



Creating a Master Application for a Migrated Study

 This workflow will need to occur before submitting a continuing review or amendment for a migrated study.

1. From the homepage in iRIS, click Find a Study.



2. Enter the legacy IRB Number (i.e. 21D.1016)

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IRB Number:

Study Status: All


Study Classification: All


Reference Number:


Include Studies that have not been assigned an IRB Number: ☐

3. Click Find.

Options

Application Find Options

Reset Find Options


Find ...

0 - 0

Principal Investigator




4. Click Open.

1 result(s) found...

Open	Study Status	IRB Number	IR
	Approved With No Further Continuing Review	21D.1016	01/0

5. Click on Study Application.

Protocol Items

	<u>Study Application</u>
	Informed Consents ▶
	Other Study Documents ▶

Submission Forms

--

6. Click on Add a new Application.

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ry Care Motivational Interviewing Nutrition Education Program for Weight Loss

Add a new Application

Approved?	Approval Date

7. For section 1.0 and 2.0, bypass them by clicking Save and Continue to Next Section (Note: If the personnel listed are not correct, you will need to submit a personnel change form).



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8. Answer the questions in Section 4.0.

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4.0 Determination Section

4.1 Is your study's objective, aim, eligibility, or outcome pre-cancer or cancer-related?

☐ Yes ☐ No

4.2 Does your study include Written, Verbal and/or Implied consent process?


☐ Yes ☐ No





4.4 Was approved or authorized by Jefferson IRB and issued a Jefferson IRB number prior to the iRIS Go Live date of 09/26/2022, and was not migrated to iRIS (i.e., you cannot find the study in iRIS), enter the Jefferson IRB number here. This will ensure that the Jefferson IRB number is assigned to this study in iRIS.

☐ Yes ☐ No

9. Click on Save and Continue to Next Section

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10. Answer the questions in Section 5.0.

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5.0 Selecting IRB of Record


5.1 Is this a multi-site study that is or is intended to be under single IRB oversight (i.e., study involves non-Jefferson/Rothman sites. Contact OHR with questions.)
☐ Yes ☒ No

5.3 Select IRB of Record:
☐ Jefferson
☐ NCI CIRB
☐ Commercial IRB (e.g. WIRB, Advarra, etc.)
☐ Academic or other external IRB

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son/Rothman sites. Contact OHR with questions.)

12. Answer the questions in Section 6.0.

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6.0 General Information (OHR-1)

6.1 Funding Sponsor name:

Add a New Sponsor to the Study

Delete	Edit	View Details	Sponsor Name	Sponsor Type	Project Number	Award Number
No Sponsor has been added to this Study						

6.2 Division:

Non-Oncology:

