



Welcome to Cayuse IRB

Guide for Submitting a New IRB Protocol

How to use this tutorial:

- This tutorial is written in the point of view of a Primary Investigator (PI), if you are not a PI, please know that you will need to adjust a few things.
- Use your keyboard's left/right/up/down arrow (or your mouse/trackpad scroll or the spacebar) to move through the PowerPoint. **Instructions are animated.**

Before You Begin an IRB Protocol...

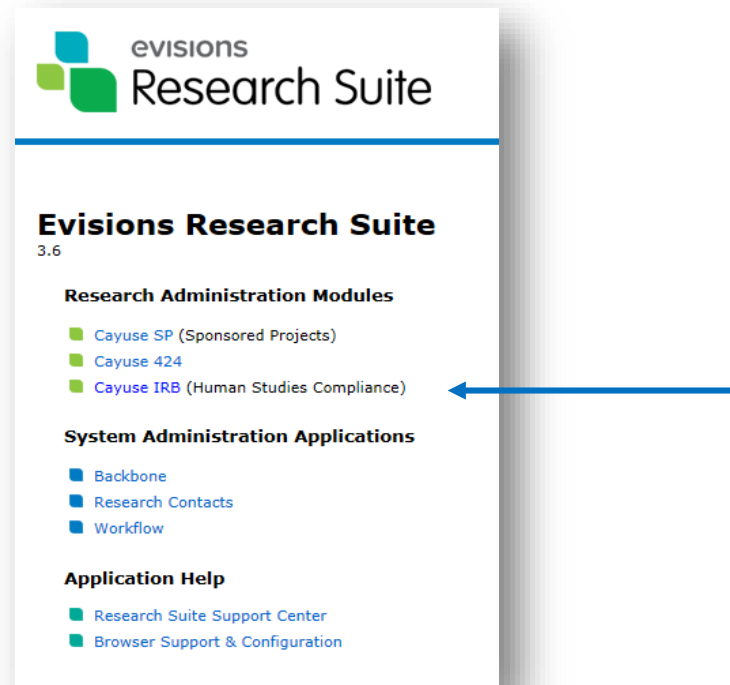
Make sure you have the following items ready*:

- Supplemental documents in individual document files (i.e. informed consent form(s), authorization(s), recruitment documents, questionnaires, etc.). Files can be in various formats (PDFs, docx) however doc. (Microsoft Word) files are preferred.
- Faculty advisor (if you are a student) and co-PI(s) CITI training copy of certificate(s).
- Ensure that you and your co-PI(s) have been “authenticated” (i.e. you can access the system) with the IRB office. If you are unsure, contact the IRB office at untirb@unt.edu or 940-565-4643.

***Important Note:** You do not have to finish the IRB protocol in one sitting. All information is saved.

After you have been “authenticated” by the IRB office, you may log into to Cayuse:

Copy and paste this link to get to the sign-on page of the Testing Environment: <https://unt-uat.cayuse424.com/>



A screenshot of the login form for the Evisions Research Suite. The form is enclosed in a red rounded rectangle. A green callout box points to the form with the text: "Username: euid@unt.edu" and "Password: cayuseirb (lowercase)". The form contains two input fields: "Username" and "Password", and a "Sign in" button. Below the form, there is a link: "Problems or questions? [Contact Support](#)".

Important Note before logging in:

1. You MUST clear your browser CACHE
2. Allow Cookies from <https://unt-uat.cayuse424.com/>
3. Enable JAVA.

Instructions to clear cache and Browser settings are here:
<http://webhelp.evisions.com/HelpFiles/SP/en/Content/Browser%20Support%20-%20Research%20Suite.htm?Highlight=browser>

Short instructions for BROWSER SETTINGS needed for UAT / Cayuse

Settings are available [online](#)

At the top left of your Firefox window, click the Firefox button and select Options.

Alternatively, if you do not see a Firefox button, click the “hamburger icon” and click Options.

Pop-up Blocker

Click Content on left menu.

Make sure that Block pop-up windows is unchecked.

Alternatively, if you wish to allow pop-ups only for Cayuse 424 while blocking pop-ups on other sites, click Exceptions and enter your institution's Cayuse 424 URL as it appears in the address bar. Then, click Allow.

Enabling Cookies

Click Privacy on left menu.

