

**IRB Protocol  
Application System  
(PAS)**

**Investigator Guide**

# Table of Contents

Introduction .....	1
Login Instructions.....	3
Dashboard Overview.....	4
IRB Tab Overview .....	10
Converting Protocols from the Old System to PAS.....	11
Protocol History Overview .....	13
Creating a New Protocol .....	14
A. Starting a new Full Application or Initial Query / Protocol Information .....	14
B. Query Exemptions (for Initial Queries Only).....	16
C. Caltech and Partner Orgs.....	17
C. Personnel .....	18
D. Funding.....	19
E. Samples and Data.....	21
F. Devices .....	23
G. Subject Selection Criteria .....	25
H. Subject Participation.....	26
I. Risks and Benefits .....	29
J. Incidental Findings.....	30
K. Subject Recruitment and Incentives .....	31
L. Informed Consent.....	33
M. Certification and Competing Interests .....	37
N. Unanticipated Events .....	37
Adding Attachments .....	39
Creating an Admin Only Amendment (AOA) .....	41
Creating a Renewal Application .....	45
Creating an Amendment Application .....	47

Creating a Data Analysis Only Application .....	49
Protocol Review .....	51
Identifying Protocol Changes .....	53
Contact Us.....	54

# Introduction

## Summary

The **IRB Protocol Application System (PAS)** is a browser-based application that allows Caltech investigators to prepare and submit research protocols to Caltech's Committee for the Protection of Human Subjects – Institutional Review Board (IRB). IRB members can use the system to review and comment on protocols prior to committee meetings. The IRB Administrator can pre-review protocol applications, organize meetings, and process meeting decisions and related correspondence with the investigators.

## Key Definitions and Concepts

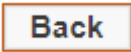
### Protocol

- Definition: a detailed plan for and description of a scientific research project or study involving the collection of data from an individual, either through direct intervention/interaction or by the use of private identifiable information. Throughout the system and this guide, “protocol” refers to the entire research project rather than any single application.
- An active protocol may include multiple associated applications, such as a query, full application, renewals, and amendments; however, only one application can be “active” at a time within a protocol (see details under *Protocol Applications* below).
- Protocol Number:
  - The naming convention for protocol numbers is IRYY-NNNN. IR identifies the protocol as an IRB protocol. YY is the last two digits of the year the query or full application was created, such as 19 for Year 2019. The year will update after a 5 year *de novo* protocol is created. NNNN is a unique number assigned for the lifetime of the protocol.
  - For *5 year de novo* renewals, the YY changes to the current year: NNNN will stay the same. For example: for original protocol number IR16-0005, the *5 year de novo* protocol number is IR21-0005, if submitted in 2021.
- Options for creating new protocols:
  - Create an initial query.
  - Create a brand-new full application.
  - Create a full (usually *De Novo*) application by copying from any existing protocol application.

### Protocol Applications

- There are five application types:
  1. Initial Query
  2. Full Application (Including *de novo* renewals)
  3. Amendment 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup>, 4<sup>th</sup>, etc. (Request to change protocol in some way)
  4. Renewal 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup>, 4<sup>th</sup> (Protocols are renewed at least annually, and study information is provided. Renewals can include requests to change the protocol)
  5. Admin Only Amendment (AOA) 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup>, 4<sup>th</sup>, etc. (Request to change personnel or funding only)
- The Informed Consent (IC) must be completed and included in full applications, amendments, and renewals, unless a waiver is requested. Some initial queries may require an IC, and the IRB Administrator will work with the investigator to create the appropriate document.
- The text in the IC is derived from protocol application responses and can be edited by the investigator. (Not applicable for initial queries)





## PAS Tips & Tricks


- PAS functions most efficiently using Google Chrome or Firefox browsers. Google Chrome is the only browser that you can use to print protocols, Informed Consent, GDPR and PIPL documents.
- Navigate PAS by using the direction buttons throughout the system  and not by using your browser back buttons.
- SAVE OFTEN! Navigating to different sections of the protocol without saving will result in lost data. The system will also time you out.
- \* A red asterisk denotes a required field
- ‡ This symbol represents a field that will be used in the Informed Consent document
- Incomplete sections will have a red flag. Before you can submit, all sections/subsections must be cleared of red flags.
- Only the PI should complete and save the Certification and Competing Interests section.

# Login Instructions

To log into the system, use your regular username and password on [access.caltech.edu](https://access.caltech.edu) and scroll down to the *Research Services* section, then click on *IRB Protocol Application System*:

## Research Services

- ✔ **IACUC Protocol Application System**    
*Submit protocols for animal research for review by Caltech's Institutional Animal Care and Use Committee (IACUC).*
- ✔ **IRB Protocol Application System**    
*Submit protocols for human subject research for review by Caltech's Institutional Review Board (IRB)*

\* We recommend adding this link to your favorites by selecting the star icon  to access it more easily from the top of your [access.caltech.edu](https://access.caltech.edu) home page.

If you do not have access to the *IRB Protocol Application System* link, contact the IRB Administrator at 626-395-8448.

If you are a JPLer or an employee of another insitution, you will be required to complete specific forms to be added to the database as a guest and gain access.

# Dashboard Overview

The Dashboard is your home page for PAS. Notifications, outstanding items and links to other areas of the application are located here.

The *Protocol Health Status for Active Approved Protocols* displays protocols that require investigator attention, such as protocol or funding expirations. Protocols in **purple** font are items that are coming up on an expiration date. Protocols in **red** font are items that have already expired.

**Quick Links**

- I want to go to:
- User Profile and Training
- IRB Protocol List
- Change Personnel/Funding (AOAs)
- Request Close Protocol
- IRB Attachment Library
- Institute SOP Repository
- Review Protocol List

**My Reports**

- select -

Check Type	Protocol Number	PI	IRB Status	Protocol Title	Expiration Date	Notify Person	Health Status
FUNDING	IR22- Initial Query	PI Name	Pending	Testing for Full application - RK test22	01/31/2023	PI	Funding AFOSR-FA9550 will expire on 01/31/2023
FUNDING	IR22- Full Application	PI Name	Active	RK Test TRB using LAB PERSON Login in Test2	12/31/2022	PI	Funding AMGEN-ARNOLD22 expired on 12/31/2022
FUNDING	IR22- Amendment 1st	PI Name	Active	Testing for Full application - RK test22	01/31/2023	PI	Funding AFOSR-FA9550 will expire on 01/31/2023
FUNDING	IR22- Full Application	PI Name	Pending	SSHU-COPY of Functional Acoustic Imaging and Brain-Machine Interfacing in Adult Human Cortex: Proof of Concept (HSR)	12/31/2022	PI	Funding ENDOW 0001 expired on 12/31/2022
FUNDING	IR19- Renewal 2nd	PI Name	Exempt	Pilot study to evaluate molecules in sweat, saliva and blood	10/31/2021	PI	Funding R01RG3746 expired on 10/31/2021
FUNDING	IR21- Initial Query	PI Name	Exempt	Heterogeneity of Gain-Loss Attitudes and Expectations-Based Reference-Dependent Labor Supply	03/31/2022	PI	Funding 1949517 expired on 03/31/2022
FUNDING	IR21- Initial Query	PI Name	Exempt	Printed biosensors to evaluate molecules in sweat, saliva and blood	07/31/2021	PI	Funding 80NSSC20M0167 expired on 07/31/2021
FUNDING	IR21- Initial Query	PI Name	Exempt	Biosensors for COVID-19 Diagnosis and Monitoring	10/31/2021	PI	Funding R01RG3746 expired on 10/31/2021
FUNDING	IR21- Initial Query	PI Name	Exempt	Development of host-depletion technologies for analysis of microbes in human samples	05/31/2022	PI	Funding 20210004 (renewal of 2018-1207) expired on 05/31/2022
FUNDING	IR21- Initial Query	PI Name	Exempt	Quantitative Analysis of Human Nasal and Oral Microbiomes	07/30/2021	PI	Funding n/a expired on 07/30/2021

1 - 10 of 17

The *List of Things to Do* section displays review comments from IRB members that require attention. You can reply directly to the comments in the text box that appears after clicking on the arrow icon. These comments are always available directly in the corresponding protocol section as well. Clicking on the “x” in the *Dismiss* column will delete the row from this table. It will not delete the comment from the protocol section.

**List of Things to Do**

**Un-read Communications**

Protocol	Communications	Reply	Dismiss
IR23-1310:Amendment 1st (Subject Recruitment and Compensation)	Shu, Steve on 2023-01-24 09:44:51 Please update your participant compensation following the guidelines established in IRB SOP 16, found on the IRB website.		×
IR23-1310:Amendment 1st (Subject Selection Criteria)	Shu, Steve on 2023-01-24 09:44:29 Please provide Exclusionary Criteria for this study.		×

1 - 2

The *List of Things to Know* section allows PIs and Admin contacts to run reports on active personnel per protocol.

▼ List of Things to Know

▼ Find Profile

Find a person and go to profile page

▼ Personnel on My Protocols (for PIs and Admin Contacts)

Q  Go Actions ▼

Protocol Number ↓	IRB Status	Name	Person Role	Training Completed	Missing Training
IR23-1313 Full Application	PENDING	Hayashi, Megan Elizabeth	PI	-	-
IR23-1313 Full Application	PENDING	Kumar, Radha	Investigator	-	-
IR23-1313 Full Application	PENDING	Shu, Shizhuang	Lead Investigator	-	-
IR23-1311 Initial Query	PENDING	Hayashi, Megan Elizabeth	PI	-	-
IR23-1310 Amendment 1st	PENDING	Hayashi, Megan Elizabeth	PI	-	-

1 - 5

To access the report, click on the *Actions* button and choose *Download* from the dropdown menu. The other options on the dropdown menu allow you to customize the table columns. You will see this *Actions* button available on most tables throughout PAS and all include the same functionality.

▼ Personnel on My Protocols (for PIs and Admin Contacts)

Q  Go Actions ▼

Protocol Number ↓	IRB Status	Name	Person Role	Training Completed	Missing Training
IR23-1313 Full Application	PENDING	Hayashi, Megan Elizabeth	PI	-	-
IR23-1313 Full Application	PENDING	Kumar, Radha	Investigator	-	-
IR23-1313 Full Application	PENDING	Shu, Shizhuang	Lead Investigator	-	-
IR23-1311 Initial Query	PENDING	Hayashi, Megan Elizabeth	PI	-	-
IR23-1310 Amendment 1st	PENDING	Hayashi, Megan Elizabeth	PI	-	-

1 - 5

Actions ▼

- Select Columns
- Filter
- Rows Per Page
- Format
- Flashback
- Save Report
- Reset
- Help
- Download

The *Quick Links* section allows you to access your User Profile, protocols, attachments, and the IRB SOP Repository. You can also make personnel and funding changes (AOA instruction found on [page 41](#)) and request to close protocols here.



**Quick Links**

I want to go to:

- User Profile and Training
- IRB Protocol List
- Change Personnel/Funding (AOAs)
- Request Close Protocol
- IRB Attachment Library
- Institute SOP Repository
- Review Protocol List

**My Reports**

- select -

**Protocol Health Status for Active Approved Protocols**

Q [Go Actions]

Check Type	Protocol Number	PI	IRB Status	Protocol Title	Expiration Date	Notify Person	Health Status
FUNDING	IR22- Initial Query	PI Name	Pending	Testing for Full application - RK test22	01/31/2023	PI	Funding AFOSR.FA9550 will expire on 01/31/2023
FUNDING	IR22- Full Application	PI Name	Active	RK Test TRB using LAB PERSON Login in Test2	12/31/2022	PI	Funding AMGEN.ARNOLD22 expired on 12/31/2022
FUNDING	IR22- Amendment 1st	PI Name	Active	Testing for Full application - RK test22	01/31/2023	PI	Funding AFOSR.FA9550 will expire on 01/31/2023
FUNDING	IR22- Full Application	PI Name	Pending	SSHU-COPY of Functional Acoustic Imaging and Brain-Machine Interfacing in Adult Human Cortex. Proof of Concept (iHSR)	12/31/2022	PI	Funding ENDDOW.0001 expired on 12/31/2022
FUNDING	IR19- Renewal 2nd	PI Name	Exempt	Pilot study to evaluate molecules in sweat, saliva and blood	10/31/2021	PI	Funding R01RG3746 expired on 10/31/2021
FUNDING	IR21- Initial Query	PI Name	Exempt	Heterogeneity of Gain-Loss Attitudes and Expectations-Based Reference-Dependent Labor Supply	03/31/2022	PI	Funding 1949517 expired on 03/31/2022
FUNDING	IR21- Initial Query	PI Name	Exempt	Printed biosensors to evaluate molecules in sweat, saliva and blood	07/31/2021	PI	Funding 80NSSC20M0167 expired on 07/31/2021
FUNDING	IR21- Initial Query	PI Name	Exempt	Biosensors for COVID-19 Diagnosis and Monitoring	10/31/2021	PI	Funding R01RG3746 expired on 10/31/2021
FUNDING	IR21- Initial Query	PI Name	Exempt	Development of host-depletion technologies for analysis of microbes in human samples	05/31/2022	PI	Funding 20210004 (renewal of 2018-1207) expired on 05/31/2022
FUNDING	IR21- Initial Query	PI Name	Exempt	Quantitative Analysis of Human Nasal and Oral Microbiomes	07/30/2021	PI	Funding n/a expired on 07/30/2021

1 - 10 of 17

As an investigator on an active IRB Protocol, you will need to set up your *User Profile*.

**Quick Links**

I want to go to:

- User Profile and Training
- IRB Protocol List
- Change Personnel/Funding (AOAs)
- Request Close Protocol
- IRB Attachment Library
- Institute SOP Repository
- Review Protocol List

Your *User Profile* contains contact information, education history, your list of active protocols, and your training. You are responsible for filling out the information in the *Contact Information* and *Education* sections. The information in the *Protocol Access* and *Training* sections will automatically populate with the list of your active protocols and your completed and still outstanding training requirements.