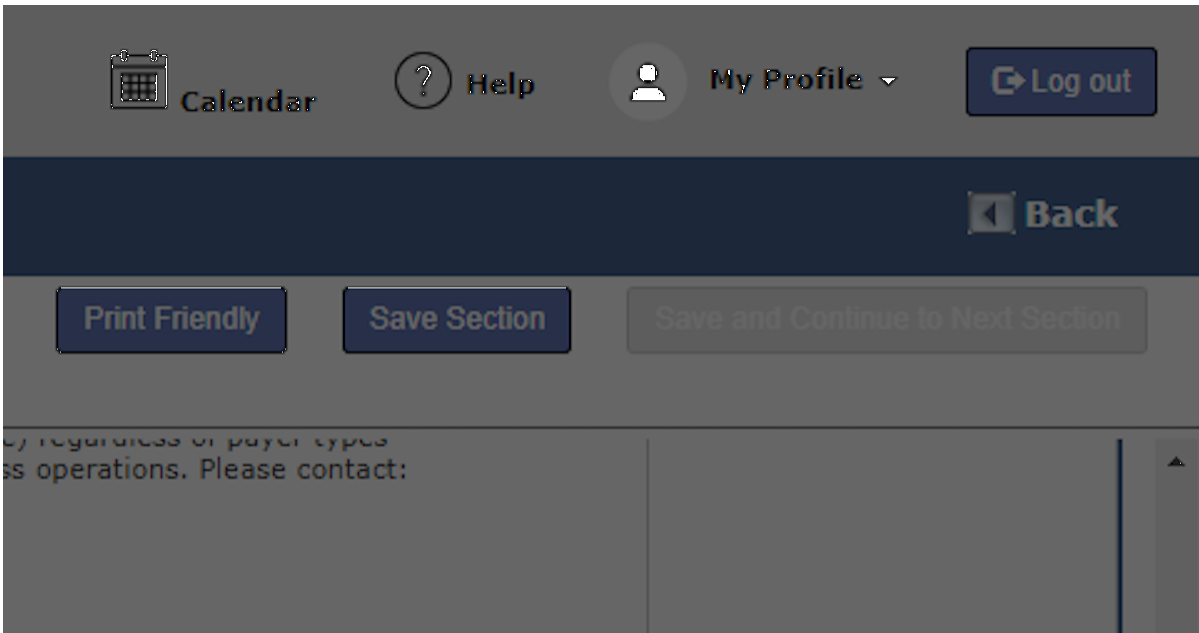
--none-- ▾

6.3 Does this study involve only data collection with no interactions with participants?

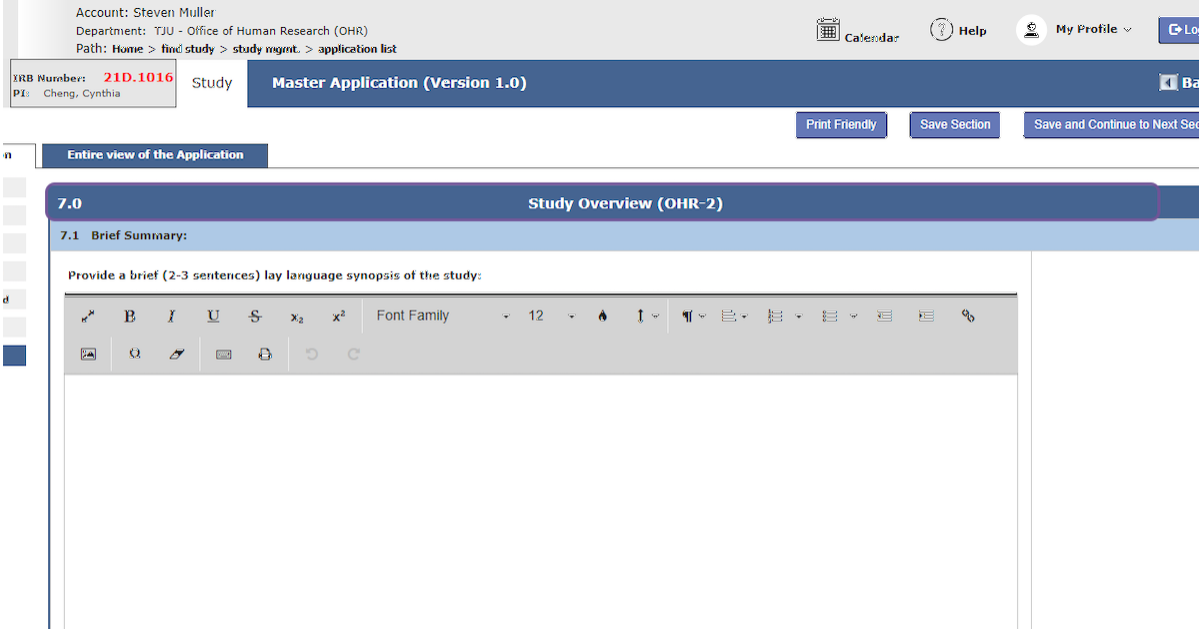
☐ Yes ☐ No

6.4 Does this study involve only collection of stored or discarded biospecimens, with or without data collection, and with no interactions with participants?"


13. Click on Save and Continue to Next Section





14. Answer the questions in Section 7.0.



15. Click on Save and Continue to Next Section.

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16. Answer the questions in Section 8.0. (if applicable)

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8.0

Subjects and Facilities (OHR-2)

8.1 Does study involve only the collection of tissue and/or data where there will be no interaction with human subjects?

☐ Yes ☐ No

8.2 What is the expected number of subjects to be enrolled?

Number of subjects per year at sites under Jefferson IRB (up to):

Total number of subjects for duration of study under Jefferson IRB (up to):

Total number of subjects nationally or internationally for duration of study (if applicable):

8.3 Identify the locations where the research will be conducted and describe the adequacy of facilities at each location:

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jects?

18. Answer the questions in Section 9.0. (if applicable)

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9.0

Drugs (OHR-2)

9.1 Does this study involve investigational or emergent use of drug(s) (ie., investigational drugs, FDA approved drugs, nutritional supplements, biologicals)?

Yes

No

Note: "Investigational use" should be applied to a drug that is under study in the research, is a comparator in a randomized study design, or is otherwise integral to the study design.

