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How to Submit Prospective and Retrospective Studies to the IRB

David Comalli

IRB Assistant Director

October 15, 2020

Slides Summary / Table of Contents

What is the IRB?

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

- #1 Priority: Protect subjects from physical, psychological, or status/financial harm
  - Even retrospective chart reviews carry risks: invasion of privacy; confidentiality breach

- #2 Priority: Protect Temple's research program
  - Federal penalties, less funding, damage to Temple's image

Human subjects research (HSR)

- A systematic investigation—designed to develop/contribute to generalizable knowledge—involving living individuals about whom an investigator conducting research obtains: 1. Identifiable private information or 2. Data through intervention or interaction with the individual.

- If a project is Human Subjects Research, it must be reviewed/approved by the IRB.

So your protocol is Human Subjects Research…

What's Next?

Submit to the IRB to be reviewed as follows…

- Exempt: A designated reviewer determines that the research is exempt from certain rules and regulations.
  - The IRB **must** review the initial protocol and modifications that may change the category.
  - Use the **Minimal Risk** protocol and consent templates.

- Expedited: A designated reviewer approves the research initially, annually (in some cases), and any modifications.
  - Does not mean faster.
  - Use the **Minimal Risk** protocol and consent templates.

- Full Board: A fully convened IRB committee reviews the research initially, annually (at minimum), and any modifications.
  - For research that doesn't fit into the above categories or is greater than minimal risk.
  - Use the **Main** protocol and informed consent templates.

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Exempt, Expedited, and Full Board...

- Cannot begin before the IRB approves the research.

- The IRB will stamp the consent form(s), and those are the ones that should be used.
  - Stamped consents can be found in the Attachments tab for every approved submission in which a consent was submitted.

- Changes to the study (recruitment methods, data collection/storage, N, tasks, personnel, etc.) should be submitted as Modifications.

- Problems (over-enrollment, unsigned consent, protocol deviation, confidentiality breach, adverse event, etc.) need to be reported to the IRB.

Exempt 4: Retrospective vs prospective chart reviews

- Retrospective = exists at the time that the IRB receives the submission.
  - Waiver of consent and HIPAA authorization is fairly simple.
  - Use the IRB's Chart Review Protocol Template.

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

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Prospective studies that are not chart reviews

- Minimal Risk studies
  - Examples include blood draws, MRI, some behavioral interventions

- Greater than Minimal Risk studies
  - Examples include drug/device trials, experimental surgeries, surveys / interviews of incriminating behavior

- Randomized trial of two SOC procedures / drugs
  - Can still be greater than minimal risk

A couple of notes...

Funding matters

- Federally-funded studies:
  - May require Single IRB.
  - Require additional language in the consent.
  - Consult with the IRB prior to submitting the protocol (and grant if multi-site).

- Industry-initiated studies:
  - Must be reviewed by WIRB, but will be submitted to the Temple IRB prior to WIRB review.
  - Must include the WIRB Initial Submission Form in the submission to the Temple IRB.

Know who can be the PI!

- Only fulltime faculty members can be the PI, unless a special PI Exception form is signed by your dean and the Vice President for Research (Michele Masucci).

- If you are not fulltime faculty and don't have that form, make sure you are not listed as the PI.
  - Even if the study is your idea, and you're doing the vast majority of work.

- If you assign the wrong PI, reach out to the IRB.
  - Only the IRB staff can change the PI for a created study.

CITI training

- Be sure to affiliate with Temple University, **<u>not</u>** Temple Hospital
  - Easiest way is signing in via the IRB website linked on previous slide

- Two required courses:
  - Biomedical Research or Social/Behavioral Research – takes ~1-4 hours
  - Practice Runs Training – 1 module, takes ~5 minutes

- Does not need to be completed prior to submitting to the IRB but…

- Needs to be completed by everyone on the study before the IRB will approve the study

General IRB tips

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

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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://www.temple.edu/research/researchadmin/era/era_login.asp

Protocol and consent templates

- Download the Word docs from the website.

- Don't leave in the instructional language.

