University of CINCINNATI

Cooperative Research - Reliance Agreements and External IRB &
Updates to Reporting in MIDAS for Clinical Research

Thursday, June 20th, 2024

University of CINCINNATI

Compliance Corner

Recently updated Clinical Research SOPs:

- **UCH-OCR-OPS-SOP-014- Prompt MIDAS Reporting of Serious Adverse Events that are both Unexpected and Related to the Research, and Reporting Emergency Use of a Research Related Treatment or Device**
  - **This SOP now includes reporting Emergency Use of Research indicated devices or treatments.**

All OCR SOPs are accessible at the following link.
And from the UC Health intranet home page utilizing the Policy Portal Search function or reach out to the Office of Clinical Research with any questions or concerns.

OCR CRP First Friday July 2024

CANCELLED

Due to the Independence Day Holiday

First Friday shall resume for August 2024

Today's Presentation:

Cooperative Research - Reliance Agreements and External IRB &
Updates to Reporting in MIDAS for Clinical Research

We will provide a reliance process overview and review and discuss relying on an External IRB including recent updates to the process for commercial IRBs and we will also address the criteria and updates regarding clinical research reporting in MIDAS.

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COOPERATIVE RESEARCH AND EXTERNAL RELIANCE

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LEARNING OBJECTIVES

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- General Reliance Overview
- Review and discuss relying on an external IRB
- Review and discuss process shifts for external reliance

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RELIANCE OVERVIEW

RELIANCE AND RELIANCE AGREEMENTS

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- **Cooperative research** refers to research involving more than one institution. This can include:
  - Collaborative research - Different parts of a protocol may be carried out at different institutions -or- an individual researcher not affiliated with UC may assist a UC study team with conducting research at UC.
  - Multi-site research - Multiple institutions may conduct the full protocol at their site.
- A **reliance agreement** is a formal written agreement that documents respective authorities, roles, responsibilities, and communication between an institution/organization serving as the IRB of Record (Reviewing IRB) and the institution relying on that IRB. This agreement can be represented in several different forms that include an IRB Authorization Agreement, Cooperative Agreement, Master Services Agreement, Master Joint Agreement, or Memorandum of Understanding.
- For UC investigators, **reliance on an External IRB** (or external reliance) refers to research UC investigators conduct where UC is ceding the IRB review (and sometimes privacy review) to an external institution's IRB.

CURRENTLY EXECUTED RELIANCE AGREEMENTS

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Unidirectional

- National Cancer Institution (NCI CIRB)
- NeuroNEXT (Mass General Brigham Incorporated, IRB; formerly Partners HealthCare System IRB)
- PETAL Network (Vanderbilt University IRB)
- Rare Lung Disease Consortium (CCHMC IRB)
- StrokeNet (UC IRB)
- Advarra
- WIRB-Copernicus Group
- Individual Investigator Agreements

Bidirectional

- SMART IRB Participating Institutions (preferred agreement with 1200+ participating institutions)
  - Includes Christ Hospital
  - Includes institutions previously participating in the Consortium of Greater Cincinnati IRBs (Jewish Hospital – Mercy Health, St. Elizabeth Healthcare, Tri-Health, Inc., CCHMC, NKU)
- Reliance with any other OHRP registered institution requires an IRB Authorization Agreement that outlines institutional responsibilities

NIH SINGLE IRB (SIRB) POLICY

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An NIH funded study being conducted at more than one U.S. site involving non-exempt human subjects research may be subject to the NIH Single IRB policy. NIH-supported studies conducting multi-site or cooperative research may need to have a single IRB, if any of the following apply:

- Submitted for an NIH grant application on or after January 25, 2018
- Submitted for an NIH Research & Development (R&D) contract solicitation issued on or after January 25, 2018
- Submitted for an NIH intramural research study with initial review on or after January 25, 2018
- Transitioned the study at one or more sites to the 2018 Requirements
- Received initial IRB approval on or after January 20, 2020

COOPERATIVE RESEARCH SIRB MANDATE

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- Effective January 20, 2020, the revised Common Rule (i.e., the 2018 Requirements) requires at 45 CFR 46.114(b) that all institutions located in the United States that are engaged in cooperative research conducted or supported by a Federal department or agency rely upon approval by a single IRB for the portion of the research that is conducted in the United States.
- Cooperative research projects are those projects covered by this policy that involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy.
- Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.

FDA-REGULATED COOPERATIVE RESEARCH (PROPOSED RULE) FOR SIRB MANDATE

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- On September 28, 2022, the FDA released a proposed rule intended to partially harmonize its current regulations with the revised common rule that recommends requiring any U.S.-located institution conducting cooperative research to rely on sIRB oversight for the research being conducted in the U.S. (with certain exceptions). This would harmonize FDA regulations with the revised Common Rule's sIRB requirements, as well as the sIRB policies enacted by the NIH.
- If the proposed rule goes into effect, we expect an increase in reliance submissions, with a likely increase in external reliance on commercial IRBs

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RELIANCE ON AN EXTERNAL IRB

CURRENT NUMBER OF EXTERNAL RELIANCE STUDIES

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Reliance on External IRBs

- 1068 open external reliance studies
  - 722 reviewed by commercial IRBs
    - Advarra: 346 studies
    - WIRB Copernicus Group: 376 studies
  - 346 reviewed by other external IRBs

CRITERIA FOR EXTERNAL RELIANCE DETERMINATIONS

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- Active OHRP Registration
- Active Federalwide Assurance
- Executed Reliance Agreement
- Complete RAP Submission
- Expedited or Full Board review (exempt and not human subjects research determinations are not eligible for reliance)
- Phase 1-4 clinical trials
- Other study types are eligible, including EFIC and UC sponsor-investigator initiated trials
- Studies that require IBC or RSC review are also eligible for reliance (IBC and RSC ancillary reviews apply)

REVIEW COMPONENTS

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Components of an institution's review process for research

When relying on an External IRB, the responsibilities are often split between the IRB of record (sIRB, CIRB) and the relying institution

UC AS THE RELYING INSTITUTION

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UC HRPP is responsible for verifying that institutional requirements are satisfied prior to relying on a Reviewing IRB (this includes commercial IRBs).