9.4 If the investigational product does not have an IND#, please certify that its intended use meets at least one of the following FDA categories for IND exemption (21 CFR 312.2) by checking applicable statement(s). If none of the following categories apply, the sponsor must obtain an IND# or IND exemption letter from the FDA.

Exemption Category 1 [21 CFR 312.2(b)(1)] - All criteria for this category must apply:

The drug product is lawfully marketed in the United States.

It is not intended to be reported to FDA in support of a new indication for use or to support any other significant change in the labeling for the drug;

It is not intended to support a significant change in the advertising for the product;

It does not involve a route of administration or dosage level, use in a subject population, or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product;

It is conducted in compliance with the requirements for IRB review and informed consent [21 CFR parts 56 and 50, respectively]; and

It is conducted in compliance with the requirements concerning the promotion and sale of drugs [21 CFR 312.7].

In Vitro Diagnostic Biological Product [21 CFR 312.2(b)(2)]:

The study is a clinical investigation involving a (a) blood grouping serum; (b) reagent red blood cells; and/or (c) anti-human globulin and the product is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure and it is shipped in compliance with Sec. 312.160.

19. Click on Save and Continue to Next Section.

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ugs, nutritional supplements, biologicals)?

20. Answer the questions in Section 10.0. (if applicable)

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10.0

Devices (OHR-2)

10.1 Does this study involve investigational or emergent use of a device or humanitarian use device (HUD)?

Yes

No

10.11 When the investigator or Jefferson holds the IDE/HDE, the Investigator/Jefferson becomes the "sponsor" of the research and assumes responsibility to ensure that all FDA regulatory criteria for sponsors are met. Please provide your plan for meeting FDA regulatory criteria for sponsors:

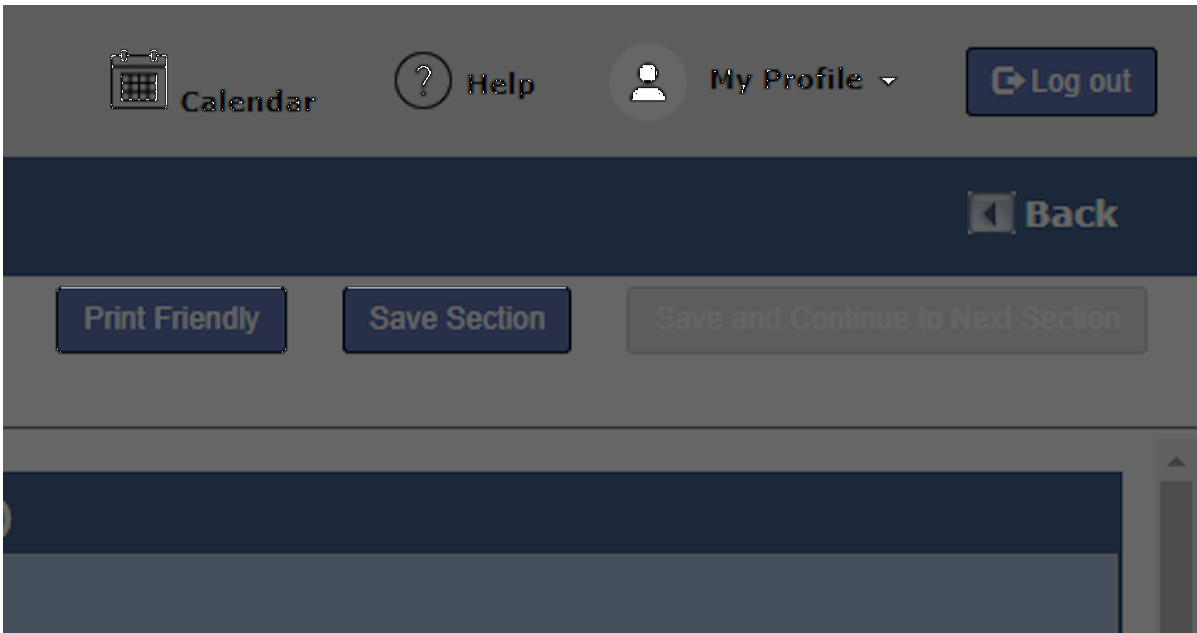
For example:

- Investigator who holds an IDE/HDE will assign some or all responsibilities to meet FDA sponsor requirements to a contract research organization (CRO).
- Investigator will undergo an audit by a CRO to ensure that procedures are in place so that all FDA regulatory requirements of sponsors will be met.
- Investigator will assign responsibility of compliance with some FDA regulatory requirements to a CRO and investigator will obtain an audit from a CRO to ensure that procedures are in place so that all other FDA regulatory requirements of sponsors will be met.