- The IRB focuses on the abstract, title, investigator, and study design
  - Particularly: timing, inclusion/exclusion, what data will be accessed / collected, privacy & confidentiality, recruitment, study methods, and consent methods

- Make sure the IRB knows what you're doing, why you're doing it, and can grant a waiver of HIPAA authorization (consult HRP-428 for the requirements) if doing a retrospective chart review.

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

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IRB document pages; look under "IN THIS SECTION"

Protocol and consent tips

- Provide Word docs and tracked changes in Word (if a response)

- Be consistent across all study documents.
  - Participant duration, N, if identifiers are linked to data via a key, etc.

- Don't describe durations with dates, use months / weeks / years.
  - Bad: Recruitment completed by December 2019.
  - Good: Recruitment completed 3 months after IRB approval.

- If recording (video or audio), it must be in the consent.

- Minimal risk research usually does not require signed consent.
  - If you need signed consent (research with minors, HIPAA, etc.), the signature blocks are in the Main Informed Consent Template.

- Only include the consent summary if the study is federally funded **and** the consent body is longer than 4 pages.

- Double-check you're using the approved document as the base for any Modifications.

- Unless you are accessing medical records, you do not need HIPAA Authorization.

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Chart review protocol template

- Don't leave in the instructional language

- When possible, use the methodology provided in the table (section 8d)

- The IRB focuses on the abstract, title, investigator, and study design (particularly timing, inclusion/exclusion, what will be accessed, and privacy & confidentiality)

- Make sure the IRB knows what you're doing, why you're doing it, and can grant a waiver of HIPAA authorization (consult HRP-428 for the requirements)

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

ERA

- ERA is the portal through which Investigators and the IRB communicate (submissions and responses) officially.

- The IRB / ERA User Guide is helpful and has screen shots, but you will waste time and effort if you don't use the table of contents.
    - https://www.temple.edu/research/researchadmin/era/era_login.asp

- 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 User Guide pages 13-15).
- Immediately add yourself to the Application for Human Research (eForm).
  - If you don't you won't be able to access the record in the future.
- When all documents (minimum eForm and protocol) are uploaded, click submit, I agree, and continue.
  - Ensure it says "Electronic Submission Pending" on the Submissions page.
  - Emails are generally sent to your / your PI's @temple.edu address.
- The Department Head needs to be in the approval route for initial subs.
  - If your PI is the DH, then add the Dean.
- Upload docs via "Add" button, Not the Attachments tab.

Screenshot notes

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

- Pop-up windows that are in the screenshot will not exist until a button (like "Add") on the main page is clicked.

- The pop-ups may appear in a different part of the screen or not be fully visible as they are in the screenshots.

- Use the red arrows to denote the button/clicking sequence.

My Human Subjects > Create New

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

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

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

Open Action Items for: MS. MARILYN LEWIS

My Human Subjects

Show/List

Search For

Create New

Standard Reports

Program Tools

Help - Dev

Help - Mgmt

My Animal Use

Technology Transfer

My Profile

Administration

Click Continue and be directed to the Initial Submission

Add documents by clicking the "Add" button

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

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

Record Number
26289

Done Save

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

👥 Human Subjects
Edit Mode
Change Project Info

| Submissions (1) | Linkages | Summaries | Attachments | Communications | Approved Docs | ? |

Home > Submissions > Initial Submission > Submission

Submission

Reviews

IC Checklist

Codicils

Communications

Personnel (1)

Departments (1)

Centers / Programs

Locations

Attachments

Status History (1)

Assignments

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

Add
No Forms have been associated with this submission.

Add Components - Google Chrome   — □ ✕

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

Upload   Upload   Close

Upload new document

Name   [   ]

Location   [Choose File] No file chosen

Category   [Attachment   ▼]

Document ID [   ]

Document Version Number [   ]

Document Version Date [   ]

Add Initial Submission Components   Add

Form Name	Type	Add
Application for Classroom Projects	Conditional Use	☐
Application for Human Research	Conditional Use	☑

Always create the Application for Human Research eForm first

Click the lower "Add" button to add the eForm

Open the eForm

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

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

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

Add additional study documents by clicking the "Add" button

Click "Choose File" and find the document

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

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

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

My example protocol f
DAVID COMALLI - RESEA

👥 Human Subjects
Edit Mode

Done   Save

Change Project Info

Submissions (3)   Linkages   Summaries   Attachments (11)   Commu

?