If Remember History is selected, cookies are already being accepted and no further changes are required. If Never remember history is selected, select Remember history or Use custom settings for history.

*If you wish to use **custom settings**, you can either check the option to Accept cookies from sites to accept cookies for all websites, or uncheck it and use the Exceptions button to allow cookies only for [Cayuse 424](#).*

If creating an exception, enter your institution's Cayuse 424 URL as it appears in your browser, then select Allow.

TROUBLESHOOTING ANSWERS

Please confirm on the pop-up/cookies because not allowing these can create resolving/connection issues. Please see page one of the attached (also screen shot below).

If you follow the instructions above/below for Windows/Firefox. I currently do not have a MAC available, but the steps should be similar. If you have any questions or concerns, please let me know and I am happy to help. Email screenshots and questions to CayuseTechSupport@unt.edu

Instructions:

Please use Firefox with settings to accept cookies, allow pop-ups from Cayuse, and enable Java Script <http://support.cayuse.com/docs/browser-support-configuration/firefox-settings> if they are not already enabled.



idp.cayuse424.com:9445

Would you like Firefox to remember this login?

@unt.edu

●●●●●●●●

Show password

Remember




Optionally, you can click "X" to *not* remember login.


- Dashboard
- Studies
- Submissions
- Tasks
- Help

Be aware, the change in regulation does not allow a grace period between the Pre-2018 and 2018 Requirements during transition. In other words, as we near the compliance deadline, there is no guarantee that a project submitted on the Pre-2018 New Project Form will be approved under the Pre-2018 regulations. There is a possibility that you will be required to submit a new project form under the 2018 Requirements even if your project has been under review leading up to the compliance date. We will do everything we can to prevent this, but it is very important for researchers to plan ahead as we near the date of January 19, 2018. ~ See [IRB website](#) for more details ~


Close




12
In-Draft



1
Awaiting Approval



1
Pre-Review



5
Under Review

My Studies

| | |
|----------------------------|--------------------------------------|
| IRB-t17-8 | My New Study |
| IRB-t17-4 | MPA 504 practice study |
| IRB-t16-30 | Study Test 1 |
| IRB-t16-29 | EASY Study |
| IRB-t16-28 | Genius Hour in the Primary Classroom |

View All

My Tasks

| | |
|----------------------------|---------------------|
| IRB-t17-8 | View Submission |
| IRB-t17-4 | Complete Submission |
| IRB-15-43 | Complete Submission |
| IRB-t16-30 | Complete Submission |
| IRB-15-35 | Complete Submission |

View All


Submissions by Type

| | |
|-----------|----|
| Initial | 21 |
| Withdrawn | |
| Modified | |
| Renewed | |
| Incident | |
| Closure | |
| Legacy | |

Approved Studies

| | |
|---------------------------|------------------------------------|
| IRB-15-40 | DV Initial App-Final Test 12-15-15 |
|---------------------------|------------------------------------|

Studies Expiring in 30 days

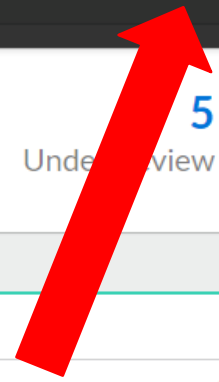


No Expiring Studies

Expired Studies


| | |
|---------------------------|--|
| IRB-15-43 | DV test #2 12-15-15 |
| IRB-15-35 | Evisions test of CPP templates 12-8-15 |
| IRB-15-19 | Evisions Training Day 1 example |
| 15-0126 | Mental Health |
| IRB-15-13 | IDA's first protocol |


Once logged in, you're first taken to this page. Click "Close" at top of screen.





cayuse IRB Dashboard 35 Ida Pl

[Dashboard](#) + New Study


12
In-Draft


1
Awaiting Approval


1
Pre-Review


5
Under Review

My Studies

| |
|---|
| IRB-t17-8 My New Study |
| IRB-t17-4 MPA 504 practice study |
| IRB-t16-30 Study Test 1 |
| IRB-t16-29 EASY Study |
| IRB-t16-28 Genius Hour in the Primary Classroom |

[View All](#)

My Tasks

| |
|--|
| IRB-t17-8 View Submission |
| IRB-t17-4 Complete Submission |
| IRB-15-43 Complete Submission |
| IRB-t16-30 Complete Submission |
| IRB-15-35 Complete Submission |