**Link Section**

Check the box to display the section, uncheck to hide:

- Contact Information
- Education
- Protocol Access
- Training

**Profile**

**Contact Information**

Person Name: **Hayashi, Megan Elizabeth** Caltech UID: \_\_\_\_\_

Division: **PROV** Job Title: **Research Compliance Administrator**

Campus Phone: **626-395-8448** Emergency Phone: \_\_\_\_\_

Building: - select - Room: - select -

Mail Code: **MC02-31** Email: \_\_\_\_\_

Medical Clearance Date: 13-SEP-22

Medical Clearance Note: \_\_\_\_\_

No OLAR Billing Reports/Emails  
 **Medical Clearance**

**Education**

Check the highest level that applies:

- High School Diploma
- Associate's Degree
- Bachelor's Degree
- Master's Degree
- PhD
- DVM
- MD

Other: \_\_\_\_\_

List of locations where you have performed research with human participants in the past.

\_\_\_\_\_

Are you affiliated with any other institutions?

- Yes  No

**Active Protocol Access**

This is a list of all protocols on which you are listed as personnel.

**Training**

Have you completed human subjects training before?

- Yes  No

**Training Completed**

Course Title	Date Completed
CITI - Caltech Controlled Substance Program	17-SEP-2018
CITI - Introduction to Working with Laboratory Animals at Caltech	17-SEP-2018
CITI - Safe Use of Isoflurane Gas Anesthesia in Rodents	20-NOV-2017
CITI - Sharps Safety	20-SEP-2018
CITI - Use of Hazardous Agents in Animal Studies	01-MAR-2021
CITI - Working with Finches in Research	25-OCT-2018
CLAS - Ethics- Animal Welfare	28-NOV-2017
CLAS - Level 2 Classroom Training	19-OCT-2017
Learn - Ethical Conduct Awareness at Caltech	28-FEB-2019
Learn - Ethical Conduct Awareness at Caltech_old	28-FEB-2019
Learn - Ethics and Welfare	28-NOV-2017
Learn - Harassment and Discrimination Prevention	22-OCT-2019
Learn - Harassment and Discrimination Prevention_Old	22-OCT-2019
Learn - Level 2 Classroom Training	19-OCT-2017
Learn - Preventing Harassment and Discrimination: Supervisors with Title IX/Clergy Module	27-JUL-2022

[Download](#)

row(s) 1 - 15 of 17

**Required Training Incomplete**

*IRB Protocol List* will take you to the list of your IRB protocols. This is also where new protocols are created.

**Quick Links**

I want to go to:

- User Profile and Training
- IRB Protocol List
- Change Personnel/Funding (AOAs)
- Request Close Protocol
- IRB Attachment Library
- Institute SOP Repository
- Review Protocol List

Admin Only Amendments (AOAs) allow you to update protocol personnel and funding sources without creating a full amendment to your protocol. *Change Personnel/Funding (AOAs)* will take you to the screen where you can create the AOA. (See [page 41](#) for more information on creating AOAs)

**Quick Links**

I want to go to:

- User Profile and Training
- IRB Protocol List
- Change Personnel/Funding (AOAs)
- Request Close Protocol
- IRB Attachment Library
- Institute SOP Repository
- Review Protocol List

Click on *Request Close Protocol* when you would like to close a protocol.

**Quick Links**

I want to go to:

- User Profile and Training
- IRB Protocol List
- Change Personnel/Funding (AOAs)
- Request Close Protocol
- IRB Attachment Library
- Institute SOP Repository
- Review Protocol List

To request to close a protocol, click on the pencil next to the protocol you wish to close.

Request Protocol Close										
<input type="text"/> <input type="button" value="Go"/> <input type="button" value="Actions"/>										<input type="button" value="Back to Dashboard"/>
Request to Close	Drop Request	Protocol	PI	Title	Doc Status	Irb Decision Meaning	Requested By	Request Close Date	Admin Close	
	-	IR22-1304B Renewal 4th	Shu, Shizhuang	sshu query test 1219 changing to full app	Decision Made	Approved	-	-	-	
	-	IR22-1302 Amendment 1st	Kumar, Radha	Test for Intial Query-Test2-1215	Decision Made	Approved	-	-	-	
	-	IR23-1310 Amendment 1st	Hayashi, Megan Elizabeth	Test Updates 1.03.23	Pending Review	-	-	-	-	

A pop-up box will open. Enter the date you request to close the protocol and click *Save*.

**Request to Close Protocol**

Protocol: IR22-1304B:Renewal 4th

Protocol Title: sshu query test 1219 changing to full app

Request Close Date:

Requested By:

The *IRB Attachment Library* includes the list of attachments designated as private, public, or specific to your lab group. Please note, your lab group name will only appear if your lab is set up in the DPM (Division Personnel Management). The

DPM is managed at the division level and the IRB does not have access to or control of the DPM data. If you would like to update your lab's information, you will need to work directly with your division.

The *IRB Attachment Library* is one way to upload documents to PAS. The second way is attaching documents directly to the protocol. (See [page 39](#) for more information on adding attachments)

**Quick Links**

I want to go to:

- User Profile and Training
- IRB Protocol List
- Change Personnel/Funding (AOAs)
- Request Close Protocol
- IRB Attachment Library
- Institute SOP Repository
- Review Protocol List

Attachment Library																	
Q		A		B		Go		Actions		C		D		E		F	
Details	Attachment Category	Owner	Attachment Name	Subject	Committee	Shared Level	Obsolete	Delete	Institute SOP	Protocol List							
	SOP	Adolphs, Ralph	<a href="#">Chan Lab Monthly Detail Statement.pdf</a>	Test AD-1	IRB	Public	-	-	-	<a href="#">IR22-1308:Initial</a>							
	Recruitment Materials	Hayashi, Megan Elizabeth	<a href="#">FLYER.docx</a>	Flyer	IRB	Private	-	X	-	-							
	SOP	Shu, Shizhuang	<a href="#">IRB Partner Org questions_20201022.pdf</a>	institute SOP	IRB	Public	-	X	Yes	-							
	Protocol Doc	Hayashi, Megan Elizabeth	<a href="#">Device Photos.docx</a>	Device Photos	IRB	Adolphs Lab	-	X	-	-							
	Other IRB Approval	Hayashi, Megan Elizabeth	<a href="#">UCLA IRB Approval.docx</a>	UCLA IRB Approval	IRB	Adolphs Lab	-	X	-	-							
	Protocol Doc	Tyszka, Julian Michael	<a href="#">COGP- GEMS Monthly report.pdf</a>	Test lab member-1	IRB	Public	-	X	Yes	-							

A) Attachments fall into 7 different categories:

Protocol Doc, Other IRB Approval, Recruitment Materials, Questionnaires, Informed Consent, Training, SOP

B) The Owner is the person who uploaded the attachment

C) The Attachment Name reflects the document name, and the hyperlink opens the attachment

D) There are 3 shared levels:

Private: accessible to only you

Public: accessible to everyone in the IRB PAS

PI Lab: accessible to everyone in the PI's laboratory (Only accessible if your lab is in the DPM (Division Personnel Management). Contact your Division if your lab is not visible here)

Attachments that are no longer in use are designated as obsolete and cannot be deleted. Attachments cannot be deleted as they still need to be accessible when viewing inactive versions of protocols.

E) Protocols that include the attachment are displayed in this column

The *Institute SOP Repository* displays the list of IRB-approved SOPs. This list will contain the most up-to-date approved SOPs.

**Quick Links**

I want to go to:

- User Profile and Training
- IRB Protocol List
- Change Personnel/Funding (AOAs)
- Request Close Protocol
- IRB Attachment Library
- Institute SOP Repository
- Review Protocol List

# IRB Tab Overview

You can locate your IRB protocols at any time by clicking the IRB tab

You can also reach this page by clicking *IRB Protocol List* from the Dashboard tab.

Dashboard **IRB** IRB Meetings Admin

Create New Protocol

\* Application Type: Initial Query  
Full Application

Protocols that you created or you are on as personnel (not Closed/Inactive):

Go Actions

Back to Dashboard Go To Closed/Inactive List

Link	Protocol Number	PI	Protocol Title	IRB Review Type	IRB Decision	Print Status Memo	Submission Date	Ratification Date	Expiration Date	IRB Meeting	IRB Status	Attachment	Link to Old System
	IR23-1316 Full Application	Adolphs, Ralph	Test Protocol for IRB Meeting	PI WIP	-	-	-	-	-	-	PENDING		
	IR23-1316 Full Application	Andersen, Richard A	Test Protocol for IRB Meeting	PI WIP	-	-	-	-	-	-	PENDING		
	IR23-1310 Amendment 1st	Hayashi, Megan Elizabeth	Test Updates 1.03.23	PI Submitted	-	-	24-JAN-23	-	-	2023 January	PENDING		
	IR23-1313 Full Application	Hayashi, Megan Elizabeth	Test Protocol 1/06/23	PI WIP	-	-	-	-	-	-	PENDING		
	IR23-1311 Initial Query	Hayashi, Megan Elizabeth	Test Query	PI WIP	-	-	-	-	-	-	PENDING		
	IR23-1310 Full Application	Hayashi, Megan	Test Updates 1.03.23	Full Committee	Approved		12-JAN-23	-	02-JAN-24	2023 January	ACTIVE		

Create a new application by choosing *Initial Query* or *Full Application* from the dropdown Application Type. For further instructions, see *Creating a New Protocol* on [page 15](#).

- A) Click on the pencil icon to open a protocol.
- B) The protocol number, protocol type, PI, and protocol title are displayed in these columns.
- C) The review type reflects where the protocol is in the review process. WIP = Work in Progress
- D) The IRB Decision is displayed here. If the protocol is under review, no decision will be displayed. Click on the paper icon to open and print the Protocol Status Memo.
- E) The IRB Status displays if a protocol is active, inactive, lapsed, closed, or pending.
- F) Click on the house icon to return to the old system. All active protocols must be converted into PAS at time of renewal or when an amendment needs to be created.

# Converting Protocols from the Old System to PAS

Active IRB protocols must be converted from the old system into PAS at the time of renewal, or if a modification to the protocol needs to be made with an amendment. Active exempt protocols will remain in the old system unless a modification to the protocol needs to be made.

Protocols that have a decision can be converted by you in PAS. Protocols that were work in progress or did not have a final IRB decision made before January 27, 2023, must be converted by the IRB Administrator. If your protocol falls into the latter category, contact the IRB Administrator at x8448 or [irb@caltech.edu](mailto:irb@caltech.edu).

## 1. Active Non-Exempt Protocol Conversions

Go to the IRB Tab or click on *IRB Protocol List* from the Quick Links section of your Dashboard.

Protocols that you created or you are on as personnel (not Closed/inactive):

Go Actions

Back to Dashboard Go To Closed/Inactive List

Link	Protocol Number	PI	Protocol Title	IRB Review Type	IRB Decision	Print Status Memo	Submission Date	Ratification Date	Expiration Date	IRB Meeting	IRB Status	Attachment	Link to Old System
	IR19-Renewal 3rd	Smith, Joseph	Cognitive challenge	PI WIP	-	-	-	-	-	-	PENDING		
	IR23-1288 Full Application	Hayashi, Megan Elizabeth	TEST	PI WIP	-	-	-	-	-	-	PENDING		
	IR23-1287 Full Application	Fisher-Adams, Grace C	Test PAS Protocol	Admin Review	Returned	-	-	-	-	-	PENDING		
	IR22-Amendment 2nd	Doe, Jane	Electromagnetic Perception and Brain Processing	IRB Decision Made	Chair/Admin Review	Approved	23-SEP-22	11-NOV-22	-	2022 November	ACTIVE		
	IR21-0363 Amendment 2nd	Bee, L.R.	Exploratory investigations	IRB Decision Made	Chair/Admin Review	Approved	23-SEP-22	11-NOV-22	21-JUL-23	2022 November	ACTIVE		
	IR21-Amendment 3rd	Tech, Cal	Investigation of Novel Interfaces	Pending IRB Update	Full Committee Review	Pending Subcommittee	04-OCT-22	-	-	2022 November	Pending		

B

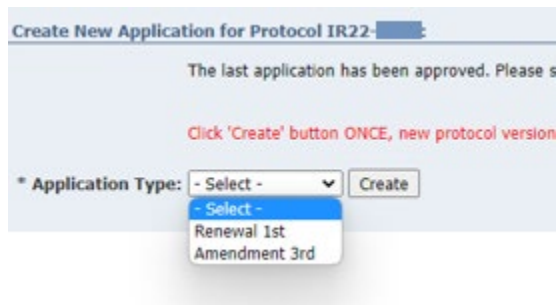
- The pencil icon identifies protocols that have already been converted into PAS or newly created protocols in PAS.
- The house icon identifies protocols that have not been converted into PAS. Protocols that have not been converted from the old system can be converted by clicking the house icon and following the instructions below.
- Protocol histories and past approvals are accessible via the house icon that links back to the old system.

### How to convert your protocol into PAS:

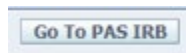
- Click on the house icon in the first column of your protocol list, which will take you back to the old system.
- From the next screen, click on the *Protocol History* button on the right or from the list on the top left.

The screenshot shows the 'Protocol Application' page. At the top, there are tabs for 'Protocols', 'IRB Meetings', and 'Setup'. Below that, there are links for 'Protocol List', 'Protocol History', and 'Protocol Application'. The 'Protocol History' link is highlighted with a red box and an arrow. On the left side, there is a 'Section Links' menu with a red box around the 'Protocol History' link. The main content area shows details for a protocol titled 'test' with protocol number 'IR15-0507'. It indicates the status is 'Work in progress' and the application type is 'Amendment 1st'. A red arrow points to the 'Protocol History' button in the top right corner of the main content area.

- From the *Protocol History* page, locate the *Create New Application* section at the bottom on the page. Select the type of application you need to create (Renewal or Amendment) and click *Create*. Only click *Create* ONCE. A new screen will not appear, so do not worry when nothing happens.



D. After clicking *Create*, click on the *Go To PAS IRB* button at the top right of the page.



- E. You will return to your list of protocols in PAS. The first column icon will now be a pencil, and not a house for the protocol that you converted. Click on the pencil icon to open your converted protocol.
- F. Previous amendments and renewals (including their respective approval memos and attachments), of converted protocols are always accessible in the old system. To return to the old system, click on the house icon in the far-right *Link to Old System* column of the converted protocol.