Add Components - Google Chrome   — □ ✕

🔒 era.temple.edu/Protocol/popUpGetAddComponent.asp?ObjectID=96C7F8B8E59B12A3E053B510...00A57C3&Submis...

Home > Submissions > Initial Submission > Submission

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

Submission

Reviews (1)

IC Checklist

Codicils

Communications

Personnel (2)

Departments (1)

Centers / Programs

Locations

Attachments (7)

Status History (4)

Assignments

Initial Submission

Document/Form Add

Application for Human Research

Upload   Upload   Close

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

Upload new document

Name	Flyer|
Location	[Choose File] Poster for put...t places.docx
Category	Attachment ▾
Document ID	
Document Version Number	
Document Version Date	

Add Initial Submission Components   Add

Form Name	Type	Add
Application for Classroom Projects	Conditional Use	☐

289-0001 Created on: 07-Nov-2019 Status: Under Development

(Route History) Submit

Remove

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

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

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)	Linkages	Summaries	Attachments (17)	Communications	Approved Docs	?

Home > Submissions > Initial Submission > Submission

Submission

Reviews (1)

IC Checklist

Codicils

Communications

Personnel (2)

Departments (1)

Centers / Programs

Locations

Attachments (13)

Status History (4)

Assignments

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

Document/Form 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.

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

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

Type the last name and select the person

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

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

Record Number
26289

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

Human Subjects
Edit Mode

Done Save

Change Project Info

| 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

| | **Type** | **Status** | | Submit |

Modification of Approved Human Research Modification Completed PDF (Mandatory Form)

Show Existing Protocol Attachments

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

Add step Add Cancel

parkm

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

○ Informational Only
● Approval Required

Submit - Google Chrome — □ ×
🔒 era.temple.edu/messaging/Submit.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

Click "Add" and repeat until all <u>new</u> personnel are added

Look at the approval route and click "Continue"

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

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

An Initial Application For Your Review ⟶ Inbox ×

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

Close

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

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

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...

H E L P

R E V I E W

R O U T E

Close

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

Comments I can see...

No Comments have been recorded

Add Comments:

To be shared with everyone

B *I* U :≡ ≡ 🔗 **A** ▾

Select a decision:

Acknowledge

PI Clarification

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

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

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

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

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

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

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

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

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

Respond to "Modifications Required to Secure Approval" by clicking the "Respond…" link; Don't create a "Modification" to respond to requested changes
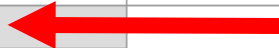
Select "Modifications Required to Secure Approval" from the dropdown (or "Deferred" if appropriate)

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

Add the new (Tracked Changes and Clean versions) documents

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

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

Record Number
26289

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 (2)   Linkages   Summaries   Attachments (14)   Communications (3)   Approved Docs   **?**

Home > Submissions > Modifications Required to Secure Approval > Submission

Submission

Reviews

IC Checklist

Codicils

Communications

Personnel (2)

Departments (1)

Centers / Programs

Locations

Attachments (7)

Status History (1)

Assignments

Modifications Required to Secure Approval
Submission Number: 26289-0002   Created on: 08-Nov-2019   Status: Under Development

Document/Form 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

Record Number
26289

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

Human Subjects

Edit Mode

[Done] [Save]

[Change Project Info]

| Submissions (2) | Linkages | Summaries | Attachments (16) | Communications (3) | Approved Docs | ? |

Home > Submissions > Modifications Required to Secure Approval > Submission

Submission

Reviews

IC Checklist

Codicils

Communications

Personnel (2)

Departments (1)

Centers / Programs

Locations

Attachments (8)

Status History (1)

Assignments

Modifications Required to Secure Approval   Submission Number: 26289-0002   Created on: 08-Nov-2019   Status: Under Development

Document/Form Add	Type	Status		
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

[Submit]

Show Existing Protocol Attachments

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

Click on the "Attachments" link within the submission

nableWeb/Compliance/SubmissionDetail.aspx?ProjID=96C7F8B8E59712A3E053B510600A57C3&ObjectID=96D84568D867134AE053B510600AC3CF&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 (2) | Linkages | Summaries | Attachments (17) | Communications (3) | Approved Docs | ? |