[View All](#)

Submissions by Type

| | |
|--------------|----|
| Initial | 21 |
| Withdrawal | 0 |
| Modification | 2 |
| Renewal | 2 |
| Incident | 0 |
| Closure | 1 |
| Legacy | 2 |

Approved Studies

| |
|--|
| IRB-15-40 DV Initial App Final Test 12-15-15 |
|--|

[View All](#)

Studies Expiring in 30 days

No Expiring Studies


[View All](#)

Expired Studies

| |
|--|
| IRB-15-43 DV test #2 12-15-15 |
| IRB-15-35 Evisions test of CPP templates 12-8-15 |
| IRB-15-19 Evisions Training Day 1 example |
| 15-0126 Mental Health |
| IRB-15-13 IDA's first protocol |

[View All](#)

Your "Dashboard" is where you can see all of your affiliated studies



https://cayuse424.com/rc/irb/#dashboard

+ New Study

My Role: Researcher
Admin
Analyst
Reviewer
Researcher

In-Draft 0

If you are an IRB member, make sure to switch your role to "Researcher" to submit a new protocol

Pre-Review 0

Under Review 0

My Studies

You Have No Studies

My Tasks

All Tasks Complete

Submissions by Type

| | |
|--------------|---|
| Initial | 0 |
| Withdrawal | 0 |
| Modification | 0 |
| Renewal | 0 |
| Incident | 0 |
| Closure | 0 |
| Legacy | 0 |

Approved Studies

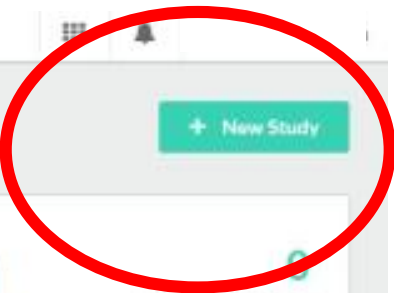
No Approved Studies

Studies Expiring in 30 days

No Expiring Studies

Expired Studies

No Expired Studies



1. Click on “+ New Study” to begin a new protocol application

2. You will be redirected to another page

- Dashboard
- Studies
- Submissions
- Tasks

My Role: Researcher

In-Draft 0

Awaiting Approval 0

Pre-Review 0

Under Review 0

My Studies

You Have No Studies

My Tasks

All Tasks Complete

Submissions by Type

| | |
|--------------|---|
| Initial | 0 |
| Withdrawal | 0 |
| Modification | 0 |
| Renewal | 0 |
| Incident | 0 |
| Closure | 0 |
| Legacy | 0 |

Approved Studies

No Approved Studies

Studies Expiring in 30 days

No Expiring Studies

Expired Studies

No Expired Studies

7 Help

Study Details Submissions

Enter study title here

PDF Delete

1. Enter the protocol title here

2. Click on the checkmark to move to the next step

Approval Date: N/A Expiration Date: N/A Organization: N/A Sponsors: N/A Active

Key Study Contacts

| Team Member | Role | Number | Em |
|------------------------|------|--------|----|
| No Key Study Contacts. | | | |

Unsubmitted

IRB-t16-4 New Study Tutorial

PDF

Delete

Approval Date:
N/AExpiration Date:
N/AOrganization:
N/ASponsors:
N/AActive Submissions:
N/A

Key Study Contacts

Team Member

Role

Number

Email

No Key Study Contacts.

The next step will be to start the IRB protocol. Click "+ New Submission"

Dashboard

Studies

Submissions

Tasks

Help

Studies Study Details

+ New Submission

Study Details

Submissions

Initial

Unsubmitted

IRB-t16-4 New Study Tutorial

PDF

Delete

Click on "Initial"



Approval Date:
N/A

Expiration Date:
N/A

Organization:
N/A

Sponsors:
N/A

Active Submissions:
N/A

Key Study Contacts

| Team Member | Role | Number | Email |
|------------------------|------|--------|-------|
| No Key Study Contacts. | | | |

