Keeping the House in Order

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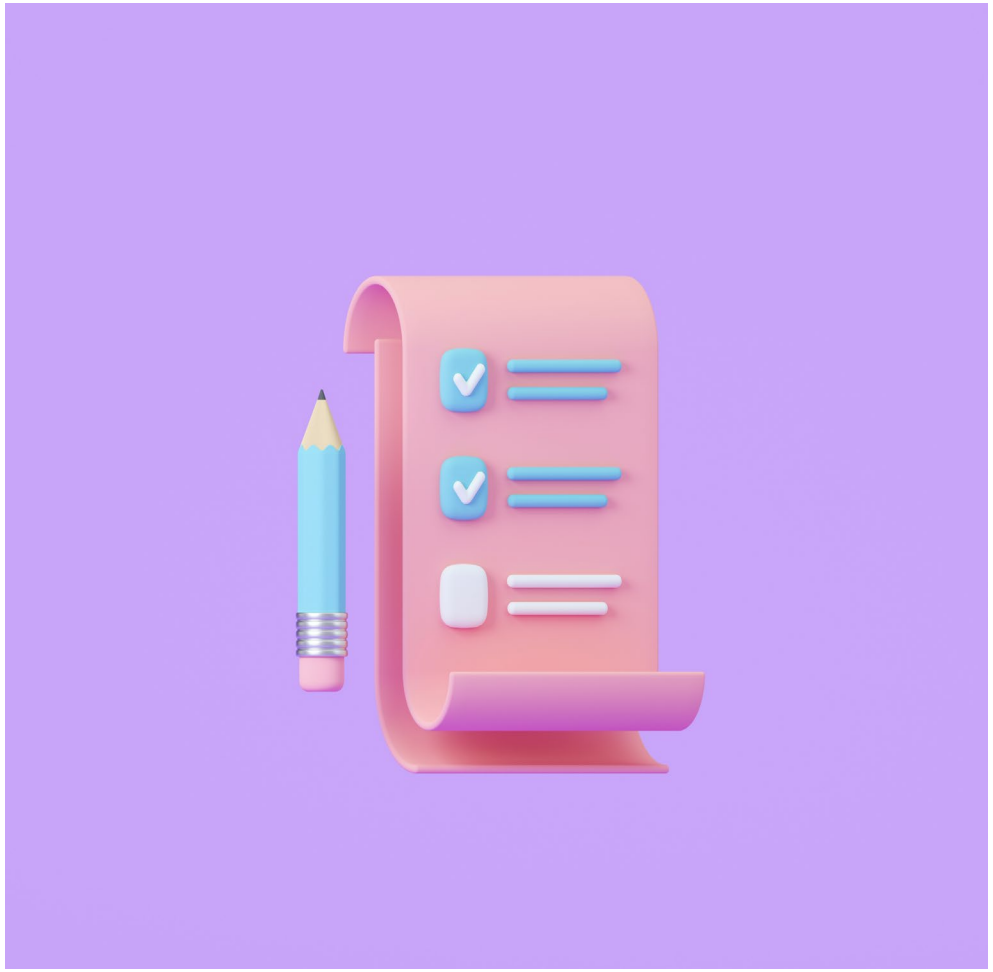
Relevant Conflicts

- I DO NOT have an actual or potential conflict of interest in relation to this program/presentation.

Objectives

- Defining appropriateness of study closure in system & record retention
- Describe best practices for approval of recruitment materials, translations & naming conventions
- Discuss how to approach outdated study documents
- Reconciling IRB fees



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Importance of Documentation

Investigators have responsibilities regarding the proper documentation of research involving human subjects, as mandated by Institutional Review Boards (IRBs) and federal regulations.

Requirements ensure the ethical conduct of research, the protection of participants' rights and welfare, and the integrity of the data collected.

List of Documents before and after approval

- Research Protocol and Amendments:
- IRB Communications
- Informed Consent Documents
- Documentation of the consent process, especially if it deviates from standard written consent (e.g., oral consent with a witness).
- HIPAA authorizations obtained
- Recruitment Materials and participant-facing materials
- Training Records
- Conflict of Interest Disclosures
- Records of data entry
- Adverse Event and Unanticipated Problem Reports
- Communication with Sponsors (if applicable
- Final Report:
- Subject Enrollment Logs

Remember your audience!

- You must provide information to subjects to be understandable.

Subjects Abilities and Limitations	Consent Process
Subject cannot read English but can read another language	Consent document and other subject-facing documents must be in the language the subject can read
Subject cannot read. Subject can fully understand spoken English but subject primarily understands another language.	Ask the subject which language s/he prefers and read either the IRB-approved English version of the consent form or IRB-approved version of the consent form translated into the subjects' preferred language. Obtain the witness's signature on the consent document. Carefully document each step of the process in the research record.
The subject does not understand or read English. The subject speaks and understands a different language but cannot read documents written in that language.	Read the IRB-approved translated consent form to the subject in the presence of a witness. Obtain the witness's signature on the consent document. Note the subject's ability to (1) understand the different language and (2) the translated consent document was provided to the subject.