Home > Submissions > Modifications Required to Secure Approval > Submission

Submission

Reviews (1)

IC Checklist

Codicils

Communications

Personnel (2)

Departments (1)

Centers / Programs

Locations

← **Attachments (9)**

Status History (2)

Assignments

Modifications Required to Secure Approval

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

Document/Form	Type	Status	
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

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

Record Number
26289

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

Human Subjects
Edit Mode

Done   Save

Change Project Info

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

Home > Submissions > Modifications Required to Secure Approval > Attachments

Attachments (9)

Attachments

Attachments

Print All   Folder Maintenance   Add Document   Delete Selected

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

Name		Category		Folder		Managed by		Submission		Versions	Last Updated		Select
Protocol		Protocol ▼		ROOT ▼		Submission Package		Modifications Required to Secure Approval		2	08-Nov-2019 9:59:58 AM		
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		☐
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 "

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

Record Number
23074

Done   Save

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

Human Subjects
Edit Mode
Change Project Info

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

Home > Submissions

Submissions

Add

Type	Submission Number	Investigator Submitted On Date	Management Submitted On Date	Internal ID	Determination	Determination Date	Date From	Date To	Access Log	
Modification	23074-0004	30-Sep-2019	N/A	N/A	Electronic Submission Pending	N/A	N/A	N/A	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

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

Record Number
23074

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

Human Subjects

Edit Mode

Done   Save

Change Project Info

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

Home > Attachments

Attachments (68)

Attachments

Attachments

Print All   Folder Maintenance   Add Document   Delete Selected

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

Name	Category ↑	Folder	Managed by	Submission	Versions	Last Updated	Select
modifications_required		ROOT ▾	Record	Review	1	20-Jul-2015 5:00:36 PM	
IRB Approved Stamped Consent	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

sity [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

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

Home > Attachments

Attachments (68)

Attachments

Print All   Folder Maintenance   Add Document   Delete Selected

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

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

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

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

Click "Add"

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

nableWeb/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 (2)   Linkages   Summaries   Attachments (17)   Communications (3)   Approved Docs   ?

Home > Submissions

Submissions

Add

Continuing Review
Modification
Reportable New Information
Close Protocol
Expired

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

Click and then complete the "Modification of Approved Human Research" eForm

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

EnableWeb/Compliance/SubmissionDetail.aspx?Projid=96C7F8B8E59712A3E053B510600A

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

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

Record Number
26289

Done   Save

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

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

Home > Submissions > Modification > Submission

Submission

Reviews

IC Checklist

Codicils

Communications

Personnel (1)

Departments (1)

Centers / Programs

Locations

Attachments (1)

Status History (1)

Assignments

Modification

Document/Form Add

Modification of Approved Human Research

Show Existing Protocol Attachments

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

M E N U

P A G E S

💾 Save

📖 Table of Contents

Quest Hist

Form Hist

🖨 Print

Modification of Approved Human Research

☐ Complete

Page 1

ᛏ TEMPLE
U N I V E R S I T Y ®

Section I

IRB Project #:   26289

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

Investigator: COMALLI, DAVID

* Department: RESEARCH: EXECUTIVE LEADERSHIP (24010)

* Physical Address: 3340 N. Broad St.

* Phone Number: 215-707-7792

Section II

* Summarize the modification:

Adding Dr. Henry Parkman as a Co-Investigator.

Section III

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

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

Yes ☐ No☐   * Investigator Protocol

Yes ☐ No☐   * Research tools

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

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

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

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

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

Record Number
26289

Done   Save

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

Human Subjects
Edit Mode
Change Project Info

Submissions (5)   Linkages   Summaries   Attachments (20)   Communications (6)   Approved Docs   ?

Home > Submissions > Modification > Submission

Submission

Reviews (1)

IC Checklist

Codicils

Communications (3)

Personnel (1)

Departments (1)

Centers / Programs

Locations

Attachments (1)

Status History (5)

Assignments

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

Document/Form Add   Type   Status   Show Route   (Route History)

Modification of Approved Human Research   Modification   Completed   PDF   (Mandatory Form)

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

IRB@temple.edu

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

215-707-3390