## 2. Active Exempt Protocol Conversions

Active Exempt protocols should remain in the old system unless modifications to the protocol need to be made. If modifications need to be made, contact the IRB Administrator at x8448 or [irb@caltech.edu](mailto:irb@caltech.edu). The IRB Administrator must convert the protocol into PAS for you. The converted protocol can then be cloned, with the modifications made to the cloned protocol.

After converting your protocol in PAS, you must validate that all converted data is accurate. PAS introduces new protocol sections and asks new questions, along with consolidating other sections. Investigators must carefully review each section to ensure data was properly converted. If you have any questions about the conversion process and/or any of the new protocol features, contact the IRB Administrator at x8448 or [irb@caltech.edu](mailto:irb@caltech.edu).

# Protocol History Overview

Dashboard **IRB** IRI

## Action Links









- Go to Protocol List
- Go to Protocol History
- Go to IRB Review
- Print Protocol (Chrome)
- Print Informed Consent
- Print Status Memo

The *Protocol History* is accessible from the *Action Links* section of the selected protocol. After clicking on *Go to Protocol History*, you will be taken to the list of all applications that correspond with the selected protocol.

Dashboard **IRB** IRB Meetings Admin

### Protocol History for Protocol IR23-1310

Q [v] Go Actions [v] Back To Protocol List

Link	Protocol	PI Name	Status	IRB Review Type	IRB Decision	Expiration Date	IRB Status	IRB Meeting	Other IRB Expiration Date	Print Status Memo	Attachments	Copy to Create New Protocol
	IR23-1310 Amendment 1st	Hayashi, Megan Elizabeth	Decision Made	Expedited Review	Expedited Approved	02-JAN-24	ACTIVE	2022 November	-			
	IR23-1310 Full Application	Hayashi, Megan Elizabeth	Decision Made	Full Committee Review	Approved	02-JAN-24	INACTIVE	2023 January	-			

1 - 2 of 2

**B C D E**

### Create New Application for Protocol IR23-1310





The last application has been approved. Please select an application type from the list to create a new application for this protocol. Protocol information will be carried over from the last 'Approved' application.

\* Application Type: - Select -

**Create**

- Select
- Renewal 1st
- Amendment 2nd

**F**

- A. Clicking the pencil icon  will open the protocol application.
- B. The *Other IRB Expiration Date* column applies only to applications that are relying on or include another institution's IRB review and approval. If the date is in red, an updated approval document from the institution must be provided (see [page 33](#) for more information on adding attachments).
- C. Click on the *Print Status Memo* icon  to download a pdf of the Status Memo.
- D. Click on the paperclip icon  to open the list of attachments for the selected application.
- E. If you would like to create a protocol that is similar to a protocol that you have already submitted, you can choose to copy an existing application to create a new protocol. Clicking the copy paper icon  will bring up the below pop-up window. Choose the type of new protocol that you would like to create.

### Create New Protocol from IR23-1310:Amendment 1st

Please choose the new protocol type to create.

New Protocol Type:  Full Application  Initial Query

- F. Amendments and renewals are created from the *Protocol History* section. (See pages [45](#) & [47](#) for additional information on creating a renewal or amendment application.)



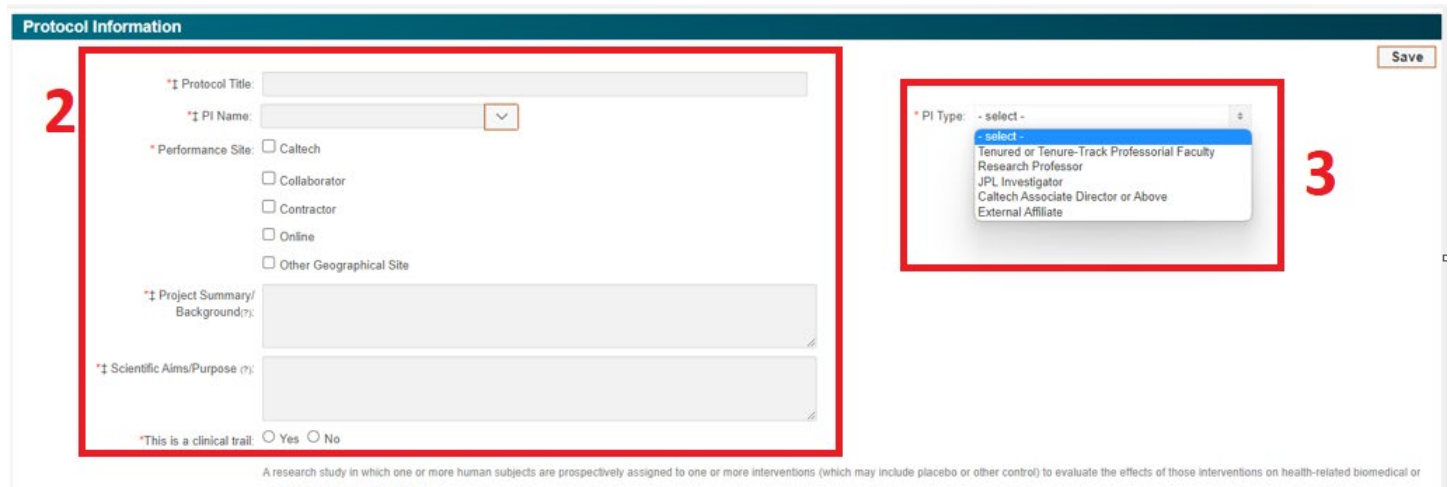
# Creating a New Protocol

## A. Starting a new Full Application or Initial Query / Protocol Information

Every protocol starts with the submission of an Initial Query or Full Application. To create a new protocol:



1. Select the application type and click *Create New Application*. Alternatively, a current protocol can be cloned to create a copy of any application (see *Protocol History Overview* on [page 13](#)). A new application will open.



2. Answer all open fields.  
Enter the Principal Investigator's name and type enter. You can search by the PI's first or last name.  
Fields with a red asterisk \* are mandatory fields.  
Fields with † will be included in the Informed Consent document.
3. The PI must be one of the options found in the dropdown list. The PI is the only person on the protocol who can certify and submit the application.

Click *Save* to create the new protocol application and be assigned a protocol number.

The screenshot displays the protocol application interface. On the left, there are two vertical menus: 'Action Links' (labeled 6) and 'Section Links' (labeled 7). The 'Section Links' menu includes items like 'PROTOCOL INFO', 'Caltech and Partner Orgs', 'Personnel', 'Funding', 'Samples and Data', 'Devices', 'Subject Selection Criteria', 'Subject Participation', 'Risks and Benefits', 'Incidental Findings', 'Subject Recruitment and Incentives', 'Informed Consent', and 'Certification and Competing Interests'. The 'Project Header' section (labeled 4) shows 'Protocol Title: Test PAS Protocol', 'Protocol Number: IR23-1287', 'Status: PI Work in Progress', 'Application Type: Full Application', 'IRB Decision: PENDING', and 'IRB status: PENDING'. A red box highlights the 'Project Header' information (labeled 5) and a message: 'You need to complete all the sections on the left before submitting this application.' The 'Protocol Information' section shows 'Protocol Title: Test PAS Protocol', 'PI Name: Fisher-Adams, Grace C', 'Division: PROV', 'Phone: 626-395-2907', 'PI Type: Caltech Associate Director or Above', 'Mail Code: MC02-31', and 'Email: gracefa@caltech.edu'. It also includes checkboxes for 'Performance Site' (Caltech, Collaborator, Contractor, Online, Other Geographical Site) and a 'Project Summary/Background' field.

4. Once the protocol application is created, you are assigned a protocol number.
5. The *Project Header* includes the protocol status, IRB review decisions, and protocol expiration date.
6. The *Action Links* allow you to navigate quickly throughout the protocol.
  - Go to Protocol List* will send you back to your complete list of protocols.
  - Go to Protocol History* will send you to a full list of protocol applications associated with this protocol (e.g., renewals, amendments).
  - Print Protocol (Chrome)* will allow you to print and/or save the protocol. Once the protocol is submitted, additional options to print the Informed Consent, GDPR and PIPL consents, and status memos will appear here.
  - Go to IRB Review* will send you to the protocol review page for this application (seen only after submission).
7. The *Section Links* allow you to navigate quickly throughout the protocol. CAPITAL LETTERS indicate the section you are currently viewing. When first creating a protocol, navigate through the application sections from top to bottom, as the sections feed from the top down. Red flags identify sections that require attention. An application cannot be submitted if any red flags are present.

The screenshot shows the 'Additional Materials & Communications' section. It features a header 'Additional Materials & Communications' and a sub-header 'Check the box to show the information:'. Below this, there are two checkboxes: 'Attachments (0/0)' (labeled 8) and 'Communications (0/0)'. To the right, there is a button labeled 'Attachments ...'.

8. The *Additional Materials & Communications* section appears at the bottom of every page. The *Attachments* button allows you to attach documents to your protocol. (See [page 39](#) for information on adding attachments.)

## Additional Materials & Communications

Check the box to show the information:

Attachments (0/0)

9

Communications (1/1)

Communications ...

9. The *Communications* button accesses the communication between investigators and the IRB. IRB review comments are displayed here, and your response comments are entered here as well. (See [page 46](#) for information on protocol review.)

## B. Query Exemptions (for Initial Queries Only)

An Initial Query application is a shortened, partial application that may be used to determine if a research study qualifies as exempt research. An Initial Query should be created if a PI believes their research qualifies as exempt or if they are unsure if their project qualifies as human subjects research.

### 1) Sponsor Request for Early Determination:

Yes  No Has a funding agency requested a memo or notification of "Delayed Onset of Research" or a "118 Determination Memo"?

- 1) If you have a Just in Time (JIT) request or other request from a research sponsor for human subjects research and you do not yet have an IRB protocol prepared and the work need not start at the inception of the award, you may request a memo, pursuant to 45 CFR 46.118 (118 Memo), which you can send to your sponsor. See IRB [SOP 9: 118 Memo](#) for additional guidance.

### 2) Use of Caltech Data:

Yes  No Does your study intend to use Caltech student, faculty or staff data that has been acquired by Caltech for business or academic purposes? If Yes, please answer additional questions in "Request to Use Caltech Community Member Data (Institutional Data)" region below.

- 2) If your study includes the use of Caltech Institutional Data, additional approvals outside of the IRB must be obtained. Institutional Data includes data generated by Caltech through the course of its business or teaching, including de-identified data. If you choose *Yes*, additional information will be requested regarding the type of data you wish to obtain. See IRB [SOP 7: Institutional Data](#) for additional guidance.

### 3) Human Subjects Research:

- Yes  No Will you obtain, use, study or analyze data or information about or biospecimens from living individual(s)?
- Yes  No Will you use the data, information, and/or biospecimens in research, (including research development, testing and evaluation), and publish those results? (Answer NO if, you are going to collect the data, information or biospecimens to generate an internal Caltech report that will not be released publicly/outside of Caltech)
- Yes  No Does your research use, study, analyze or generate information about individuals where the identity of the subject is or may be readily ascertained by you or where the identity is associated with the information when you receive it?
- Yes  No Does your research use, study, analyze or generate information about individuals that, if disclosed, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation?
- Yes  No Does your study involve minor persons (less than 18 years of age)?
- Yes  No Does your study involve Caltech students, staff or faculty?
- Yes  No Does this study involve deception?

- 3) Answer all questions in the Human Subjects Research section.

### 4) Reliance:

- Yes  No Would you like to rely upon another institution's IRB to be the IRB of record for this study?
- Yes  No Will the data collection for this study take place entirely at the other institution?

- 4) If you would like to rely upon another institution's IRB to be the IRB of record, additional paperwork will be required. Please contact the IRB Administrator at x8448 or [irb@caltech.edu](mailto:irb@caltech.edu).

5) Will you be recruiting, or collecting data from, participants who are, or may be, in the European Economic Area?

Yes  No Please answer additional questions in GDPR section below if Yes.

6) Will you be recruiting, or collecting data from, participants who are, or may be, in China?

Yes  No Please answer additional questions in PIPL section below if Yes.

5) If you will recruit, or collect data from, participants who are, or may be in the European Economic Area or China, additional GDPR or PIPL questions must be answered. A separate GDPR or PIPL notice and consent form must be signed by these participants. See IRB [SOP 5: GDPR/PIPL](#) for additional guidance.

7) Will participants be required to complete survey, test, or questionnaire?

Yes  No If yes, please attach copies of your survey or test questions.

8) Will you be recruiting participants via advertising?

Yes  No If yes, please attach copies of your recruitment materials, text, bulletins, etc.

6) Answer questions 7 & 8. Attach any relevant copies of surveys, tests, questionnaires, and recruitment materials. See IRB [SOP 4: Study Participant Recruitment Materials](#) for additional guidance.

9) Do you believe that this project should be exempt from IRB review?

Yes  No Please identify the exemption(s) from the regulations [45 CFR 46.104 ] that you believe to be applicable to this study.

7) If you believe your study to be exempt from IRB review, you will be asked to identify the exemption that you believe to be applicable to your study. Choose the exemption category and answer the questions, including your justification for choosing that exemption.

## C. Caltech and Partner Orgs

**Collaboration Description**

\*† Please describe any collaborative work, or by contractors or vendors who are performing work or providing samples and how research data/biospecimens will be shared.

**1**

Save the above changed data before working on the next section.

**Save Collaboration**

**Organizations**

**2**

[Add Organization](#)

Update	Remove	Name	PI	Sample List	Location	IRB of Record	Is this Institution's IRB Approval required before Caltech can proceed with its human subjects research?	Ptnr IRB Appr Date	Ptnr IRB Exp Date	Country	Line Num
<input type="checkbox"/>	<input type="checkbox"/>	CALTECH	Fisher-Adams, Grace C		Domestic					United States	1

1 - 1

**Organization Role with Samples**

Go to [Samples and Data](#) section to modify this matrix.