Translation Options

- Qualified translator
- Back/ Forward Translation: Rule 4:1 per document
- Certified Translator
- Short Form
- https://hsro.uresearch.miami.edu/submit-to-the-irb/forms-and-templates/templates/index.html
- https://hsro.uresearch.miami.edu/resources-and-guidance/informed-consent/translations/index.html

Recruitment materials

- Investigator Manual Chapter 6
- Recruitment material must comply with the University of Miami's Visual Identity Guidelines.
- Tailor your recruitment process and materials to your target population.
- Worksheet: HRP-315 Advertisements
  - https://hsro.uresearch.miami.edu/_assets/pdf/hrp-315-worksheet-advertisements.docx

IBIS and Document Section

- IBIS designates specific sections in which to upload documents
  - Protocol*
  - Informed Consent Form*
  - Recruitment Materials*
  - Drug/ Device
  - Other Attachments (possibly*)
    - * Watermarked Sections
- IBIS is an auditing trail of materials: UPDATE-NO REMOVE
- If a document is no longer used, you can re-name “DO NOT USE”

Study Closure… You're not Done at Approval!

- Investigators may close a study when:
  - The study is permanently closed to enrollment or was never open for enrollment;
  - They have completed all interactions and interventions with subjects, including long-term follow-up; and
  - The study is no longer collecting or analyzing private, identifiable information about the participants.
- To close a study, complete the Continuing Review Smart Form in IBISResearch, attach all requested supplements, and have the Smart Form submitted by the PI by clicking the "Submit" activity.
- If the appropriate research milestones are complete, the study will be closed to discontinue IRB oversight.

IRB systems

- Upgrade to IRB10.5
- Best Practices
- Key IBISResearch fields
- Velos/REDCap Expectations
- Training & Support

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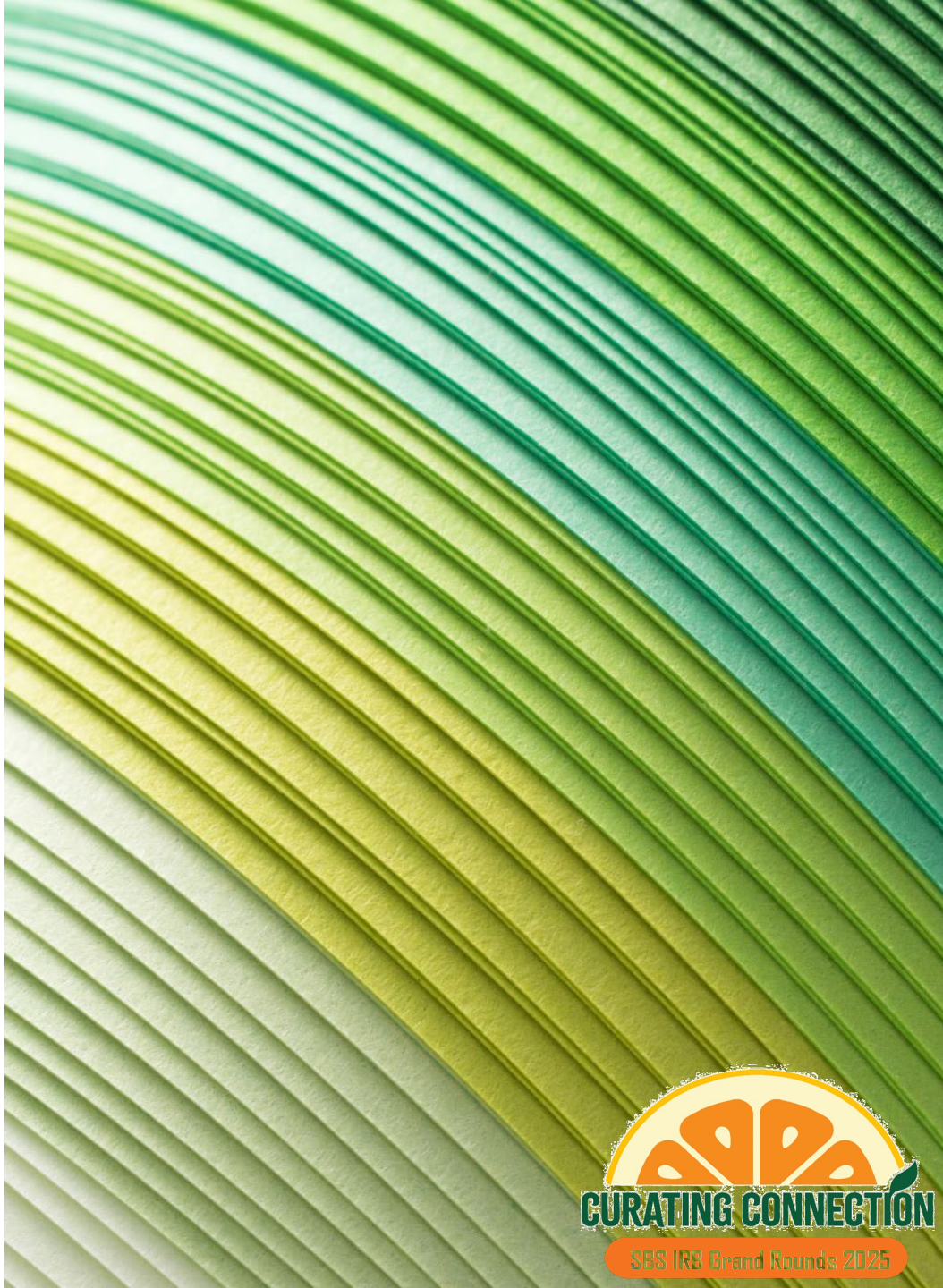
Coming Soon!! IRB10.5