Note: If you intend to use someone who is in-house and who has expertise on sponsor requirements, please justify that that person has equivalent expertise to a CRO.

21. Click on Save and Continue to Next Section

23. Click on Save and Continue to Next Section



24. Answer the questions in Section 12.0. (if applicable)

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12.0Recruitment & Consent Process (OHR-2)


12.1 Do you intend to obtain consent from the participants for this study?

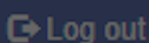
☐ Yes ☐ No

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
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
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
-2)


26. Answer the questions in Section 13.0. (if applicable)

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13.0Radiation

13.1 Does this study involve the use of radioactive material or radiation source?

☐ Yes ☐ No

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28. Answer the questions in Section 15.0. (if applicable)

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15.0

Data Collection & Waiver of Consent (OHR-3/4)

Under the Common Rule, the IRB may waive the requirement for written consent, or the consent process as a whole, when certain criteria apply. Under HIPAA, the IRB also may waive the requirement to obtain written authorization for use of protected health information (PHI) for research purposes, when certain criteria apply.

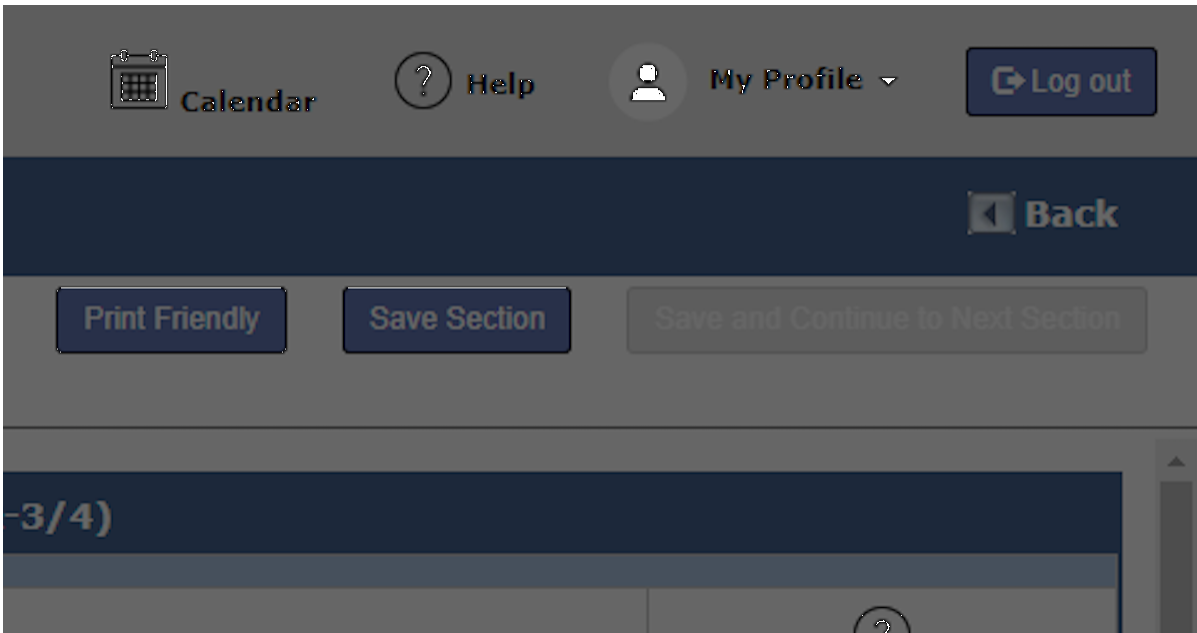
15.2 Please list all data that will be collected for this study:

This includes all study data, including health-related data and identifiers.

15.3 What are the specific sources of the data to be collected? (i.e., Dr. X's outpatient records, hospital EMR, Pathology records, etc.)

15.4 Complete the table below by checking as applicable:

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30. Answer the questions in Section 16.0.

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16.0 Application Complete

16.1 Click Save & Continue to proceed to the Initial Review Submission Packet.

The Initial Review Submission Packet is a short form filled out after the protocol application has been completed. This is an area to attach protocol-related documents, consent forms, and review the application.

31. You will be routed to attach protocol-related documents, consent forms, and review the application.

This Workflow was created with Tango.