- Human subjects research training completion
- Disclosure of potential financial conflicts and management plans
- PI UC affiliation and experience
- Record of protocol and any other pertinent study documents
- HIPAA waiver request when the Reviewing IRB is not serving as the privacy board
- Applicable executed reliance agreement
- Applicable ancillary review(s)
- **Site specific information**
- **UC specific informed consent template language**

UC SERVING AS RELYING INSTITUTION

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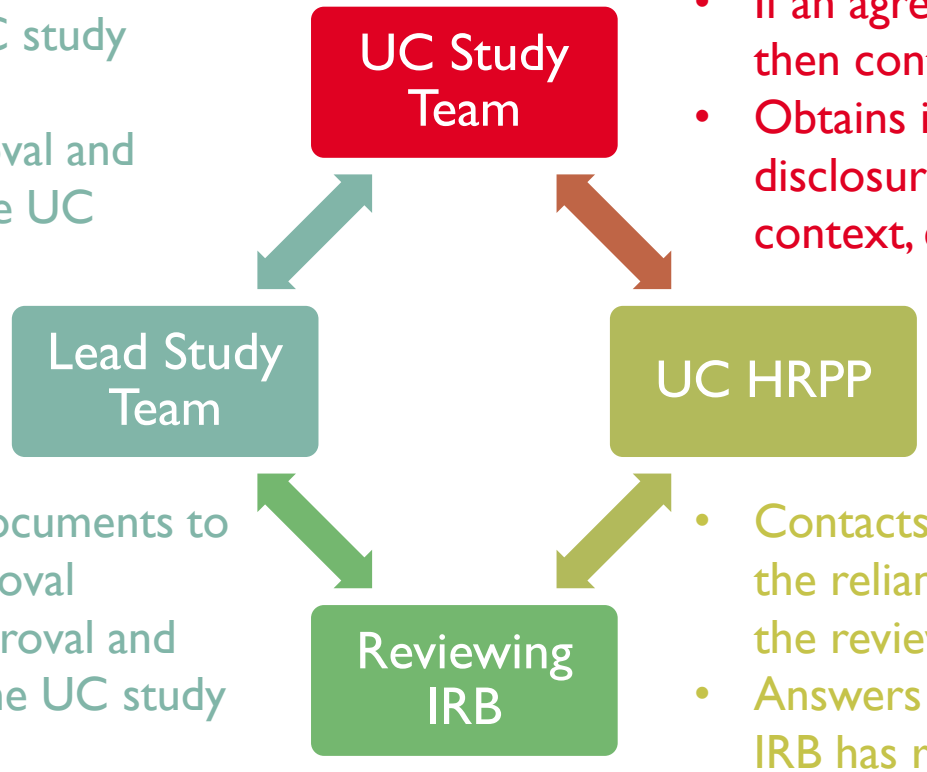
- Obtains UC local context and ICF template language from UC study team for Reviewing IRB
- Sends Reviewing IRB approval and approved documents to the UC research team



- Completes RAP reliance submission
- If an agreement has not been executed, then contacts the UC HRPP
- Obtains instructions for COI disclosures, incorporating local context, etc.

- Submits UC site-specific documents to the Reviewing IRB for approval
- Obtains Reviewing IRB approval and approved documents for the UC study team

- Contacts Reviewing IRB to establish the reliance agreement and facilitate the review
- Answers any questions the Reviewing IRB has regarding the reliance agreement

LOCAL CONTEXT REVIEW

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- The review of a protocol by a single IRB applies to all relying sites. However, there are often local regulations, policies and consent language that need to be considered and addressed for each local site. These issues need to be considered during the review process and are referred to as **local context**.
- Commercial IRBs WIRB and Advarra both previously established a process with UC to review local context and incorporate requirements into informed consent documents. In late 2023, Advarra informed UC that the verification of incorporation of local context information would no longer be conducted with their IRB.
- To satisfy UC HRPP/IRB communication and responsibilities with reliance agreements, we have updated external reliance-related templates and procedures to maintain this local context review process with the UC HRPP/IRB during the external reliance process.
- WIRB Copernicus Group continues to maintain their process of verifying UC's local context.
- Studies involving reliance on an external IRB *with the exception of WIRB Copernicus Group and NCI CIRB* should submit reliance documentation with the incorporation of local context requirements into drafted local consents for review by UC HRPP/IRB.

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UPDATE: PROCESS SHIFTS FOR EXTERNAL RELIANCE

RESPONSIBILITIES

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THE UC HRPP/IRB IS RESPONSIBLE FOR REVIEW OF LOCAL BOILERPLATE LANGUAGE IF THE IRB OF RECORD IS NOT COLLECTING AND VERIFYING THIS INFORMATION.

- Effective February 1st, 2024, research teams are expected to provide the following documents for all reliance submissions.
  - **Draft consent forms containing UC boilerplate language and**
  - **The latest version of the HRP-508R**

The documents are accessible in the RAP Library

UPDATED TEMPLATES

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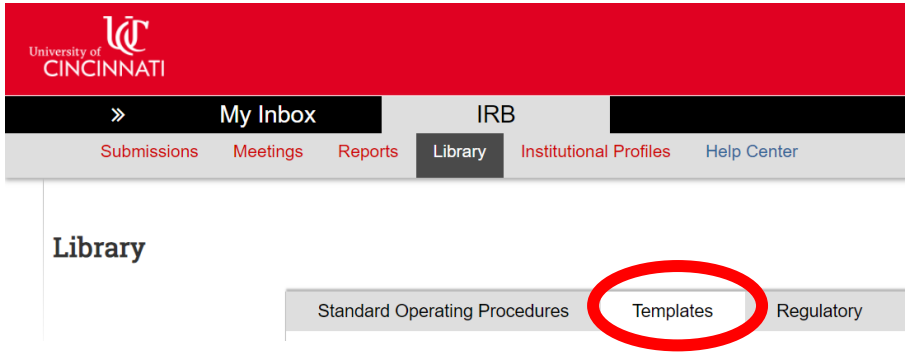
RAP > IRB > LIBRARY > TEMPLATES > EXTERNAL IRB RELIANCE STUDY