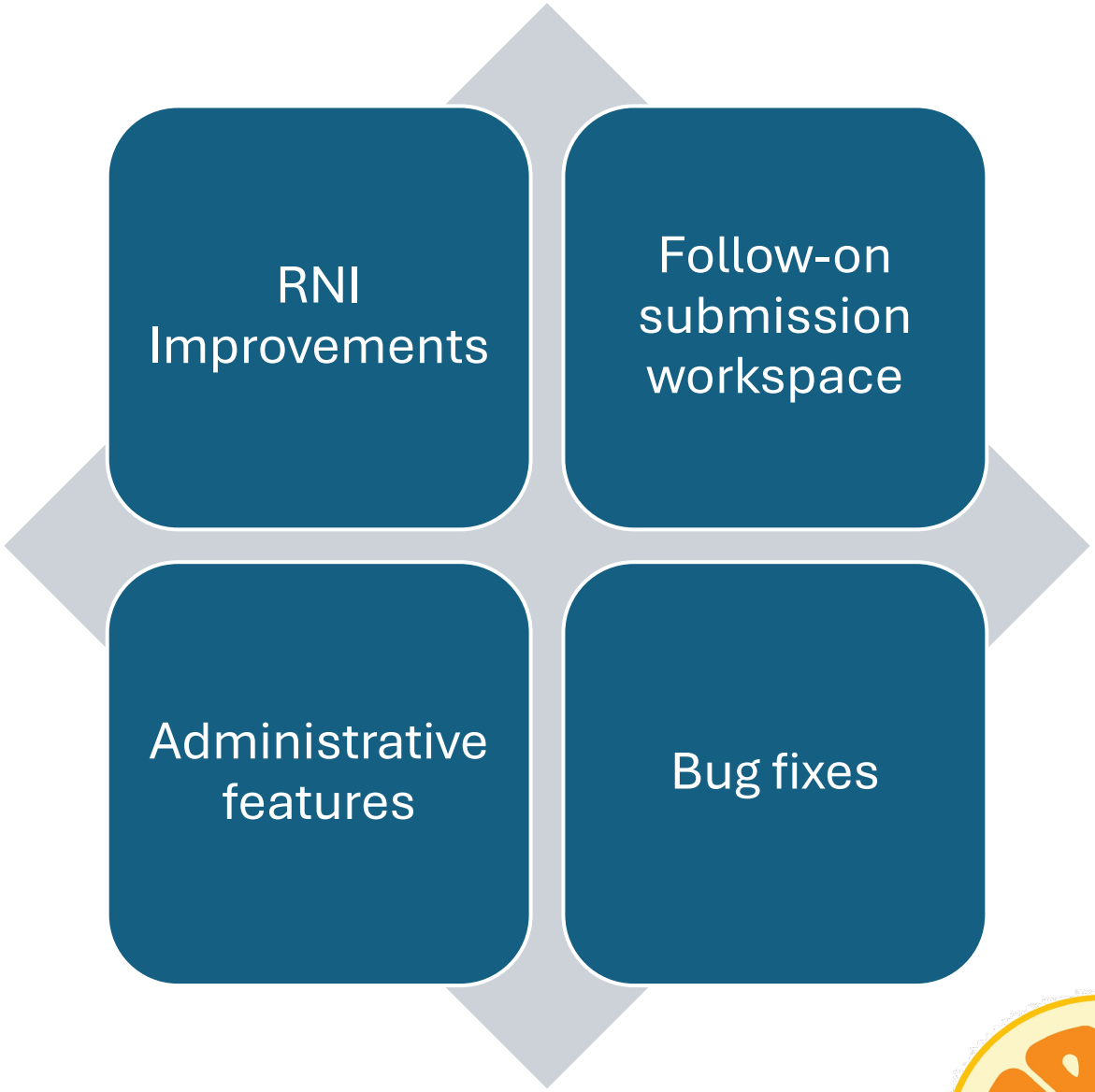
Check out the Huron 10.5 Upgrade website! This website serves as a resource repository for users impacted by the 10.5 upgrade. You will be able to readily access release notes, contact information, key project milestones, and software version transition videos.