**3**

1. Describe the details of your collaboration, as appropriate. Include details about what each partner organization will do, how they will interact with participants and how they will interact with Caltech and any other collaborators. Include how the data or biospecimens collected for the study will be shared with all collaborators. Click *Save Collaboration* before moving on to the *Organizations* section.

2. Click on *Add Organization* to add all partner organizations. A pop-up box will open. Answer the questions and click *Create*. If your partner organization is not included on the drop-down list, click the box *Org not on the above list* and type in the name of your new organization. The IRB Administrator

will receive an alert and will update the Partner Organization list. The organization will automatically update your protocol once the partner organization is approved.

**Partner Org Details** Back Create

\* - required field; † - Info used in Informed Consent Form

\* Partner Organization:

Org not on the above list (check the box and enter new org below for Admin to review and setup)

\* Location:

\* Country:

\* IRB Of Record:

\* Will human subjects research be performed here?  Yes  No

\* Is this Institution's IRB Approval required before Caltech can proceed with its human subjects research?  Yes  No

Partner IRB Approval Date (DD-MON-YY):

Partner IRB Expiration Date

Caltech will automatically appear in the *Organizations* table. You must open the Caltech line to answer the second question.

**Partner Org Details** Back Update

\* - required field; † - Info used in Informed Consent Form

\* Partner Organization: CALTECH

\* IRB Of Record:

\* Will human subjects research be performed here?  Yes  No

The question *Will human subjects research be performed here?* is asking if the organization will participate in human subjects research.

Examples:

Caltech or a partner organization is performing online surveys. Even though participants will not physically be on site, the organizations are still performing human subjects research, so the answer is YES.

If a vendor is supplying deidentified urine samples for a study, the answer is NO.

- The *Organization Role with Samples* will display a read-only matrix of the data and biospecimens collected for this study. The matrix will populate here once you complete the *Samples and Data* section of the protocol.

## C. Personnel

**Personnel** Add New

Each protocol must have one PI who is default to be communication contact. And at least one person is selected as communication contact.

Update	Remove	Name	Organization	Role	Minor	Comm Contact	MD	Foreign	Job Title	Completed Training	Missed Training	Admin Approved	Start Date	End Date	AOA Change Note	Line Num
<input checked="" type="checkbox"/>	X	Fisher-Adams, Grace C	CALTECH	PI - Caltech Associate Director or Above	-	Y	-	-	General Administration Mgmt	-	-	-	-	-	-	1

- The PI will automatically be entered from the data used to create the protocol. Click the checkmark icon to open the detail of the line.

2. Click the *Add New* button to add new personnel to the protocol. Answer the questions and click *Create*.

### Person Roles:

Investigator/Admin Contact = An investigator that will also be the Administrative Contact for the protocol

Lead Investigator = The non-PI lead investigator (protocols are not required to identify a lead)

Partner Org PI = The PI of any partner organization

Investigator = All investigators on the protocol that are not the PI, Lead Investigator, Partner Org PI, or Administrative Contact

Administrative Contact = This contact is strictly administrative and does not recruit, consent, or perform work with participants. This person typically manages the protocols and is the point person for communication with the IRB. Administrative contacts have no training requirements.

Receive Communication: If checked, this person will receive all system-generated communications. The PI will always have this checked.

Individual is under 18 years of age: Check this is you will have minor researchers working on your protocol. See IRB [SOP 17: Minors Working with the IRB](#) for additional guidance.

Training certificates no longer need to be attached for Caltech personnel. Training completion will be uploaded into PAS by the IRB Administrator on a weekly basis. An Investigator's missing training will be displayed in the *Missed Training* column of the Personnel table.

Training certificates must be attached for all non-Caltech personnel.

See the [IRB website](#) for additional information regarding training requirements.

## D. Funding

Click the *Add Funding* button to open the Funding Detail page. Answer the questions and click *Create*.

## Funding Detail

Back Create

It is imperative that you indicate Department of Defense (DARPA, Army, Navy, Air Force, etc.) funding by checking the DOD Award checkbox, if used.

\* - required field; ⓘ - Info used in Informed Consent Form

### Funding Information

\* Caltech Role in this Funding:  Primary Awardee  Sub-Awardee (receive funds from prime awardee partner org - enter info below)

\* Funding Category:  Caltech PTA Award  Non PTA Award  Pending Funding

The correct award number you enter may not include your PI's name. In these cases, it will often be a Division Chair, Provost, or Vice Provost.

\* PTA Award Number:

Funding Agency Name:

Funding Source Award Number:

Award Title:

Funding Start Date:

End Date:

\* Funding Agency Type:  DOD  PHS/NIH  NSF  NASA  Non-Federal

\* Are any Partner Orgs being paid from this Caltech Award?  Yes (Fill in Procurement Contact and Partner Org)  No

**PTA Award Number:** PAS is connected to the grants database. Search for your award by typing the **award** number of the PTA (Project-Task-**Award**) into the text line. The Funding Agency Name, Award Title, Start and End Dates will automatically populate.

Example: PTA = HSS.PROTOCOL-IRB-**NIHP.123456** (Project = HSS.PROTOCOL, Task = IRB, **Award = NIHP.123456**)

When Caltech is the Prime Awardee with sub-award recipients, additional questions regarding the Sub-awardee will open and must be answered.

\* Are any Partner Orgs being paid from this Caltech Award?  Yes (Fill in Procurement Contact and Partner Org)  No

\* Caltech Procurement Contact:

\* Partner Orgs (Options on the left, move the selected to the right):

University of California, Los Angeles (UCLA)

**Caltech Procurement Contact:** Include the Caltech Procurement personnel who is working with you on this subaward.  
**Partner Orgs Receiving/Sending Funds From/To This Award:** Highlight the partner organizations that are receiving funds from this award in the left column and shuttle them to the right column.  
**Partner Org Sub-Award Info:** Enter the Caltech Sub-Award Number and click *Update*. This number typically begins with an S followed by 6 numbers. Example: S123456

### Partner Org Sub-Award Info

Partner Org: University of California, Los Angeles (UCLA)

Caltech Sub-Award Number:

Line Num: 1

Back Update

When Caltech is a Sub-Awardee, additional questions regarding the Prime Awardee will open and must be answered.

### Prime Awardee Partner Org

Prime Awardee Partner Org:

Prime Sponsor:

Prime Award Number:

## E. Samples and Data

**Data and Specimen Sharing/Collaboration**

Here is the description of your collaboration:  
 Collaboration details. **1**

Please include all data sources and specimens/biospecimens you will gather for your research. **2**

**Data/Biospecimen List**

**3**

Update	Dup	Remove	Sample Name	Long Term Storage Desc	Genomic Data	Future Use	Data Identifiable?	Demographic Info Associated	Line Num
<input checked="" type="checkbox"/>			Survey or Questionnaire Data	Surveys will be electronically stored on the PIs secure server.	No	No	Coded	Yes	1

**Add Data/Biospecimen** **2**

1. The information entered under the *Collaboration* question in the *Protocol Information* section will automatically display here. This text will be read-only and editable from the *Protocol Information* section. Ensure that the collaboration text corresponds correctly with the data and biospecimens that you enter in this section.
2. Click the *Add Data/Biospecimen* button to add the data and/or biospecimens that you will collect for this study. Answer the questions on the *Sample Details* page.

Select the type of biospecimen or data you plan to collect from the drop-down list.

\* These Data/Biospecimens will be:  Anonymous  Deidentified  Coded  Identifiable

See [SOP 13](#) for guidance on how to properly classify the identifiability of your research data.

Refer to IRB [SOP 13: Anonymous, De-identified & Coded Data](#) to determine the identifiability of your data/biospecimens.

\* Organizations Involved in Recruiting (Options on the left, move the selected to the right):

University of California, Los Angeles (UCLA)  CALTECH

\* Organizations Involved in Consenting:

University of California, Los Angeles (UCLA)  CALTECH

\* Organizations Involved in Collecting:

University of California, Los Angeles (UCLA)  CALTECH

(WHEN CALTECH SELECTED TO COLLECT)  Yes  No  
 Will data/biospecimens be shared with a Collaborator?

\* Will there be a Data Transfer Use Agreement or Materials Transfer Agreement for these data/biospecimens?  Yes (Please attach a copy of the DTUA or MTA)  No (Please contact OTTC to ensure an agreement is not required.)

\* Organizations Involved in Receiving:

CALTECH  University of California, Los Angeles (UCLA)



The questions with corresponding shuttle boxes identify which organization(s) are responsible for recruiting and consenting participants, and collecting, receiving, analyzing, and storing the data or biospecimens for your study. Highlight the appropriate organization(s) in the left column and shuttle them to the right column using the arrow buttons, or by double-clicking on the organization.

After entering a biospecimen or data line, a table will be created with your data.

- Click on the check icon in the *Update* column to open and edit a specific line of the table.

### Data/Biospecimen List

A	B	C	Sample Name	Long Term Storage Des
Update ✓	Dup 📄	Remove ✕	Blood	Blood samples will be store
Update ✓	Dup 📄	Remove ✕	Survey or Questionnaire Data	Surveys will be electrical PIs secure server.

- A blue check mark indicates that the required items in a particular line are complete. A red flag indicates something is required in that line. Clicking on the blue check mark or red flag will open the detail of that line.
- Clicking on the *Dup* column icon will create a cloned duplicate copy of that line. You must make a change to the cloned duplicate line to clear its red flag.
- Clicking the X in the *Remove* column will delete the line.

Organization Responsibility for Data and Biospecimens								
Organization	Data/ Biospecimen	* Role	Recruiting	Consenting	Collecting	Receiving	Analyzing	Storing
CALTECH	Blood	<input checked="" type="radio"/> Collaborator <input type="radio"/> Source <input type="radio"/> Vendor	✓	✓	✓	✓	✓	✓
CALTECH	Survey or Questionnaire Data	<input checked="" type="radio"/> Collaborator <input type="radio"/> Source <input type="radio"/> Vendor	✓	✓	✓	✓	✓	✓
University of California, Los Angeles (UCLA)	Blood	<input checked="" type="radio"/> Collaborator <input type="radio"/> Source <input type="radio"/> Vendor	✓	☐	☐	☐	✓	☐
University of California, Los Angeles (UCLA)	Survey or Questionnaire Data	<input checked="" type="radio"/> Collaborator <input type="radio"/> Source <input type="radio"/> Vendor	✓	✓	✓	✓	✓	✓

The answers to the shuttle box questions will populate the *Organization Responsibility for Data and Biospecimens* matrix. Choose the role that each institution plays for each data/biospecimen.

Collaborator: Receives data/biospecimens (also choose if the organization is the source and receives)

Source: Collects and provides the data/biospecimens

Vendor: A commercial company who provides the data/biospecimens

You can update the responsibility checkboxes from the matrix. Updates made here will automatically update the associated data/biospecimen's line from the table above. Click *Save* often to avoid data loss.

† How will participant data/biospecimens be stored and what measures will be used to protect participant confidentiality and privacy during the study?

Participant Data/Biospecimens will be stored securely [in/how] at [insert Institution(s)]. The following measures will be used to protect participant confidentiality and privacy during the study: [insert explanation, e.g., all data will be coded and deidentified prior to publication].



286 of 4000

† After the study is complete, will the data/biospecimens be destroyed or will they be stored? If the data/biospecimens will be stored, include the storage timeframe (e.g., indefinitely, one year following the end of the study) and the measures that will be used to protect participant confidentiality and privacy.

After the study, participant Data/Biospecimens will be stored securely [in/how] at [insert Institution(s)]. The following measures will be used to protect participant confidentiality and privacy during the study: [insert explanation].



234 of 1000



Save

Two questions about privacy measures and what will happen to the data/biospecimens after the study is complete will follow the matrix. Update the provided template text and click *Save*.

† Describe how the data/biospecimens that will be used for future studies will be stored, including the measures used to ensure participant confidentiality.

Participant Data/Biospecimens used for future studies will be stored securely [in/how] at [insert Institution(s)]. The following measures will be used to protect participant confidentiality and privacy during the study: [insert explanation].

241 of 4000

† Future Use Storage Type:

Kept indefinitely  Stored for specific timeframe

† Please provide the timeframe that the data/biospecimens will be kept:

If any data/biospecimens will be stored and used in future studies, two additional questions regarding privacy measures and storage type must be answered. Update the provided template language, include the timeframe as appropriate, and click *Save*.

## F. Devices

Device List

Add Device



If your study involves any devices, they must be entered into this section. Click the *Add Device* button and complete the questions.

\* Device Type:  Commercial  Experimental

Choose the type of device that you will use in your study: Commercial or Experimental

\* Device Type:  Commercial  Experimental

\* Commercial Device: - select -

- select -
- Electrocardiogram (ECG or EKG)
- Electroencephalogram (EEG)
- Eye Tracker
- Hear Rate Monitor
- MRI
- Pulso Oximeter
- Sphygmomanometer (blood pressure cuff)
- Spirometer
- Stationary Bicycle
- Ultrasound

\* Describe the Device:

Participant interact with the device?

If the device is Commercial, choose the device type from the drop-down list. If your commercial device is not included on this list, email the IRB Administrator at [irb@caltech.edu](mailto:irb@caltech.edu) and they will add your device to the list, as appropriate.

When some commercial devices are chosen (e.g., MRI), template text will populate for the *Describe the Device*, *What the participant needs to do*, and *Describe the risks associated with using this device* questions. There is no need to provide anything further in these sections unless you are modifying language. If you wish to modify any IRB provided language, check the box so the IRB is notified.

**Modify IRB provided language**

If the device is Experimental, you will be asked to provide the name of the experimental device.

\* Device Type:  Commercial  Experimental

\* Experimental Device Name:

After describing the device, the risks and how it will be used in the study, there will be a series of FDA-related questions that will help you to determine if the device is not subject to FDA regulations, if the device is exempt from FDA regulations, or if an Investigational Device Exemption (IDE) application to the FDA is required.

Please refer to IRB SOP 19: Investigational Devices for additional guidance.

Example 1: The study is not subject to FDA Regulations

\* Is the device the object of the study in people?  Yes  No

The study is NOT subject to FDA Regulations. The device is used as a tool and not the focus of the study.