External IRB Reliance Study

For use with a [illegible] relying on an External IRB

Filter by Name | Enter text to search for | + Add Filter | ✖ Clear All

Name	Document
Advarra Cover Page	Advarra Cover Page(0.02)
CGCI Signature Page	CGCI Signature Page(0.02)
Christ IRB Review Page	Christ IRB Review Page(0.01)
HRP-508R TEMPLATE Reliance on External IRB	HRP-508R TEMPLATE Reliance on External IRB(0.05)
Quorum Cover Page	Quorum Cover Page(0.01)
SMART IRB Acknowledgement Letter	SMART IRB Acknowledgement Letter(0.02)
UC IRB Authorization Agreement (UC Reviewing Institution)	UC IRB Authorization Agreement(0.08)
UC IRB Authorization Agreement (UC Relying Institution)	UC IRB Authorization Agreement (UC Relying Institution).docx(0.01)
UC Local Context Reference Sheet 24AUG2023	UC Local Context Reference Sheet 24AUG2023(0.04)
WIRB (WCG) Boilerplate Local Context Form	UC WCG Reference language 09152023.docx(0.01)
Advarra Boilerplate Local Context Form	Univ of Cincinnati - Advarra MLD FINAL v.092023.docx(0.02)
WIRB Cover Page	WIRB Cover Page(0.01)

REVISED HRP-508R

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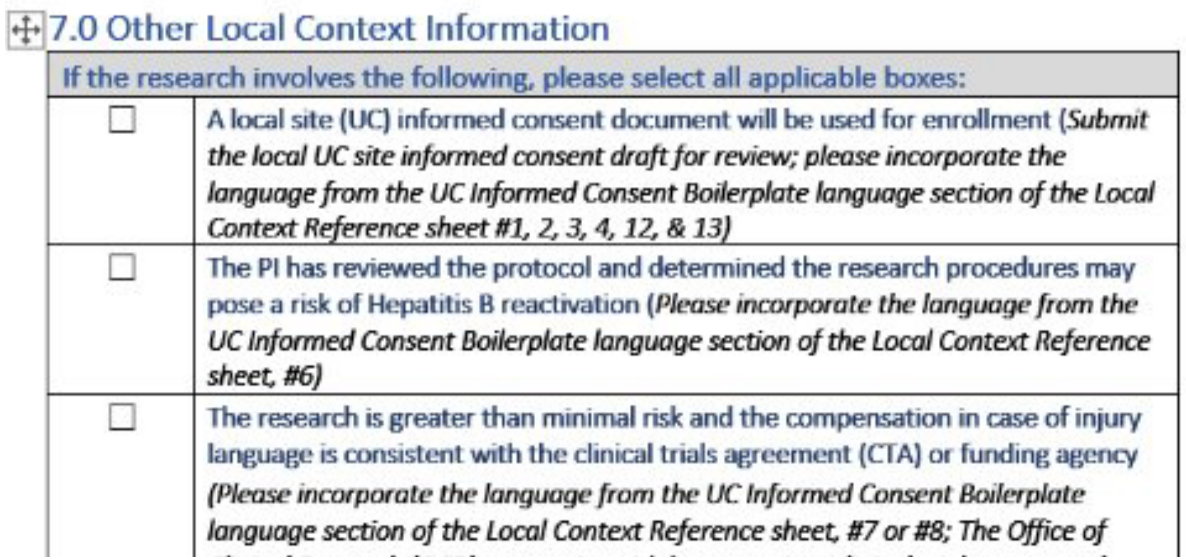
COMPLETE ALL SECTIONS OF THE HRP-508R RELIANCE ON EXTERNAL IRB SUPPLEMENT FORM

- If the study team will obtain a signed consent and/or assent/parent permission and a local site (UC) informed consent document will be used for enrollment, then the UC IRB will verify the applicable boilerplate language is included in consent form(s).



7.0 Other Local Context Information

If the research involves the following, please select all applicable boxes:	
☐	A local site (UC) informed consent document will be used for enrollment (*Submit the local UC site informed consent draft for review; please incorporate the language from the UC Informed Consent Boilerplate language section of the Local Context Reference sheet #1, 2, 3, 4, 12, & 13)*
☐	The PI has reviewed the protocol and determined the research procedures may pose a risk of Hepatitis B reactivation (*Please incorporate the language from the UC Informed Consent Boilerplate language section of the Local Context Reference sheet, #6)*
☐	The research is greater than minimal risk and the compensation in case of injury language is consistent with the clinical trials agreement (CTA) or funding agency *(Please incorporate the language from the UC Informed Consent Boilerplate language section of the Local Context Reference sheet, #7 or #8; The Office of*