If you have any questions, please contact:

Lindsey Stern-Shuch, 10.5 Upgrade Project Manager, lsternshuch@miami.edu – Overall project, COI & IACUC	Erika Vizcarrondo erikavizcarrondo@miami.edu – ORA & IRB	Kanchan Sakhrani, 10.5 Technical Lead, k.sakhrani@miami.edu – Technical inquires for overall upgrade



Highlights for IRB10.5



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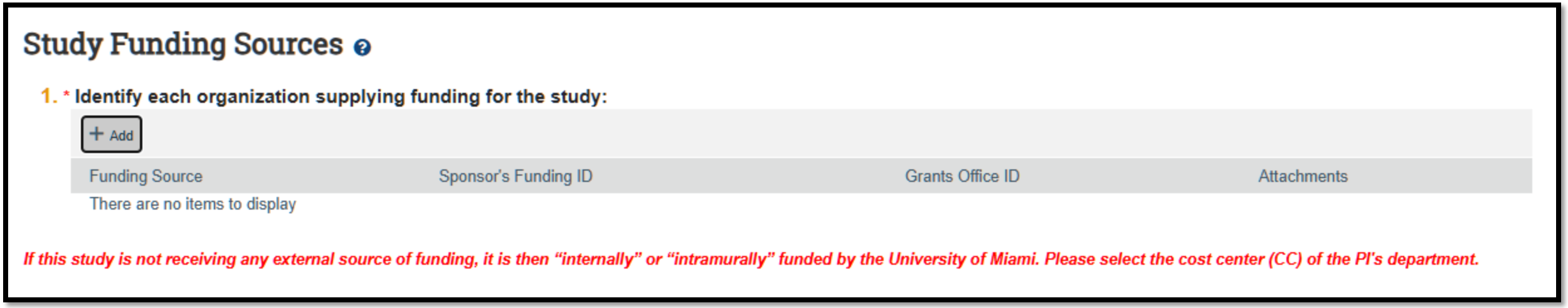
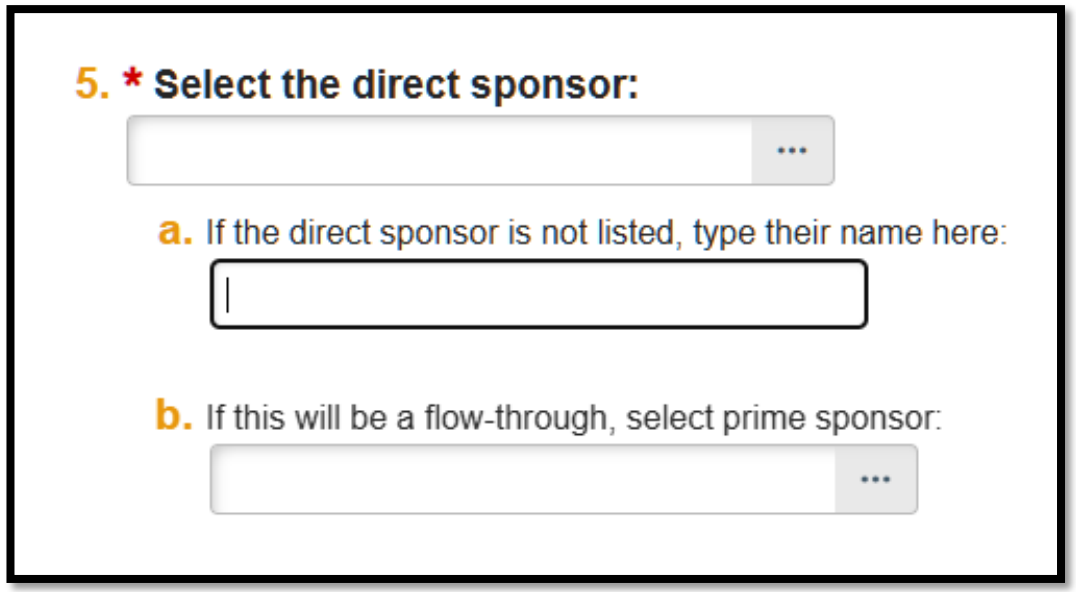
Best Practices

Funding Sources in IBIS





- Downstream systems that are connected to Funding Sources from IBIS:
  - Awards -> Workday
  - IRB -> Velos --> Workday*
  - Grants -> Agreements
  - IRB/Grants/Agreements -> COI
  - IRB -> Grants*

*Industry Funded

Dual Submission Best Practices

Grants & IRB Integration

[Grants and IRB Manage Relationship - Job Aid.pdf | Powered by Box]

Effective July 29th, 2024

WHAT

Simultaneous submission to:

- Institutional Review Board (IRB)
- Office of Research Administration (ORA)

Important Steps

- **Link Projects in IBIS System**
  - ❑ Relate the Funding Proposal in the Grants module to the IRB submission in the IRB module.
- **Review Process**
  - ❑ ORA will review the submission.