#### Example 2: The study is Exempt from IDE Regulations

\* Is the device the object of the study in people?  Yes  No

\* Is the device approved by the FDA for the purpose used in this study?  Yes  No

\* Is this device being modified in any way to improve efficacy?  Yes  No

Study EXEMPT from IDE Regulations.

#### Example 3: The study is NOT Exempt from FDA Regulations

\* Is the device the object of the study in people?  Yes  No

\* Is the device approved by the FDA for the purpose used in this study?  Yes  No

\* Is this device being modified in any way to improve efficacy?  Yes  No

\* Describe the modification:

\* Is the device a diagnostic device?  Yes  No

Study NOT EXEMPT from FDA Regulations. This study will require an Investigational Device Exemption (IDE) application to the FDA.

If a study is determined to be not exempt from FDA Regulations, the FDA device risk level must be determined as a significant risk device or a non-significant risk device. A significant risk device presents a potential for serious risk to the health, safety, or welfare of a participant. The study risk determination is based on the proposed use of a device in a study, and not on the device alone.

A non-significant risk device requires an Abbreviated IDE with Caltech IRB approval.

A significant risk device requires a Full IDE with Caltech IRB **AND** FDA approval.

For additional information about significant risk determinations please see the [FDA Information Sheet Guidance for IRBs, Clinical Investigators and Sponsors – Significant Risk and Nonsignificant Risk Medical Device Studies](#).

Following the FDA questions, you will be asked to provide your risk type assessment for the device: Minimal Risk or Greater than Minimal Risk.

Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Greater than Minimal Risk: Risk is greater than those risks ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

## G. Subject Selection Criteria

Answer all questions and click *Save*.

Vulnerable Populations  **Minors**  
(Select all that apply):

Prisoners

Indigenous Persons

Medical Condition (Specify)

**Caltech Students (Not members in the PI's lab)**

Caltech Lab Members (Students, Postdocs, Staff, Faculty)

Pregnant Women

Foreign Language (Non-English Speaking)

Economically or Socially Disadvantaged

Impaired Capacity (Specify)

Caltech Staff, including Postdocs (Not members in the PI's lab)

See [SOP 12](#) for guidance on what is required in the protocol and informed consent document.

\* If Caltech Students, Staff or Lab Members are selected, describe measures implemented to protect their privacy and to ensure coercion is reduced.

\* If any checked, justification for enrolling vulnerable populations.

Justification must be included when vulnerable populations are recruited for your study.

If Caltech students, staff or lab members are recruited for your study, additional protections must be included in your protocol and Informed Consent. Unless appropriately justified and approved by the IRB, PIs should not recruit students from their classes. Language specifying this should always be included here and under the Exclusionary Criteria question. Refer to IRB [SOP 12: Students and Lab Members as Research Study Participants](#) for guidance.

If your study includes the participation of any vulnerable populations, additional CITI training courses will likely be required. Please refer to the IRB website's [training page](#) for guidance. If you have any additional questions about training, contact the IRB Administrator at [irb@caltech.edu](mailto:irb@caltech.edu).

## H. Subject Participation

In this section, the IRB asks you to describe what your participants will be asked to do, when, how often, and what they can expect to experience.

### Use Caltech Community Member Data (Institutional Data):

\* I would like to use Institutional Data from Caltech regarding (Check all that Apply):

Students (e.g. Data from Registrar, Housing, Institutional Surveys, Activity related to UID etc.) Approver: Vice President for Student Affairs (Kevin Gilmartin)

Staff (e.g. Data including Employee Records, Activity related to UID, Training, etc.) Approver: Associate VP for Human Resources Staff (e.g. Data including Employee Records, Activity related to UID, Training, etc.) Approver: Associate VP for Human Resources (Julia McCallin)

Faculty/Postdoc (e.g. Data including Faculty or Employee Records, Activity related to UID, Training, etc.) Approver: Provost Faculty/Postdoc (e.g. Data including Faculty or Employee Records, Activity related to UID, Training, etc.) Approver: Provost (David Tirrell)

\* List, name or describe the Institutional data you are requesting:

1

\* The data received from Caltech will be:

Anonymous     Deidentified     Coded/Traceable

\* Describe how the data will be stored and secured after receiving it from Caltech:

See [SOP 13 need URL](#) for guidance on how to properly classify the identifiability of your research data.

\* The data will be reported in research papers as:

Anonymous     Deidentified     Coded/Traceable     Aggregated (Not Identifiable to an Individual)

\* After use, the data will be:

Destroyed Upon Completion of the Project     Stored for Future Use

2

\* I plan to:

Obtain Informed Consent from Each Caltech Community Member     Notify the Caltech Community Members     Request a Waiver

3

If your study includes the use of Caltech Institutional Data, additional approvals outside of the IRB must be obtained. Institutional data includes data generated by Caltech through the course of its business or teaching, including de-identified data. Refer to IRB [SOP 7: Institutional Data](#) for guidance.

1. Choose the type of institutional data that you plan to collect.
2. Provide details of how the data will be stored and secured.
3. Provide how you plan to notify the Caltech community members whose data will be included in your study.

Physical Discomfort:  The subject may experience physical discomfort.

If checked, describe the physical discomfort and methodologies to alleviate the discomfort. This will be included in the ICF.

\*† Description: Physical discomfort will occur

00 of 4000

Psychological Discomfort:  The subject may experience psychological discomfort.

Most questions in this section require you to check boxes if the listed item is included in your study. For example, if there is physical discomfort, check the box and describe the physical discomfort. If there is no psychological discomfort, do not check the box.

Physical Contact:  The research requires the investigator to have physical contact with the subject. Example: Investigator

If checked, describe the nature of the physical contact and measures employed to mitigate discomfort. This will be include

\*‡ Description: Part of this study requires that the researcher have physical contact with you. The contact consists of [helping you/attaching a device/etc.] that requires the researcher to touch your [body part] [briefly/for (time)]. The contact will be [light/firm/periodically firm/light] and you [will/will not] be restrained [if will: for x minutes] during the study. The researcher will inform you of what will happen throughout this interactive time. At any time during the study, you have the right not to be touched if you say you don't want to be touched anymore. If the physical contact is necessary for the study (for example, a device must be attached to your body), you can withdraw from the study at any time.

Template language is provided for some questions, such as for Physical Contact. Update the template language with your study specific details. See IRB [SOP 6: Physical Contact with Study Participants](#) for guidance.

Fasting:  This study requires participants to fast (abstain or limit food intake) for any length of time before and/or during the research.

If checked, see [SOP 3](#) for required elements in protocol and informed consent document.

\*‡ Description:

Fasting begins prior to providing informed consent.

\* Fasting Consent Method:  By email  Over the phone

If fasting prior to consent, general consent must be given. See policy and [SOP 3](#).

If fasting is included in your study, you will be asked to provide additional details including if participants will be asked to fast prior to providing informed consent. See IRB [SOP 3: Fasting in Human Subjects Research](#) for guidance on studies that include fasting.

Consume Food and/or Beverage:  Participants will consume food and/or beverage as part of the research

If checked, describe the foods and safeguards in place for participants with allergies. This will be included in the ICF.

\*‡ Allergy Concerns:

\*‡ Sanitation Procedures:

If the consumption of food and/or beverages are included in your study, you will be asked to provide additional details regarding how you will handle allergy concerns and how you will properly sanitize your study space.

Use of Deception or Incomplete Disclosure:  The research involves the use of deception or incomplete disclosure. Deception is when a researcher gives false information to participants or intentionally misleads them about some key aspect of the research. Incomplete Disclosure is a type of deception that involves withholding some information about the real purpose of the study, or the nature of the research procedures

\* Justification for Deception or Incomplete Disclosure:

If you plan to use deception or incomplete disclosure, it is very important that you provide detailed justification.

# I. Risks and Benefits

The *Risks and Benefits* section displays two tables: *Risks & Discomforts Associated with Devices* and *Risks & Discomforts Associated with Activities*. These tables contain the risk text that was already entered into the *Devices* and *Subject Participation* sections and are read-only.

Risks & Discomforts Associated with Devices		
The following have been identified as risks associated with this research from your application and will be included in your informed consent. There may be additional risks with the research.		
Device	Risk Description	Risk Classification (if Any)
MRI	MRI poses life-threatening physical risks if you have objects in or attached to your body that are metal, such as a cardiac pacemaker, metallic clips (i.e., an aneurysm clip in the brain), or metal fragments such as shrapnel, bullets, or small pieces of metal from metal working. Please tell the researcher if you have any metal items in your body. You may also be unable to be in the MRI if you have metal-containing tattoos on your skin, since these can heat up, or if you wear metal braces that cannot be removed. You will be asked to fill out an additional safety questionnaire and answer questions to one of the MRI staff before your MRI session. You will also be required to walk through a metal detector before going into the scanner (like at the airport). As a general rule, all metallic objects must be removed before entering the magnet room. This includes keys, jewelry, pocketknives, money clips, paper clips, safety pins, hairpins, and barrettes. In addition, objects such as watches, credit cards, and hearing aids could be damaged in the presence of the magnetic field. A locker will be provided for you to secure all your items and valuables. If you are pregnant, or are trying to get pregnant, the effects of the scan on a fetus are not well studied and you will not be able to participate in any MRI studies. If all metallic objects have been removed from your body, there are no known significant physical risks with MRI. There is no known risk associated with the time spent in an MRI scanner for healthy participants. MRI scanning is painless but you may feel some discomfort during the scan. Some people experience claustrophobia when placed inside the scanner, discomfort from the loud hammering and beeping noises, or mild nerve stimulation or twitching in your extremities (hand, feet). If you feel heating when other monitoring equipment is used inside the scanner, please report this and the scan will be stopped. You may also discontinue the scan at any time, for any reason, by pushing a button while you are in the scanner. The MRI machine at Caltech may be used by other universities or by industry. It is cleaned between uses.	Minimal Risk

Risks & Discomforts Associated with Participant Activities	
The following have been identified as risks associated with this research from your application and will be included in your informed consent. There may be additional risks with the research.	
Activity	Risk Description
Physical Discomfort	Physical discomfort will occur.
Psychological Discomfort	Psychological discomfort will occur.
Physical Contact	Part of this study requires that the researcher have physical contact with you. The contact consists of [helping you/attaching a device/etc.] that requires the researcher to touch your [body part] [briefly/for (time)]. The contact will be [light/firm/periodically firm/light] and you [will/will not] be restrained [if will: for x minutes] during the study. The researcher will inform you of what will happen throughout this interactive time. At any time during the study, you have the right not to be touched if you say you don't want to be touched anymore. If the physical contact is necessary for the study (for example, a device must be attached to your body), you can withdraw from the study at any time.

Below the read-only tables, are additional questions that must be answered about the risks and benefits of your study.

For the following, consider the risk for the overall project:

1. Risk Type:  Check one of the following based upon the definition of Minimal Risk: Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.  Minimal Risk  Greater than Minimal Risk

2. Describe any additional risks associated with the combination of devices and/or activities (if any): None

3. Overall, describe how you are going to mitigate risk: We will mitigate all risks by doing a, b, and c.

4. Justification for risk: Explain how these risks compare to what is commonly encountered in everyday life, how the risks have been minimized, and why the residual risks are outweighed by the scientific and societal benefits of the study. The risks of this study are of no greater risk than compared to what is commonly encountered in everyday life.

- Choose the risk type of your study, either Minimal Risk or Greater Than Minimal Risk. Minimal Risk = the probability and magnitude of harm or discomfort anticipated in the research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. The IRB may determine that the risk type you choose is incorrect and will update the risk type following review of your study.
- The description of device and activity list are already included in the tables above. This question asks if there are any additional risks with the combination of devices and/or activities. For example, if a participant is playing video games while in the MRI scanner, is there any additional risk with the combination of these two things?



3. Describe how the risks are minimized if they can be.
4. Explain how these risks compare to what is commonly encountered in everyday life and why the residual risks are outweighed by the scientific and societal benefits.

Complete the remaining questions regarding benefits, alternatives, and withdrawal procedures, and click the *Save* button.

## J. Incidental Findings

An Incidental Finding (IF) is a physiological or psychological finding of clinical significance which is analytically valid and reveals a well-recognized risk of a health condition. See IRB [SOP 8: Incidental Findings](#) for guidance.

To add an IF to your study, click the *Add New* button. You will be asked to provide the source of the IF and a description. You will also be asked to determine if the IF is serious or non-serious and actionable or non-actionable.

The Incidental Finding is (\* Select one):

- (2a) A Serious IF (including fMRI) Findings likely to result in death or grave harm (e.g., aneurism, heart arrhythmia, HD gene).  
 (2b) A Non-Serious IF Findings unlikely to result in possible death or grave harm (e.g., gene related to lactose intolerance, polyp) and

AND (\* Select one):

- (2c) An Actionable IF (including fMRI) Findings related to a disease/condition for which there is a potential treatment or prevention (e.g., cancerous tumor, breast cancer gene).  
 (2d) A Non-Actionable IF Findings related to a disease/condition that cannot be treated or prevented (e.g., HD gene).

Serious (2a) and Actionable (2c) IFs MUST be reported to participants. Provide the description of your process for reporting an IF to the participant and provide the language explaining the IF and your process that will be included in the Informed Consent. The IRB prefers that a licensed professional or clinician of a relevant specialty should disclose these types of IFs to participants. In the absence of a lab's ability to identify a licensed professional or clinician, an investigator with the expertise (e.g., a post-doc that also has an MD) and training to disclose IFs to participants should be identified in the protocol and may be approved by the IRB to deliver IFs.

The Incidental Finding is (\* Select one):

- (2a) A Serious IF (including fMRI) Findings likely to result in death or grave harm (e.g., aneurism, heart)  
 (2b) A Non-Serious IF Findings unlikely to result in possible death or grave harm (e.g., gene related to lactose

AND (\* Select one):

- (2c) An Actionable IF (including fMRI) Findings related to a disease/condition for which there is a pote  
 (2d) A Non-Actionable IF Findings related to a disease/condition that cannot be treated or prevented (e.g., HD

**Because your IF is serious and actionable, the IRB will require you to report in**

\* Please provide a description of your process for reporting an IF to the participant.