LOCAL CONTEXT REFERENCE SHEET

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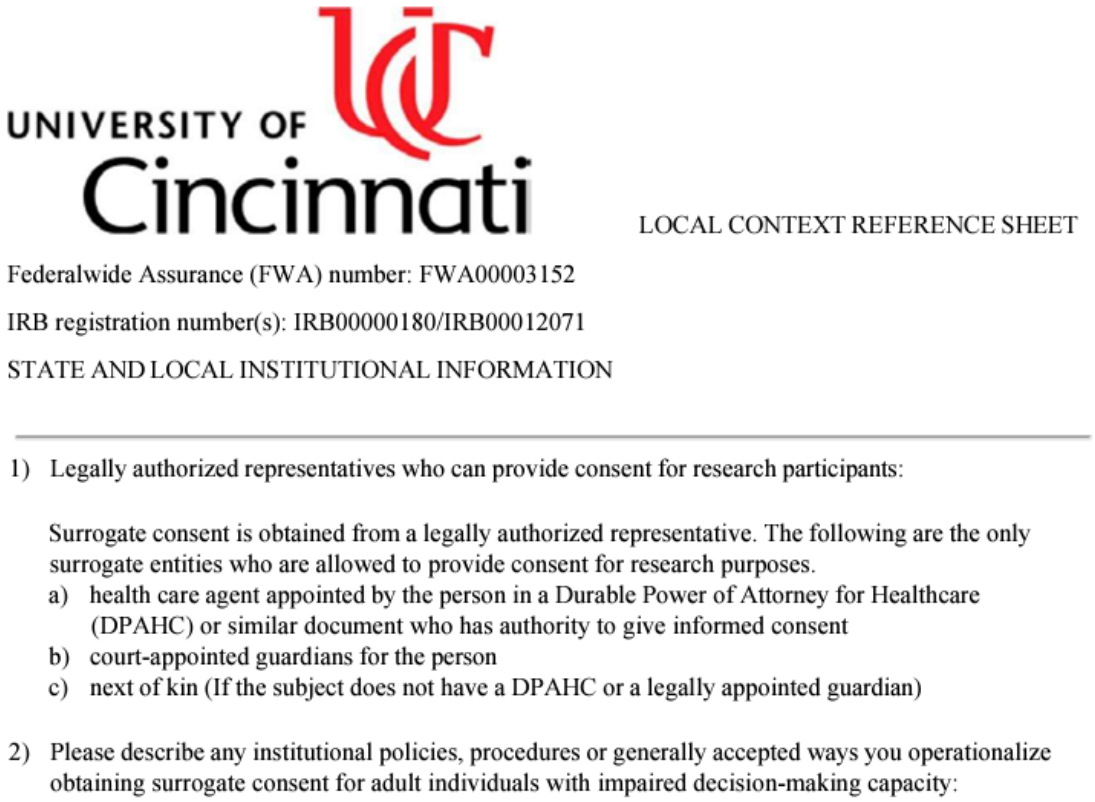
UC LOCAL CONTEXT REFERENCE SHEET



UNIVERSITY OF Cincinnati

LOCAL CONTEXT REFERENCE SHEET

Federalwide Assurance (FWA) number: FWA00003152

IRB registration number(s): IRB00000180/IRB00012071

STATE AND LOCAL INSTITUTIONAL INFORMATION

1) Legally authorized representatives who can provide consent for research participants:

Surrogate consent is obtained from a legally authorized representative. The following are the only surrogate entities who are allowed to provide consent for research purposes.

a) health care agent appointed by the person in a Durable Power of Attorney for Healthcare (DPAHC) or similar document who has authority to give informed consent
b) court-appointed guardians for the person
c) next of kin (If the subject does not have a DPAHC or a legally appointed guardian)

2) Please describe any institutional policies, procedures or generally accepted ways you operationalize obtaining surrogate consent for adult individuals with impaired decision-making capacity:

- Pages 1 – 4 describe the state and institutional information
  - Age of majority
  - Vulnerable populations
  - COIs

LOCAL CONTEXT REFERENCE SHEET

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UC LOCAL CONTEXT REFERENCE SHEET

The following points must be addressed in the informed consent form for research in which UC is relying on another IRB.

1) Add "University of Cincinnati" as a heading at the top of the informed consent form and/or assent form(s) followed by the line, "Consent to Participate in Human Research".

2) Identify the University of Cincinnati Principal Investigator (first and last name) and a 24 hour emergency contact number on the first page of the consent document.

3) Include an area to capture the subject's name and date of birth on the first page of the consent document.

4) Identify the University of Cincinnati Principal Investigator (first and last name) and a 24 hour emergency contact number on the first page of the consent document. Also include the name of the facilities being utilized (e.g., UC Medical Center, West Chester Hospital, Holmes Hospital, Medical Arts Building, etc.). Suggested language for including multiple hospital and university locations: "Research will take place at University of Cincinnati and the facilities of the affiliated health systems UC Health, LLC and University of Cincinnati Physicians Company, LLC."

5) In the case of Phase I research, include a statement providing a description and explaining the purpose of this type of research. Suggested language:

   A Phase I study is the first step in testing an investigational drug in humans. An investigational drug, in this phase, has not been shown to be effective in treating a disease and has not been approved by the Food and Drug Administration.

- Pages 5 – 8 is where you will find the Consent Boilerplate Language to include in the UC site consent form(s)

FAQS

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DO WE INCLUDE ALL OF THE BOILERPLATE LANGUAGE?

- Language that applies to the research should be included.

WHAT DO WE DO IF WE HAVE MULTIPLE CONSENT FORMS?

- Language that applies to the research should be included. We know that some consent forms are modified for understandability or are directed at a specific population. For example, we would not expect to see HIPAA authorization language in a pregnant partner follow-up consent, if PHI is not being collected from the partner.

FAQS

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DOES THE LANGUAGE NEED TO BE VERBATIM?

- If **HIPAA** language is required, then the HIPAA Authorization language should be **verbatim.**
  - *Note For item #14, only the bullet points that apply need to be included*
  - HIV testing • AIDS or AIDS related condition, • psychiatric condition(s) • alcoholism • drug abuse
- Compensation in case of injury language is expected to be included in the UC consent when the research is greater than minimal risk. When a funding sponsor is paying for study related injuries, then the language should be consistent with the clinical trials agreement.
- Payment using Greenphire ClinCard is recommended to be template. If changes need to be made, then we recommend contacting Sponsored Research Services (Lilia Gruseck) to ensure the language change is acceptable. This could avoid modification of consent documents with the IRB of Record in the future.