Note: ORA will discard the submission if the projects are not linked in the IBIS system.

WHO

- **Investigator (PI) or**
- **Department**

WHERE

IBISResearch System

- Grants Module (Funding Proposal)
- IRB Module (IRB Submission)

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Best Practices for Funding Sources

- Make sure the Funding Source is a valid organization coming from Workday (i.e., SPN ID)
- If Industry Sponsored study, make sure a valid Account Number is entered in IRB
- If a Grant/Award/Agreement exists, make sure to link the submission to IRB, and vice versa using Manage Relationships activity

What does “billable” mean to you?

5. * **Does this study include any procedures, items, and/or services that could generate a charge in the UM billing system (Epic/UChart), regardless of whether the charge/bill is paid for by the research subject’s insurance or the industry sponsor/NIH funding entity?**

○ Yes ● No

If “Yes”, please add MCA Review Group as an ancillary reviewer via the Manage Ancillary Reviews activity.

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What does “billable” mean to you?

5. * **Does this study include any procedures, items, and/or services that could generate a charge in the UM billing system (Epic/UChart), regardless of whether the charge/bill is paid for by the research subject’s insurance or the industry sponsor/NIH funding entity?**
   ○ Yes ● No

   If “Yes”, please add MCA Review Group as an ancillary reviewer via the Manage Ancillary Reviews activity.

UM Policies triggered by this question (at this time of presentation):

If Yes: Velos Tracking Policy - https://umhs-umhc.policystat.com/policy/11169096/latest/
This includes MCA Review for initial and follow on submissions*

If No: REDCap Accrual Policy - https://umiami.policystat.com/policy/14766893/latest/

This question impacts patient billing in UChart, and must be answered correctly to ensure accurate and timely billing for the University.

IBIS/Velos Relationship & Billing Compliance

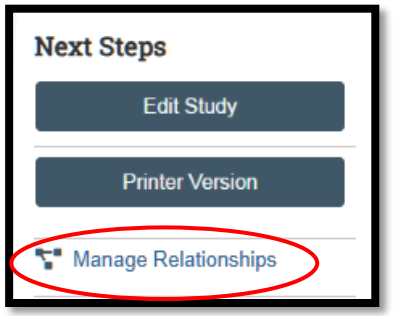
1

5. * **Does this study include any procedures, items, and/or services that could generate a charge in the UM billing system (Epic/UChart), regardless of whether the charge/bill is paid for by the research subject's insurance or the industry sponsor/NIH funding entity?**

○ Yes ○ No Clear

If "Yes", please add MCA Review Group as an ancillary reviewer via the Manage Ancillary Reviews activity.

2



3 UNIVERSITY OF MIAMI

YES

4

wcg velos

MEDICARE COVERAGE ANALYSIS

Confidential. Do not distribute outside of the University of Miami.

FINAL

5 CRRC Monitored

6 U Chart

Velos Patient Statuses need to be entered within 2 Business Days

Best Practices for Research Billing

Always ensure you are adding patients in Velos using the Patient Lookup Tool/PLT

Always ensure you are selecting the patient with the correct UMMG MRN

Always ensure you are updating patient statuses within 2 business days – *this may mean 48 hours from the UChart registration date*

If MCA Review Group indicates the study does not need an MCA, if indicated to change Billing question from Yes to No, please do!

IBIS/REDCap Relationship

1

5. * **Does this study include any procedures, items, and/or services that could generate a charge in the UM billing system (Epic/UChart), regardless of whether the charge/bill is paid for by the research subject's insurance or the industry sponsor/NIH funding entity?**
Yes No Clear

If "Yes", please add MCA Review Group as an ancillary reviewer via the Manage Ancillary Reviews activity.

2

NO

REDCap

Report Accruals*

3

Record ID	Demographics
1	
2	
3	
4	
5	

*A. **For non-cancer-related protocols**:
1. For research projects **requiring Continuing Review**, at the time of Continuing Review - report aggregate accruals as of the last submitted Continuing Review. *A notification to key personnel with an institutional REDCap survey link will be sent 30 days prior to the Continuing Review deadline.*
2. For research projects that **do not require a Continuing Review**, annually by the end of February - report aggregate accruals as of the previous calendar year. A notification to key personnel with an institutional REDCap survey link will be sent every January.
B. **For cancer-related protocols**, report accruals of study participants into REDCap within 5 days of consent. A notification to key personnel with a link to a REDCap Accruals project will be sent once the protocol receives IRB approval.