Dashboard

Studies

Submissions

Tasks

Help

Studies Study Details Submission Details

1 In-Draft

Submission is with researchers

2 Awaiting Approvals

Submission is awaiting certification or approval

3 Pre-Review

Submission is being prepared for review

Unsubmitted

Initial

IRB 1234 - New Study Tutorial

✎ Edit

📄 PDF

🗑️ Delete

☰ Checklist

2. Or you can click "Edit" to go directly into the protocol-this is the preferred method.

Current Analyst:

A

view Board:

A

Decision:

N/A

Meeting Date:

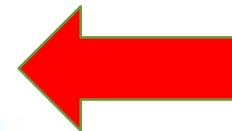
N/A

Required Tasks:

✓ Assign PI

• Assign PC

• Complete Submission



1. You can check the tasks you need to complete here and you can also click on the tasks to be redirected to that page.

| Name | Role | Result | Date |
|-------------|------|--------|------|
| No entries. | | | |

Testing the efficacy of Cavuse IRB - Initial

CREATE PDF

COMPARE

SAVE

1. Once you click "Edit" or any of your "Tasks", you will be redirected to the protocol questions.

2. These are the sections of the protocol. You can move through any section by clicking on them and your work will be automatically saved.

3. Once a section's required answers (*) have been answered, a checkmark will appear on the section. All sections must have a checkmark in order to complete final submission.

4. You can also click on this next button to move through the protocol.

If you are unsure what the IRB is looking for in your answers, please click on the gray "?" at the right of each question for hints and advice.

If you are unsure what the IRB is looking for in your answers, please click on the gray "?" at the right of each question for hints and advice.

In w

human subjects?

nutrition and kinesiology.

(SBER), e.g., consumer preference and psychology.

* What kind of funding or support do you have for this study with human subjects?

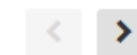
For a

any

the Proposal Num

Other type, such as private sources.

None



Sections

Core Info- Funding, ... ✓

Personnel- PIs, status, tra...

Section 1- Research Focus ...

Section 2- Methods

Section 3- Subjects & Recr...

Section 4- Data Collection

Section 5- Vulnerable Subj...

Section 6- Data Security

Section 7- Potential Risks ...

Section 8- Affiliations

Section 9- Informed Conse...

Section 10- Study PI(s) Dec...

ATTACH

Who is the Primary Contact (e.g. study director, lab manager)?

Unless there is someone designated, enter yourself with the FIND PEOPLE button.

FIND PEOPLE

Faculty Advisor

FIND PEOPLE

Human Subjects Protection Training

Please provide your CITI ID number, completion date, and expiration date and attach

ATTACH

Do you have an External or Unaffiliated Co-PI?

- Yes
 No

If any, select the Co-PIs for this study

A co-PI applies when there is a collaborative research project being proposed in this protocol.

FIND PEOPLE

Human Subjects Protection Training

Please provide the CITI ID number, completion date, and expiration date for each Co-PI and attach a copy of the CITI transcript.

1. For the question “who is the Primary Contact (PC)”, you will enter your name by clicking on the “Find People” button. A small screen will pop up on the screen.

FACULTY ✕ 🔍

| Name | Organization | Email | Phone |
|---|--------------|-------|-------|
| Type in your name and click enter on your keyboard. | | | |

Selected Records * Select a single record.

No records selected. Select a record and click Save to apply.

⌕ CANCEL 💾 SAVE

IRB NUMBER: T-IRB-17-18

PRINCIPAL INVESTIGATOR

FACULTY

| Name | Organization | Email | Phone | |
|-----------------|------------------|---------------------------|--------------|---|
| Frances Faculty | Anatomy - Cayuse | CayuseTechSupport@unt.... | 503-297-2108 | + |

Selected Records * Select a single record.

CANCEL SAVE

1. Select your name and click "Save".

2. The same process is needed for faculty advisors and co-PI(s). If you do not find your faculty advisor or co-PI(s) name, please contact the IRB office untirb@unt.edu. They will need to be manually entered into the system which will take 24hrs to become active.

| Phone | Email | |
|-------------|-------------------------------|---|
| 940-565-... | Janice.Magrini@unt.edu | × |
| | Michelle.Myers@unt.edu | × |
| 940-369-... | Jillian.Byrne-Sweeney@unt.edu | × |

How will you obtain and document parental/guardian consent and child/minor/ward assent? ⓘ

