved	17-Aug-2016	01-Sep-2016	31-Aug-2017	Log	Delete
Initial Submission	N/A	18-Jun-2015	16-Jul-2015	N/A	Modifications Required to Secure Approval	N/A	N/A	N/A	Log	Delete
Modifications Required to Secure Approval	N/A	31-Aug-2015	01-Sep-2015	N/A	Approved	01-Sep-2015	01-Sep-2015	31-Aug-2016	Log	Delete
Modifications Required to Secure Approval	N/A	21-Jul-2015	21-Jul-2015	N/A	Modifications Required to Secure Approval	N/A	N/A	N/A	Log	Delete
Reportable New Information	23074-0005	N/A	N/A	N/A	Under Development	N/A	N/A	N/A	Log	Delete

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

edu/EnableWeb/Compliance/Attachments.aspx?Projid=04EB302728B5126CE053B510600A8005&ProjAttachFolderId=ROOT&Page=SumAttachments - Google Chrome

city [US] | era.temple.edu/EnableWeb/Compliance/Attachments.aspx?Projid=04EB302728B5126CE053B510600A8005&ProjAttachFolderId=ROOT&Page=SumAttachments

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

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

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

edu/EnableWeb/Compliance/Attachments.aspx?Projid=04EB302728B5126CE053B510600A8005&ProjAttachFolderId=ROOT&Page=SumAttachments - Google Chrome

ity [US] | era.temple.edu/EnableWeb/Compliance/Attachments.aspx?Projid=04EB302728B5126CE053B510600A8005&ProjAttachFolderId=ROOT&Page=SumAttachments

Record Number


23074

Done

Save

Effect of Fatigue on Concussion Ocular-Motor Screening Assessments

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

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[Communications \(40\)](#)

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[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	Stamped Consent	ROOT	Record	Modifications Required to Secure Approval	1	01-Sep-2015 5:34:55 PM	
IRB Approved Stamped Consent	Stamped Consent	ROOT	Record	Modification	1	28-Feb-2017 4:28:56 PM	
IRB Approved Stamped Consent	Stamped Consent	ROOT	Record	Modifications Required to Secure Approval	1	31-Aug-2017 10:45:09 AM	
IRB Approved stamped Consent Form	Stamped Consent	ROOT	Record	Modifications Required to Secure Approval	1	27-Aug-2018 4:17:33 PM	
HIPAA	Attachment	ROOT	Submission Package	Initial Submission	1	18-Jun-2015 11:21:45 AM	
Consent Form	Attachment	ROOT	Submission Package	Initial Submission	1	18-Jun-2015 11:30:19 AM	

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

Create another submission by clicking the dropdown menu on the “Submissions” page

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

np-era-app.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 Protocol

Edit Mode

Submissions (2)

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Home > Submissions

Submissions

Add

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

Continuing Review

Amendment

Reportable New Information

Close Protocol

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

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




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

Record Number
26289

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 Human Subjects
Protocol

[Edit Mode](#)

Done

Save

Submissions (2)

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

Submissions

Add

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

Continuing Review
Amendment
Reportable New Information
Close Protocol

Click “Add”

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




np-era-app.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
Protocol

[Edit Mode](#)

Done

Save

Submissions (2)

Linkages

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

Submissions

Add

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

Continuing Review
Amendment
Reportable New Information
Close Protocol

Click and then complete the “Amendment to Approved Human Research” eForm

https://np-era-app.temple.edu/EnableWeb/Compliance/SubmissionDetail.aspx?Projid=96C7F...

np-era-app.temple.edu/EnableWeb/Compliance/SubmissionDetail.aspx?Projid=...

Record Number
26289

Done Save

My example protocol for the talk t
DAVID COMALLI - RESEARCH: EXECUTIVE

Submissions (3) Linkages Summaries Attachments Communications (6)

Home > Submissions > Amendment > Submission

Submission

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

Amendment

Document/Form [Add](#)

[Amendment to Approved Human Research](#)


https://np-era-app.temple.edu/ComplianceNet/SharedSystems/EForms/Form.aspx?objectFormID=C57CD71D-0D96-422A-9DEB-034D82A0CAD9&recor...

np-era-app.temple.edu/ComplianceNet/SharedSystems/EForms/Form.aspx?objectFormID=C57CD71D-0D96-422A-9DEB-034D82A0...

Updated By: DAVID COMALLI @ 2

Amendment to 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 amendment:

Section III

Were any of the documents below affected by the amendment?

* This amendment request includes the addition of any radiation imaging or a change in sponsored imaging request.

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

https://np-era-app.temple.edu/EnableWeb/Compliance/SubmissionDetail.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&ObjectID=DAC0807F3E671C39E0538337600A48C9&Page=SubmissionDetail - Google Chrome



np-era-app.temple.edu/EnableWeb/Compliance/SubmissionDetail.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&ObjectID=DAC0807F3E671C39E0538337600A48C9&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
Protocol

[Edit Mode](#)

Done

Save

Submissions (3)

Linkages

Summaries

Attachments

Communications (6)

Approved Docs



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Submission

[Reviews](#)

[IC Checklist](#)

[Codicils](#)

[Communications](#)

[Personnel \(4\)](#)

[Departments \(1\)](#)

[Centers/Programs](#)

[Locations](#)

[Attachments \(1\)](#)

[Status History](#)

[Assignments](#)

Amendment

Submission Number: 26289-0003

Created on: 21-Mar-2022

Status: Under Development

Document/Form [Add](#)

Type

Status

[Submit](#)

[Amendment to Approved Human Research](#)

Amendment

Incomplete

(Mandatory Form)

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

https://np-era-app.temple.edu/EnableWeb/Compliance/SubmissionDetail.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&ObjectID=DAC0807F3E671C39E0538337600A4BC9&Page=SubmissionDetail - Google Chrome

np-era-app.temple.edu/EnableWeb/Compliance/SubmissionDetail.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&ObjectID=DAC0807F3E671C39E0538337600A4BC9&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 Protocol
[Edit Mode](#)

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

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[Personnel \(4\)](#)

[Departments \(1\)](#)

[Centers/Programs](#)

[Locations](#)

[Attachments \(1\)](#)

[Status History](#)

[Assignments](#)

Amendment

Submission Number: 26289-0003 Created on: 21-Mar-2022 Status: Under Development

Document/Form [Add](#)

[Amendment to Approved Human Research](#)

Type	Status
Amendment	Completed

[Submit](#)

Submit - Google Chrome

np-era-app.temple.edu/messaging/Submit.asp?ObjectID=DAC0807F3E671C39E0538337600A4BC9&Ro...

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](#)

Step 2

PI FYI

DAVID COMALLI

Step 4

IRB Check-In: Received by IRB

IRB OFFICE

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No comments have been recorded yet



IRB@temple.edu

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

215-707-3390