How many IRB systems are at UM, and how do I access my data?

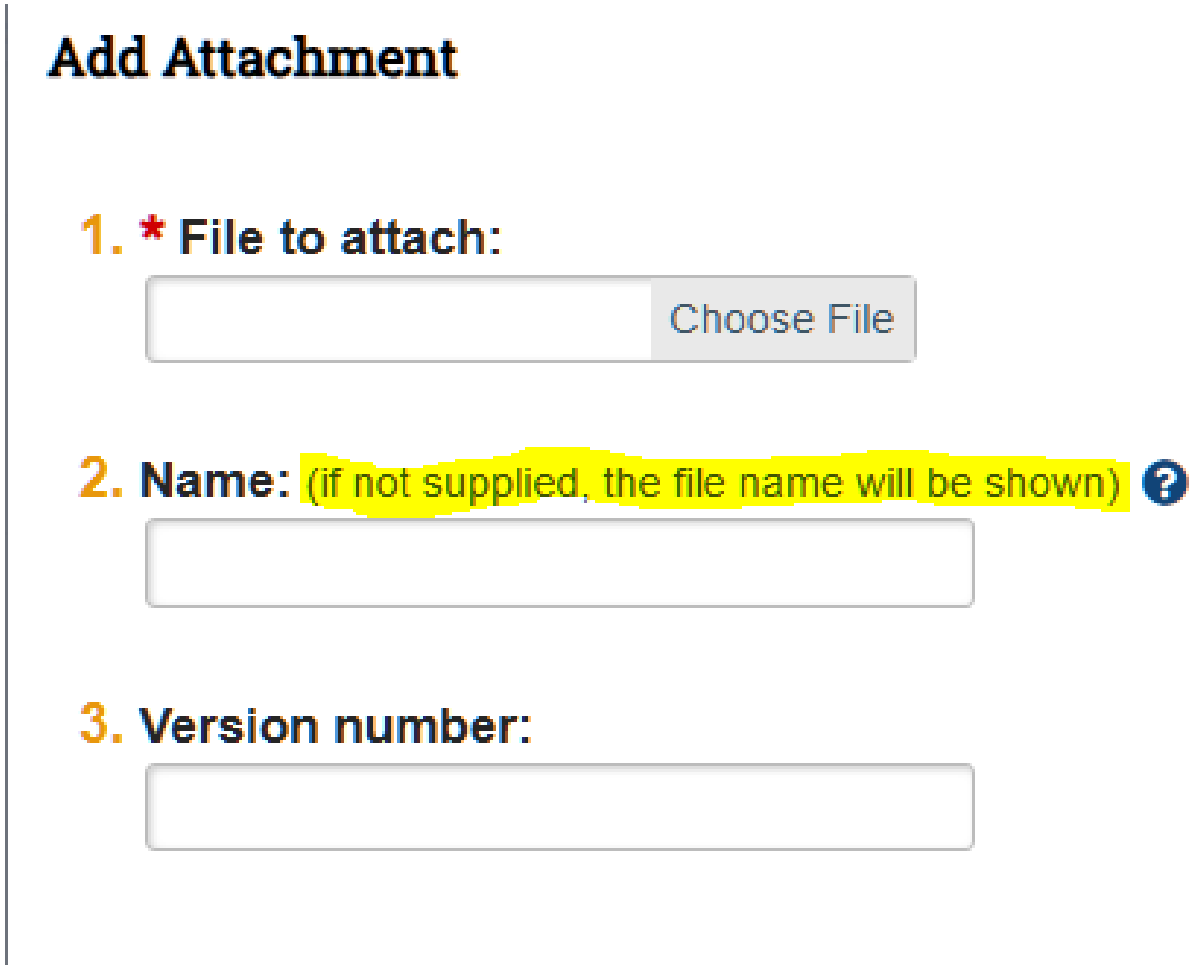
eProst Archive – flat file – Contact OVPRS Help Desk for any information you may need for studies that were active/closed before 2013

IRB8/eProst Legacy – www.eprost.med.miami.edu – this is **READ ONLY**, and is behind the clinical firewall – log into VPN in order to access this system for any studies that were approved between 2013 and 2022. Contact OVPRS Help Desk for access.

IRB10/IBISResearch IRB - https://ibis-research.miami.edu/IRB/ - this is the current live environment that has all active and in-review studies, including those from prior systems.