\* Please provide the language explaining this process and the IF to the participant.

Any other combination of serious or non-serious and actionable or non-actionable, gives you the option of how you wish to handle the IF. You can choose to report the IF, never report the IF, or allow the participant to choose whether or not they want to receive the IF information.

The Incidental Finding is (\* Select one):

(2a) A Serious IF (including fMRI) Findings likely to result in death or grave harm (e.g., aneurism, heart arrhythmia, HD gene).

(2b) A Non-Serious IF Findings unlikely to result in possible death or grave harm (e.g., gene related to lactose intolerance, polyp) and

AND (\* Select one):

(2c) An Actionable IF (including fMRI) Findings related to a disease/condition for which there is a potential treatment or prevention (e.g., cancerous tumor).

(2d) A Non-Actionable IF Findings related to a disease/condition that cannot be treated or prevented (e.g., HD gene).

**Because your IF is either not serious or non-actionable, you have the option to report any IF to the participant. (Select one.)**

Please choose one.

We will report the IF to the participant  We will never report the IF to the participant  We will allow the participant to choose whether or not to receive the IF

If you choose to report the IF to the participant, you will be asked to provide the description of your process for reporting an IF to the participant and provide the language explaining the IF and your process that will be included in the Informed Consent. Only appropriately trained personnel may disclose IFs to participants. The IRB may determine the designated personnel are not appropriately situated to disclose IFs, and in which case, will recommend alternative personnel to make such disclosure.

\* Please provide a description of your process for reporting an IF to the participant.

\*‡ Please provide the language explaining this process and the IF to the participant.

## K. Subject Recruitment and Incentives

Check off all recruitment methods and provide a brief description of how you plan to recruit participants for your study. See IRB [SOP 4: Study Participant Recruitment Materials](#) for guidance. Attach all recruitment materials to this section of the protocol.

If you are providing compensation for study participants, template text will be provided in the compensation description box. Edit this text according to the specifics of your study. IRB [SOP 16: Research Participant Compensation/Incentives](#) will provide guidance, including suggested compensation ranges.

## Compensation and Incentives

\* Participant recruitment or participation compensation and Incentives will be given:

Yes  No

\* Describe the compensation and incentives if given, or justify if not given:

Your compensation will be \$xx/hour. Extra rewards in increments of \$xx/hour will be given for the successful completion of xx tasks. You will be compensated by [cash, check, gift card, other] which will be provided to you [immediately, in about a month, other] after your participation.



286 of 4000

Hourly Rate Payments for Participation

Extra Rewards (Earning extra rewards based on performance)

Generic Incentives (Reward for showing up/starting/completion etc.)

If you receive more than \$600 in one year for taking part in these research studies, Caltech must report this income to the IRS and you will receive an Internal Revenue Service (IRS) Form 1099. You are responsible for paying any tax that is due on payments you receive for such participation. You are encouraged to consult with your tax advisor to determine your tax obligations on this income whether or not you receive a 1099.

\* Reimbursement of Travel Costs (Specify which costs reimbursed)

Yes  No

See [SOP 16: Research Participant Compensation/ Incentives](#) for required elements in the protocol and informed consent document.

Make sure to click the *Save Recruitment and Incentives* button BEFORE moving further on this page.

**Save the above changed data before working on GDPR and PIPL sections.**

**Save Recruitment and Incentives**

If you will be recruiting participants from the European Economic Area or from China, you must complete the associated sections to be consistent with GDPR (EEA) and/or PIPL (China) protection requirements. See IRB [SOP 5: GDPR & PIPL](#) for guidance.

### General Data Protection Regulation (GDPR) in the European Economic Area

The General Data Protection Regulation (GDPR) may apply to users of our websites or mobile applications who are located in the European Economic Area (European Union, Iceland, Lichtenstein, and Norway). .... consistent with GDPR requirements.

The regulatory requirements for GDPR are found at [GDPR Info](#). Refer to [SOP 5: GDPR/PIPL](#) for required elements in the protocol and informed consent document. Recruiting participants in the European Economic Area (European Union, Iceland, Lichtenstein, and Norway), requires separate privacy notices depending on how data is collected: direct contact or online. These questions will help you to determine which notice is applicable to your study.

Are you recruiting, or collecting data from, subjects who are, or may be, in the European Economic Area?

Yes  No

**Complete GDPR by clicking on Edit button.**

**Edit GDPR**

### Personal Information Protection Law (PIPL) of the People's Republic of China

The Personal Information Protection Law (PIPL) may apply to users of our websites or mobile applications who are located in China. These laws set forth a framework for the processing of personal data, the cross-border transfer of personal data, and the safeguarding of personal data. These laws also afford individuals rights with respect to their personal data. Caltech is committed to take reasonably necessary steps to ensure that personal data is protected consistent with PIPL requirements.

The regulatory requirements for PIPL are found at [China Briefing](#). Refer to [SOP 5: GDPR/PIPL](#) for required elements in the protocol and informed consent document.

Recruiting participants in China require separate privacy notices depending on how the data is collected: direct contact or online. These questions will help you to determine which notice is applicable to your study.

Are you recruiting, or collecting data from, participants who are, or may be, in China?

Yes  No

**Edit PIPL**

Clicking *Yes* or *Edit GDPR/Edit PIPL* will open a new form. These questions and answers will populate the GDPR or PIPL consent form that is a requirement in addition to the study's full Informed Consent.

In the *Retention of Your Personal Data* section of the GDPR or PIPL form, you will be asked to choose which retention schedule you will follow. Choose the appropriate option and update the provided template language appropriately.

## Retention of Your Personal Data

Include the retention period (how long will you keep the data for after the end of the project). If the retention period depends on other factors, you don't have to mention an exact period of time, but you will have to mention the factors that influence the establishment of the period.

\* Choose only one of the two options.

### Option A

Edit and use this paragraph in Informed Consent

We retain your personal data for [INSERT RETENTION TIME] after the project is completed, unless required by law or to protect our legal rights.

### Option B

Edit and use this paragraph in Informed Consent

The period of time for which we retain your personal data depends on [INCLUDE THE SPECIFIC FACTORS THAT WILL INFLUENCE THIS PERIOD OF TIME (E.G., TO FULFILL THE OBJECTIVES OF THE RESEARCH; TO ENSURE THE INTEGRITY OF THE RESEARCH, TO USE FOR FUTURE RESEARCH [DESCRIBE])]. We may also keep your information for longer periods if required by law or to protect our legal rights.

**PLEASE NOTE:** If you will be recruiting participants from the European Economic Area or from China, you **MUST** have participants sign both the general Informed Consent document **AND** the GDPR or PIPL consent.

## L. Informed Consent

Many of your responses throughout the application are automatically imported into a draft of the Informed Consent (IC). The *Informed Consent* section will include several questions about the consent process.

To generate a draft Informed Consent document, the system will automatically use your application responses to generate an Informed Consent draft document. If this is an amendment or renewal, you will be asked if you would like to use the same version of the current Informed Consent or if you would like to make changes.

**4**

After creating your informed consent, please carefully review and edit the draft before submitting your application.



The draft document will not be generated if you request to waive consent, use an alternate template, or rely on another institution to conduct the consent process. In these cases, please attach all relevant documents and/or scripts by using the "Attachments" button.

Consent will be signed by the subject or the subject's legally authorized representative (45 CFR 46.117). If the subject is a minor, the consent must be signed by the parent or legally authorized representative.

**Informed Consent form has NOT been created.**

The screenshot shows a form titled "Informed Consent form has NOT been created." with three numbered callouts:

- 1**: A box containing the "Signed Informed Consent Required" section with options: "Assent Required (For children age 7-17, please attach) in addition to signed parental consent", "Signed Informed Consent obtained by Caltech investigators using a non-Caltech template (please attach)", and "Informed Consent obtained by another institution (please attach)".
- 2**: A box containing the "Consent/Assent will be obtained:" section with options: "In person", "Telephone", "Mail", "e-Mail", "Video Call", and "Website".
- 3**: A box containing the "Describe Process for Obtaining Consent:" text area.

1. Choose the type of Informed Consent that you will use for your study.
2. Choose how consent will be obtained.
3. Describe the process of how investigators will obtain consent from participants.
4. Click *Save* after the above questions are answered.
5. Click *Create/Edit Consent Form* to begin the process of creating your Informed Consent. This will open a draft of the consent form.

If you will use a non-Caltech template IC or an IC obtained from another institution, please make sure to attach that form for review.

- Waiver of Written Informed Consent requested (please attach)**
- Waiver of Informed Consent requested (both written and verbal)**

\* **Justification:**

If you wish to request a waiver, check the appropriate option and provide detailed justification for your request. The IRB will review your justification and determine if the request for a waiver is appropriate.

1. As is the case in the main application, all sections of the Informed Consent (IC) must be completed before generating a PDF of the document. Because IC sections are automatically populated by your application responses, they will be accompanied by a blue check mark, rather than a red flag. Sections with red flags were not properly completed in the application, or there are additional questions that need to be answered, as in the *Confidentiality of Records* section of the IC.
2. The **red text** in the template is populated directly from your responses in the main application. All red text must be reviewed and edited to ensure that the language is at an appropriate reading level (8<sup>th</sup> grade) and is grammatically and syntactically correct.
3. The *Edit* button will open a pop-up window that allows you to edit the red text that was automatically inserted from the application.

When you are finished editing the entry, click the *Save* button to save the revised text. Repeat this process for all red text that need revisions in the IC draft form. Changes to these sections will automatically update the corresponding sections in the protocol. If there is no *Edit* button, then you must make the change directly in the corresponding section of the protocol.

4. The black text in the IC template is static and cannot be changed. Three sections allow you to request a modification to the black text (*Purpose, Benefits and Compensation*). Click the *Edit* button and then on the *Request to edit fixed (black) text* button in the pop-up window. Make the necessary modifications and click *Save*. The modified language must be reviewed and approved by the IRB before it can be incorporated into the IC.

**Informed Consent - Purpose Edit**

Request to edit fixed (black) text

PI Edited Text:

The purpose of this study is research. This is not a clinical study and we do not provide medical treatment. Provide a description in simple English of the scientific purpose and the aims of the study.

While we will be happy to talk to you more about the scientific findings of our work, we will not be able to give you any clinical feedback. This means we cannot tell you how you compare to other people on any measures.

428 of 4000

5. The *Confidentiality of Records* section has two questions that require attention. Choose if participant identity will be revealed or protected.

**Confidentiality of Records:**

\* Participant Identity will be:  
 Revealed  Protected

Identity Revealed	Identity Protected
<p>This study will require revealing your identity by publishing your name or images of you. This means that you can be identified and all your data will be associated with your identify so that anyone can know those data about you. If you agree to this, it is important to realize that we will have no control over how those data are used.</p> <p>Specific types of data that will be released are:</p> <ul style="list-style-type: none"> <li>- publication of your name or any other identifying information together with our research data;</li> <li>- showing video recordings of you;</li> <li>- presenting audio recordings of you;</li> <li>- publishing any data from which you could be identified (e.g., genetic data, autobiographical data).</li> </ul> <p>I give consent for my identity to be revealed in publications or presentations resulting from this study:            Please initial: _____</p>	<p>Any information from this study in which you might be identified will be confidential. We will take reasonable steps to ensure that no unauthorized person will have access to the data and/or biospecimens used or created in this study. If the information generated during this study is published, you will never be identified by name. By signing this form, however, you allow us to make your records available to the Caltech Institutional Review Board (IRB) and administrative authorities, Collaborators and their IRBs, and Regulatory Agencies as required by law.</p>

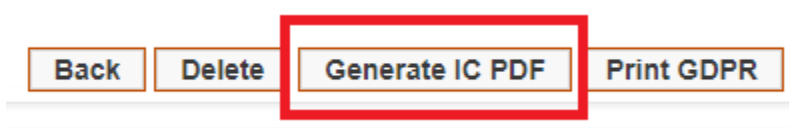
Choose if you will work with the IRB to apply for a Certificate of Confidentiality (COC) with the NIH.

Will you work with the IRB Office to apply for a Certificate of Confidentiality (COC) with the NIH? Issuance of a COC for research that is not funded by NIH is at the discretion of NIH.

Yes  No

If you protocol is funded by the NIH, a COC is automatically provided. If your protocol is not funded by the NIH, you have the option to choose to apply for a COC. Under federal law, a COC allows Caltech, the investigators, and others who have access to research records to refuse to disclose identifying information in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. Additional information on [Certificate of Confidentiality \(COC\)](#) can be found on the NIH website.

6. The *Back* button will return to the application.
7. If you would like to delete the entire IC draft and start over, click the *Delete* button. You will be able to start over, with the responses pulled from your application.
8. If you will recruit from the EEA or China, the GDPR and PIPL consent forms will be available for printing here. They will also be available from the application's *Action Links* as well.



When you have finished reviewing, editing, and saving the text in the IC draft, click *Generate IC PDF* to create a PDF copy of the draft. This is the version that will be reviewed by the IRB and, if approved, used to consent participants in your study. Once the PDF is generated, a *Print Informed Consent* button will appear in the *Action Links* section of your main application. Clicking this will allow you and IRB reviewers to open the IC PDF at any time. After generating the IC PDF, click the *Back* button to return to the application to complete the final submission steps.

## M. Certification and Competing Interests

### Certification and Competing Interests

Save

PI Grace C Fisher-Adams has a current disclosure on file in Caltech's Disclosure of Financial Interests and Commitments system.

\* Do you, your family, or any member of the study team have an outside relationship (paid or unpaid) or commitment with any entity providing materials, devices, compounds, or other support for this project?

Yes  No

\* If yes, please provide a brief description of the details of financial interest or outside relationship.

\* Is this relationship included in your or their Disclosure of Financial Interest & Commitment (DFIC)?

Yes  No

\* Do you, your family, or any member of the study team have a relationship (paid or unpaid) or commitment with any entity that could reasonably appear to benefit from the outcomes of this project?