B **I** U ~~S~~ ☰ ☰ 🔗 🖼

1. Throughout the application you will be asked to attach certain documents

Attach assent form

ATTACH

Attach parent/guardian

ATTACH

2. Click on "Attach" and a pop up on your screen will appear.

1. Click on the “+” sign to add an attachment.

- Dashboard
- Studies
- Submissions
- Tasks
- Meetings
- Reporting
- Settings
- Help

- Sections
- Core Info- Fund...
- PIs, S...
- Section 1- Resear...
- Section 2- Metho...
- Section 3- Subjects ...
- Section 4- Data Coll...
- Section 5- Data Sec...
- Section 6- Potential ...
- Section 7- Affiliations
- Section 8- Informed...
- Section 9- Study PI(s...

Click the plus button to upload files or add links.

CANCEL APPLY

2. You can Add Files (Word documents, pdfs, images, etc.) or Add Links

- Add Link
- Add File

3. Click “Apply” to attach

How will yo... d/minor/ward assent?

B I U S [list icon] [link icon] [image icon]

Attach assent form

ATTACH

Attach parent/guardian consent form

ATTACH

Section 9- Study PI(s) Declaration

THE UNT IRB DECLARATION BY ALL INVESTIGATORS:

- This proposal is guided by the ethical principles regarding research involving human subjects as set forth in the [Belmont Report](#).
- I/We agree to abide by the policies and procedures of the IRB at UNT, including obtaining appropriate training in human subject research for myself and those involved in its conduct.
- I/We will not initiate any research associated with this proposal on or off campus until authorized by the IRB.
- I/We will report to the IRB about any adverse events or unanticipated problems (unexpected, possible greater risk, etc.) that occur.
- I/We will inform the IRB of a need to modify the study design requiring an amendment.
- I/We understand that approval, when granted, is valid for up to one year and will submit a renewal for its continuation if needed.

*By entering your name below, you as the PI are agreeing to adhere to the ?UNT IRB DECLARATION? above and are acknowledging responsibility for any Co-PIs and research assistants listed in the protocol and their adherence to the ?UNT IRB DECLARATION?

Signature of Principal Investigator (please enter your name below):

TYPE YOUR NAME HERE

The final section of the application requires you to “sign” after reading the “Declaration”. Please type your name in the box.

- Dashboard
- Studies
- Submissions
- Tasks
- Meetings
- Reporting
- Settings
- Help

- Sections
- Core Info- Funding, ... ✓
 - Personnel- PIs, statu... ✓
 - Section 1- Research ... ✓
 - Section 2- Methods ✓
 - Section 3- Subjects ... ✓
 - Section 4- Data Coll... ✓
 - Section 5- Data Sec... ✓
 - Section 6- Potential ... ✓
 - Section 7- Affiliations ✓
 - Section 8- Informed ... ✓
 - Section 9- Study PI(s... ✓

Section 9- Study PI(s) Declaration

1. Once all of the sections have been completed (all have checkmarks), and you have *reviewed* your application, you can submit your application.

2. You can review your application by clicking through the sections or by creating a PDF version of the protocol.

- THE UN
- T
 - I/
 - re
 - I/
 - I/
 - I/
 - I/

search involving human subjects as set forth in the [Belmont Report](#) at UNT, including obtaining proposal on or off campus until anticipated problems (unrequiring an amendment. to one year and will submit a

* By entering your name below, you as the PI are agreeing to adhere to the ?UNT IRB DECLARATION responsibility for any Co-PIs and research assistants listed in the protocol and their adherence to the ?UNT IRB DECLARATION?

Signature of Principal Investigator (please enter your name below):

TYPE YOUR NAME HERE

- Routing
Send to PI for certification? ▾
- COMPLETE SUBMISSION ▶

3. Click on "Complete Submission" when you are ready. You will be redirected to another page.



[Dashboard](#)[Studies](#)[Submissions](#)[Tasks](#)[Help](#)[Studies](#) / [Study Details](#) / [Submission Details](#)**1 In-Draft**
Submission is with researchers**2 Awaiting Approvals**
Submission is awaiting certification or approval**3 Under-Review**
Submission is with reviewers**Under-Review**
Submission is with reviewers

Unsubmitted

Initial

IRB-t16-4 - New Study Tutorial

View

PDF

Delete

Checklist

PI:
Desiree VeraCurrent Analyst:
N/ADecision:
N/ARequired Tasks:
N/AReview Type:
N/AReview Board:
N/AMeeting Date:
N/A

Approvals

Task History

Research Team

| Name | Role | Status | Date |
|---------------|---------------------------|-----------------------|------|
| Frank Faculty | Co-Principal Investigator | Pending Certification | |
| Desiree Vera | Principal Investigator | Pending Certification | |

After clicking on the "Complete Submission" button, you will be redirected to this page where you will need to click on "Certify".