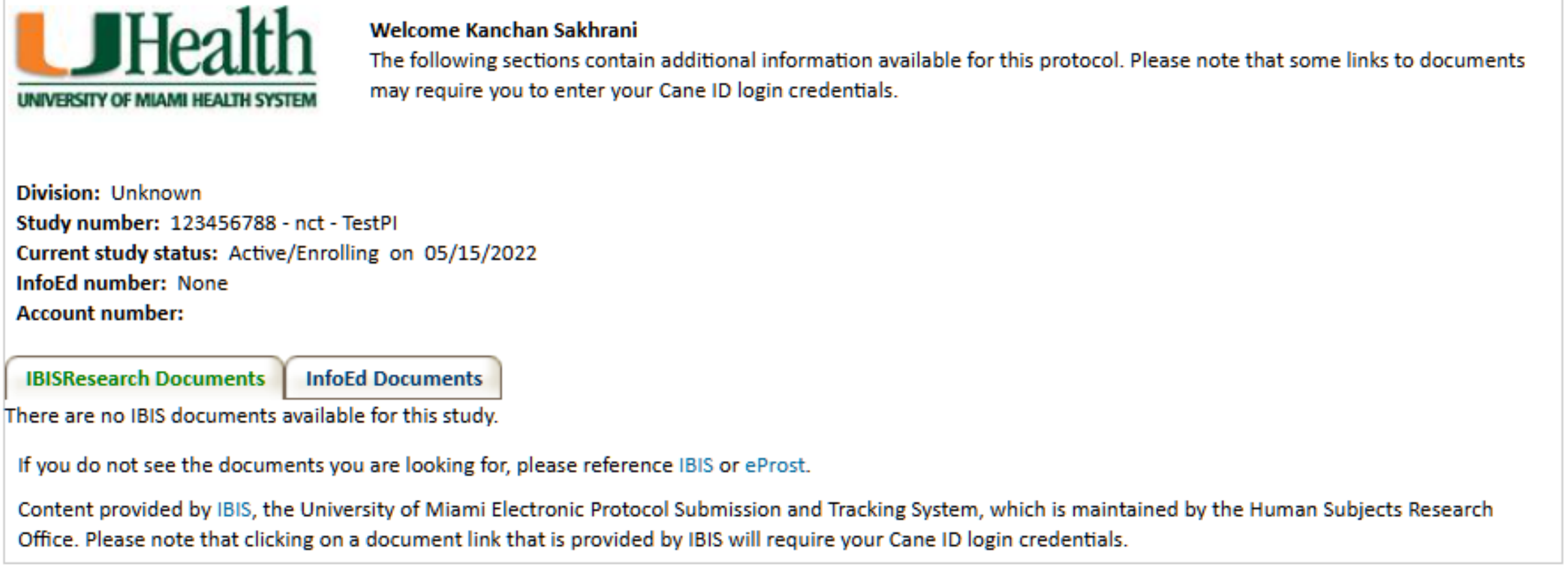
How should I label my documents in IRB?

Document naming conventions



Category
Funding Source Attachment
Data Collection Sheet
HIPAA Form
Questionnaire/Survey/Interview/Diary
Press Release
Certificate of Confidentiality
Genomic Data Sharing Plan
NIH Institutional Certification
Correspondence
Protocol
Consent Form
Recruitment Materials
Drug Attachment
Device Attachment
IRB Protocol
Sponsor Attachment
Other

IRB Documents and Velos D-Link



Smartform/Policy Matrix

Policy	System/Location	Description/Trigger	Action/Expectation
Clinical Trial Management (CTM) and Participant Enrollment and Tracking Policy	IRB Scope Q5	• each clinical research study that includes services **billable** to any third party payer… shall be registered in the Clinical Trial Management System ("the CTMS") called Velos • The Medicare Coverage Analysis (the "MCA") must be uploaded in the CTMS before any participants are enrolled in the study;	• If Yes, Study Enrollment is tracked in Velos • If Yes, MCA Ancillary Review Group needs to be added to IRB study
Clinical Trial Management (CTM) and Participant Enrollment and Tracking Policy	Velos Patient Status	• each individual participant's status must be updated to "Informed Consent Signed" in the CTMS within 2 business days after informed consent is obtained; • "Off Study" status of each participant must be entered in the CTMS within 2 business days of participant withdrawal or completion of all in-person study visits	Patient Statuses must be updated within 2 business days* **UChart patient needs to be registered prior to adding to Velos*
Enrollment Tracking Using REDCap	IRB Scope Q5	track aggregate accruals in clinical research studies (e.g., interventional non-treatment and non-interventional) that fall outside the scope of the existing Clinical Trial Management (CTM) and Participant Enrollment and Tracking Policy (VELOS).	If no: For non-cancer-related protocols, it is the responsibility of UM faculty and research personnel conducting human subject research studies, as defined above, to report their accruals on an annual basis.
Code of Federal Regulations	Title 21 CFR Part 11	implement controls, including audits, system validations, audit trails, electronic signatures, and documentation for software and systems involved in processing the electronic data that FDA predicate rules require them to maintain.	• Part 11 documentation for Implementation, Updates, and System Training on Velos, IRB10, Complion, etc. • Electronic Records/eSignatures • audit trail, requiring a username/password for login, a password for e-signature, ability to create copies, etc
Clinical Trial Disclosure: Determination and Protocol Registration	Clinical Trial activity in IRB; IRB Scope Q4-4c	for a study to be considered a Clinical Trial, it must involve an intervention designed to affect a health-related biomedical or behavioral outcome.	If the criteria are met, CTD Ancillary Review Group needs to be added to IRB Study. Clinical Trial activity needs to be updated in IRB
ORA/HSRO Business Process change (Dual Submission)	Manage Relationships	this change only impacts industry sponsored studies. All other projects do not require simultaneous submission to the IRB and ORA (e.g., grant proposals).	The protocol must be submitted to the IRB in IBIS within two weeks of submitting to ORA.
Conflict of Interest, Conflict of Commitment, Foreign Influence, and Institutional Conflict of Interest Policy	Disclosure Profiles in COI	All Covered Persons (University Officials, Faculty members, UHealth employees, Investigators, University administrators and staff;) upon employment or contract with the University and at least annually:	• Covered Persons who are UHealth employees must comply with additional requirements as listed in the UHealth section. • Covered Persons who are Investigators must also comply with additional requirements articulated in the Scholarly Activities section