FAQS

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BOILERPLATE LANGUAGE WE EXPECT TO SEE

UC Boilerplate Language items
(1) University of Cincinnati + Consent to Participate
(2) UC Investigator + 24-hour emergency number
(3) Subject Name and DOB
(4) Include name of facilities being utilized
(11) Study team contacts and phone numbers
(12) Whom to contact
(13) Agents of UC will be granted access
(15) signature & date line for pt, LAR, and person obtaining consent (authority of LAR)

FAQS

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BOILERPLATE LANGUAGE WE EXPECT TO SEE, IF INDICATED ON THE HRP-508R OR OTHER STUDY DOCUMENT

UC Boilerplate Language items
(5) Phase I research
(6) Hepatitis B reactivation risk
(7) Compensation of injury when the sponsor will only pay for emergency care
(8) Compensation of injury when sponsor will pay for study-related injuries
(9) & (14) *When HIPAA authorization is required
(10) Payment using prepaid debit cards

FAQS

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WHAT IF THE STUDY SPONSOR OR REVIEWING IRB DOES NOT ALLOW FOR CHANGES TO THE CONSENT FORM?

- We will need documentation (a response from investigators) as to the justification (i.e., the sponsor refused/declined/provide reason). In some cases, it may be appropriate to create an addendum to the consent form. This will be determined on case-by-case basis.

WHAT IF THE STUDY SPONSOR OR REVIEWING IRB DOES NOT ACCEPT THE UC HIPAA AUTHORIZATION LANGUAGE?

- You will need to contact Office of Clinical Research to have the language reviewed and approved. Documentation of the approval can be uploaded in the submission as a comment.

FAQS

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WHAT IF THERE ARE ALTERATIONS TO THE STUDY OR THE CONSENT FORM?

- If there are any alterations to the study or the informed consent document that might affect local boilerplate language, then a modification will need to be submitted.
- An updated HRP-508R and revised consent(s) should be submitted for review.

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QUESTIONS?

IRBRELIANCE@UC.EDU

MIDAS Incident Reporting system

<u>UCH-OCR-OPS-SOP-014:</u> Prompt MIDAS Reporting of Serious Adverse Events that are both Unexpected and Related to the Research, and Reporting Emergency Use of a Research Related Treatment or Device

What is expected to be reported in MIDAS for Clinical Research:

- **"Unexpected"**: An event that is not an anticipated event for the study drug, device, or procedure and is not explained in the Informed Consent Statement that the study subject reviewed and signed
- **"Related"**: An event thought to be caused by any drug given to a subject as part of the study, a device used in the study, or a procedure that is carried out as part of the study. The term "adverse drug reaction" (ADR) may also be used if the SAE is related to the investigational product.
- **<u>NEW:</u> Emergency Use of Research Drug or Devices for Standard of Care**
- **Patient/Subject Deaths**

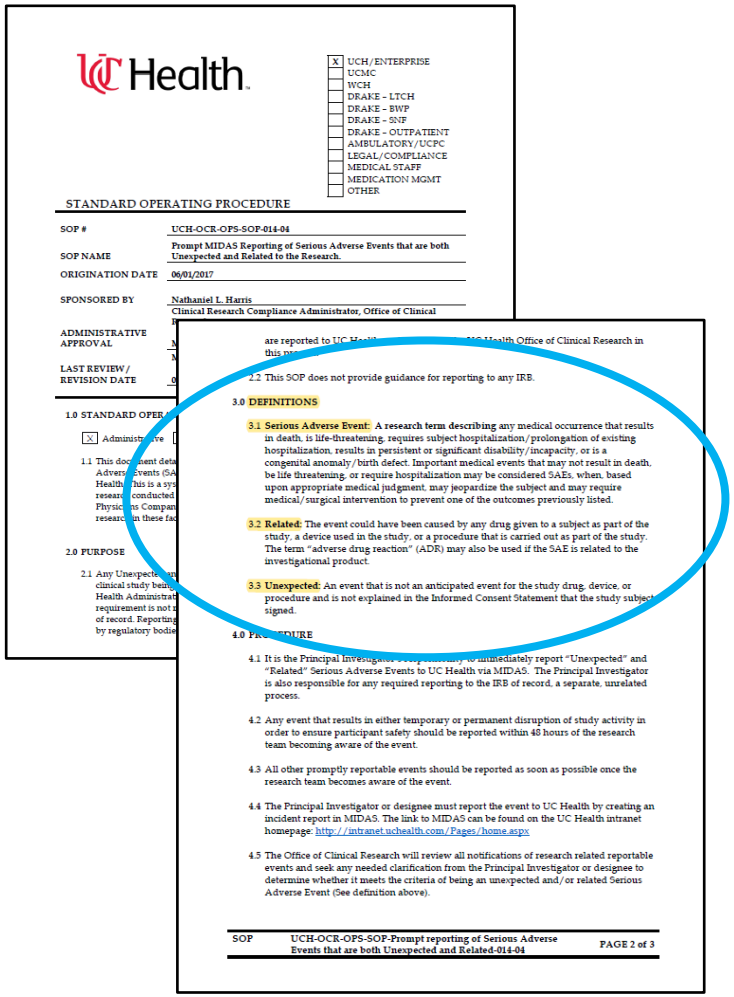
Research Subject Safety Initiatives

MIDAS Incident Reporting System	
WHO All UC Health/ UC Physicians Associates	**WHAT** Healthcare Analytics Tool
HOW Internal and External Reporting	**WHY** Reduction of Risk

Research Subject Safety Initiatives

MIDAS Use in Clinical Research	
WHO Clinical Research Professionals Research Team Clinical Care Team	**WHAT** Related or Unexpected Serious Adverse Events
HOW Internal reporting via Midas	**WHY** Inform UC Health of research-related adverse events

Research Subject Safety Initiatives



Health

- [X] UCH/ENTERPRISE
- [ ] UCMC
- [ ] WCH
- [ ] DRAKE - LTCH
- [ ] DRAKE - BWP
- [ ] DRAKE - SNF
- [ ] DRAKE - OUTPATIENT
- [ ] AMBULATORY/UCPC
- [ ] LEGAL/COMPLIANCE
- [ ] MEDICAL STAFF
- [ ] MEDICATION MGMT
- [ ] OTHER