Yes  No

\* Does this study involve testing the efficacy of a tool, device, or other type of intellectual property (e.g., software) developed by a member of the study team or their family?

Yes  No

**I may have financial interests and/or relationships or affiliations which could be perceived as conflicting with or compromising this research.**

\* Certification:

I have read Caltech's IRB Policies and applicable SOPs and will comply with them and Caltech's Federalwide Assurance.

I further declare the information provided in the accompanying protocol is accurate to the best of my knowledge. Any proposed revisions to this study will be promptly forwarded in writing to the IRB for approval

Any untoward experience, emergent problem or significant deviation from my protocol will be reported to the IRB for reconsideration.

Signed and Submitted By:

Date:

**The PI must be the person to complete the *Certification and Competing Interests* section.** Once all questions are

answered, click *Save*. Once this section is complete and saved, a yellow **Submit** button will appear at the top right of all pages of the main application. The PI will be able to submit the protocol for review once this button appears.

## N. Unanticipated Events

An unanticipated event includes any incident, experience, or outcome that meets all the following criteria:



1. unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
2. related or possibly related to participation in the research (in this guidance document, *possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
3. suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.


Unanticipated events must be reported as soon as possible to the IRB via email at [irb@caltch.edu](mailto:irb@caltch.edu) or phone at 626-395-8448 and entered into PAS under the appropriate protocol.

**Unanticipated Event**

\* Unanticipated event:  Yes  No



Answer *Yes* then click *Add Event*

\* Unanticipated Event Date:  

\* PI Involved:

\* Event Description:

Subcommittee:

Outcome:

Report Sent:  OHRP Report  
 FDA Report  
 Other Agency Report (Specify)

You are responsible for completing the first three questions. The remaining information will be entered by the IRB.

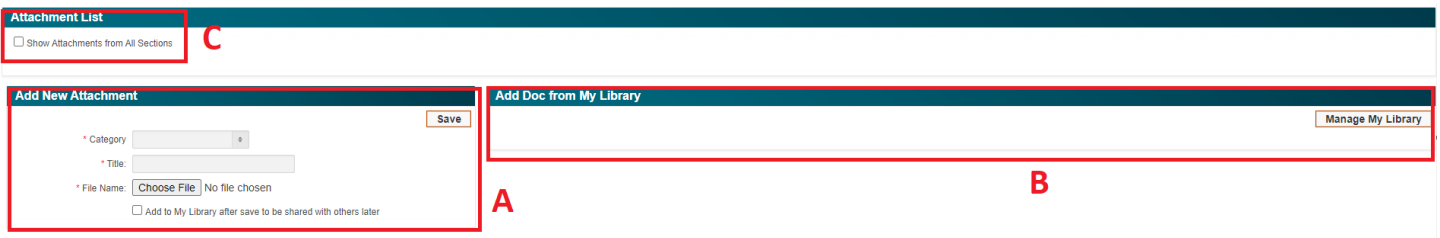
# Adding Attachments

There are two ways to add attachments to your application:

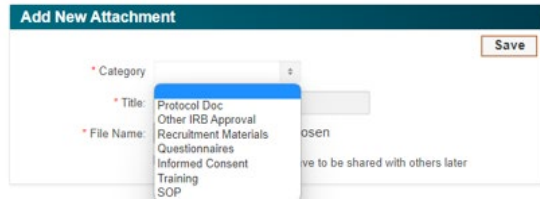
1. Attachments can be made directly to each page of your protocol application. The *Additional Materials & Communications* section appears at the bottom of every page. The *Attachments* button allows you to attach documents and view documents that are already attached. Clicking the *Attachments* box will open another *Attachments* button to click.



The attachment page will open where you can add new attachments or attach documents that you already have saved in your Library.



- A. Choose the attachment category from the drop-down list.



Check the box for *Add to My Library* which will save the attachment to your document library.

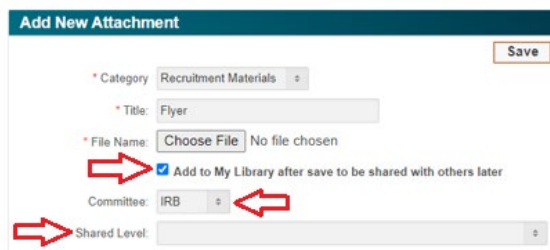
Choose the appropriate committee for this attachment.

Choose the appropriate shared level. There are 3 shared levels:

Private: accessible to only you

Public: accessible to everyone in the IRB PAS

PI Lab: accessible to everyone in the PI's lab group (Only accessible if your lab is in the DPM (Division Personnel Management)). Contact your Division if your lab is not visible here)



- B. You can also add attachments from your Library, which includes all attachments that you previously saved to your Library, or those that you built directly into your Library. (See #2 below)

- C. You can also access all documents that have already been attached to the application. An attachment can only be attached to your protocol once, but once attached is accessible from every section of the protocol.
2. The *IRB Attachment Library* in the *Quick Links* section of your Dashboard displays all documents that you have added directly to the Library or through a protocol application.

**Quick Links**

I want to go to:

- User Profile and Training
- IRB Protocol List
- Change Personnel/Funding (AOAs)
- Request Close Protocol
- IRB Attachment Library**
- Institute SOP Repository
- Review Protocol List

**Attachment Library**

Q ▾   Actions ▾

Details	Attachment Category	Owner	Attachment Name	Subject	Committee	Shared Level	Obsolete	Delete	Institute SOP	Protocol List
	SOP	Adolphs, Ralph	<a href="#">Chan Lab Monthly Detail Statement.pdf</a>	Test AD-1	IRB	Public	-	-	-	<a href="#">• IR22-1308:Initial</a>
	Recruitment Materials	Hayashi, Megan Elizabeth	<a href="#">FLYER.docx</a>	Flyer	IRB	Private	-	X	-	-
	SOP	Shu, Shizhuang	<a href="#">IRB Partner Org questions_20201022.pdf</a>	institute SOP	IRB	Public	-	X	Yes	-
	Protocol Doc	Hayashi, Megan Elizabeth	<a href="#">Device Photos.docx</a>	Device Photos	IRB	Adolphs Lab	-	X	-	-
	Other IRB Approval	Hayashi, Megan Elizabeth	<a href="#">UCLA IRB Approval.docx</a>	UCLA IRB Approval	IRB	Adolphs Lab	-	X	-	-
	Protocol Doc	Tyszka, Julian Michael	<a href="#">COGP- GEMS Monthly report.pdf</a>	Test lab member-1	IRB	Public	-	X	Yes	-

- A. Attachments fall into 7 different categories:  
Protocol Doc, Other IRB Approval, Recruitment Materials, Questionnaires, Informed Consent, Training, SOP
- B. The Owner is the person who uploaded the attachment
- C. The Attachment Name reflects the document name, and the hyperlink opens the attachment
- D. There are 3 shared levels:  
Private: accessible to only you  
Public: accessible to everyone in the IRB PAS  
PI Lab: accessible to everyone in the PI's lab group  
Attachments that are no longer in use are designated as obsolete. Attachments cannot be deleted as they still need to be accessible when viewing inactive versions of protocols.
- E. Protocols that include the attachment are displayed in this column

# Creating an Admin Only Amendment (AOA)

Admin Only Amendments (AOAs) allow you to make personnel and funding updates to your protocols. AOAs are created independently of your application, so you may have a renewal or amendment application in process and still be able to submit an AOA to update personnel or funding.



**Quick Links**

I want to go to:

- User Profile and Training
- IRB Protocol List
- Change Personnel/Funding (AOAs)
- Request Close Protocol
- IRB Attachment Library
- Institute SOP Repository
- Review Protocol List

The *Change Personnel/Funding (AOAs)* option from your *Quick Links* section of your Dashboard will take you to the screen where you can create the AOA.

Click on the person icon in the *Create/Update Admin Only Amendment* column of the protocol you wish to update.

Admin Only Amendments (AOA) for Personnel/Funding Change									
Protocol Number	PI	Protocol Title	Doc Type	Decision	Admin Only Amendments	Create/Update Admin Only Amendment	Protocol id	Prot version id	
<a href="#">IR22-1307</a> Full Application	Kumar, Radha	RK Test TRB using LAB PERSON Login in Test2	Full Application	Approved	<ul style="list-style-type: none"><li>• AOA-01-Change Personnel (Request Completed)</li></ul>		10015	2450	
<a href="#">IR22-1308</a> Full Application	Adolphs, Ralph	Test as Chair person login-1	Full Application	Approved	<ul style="list-style-type: none"><li>• AOA-02-Change Funding (Request Completed)</li><li>• AOA-01-Change Personnel (Request Completed)</li></ul>		10017	2452	

From the next screen, choose *Change Personnel* or *Change Funding* depending upon what updates you need to make.

Admin Amendment List

**Project Header**

Protocol Title: **RK Test TRB using LAB PERSON Login in Test2**

Protocol Number: **IR22-1307**      Application Type: **Full Application**

Status: **Decision Made**      Status: **ACTIVE**

IRB Decision: **Approved**      Reviewed in IRB Meeting: **2022 November**

Decision Date: **12/01/2022**      Expiration Date: **11/30/2023**

**Create New Admin Only Amendment**

You can create and submit Admin Only Amendments (AOAs) to change personnel or funding. You can only have one type of active AOA at one time.

New AOA Type:

- Change Personnel
- Change Funding

## Updating Personnel:

You can add, update, or remove personnel at any time with the submission of an AOA. To add personnel, click on the *Add New* button found to the right of the page. To update current personnel, including making changes or removing, click on the pencil next to the person you wish to update.

**Admin Amendment Setup**

Back
Update
Delete

Admin Amendment Number: **AOA-03**

Request Type: **Change Personnel**

Status: **Working in Process**

Ready to Submit:

**AOA Personnel - Requested Changes**

Add New

**Existing Personnel**

You can not change PI via AOA.

Request to Change	Name	Organization	Role	Comm Contact	Minor	Start Date	End Date	Change Note	Line Num
	Lopez, Juan Jesus	CALTECH	Administrative Contact -	Y	-	07-DEC-22	-	Added on 12/07/2022 by AOA-01.	2

1 - 1

PI Comments:

Submission Date:

A pop-up box will open when adding new personnel. Answer the questions and click *Create*.

**Other Investigators**

Back
Create

Check Non-Caltech Person box to enter Non-Caltech person information.

\* - required field; ‡ - conditionally required field

Change Type:  Added

Non-Caltech Person

\* Person Name:  ⋮

\* Organization:

\* Person Role:

Receive Communication

Individual is under 18 years of age

Start Date:

End Date:

Active Employee:

**Person Roles:**

Investigator/Admin Contact = An investigator that will also be the Administrative Contact for the protocol

Lead Investigator = The non-PI lead investigator (protocols are not required to identify a lead)

Partner Org PI = The PI of any partner organization

Investigator = All investigators on the protocol that are not the PI, Lead Investigator, Partner Org PI, or Administrative Contact

Administrative Contact = This contact is strictly administrative and does not recruit, consent, or perform work with participants. This person typically manages the protocols and is the point person for communication with the IRB

Receive Communication: If checked, this person will receive all the system-generated communications. The PI will always have this checked.

**Individual is under 18 years of age:** Check this is you will have minor researchers working on your protocol. See IRB [SOP 17: Minors Working with the IRB](#) for additional guidance.

A pop-up box will open when updating or removing current personnel. Update as necessary and click *Create*.

### Other Investigators

Check Non-Caltech Person box to enter Non-Caltech person information.

Back Create

\* - required field; ‡ - conditionally required field

Change Type:  Updated  Removed

Non-Caltech Person

\* Person Name: **Hayashi, Megan**

\* Organization: CALTECH

\* Person Role: Administrative Contact

Receive Communication

Individual is under 18 years of age

Start Date: **07-DEC-22**

End Date:

Active Employee: Y

### **Updating Funding:**

You can add, update, or remove funding sources at any time with the submission of an AOA. To add a funding source, click on the *Add New* button found to the right of the page. As with personnel, to update funding, including making change or removing, click on the pencil next to the funding source you wish to update. A pop-up box will open when adding new funding. Answer the questions and click *Create*.

### Funding Detail


It is imperative that you indicate Department of Defense (DARPA, Army, Navy, Air Force, etc.) funding by checking the DOD Award checkbox, if used.

Back Create

\*Request Type:  Added

\*Caltech Role:  Primary Awardee  Sub-Awardee

\*Funding Category:  Caltech PTA Award  Non PTA Award  Pending Funding

\*PTA Award Number:  

\*Funding Agency Name:

\*Award Title:

Funding Start Date: End Date:

\*Funding Agency Type:  DOD  PHS/NIH  N/A

\*Are any Partner Orgs being paid from this Caltech Award?  Yes  No

Change Note:

Line Num:

**PTA Award Number:** PAS is connected to the grants database. Search for your award by typing the award number of the PTA (Project-Task-Award) into the text line. The Funding Agency Name, Award Title, Start and End Dates will automatically populate.

When Caltech is a Sub-Awardee, additional questions regarding the Prime Awardee will open and must be answered.

**Prime Awardee Partner Org**

Prime Awardee Partner Org:

Prime Sponsor:

Prime Award Number:

When Caltech is the Prime Awardee with sub-award recipients, additional questions regarding the Sub-awardee will open and must be answered.

\*Are any Partner Orgs being paid from this Caltech Award?  Yes  No

Caltech Procurement Contact:

Partner Orgs Receiving/Sending Funds From/To This Award:

<input type="text"/>	<input type="button" value="↔"/>	<input type="text"/>
<input type="text"/>	<input type="button" value="»"/>	<input type="text"/>
<input type="text"/>	<input type="button" value="&gt;"/>	<input type="text"/>
<input type="text"/>	<input type="button" value="&lt;"/>	<input type="text"/>
<input type="text"/>	<input type="button" value="«"/>	<input type="text"/>

Caltech Procurement Contact: Include the contact person who is working with you on this subaward.  
Partner Orgs Receiving/Sending Funds From/To This Award: Highlight the partner organizations in the left column that are receiving funds from this award and shuttle them to the right column.