OVPRS Help Desk/Support

- Get Help
- IRB10 System Training in Qualtrics
- Office Hours –
    - Velos Office Hours - 1 hour weekly (Monday)

Reconciling IRB Fees

Is the study receiving Industry support?

- Yes → IRB fees are applicable
- No→ IRB fees are not applicable

Jeanette Mestepey
Sr Finance Manager
Office of the Vice Provost for Research + Scholarship

University IRB Fees

Located on HSRO webpage →

The University of Miami's, Human Subject Research Office (HSRO) will assess the following fees:

1. **HSRO Processing Fee:** A fee that is charged according to submission type (see below HSRO fee schedule) and applicable to all industry supported studies.

2. **External IRB Administrative Fee:** A one-time fee charged to a new submission and applicable to all industry supported studies (see below HSRO fee schedule).

All fees will be collected through a Central Workday Journal and will post to spend category SC08007 - Interdepartmental / Intercompany - IRB Protocol Review Fee

The account/driver information provided in the billing activity will be used to process HSRO fees. If a sponsored account has not been established prior to the submission, the appropriate account to be used for payment is the corresponding Departmental IRB account number.

HSRO Fee Schedule

Submission Type	Type	Fees
New Studies		$3,000
Continuing Review		$1,300
Request for Modification, there are two types:	Other parts of the study	$550
	Study team member Information	No charge
Modification & Continuing Review	when submitted simultaneously	$1,800
Final Review		$250
External IRB Administrative		$1,500

How are IRB fees assessed?

- Each quarter, a report is generated for all studies applicable to the IRB fee schedule
- The information that was provided with the submission is used to submit a charge in Workday
  - The journal will indicate in the Memo the details on the charge to include:
    - Submission number
    - PI Name
- Study teams can use the determination letter along with a copy of the fee schedule for supporting documents to reconcile the charge

When are IRB Fees assessed?

- **Depending on funding source selected in section 1:**


Study Funding Sources

1. * Identify each organization supplying funding for the study:

Funding Source	Sponsor's Funding ID	Grants Office ID	Attachments

f this study is not receiving any external source of funding, it is then "internally" or 'intramurally" funded by the University of Miami. Please select the cost center (CC) of he PI's department.

  - **This will map the source of funding and if its industry the submission will appear in the IRB billing report.**

- **When IRB fees are applicable the system will require you to complete section 14**
  - **It is important to input a valid account number**

14. * Driver Worktag ID (Account Number):
Please enter the submission Driver ID (Account Number). By submitting this activity, authorization is granted to the HSRO to use the Driver ID provided below for IRB fees.

What if you don’t know the driver number to input in section 14?

- Use the departmental one for IRB fees

- Once you have the account set up
  - Submit a modification to change the account number
  - We quarterly bill to allow the time to submit this modification as this will update the driver to use for the IRB charge

- In the modification make sure you write the reason you are submitting is only to update the account umber
  - The HSRO team can cross check these modifications, so they are not billed the modification fee

Workday information and contact

- If you find that in Workday you need more information on a charge or need to reconcile charges to close out a study

  - Reach out to:
    - Jeanette Mestepey jmestepey@miami.edu **and**
    - Dr. Di Ding Dding@med.miami.edu
    - When applicable, please be sure to include a copy of the journal with your request

Central IRB / Multi-Site Fees

- We continue to explore this avenue
- Currently there are no fees assessed for these
- More information coming soon!

Thank you for attending and “U”

IRB Grand Rounds - Continuing Nursing Education (CNE) Evaluation and Registration

Nursing Continuing Professional Development (NCPD)

The University of Miami School of Nursing and Health Studies is accredited as a provider of nursing continuing professional development by the American Nurses Credentialing Center's Commission on Accreditation.

Thank you!/ Questions?

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