STANDARD OPERATING PROCEDURE

SOP #	UCH-OCR-OPS-SOP-014-04
SOP NAME	Prompt MIDAS Reporting of Serious Adverse Events that are both Unexpected and Related to the Research.
ORIGINATION DATE	06/01/2017
SPONSORED BY	Nathaniel L. Harris Clinical Research Compliance Administrator, Office of Clinical
ADMINISTRATIVE APPROVAL	
LAST REVIEW / REVISION DATE	

are reported to UC Health Office of Clinical Research in this

2.2 This SOP does not provide guidance for reporting to any IRB.

3.0 DEFINITIONS

3.1 **Serious Adverse Event:** A research term describing any medical occurrence that results in death, is life-threatening, requires subject hospitalization/prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect. Important medical events that may not result in death, be life threatening, or require hospitalization may be considered SAEs, when, based upon appropriate medical judgment, may jeopardize the subject and may require medical/surgical intervention to prevent one of the outcomes previously listed.

3.2 **Related:** The event could have been caused by any drug given to a subject as part of the study, a device used in the study, or a procedure that is carried out as part of the study. The term "adverse drug reaction" (ADR) may also be used if the SAE is related to the investigational product.

3.3 **Unexpected:** An event that is not an anticipated event for the study drug, device, or procedure and is not explained in the Informed Consent Statement that the study subject signed.

4.0 PROCEDURE

4.1 It is the Principal Investigator's responsibility to immediately report "Unexpected" and "Related" Serious Adverse Events to UC Health via MIDAS. The Principal Investigator is also responsible for any required reporting to the IRB of record, a separate, unrelated process.

4.2 Any event that results in either temporary or permanent disruption of study activity in order to ensure participant safety should be reported within 48 hours of the research team becoming aware of the event.

4.3 All other promptly reportable events should be reported as soon as possible once the research team becomes aware of the event.

4.4 The Principal Investigator or designee must report the event to UC Health by creating an incident report in MIDAS. The link to MIDAS can be found on the UC Health intranet homepage: http://intranet.uchealth.com/Pages/home.aspx

4.5 The Office of Clinical Research will review all notifications of research related reportable events and seek any needed clarification from the Principal Investigator or designee to determine whether it meets the criteria of being an unexpected and/or related Serious Adverse Event (See definition above).

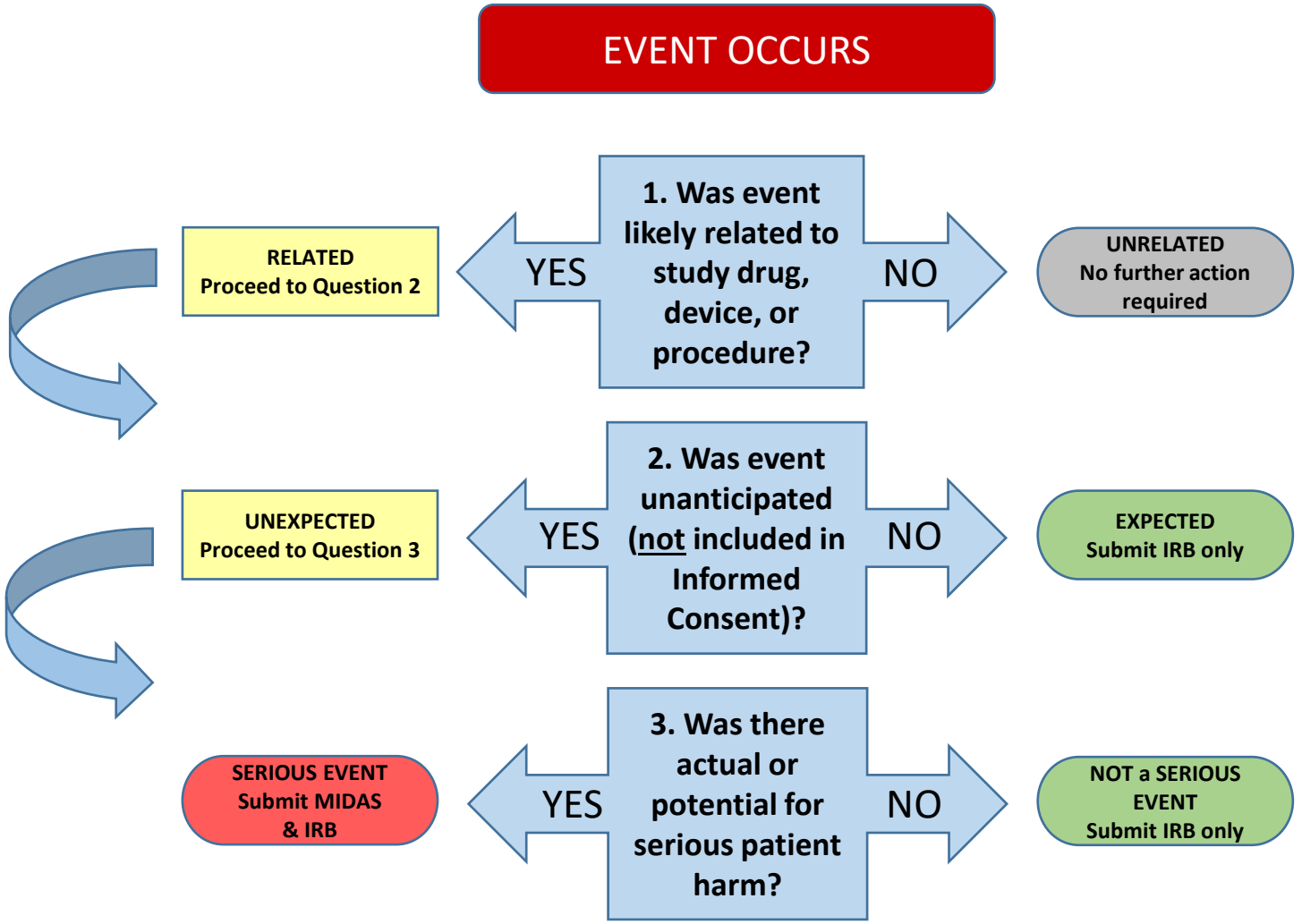
SOP UCH-OCR-OPS-SOP-Prompt reporting of Serious Adverse Events that are both Unexpected and Related-014-04 PAGE 2 of 3