You will need to "Certify" each time you submit revisions, amendments, renewals.

Routing:

Return

Certify



Dashboard

Studies

Submissions

Tasks

Meetings

Reporting

Settings

Help

Studies Study Details Submission Details

1 In-Draft
Submission with researchers

2 Drafted Submission

3 Drafted Submission

4 Drafted Submission

Initial

08/21/2017 4:14 PM

View

PI:

Desiree Vera

Review Type:

Initial

Approvals

Research Team

Name

Frank Faculty

Desiree Vera



Submission Certification

I confirm that I have the proper training, expertise and resources to conduct this study. I understand and accept my responsibilities as the Principal Investigator for this study. I confirm that I have no significant financial conflict of interest in this project or have disclosed a conflict per institutional policies and federal requirements. I confirm that the information provided in this application is true, complete, and accurate to the best of my knowledge; that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties; and agree to accept responsibility for the oversight and scientific conduct of the project.

Cancel

Confirm



Rating

Return

Certify

1. Read the Submission Certification and click on "Confirm" if you agree.

2. Selecting "Confirm" will also send your application to the faculty advisor and co-PI(s) that you have listed.

Dashboard

Studies

Submissions

Tasks

Help

Studies Study Details Submission Details

1 In-Depth Submission with researchers

Unsubmitted

Initial

IRB 110-4 - New Study Tutorial

View

PDF

PI:

Desiree Vera

Review Type:

N/A

Review Board:

N/A

Meeting Date:

N/A

Approvals

Task History

Research Team

| Name | Role | Result | Date |
|---------------|---------------------------|-----------------------|---------------------|
| Frank Faculty | Co-Principal Investigator | Pending Certification | |
| Desiree Vera | Principal Investigator | Certified | 01-13-2016 10:37 AM |

1. Your protocol will remain “Unsubmitted” until your listed faculty advisor or co-PI(s) have logged in and reviewed the application and have “Certified”. They will receive a notification email to do this.

2. Once everyone has “Certified”, the application will be sent to the IRB office to begin the review process.

Dashboard

Studies

Submissions

Tasks

Help

+ New Study



12
In-Draft



1
Awaiting Approval



1
Pre-Review



5
Under Review

My Studies

| | |
|----------------------------|--------------------------------------|
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| IRB-t16-29 | EASY Study |
| IRB-t16-28 | Genius Hour in the Primary Classroom |

View All

My Tasks

| | |
|---------------------------|---------------------|
| IRB-t17-8 | View Submission |
| IRB-t17-4 | Complete Submission |

View All

Submissions by Type

| | |
|--------------|----|
| Initial | 21 |
| Withdrawal | 0 |
| Modification | 2 |
| Renewal | 2 |
| Incident | 0 |
| Closure | 1 |
| Legacy | 2 |


You can keep track of your studies and where they are in the review process by looking at these sections on your Dashboard.

Approved Studies

| | |
|---------------------------|------------------------------------|
| IRB-15-40 | DV Initial App-Final Test 12-15-15 |
|---------------------------|------------------------------------|

View All

Studies Expiring in 30 days


No Expiring Studies

Expired Studies

| | |
|---------------------------|--|
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| IRB-15-35 | Evisions test of CPP templates 12-8-15 |
| IRB-15-19 | Evisions Training Day 1 example |
| 15-0126 | Mental Health |
| IRB-15-13 | IDA's first protocol |

View All

If you have any issues or questions, please contact the IRB Office: untirb@unt.edu or (940) 545-4643. For more information, please visit our website at

<https://research.unt.edu/faculty-resources/research-integrity-compliance>

As this is a new IRB system, if you find any issues (typos, unclear questions, etc.) please let us know. It is being used as a test environment now and we acknowledge there will be changes along the way. Thanks so much for your willingness to be a test user and we look forward to receiving your feedback.