# Creating a Renewal Application

Up to four renewals may be submitted for a protocol before a *De Novo* application (i.e., a new protocol) is required. A renewal may only be created for an approved protocol with no other “*Work in Progress*” applications pending. A renewal application can be created from the *Protocol History* page (see [page 13](#)). The *Protocol History* page is accessible from the *Action Links* section of the selected protocol. After clicking on *Go to Protocol History*, you will be taken to the list of all applications that correspond with the selected protocol.

### Action Links

- Go to Protocol List
- Go to Protocol History
- Go to IRB Review
- Print Protocol (Chrome)
- Print Informed Consent
- Print Status Memo

From the *Protocol History* page, locate the *Create New Application for Protocol* section at the bottom of the page. Select the *Renewal #* application type from the drop down and click *Create*.

### Protocol History for Protocol IR23-1310

Q  Go Actions

Link	Protocol	PI Name	Status	IR
	IR23-1310 Amendment 1st	Hayashi, Megan Elizabeth	Decision Made	Expedited R
	IR23-1310 Full Application	Hayashi, Megan Elizabeth	Decision Made	Full Commit

### Create New Application for Protocol IR23-1310

The last application has been approved. Please select an application type from the list to create a new applic

\* Application Type:

- Select -
- Renewal 1st
- Amendment 2nd

This will open a renewal application.



Section Links
<b>RENEWAL</b>
Protocol Info
Caltech and Partner Orgs
Personnel
Funding
Samples and Data
Devices
Subject Selection Criteria
Subject Participation
Risks and Benefits
Incidental Findings
Subject Recruitment and Compensation
Informed Consent
Certification and Competing Interests
Unanticipated Event

**A**

IRB Decision:

Decision Date:

\* - required field; ‡ - Info used in Informed Consent Form

## Renewal

Please review your files (i.e., material submitted with the original application, together with any subsequent changes) and then provide other institutions/organizations, current copies of their IRB approval(s) will be required for this Committee's records. Approval for current paperwork from you.

\* - required field; ‡ - Info used in Informed Consent Form

**B**

\* Project Status:  Still Active  Terminated

\* Detailed summary of the work in the past year:

\* Changes in recruitment practices (?):  Yes  No

\* Unanticipated event(s):  Yes  No

Number of participants enrolled during the last year:

Reason to continue:

- The renewal application will automatically include all information from the last approved application under the selected protocol. The red flagged *Renewal*, *Certification and Competing Interests*, and *Unanticipated Events* sections require attention.
- Provide the IRB with an update of what has occurred with this protocol over the past year. If an unanticipated event occurred that you did not previously enter into PAS, make sure click *Yes* on the *Renewal* section along with the *Unanticipated Events* section.

Necessary modifications can be made to any section of the protocol during renewal.

# Creating an Amendment Application

Amendments allow you to make modifications to your protocol. An amendment application can be created from the *Protocol History* page (see [page 13](#)). The *Protocol History* page is accessible from the *Action Links* section of the selected protocol. After clicking on *Go to Protocol History*, you will be taken to the list of all applications that correspond with the selected protocol.

REMINDER: Personnel and Funding updates should be made with an Admin Only Amendment (AOA) (see [page 41](#)).

### Action Links

- Go to Protocol List
- Go to Protocol History
- Go to IRB Review
- Print Protocol (Chrome)
- Print Informed Consent
- Print Status Memo

From the *Protocol History* page, locate the *Create New Application for Protocol* section at the bottom of the page. Select the *Amendment #* application type from the drop down and click *Create*.

### Protocol History for Protocol IR23-1310

Q  Go Actions

Link	Protocol	PI Name	Status	IR
	IR23-1310 Amendment 1st	Hayashi, Megan Elizabeth	Decision Made	Expedited R
	IR23-1310 Full Application	Hayashi, Megan Elizabeth	Decision Made	Full Commit

### Create New Application for Protocol IR23-1310

The last application has been approved. Please select an application type from the list to create a new applic

\* Application Type:

- Select -
- Renewal 1st
- Amendment 2nd

This will open an amendment application.

**Action Links**

- [Go to Protocol List](#)
- [Go to Protocol History](#)
- [Delete Amendment 2nd](#)
- [Print Protocol \(Chrome\)](#)

**Project Header**

Protocol Title: **Test Updates 1.03.23**

Protocol Number: **IR23-1310**

Status: **PI Work in Progress**

IRB Decision:

Decision Date:

You need to complete all the sections on the left before submitting this application.

\* - required field; ‡ - Info used in Informed Consent Form

**Section links**

- AMENDMENT** A
- Protocol Info
- Caltech and Partner Orgs
- Personnel
- Funding
- Samples and Data
- Devices
- Subject Selection Criteria
- Subject Participation
- Risks and Benefits
- Incidental Findings
- Subject Recruitment and Compensation
- Informed Consent
- Certification and Competing Interests B
- Unanticipated Event B

**Amendment**

Please submit this form if you are requesting changes (Amendments) be made to a previously approved human subject the approved protocol are implemented. You will be promptly notified by the IRB as to whether or not this Amendment v please contact the IRB Administrator at x8448 or irb@caltech.edu.

Short Name:

Summary:

Section Changed from Amendment 1st

**Additional Materials & Communications**

Check the box to show the information:

Attachments (0/0)  Communications (0/0)

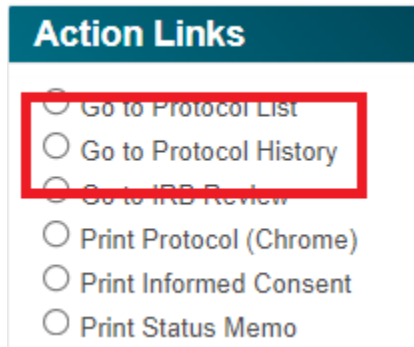
- A. The amendment application will automatically include all information from the last approved application under the selected protocol. The red flagged *Amendment*, *Certification and Competing Interests*, and *Unanticipated Events* sections require attention.
- B. Provide the IRB with a summary of what you are updating in the amendment application.

Click on the protocol section name (e.g., *Protocol Info*, *Devices*, etc.) to make the necessary modifications in the corresponding sections of the amendment application.

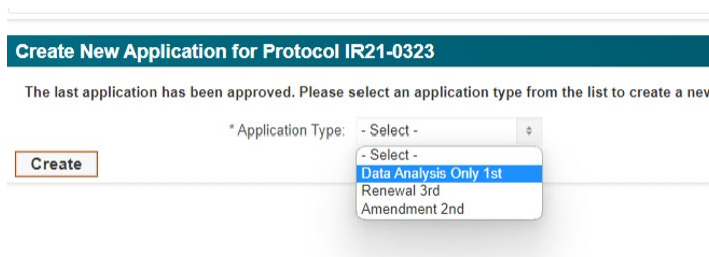
## Creating a Data Analysis Only Application

A Data Analysis Only (previously Limited Continuation) application may be created when your study is no longer recruiting participants and collecting data. You may only continue analysis of previously collected data prior to this application. You may not recruit any new participants and therefore will not submit an informed consent or make any updates to the protocol. Up to four Data Analysis Only renewals may be submitted for a protocol.

A Data Analysis Only application can be created from the *Protocol History* page (see [page 13](#)). The *Protocol History* page is accessible from the *Action Links* section of the selected protocol. After clicking on *Go to Protocol History*, you will be taken to the list of all applications that correspond with the selected protocol.



From the *Protocol History* page, locate the *Create New Application for Protocol* section at the bottom of the page. Select the *Data Analysis Only #* application type from the drop down and click *Create*.



This will open a Data Analysis Only application.

**Section Links**

**DATA ANALYSIS ONLY\***

Protocol Info

Caltech and Partner Orgs

Personnel

Funding

Samples and Data

Devices

Subject Selection Criteria

Subject Participation

Risks and Benefits

Incidental Findings

Subject Recruitment and Compensation

Informed Consent

Certification and Competing Interests\*

Unanticipated Event\*

IRB Decision: \_\_\_\_\_

Decision Date: \_\_\_\_\_ Expiration Date: \_\_\_\_\_

\* - required field; † - Info used in Informed Consent Form

**A**

**Data Analysis Only**

This application is for Data Analysis Only. To qualify for Data Analysis Only, you may only continue analysis of previously collected data prior to this application. You may not recruit any new participants and therefore you will not submit an informed consent. This Data Analysis Only application, if approved, will be valid for one year.

\* Detailed summary of the work in the past year:

\* In the past year, have you had any unanticipated events that were not reported?  Yes  No

\* Number of participants enrolled during the last year (enter 0 if none):

\* Reason To Continue:

**B**

- A. The Data Analysis Only application will automatically include all information from the last approved application under the selected protocol. The red flagged *Data Analysis Only*, *Certification and Competing Interests*, and *Unanticipated Events* sections require attention. You will NOT be able to edit any other sections, as there should be no updates as the study is no longer recruiting participants.
  
- B. Provide the IRB with an update of what has occurred with this protocol over the past year and the reason to continue, which should be for data analysis. If an unanticipated event occurred that you did not previously enter into PAS, make sure click *Yes* on the Renewal section along with the *Unanticipated Events* section.

# Protocol Review

The *Additional Materials & Communication* section is found at the bottom of every page of the application.

Click on the *Communications* checkbox to display the communication between investigators and the IRB. IRB reviewer comments that need to be addressed are displayed here, and you can send return comments back in the same location.

**Additional Materials & Communications**

Check the box to show the information:

Attachments (0/0)  Communications (1/1)

Clicking the *Communications* checkbox will display the IRB reviewer comments for the section of the protocol that you are in.

**Additional Materials & Communications**

Check the box to show the information:

Attachments (0/0)  Communications (1/2)

**Communications**

Show All (1/2)

Entered By	Communications	Mark as Read
Megan E Hayashi 2023-01-26 17:02:34	Please provide additional detail about the scientific aims of your study.	

Clicking the *Show All* checkbox will display the comments for the entire application. The *Section* column identifies the section of the protocol the comment refers to.

**Additional Materials & Communications**

Check the box to show the information:

Attachments (0/0)  Communications (1/2)

**Communications**

Show All (1/2)

Section	Entered By	Communications	Mark as Read
Subject Recruitment and Incentives	Megan E Hayashi 2023-02-01 17:43:34	Please attach the recruitment flyer.	
Protocol Info	Megan E Hayashi 2023-01-26 17:02:34	Please provide additional detail about the scientific aims of your study.	

If you wish to respond to a reviewer's comment, click the *Communications* checkbox and then click the *Communications* button that appears.

**Additional Materials & Communications**

Check the box to show the information:

Attachments (0/0)  Communications (1/1)

**Communications ...**

After clicking the second *Communications* button, a pop-up window will open displaying a log of all communications. The *Section* will automatically populate with the name of the protocol section where you opened the *Communications* window.

Communication Log for			
Section name	Communication Log	Email Sent	Delete
Subject Recruitment and Incentives	Megan E Hayashi:2023-02-01 17:43:34 Please attach the recruitment flyer.		×
Protocol Info	Megan E Hayashi:2023-01-26 17:02:34 Please provide additional detail about the scientific aims of your study.		

You can keep this pop-up window open and respond to comments in other sections of the protocol, but make sure you have the correct section chosen before you click *Save*.

Once you have addressed all reviewer comments, let the IRB know by entering a comment noting this. Click *Send Message* to send the IRB your replies.

# Identifying Protocol Changes

The comparison feature is available only for protocols that include more than one application. The feature can be found on the *Renewal* or *Amendment* sections of Renewal or Amendment applications. This feature provides a summary of the updates made to the protocol. Investigators and reviewers can read this overview along with what changes were made in each section that has been updated.

Section Links	Section links
<b>RENEWAL</b>	<b>AMENDMENT</b>
Protocol Info	Protocol Info
Caltech and Partner Orgs	Caltech and Partner Orgs
Personnel	Personnel
Funding	Funding
Samples and Data	Samples and Data

## Amendment

Save

Please submit this form if you are requesting changes (Amendments) be made to a previously approved human subjects protocol. Protocol Amendments shall be submitted and approved by the IRB before any deviations from the approved protocol are implemented. You will be promptly notified by the IRB as to whether or not this Amendment will be considered for expedited review or whether it requires full IRB review. If you have any questions, please contact the IRB Administrator at x8448 or irb@caltech.edu.

Short Name: New Biospecimen Colletion - Saliva

Summary: We will collect saliva samples from participants. The participants will self-collect samples with saliva collection tubes provided in our laboratory. These samples will be analyzed and stored indefinitely for future studies.

224 of 4000

A

## Section Changed from Full Application

### Changes in Samples

Field Name	Amendment 1st	Full Application
New Sample Added	Saliva	not exists
Please provide the timeframe that the data/biospecimens will be kept:	The aspirate biospecimens will be stored for 5 years. The saliva biospecimens will be stored indefinitely.	Data/Biospecimens will be stored for 5 years.
Describe how the data/biospecimens that will be used for future studies will be stored, including the measures used to ensure subject confidentiality.	Participant Data/Biospecimens used for future studies will be stored securely in locked files at UCSB. The following measures will be used to protect participant confidentiality and privacy during the study: The aspirates will be used in studies for the next 5 years. Saliva will be stored indefinitely. These samples will be coded and deidentified before papers are published.	Participant Data/Biospecimens used for future studies will be stored securely in locked files at UCSB. The following measures will be used to protect participant confidentiality and privacy during the study: Explanation.

### Changes in Subject Participation

Field Name	Amendment 1st	Full Application
Description of Subject Participation	The participant will lie in an MRI playing video games. Aspirate and saliva biospecimens will be collected in the laboratory.	The participant will lie in an MRI playing video games.

- A) A summary of what is included in the Renewal or Amendment is found here.
- B) Updates are organized by protocol section.
- C) Each protocol section is organized by the fields within the section that have been updated.
- D) This column reflects the updates made in the amendment or renewal.
- E) This column reflects what is in the current approved version of the protocol.



## Contact Us

If you have questions about the application or require assistance during the submission process, please contact the IRB Office at **626-395-8448** or email us at [irb@caltech.edu](mailto:irb@caltech.edu).

For more information about the IRB, visit <https://irb.caltech.edu>.