Operational Definitions

Related Event	**Event is likely caused by a drug or device used in a study**
Unexpected Event	**An unanticipated event related to a study that is not discussed as part of Informed Consent**
Serious Adverse Event	**Patient experienced or COULD HAVE experienced any of the following had it not been for medical intervention:** • ***Serious life-threatening condition or death*** • ***Hospitalization or extended admission*** • ***Significant or long-term disability or debilitation*** • ***Birth Defect/Fetal Demise***

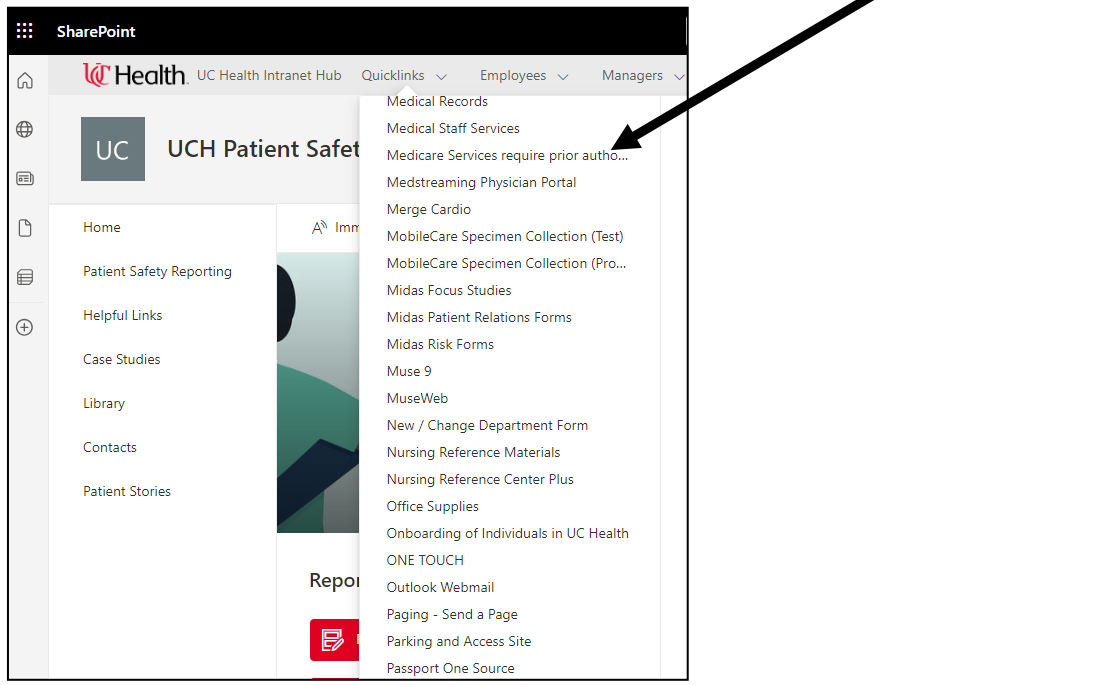
Research Subject Safety Initiatives

UC Health

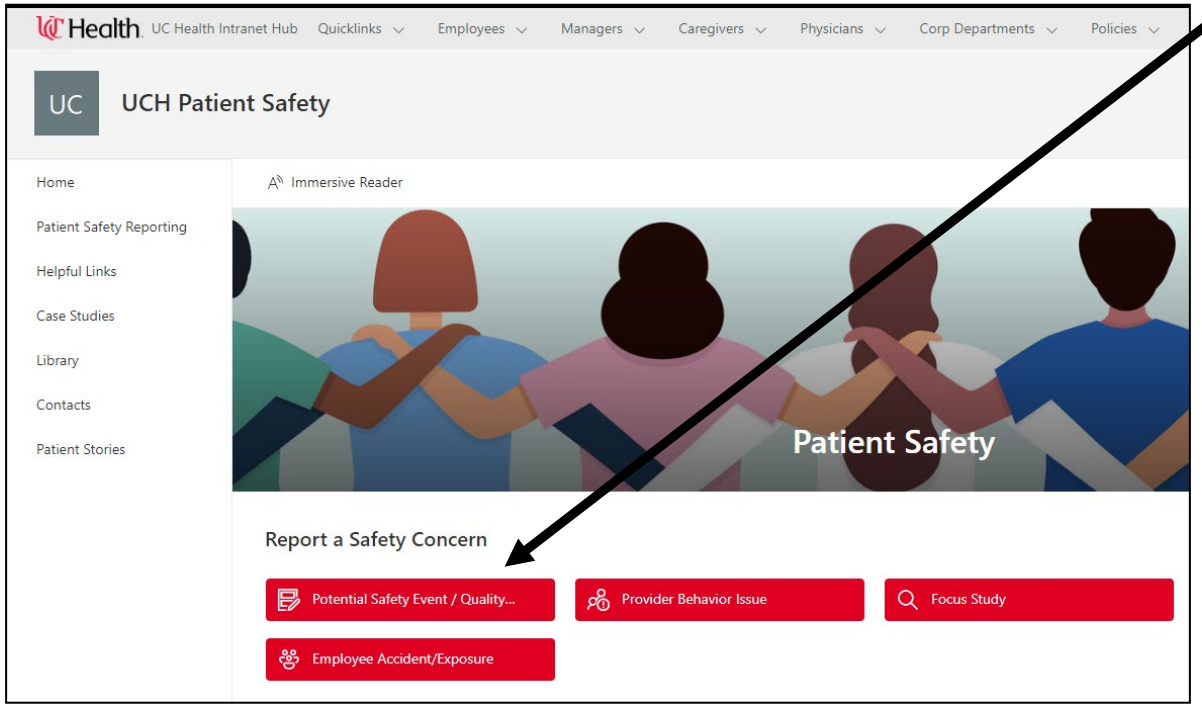


Research Subject Safety Initiatives

From the UC Health intranet homepage, use the “Quicklinks” dropdown list to find and click on “MIDAS Patient Relations Form”



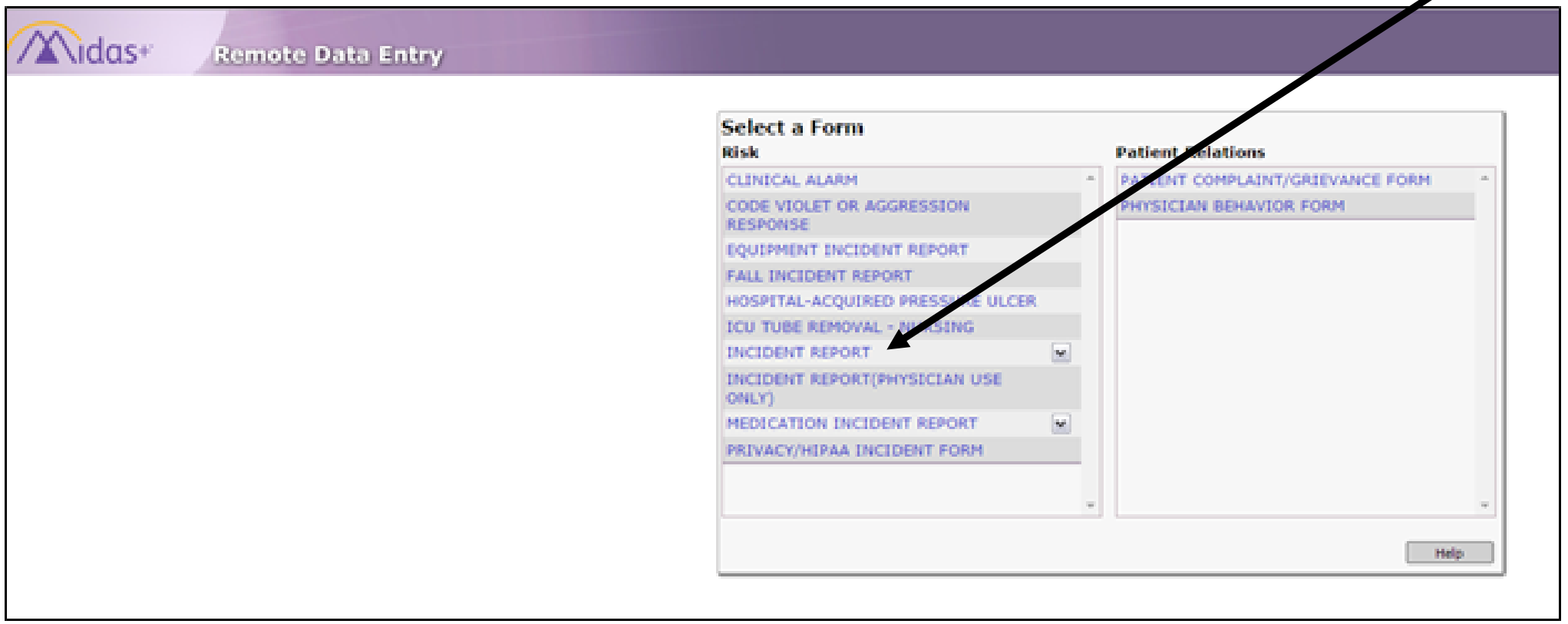
This will take you to the UCH Patient Safety page, where under “Report a safety Concern” you will click “Potential Safety Event / Quality Concern”



Research Subject Safety Initiatives

UC Health

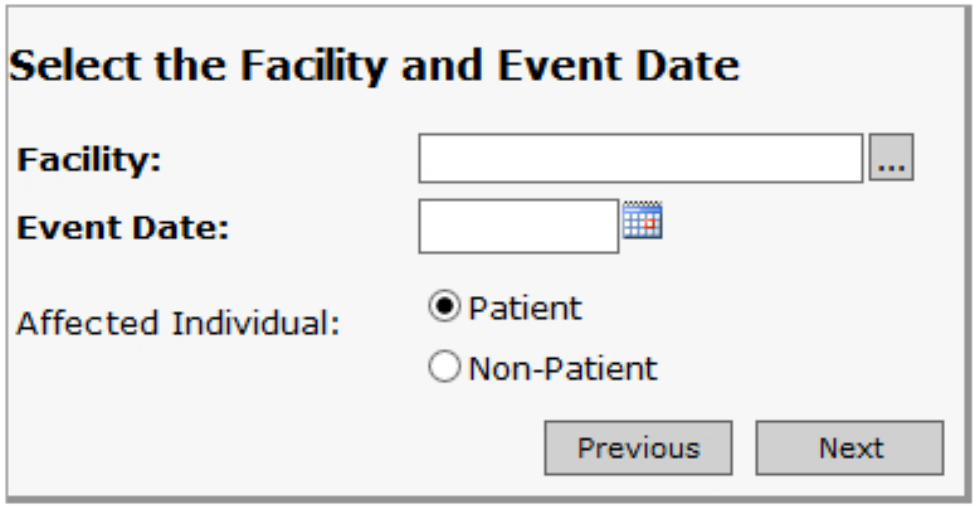
This will bring you to the following screen: Please choose “Incident Report”.



Research Subject Safety Initiatives

UC Health

- **Choosing Incident report will bring you to the following screen:**



- **On this screen please choose "Patient" as the "Affected Individual". Also choose the appropriate Facility and Event Date, and click "Next".**

1. **Protected Health Information such as the Patient Medical Record Number (MRN) or**

2. **patient specific Hospital Account number will be required in order to complete the report.**

3. **Please follow the onscreen directions to complete the report.**

Questions?

Nathaniel L. Harris
Clinical Research Compliance Administration,
Education and Training
University of Cincinnati
Office of Clinical Research