OREGON CLINICAL & TRANSLATIONAL *Research Institute*

OHSU

OCTRI Research Forum: Subject Injury Policy, Identification, and Reporting at OHSU

DATE: January 29, 2026

Paul Newton, JD, OHSU HRPP Director and IRB Chair, Heather Bengtson, Manager CRBO
Timothy Tripp, IRAT Manager, Kathryn Schuff, IRB Vice Chair

Subject Injury Definition:

- A subject injury is an adverse experience:
  - arising directly from or contributed to by the research; and
  - not due to the subject's primary disease or other condition; and
  - would not have been expected from the standard treatment for the subject's condition using currently accepted therapies

OHSU

Identifying A Subject Injury

- When the study team is notified of an adverse experience, the event needs to be evaluated to determine if it is also considered an injury
- The principal investigator is responsible for making the determination whether an injury has occurred

OHSU

Subject Injury Identification Exercise

Is it subject injury?

- Clinical trial of investigational chemotherapy in cancer usually treated with oral tyrosine kinase inhibitor
  - Disease progression?

Exercise Answers

Clinical trial of investigational chemotherapy in cancer usually treated oral with tyrosine kinase inhibitor:

- Disease progression: Not Subject Injury
- Anticipated side effect of research medication the same as tyrosine kinase inhibitor side effect: Not Subject Injury
- Unanticipated side effect of research medication the same as tyrosine kinase inhibitor side effect: Not Subject Injury
- Anticipated side effect of research medication different than expected tyrosine kinase side effect: Subject Injury
- Unanticipated side effect of research medication different than expected tyrosine kinase side effect: Subject Injury

OHSU

New Drug, No Comparator

Gastrointestinal Stromal Tumor (GIST) has 4 available approved drugs that are all oral tyrosine kinase inhibitors. A new investigational drug study uses an IV antibody. There are no other approved IV antibody treatments for GIST.

- Would infusion related allergic reactions be subject injuries?

OHSU

OHSU Subject Injury Position: Industry Sponsored Studies

OHSU believes that our research subjects should not bear the financial burden of participation in the development of products for companies; therefore, OHSU will not bill subject injuries to subjects or their insurance

- Oregon law specifically excludes research complications from required coverage (ORS 743A.192)
- Where coverage exists, a patient should not bear the financial burden of copayments and deductibles
- Some research subjects are not insured

Policy: Billing Insurance Not Allowed for Industry Sponsored Studies

- Industry sponsors must pay ALL costs for evaluation and treatment resulting from subject injury. Subject's insurance cannot be billed:
  - Solely
  - First, with sponsor paying remainder
  - First, with sponsor paying if insurance doesn't cover
- Why:
  - The sponsor is benefiting from the study and the subjects should not be harmed financially for participating in the study
  - If insurance pays, it still generates co-pays/deductibles
  - Violates Medicare Secondary Payer rules
- Exceptions:
  - Marketed drugs/devices being used for their approved purposes
  - Category B devices (sometimes – check with your IRAT contact)
  - OHSU personnel caused the injury (OHSU pays for the injury)

OHSU

OHSU Position on Limiting Liability to Subject Following Instructions

OHSU does not allow sponsors to require that subjects follow instructions in order to have the costs of research related injuries covered. This language appears exculpatory/asks subjects to waive their legal rights.

- **45 CFR 46.116 and 21 CFR 50.20** state: No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

OHSU

Subject Injury Coverage: Investigator-Initiated studies

- OHSU *may* cover the injury dependent upon various factors including:
  - Oregon Tort Claims Act
  - OHSU's insurance
  - the role of OHSU personnel in causing the injury

- Studies funded through federal grants do not cover subject injuries

Subject Injury Consent Language

- Consent boilerplate liability language
  - Specifies what injuries are covered (just those caused by drug, or drug *and* procedures, or just procedures, etc. based on the study)
  - Intentionally doesn't detail who will pay for what injuries in what circumstances (e.g., OHSU for some/sponsor in others)

- Select the correct boilerplate consent language to ensure consent language will match the executed contract terms:
  - Funding type and type of study (device vs. drug) is important:
    - Category B device (device + procedures vs. study procedures only)
    - Approved drug with research-only procedures

OHSU

Sponsors and Boilerplate Liability Language in Consent:

- Don't negotiate the liability language!
- Do not edit the boilerplate language without prior IRB approval.
- Do not insert unallowed limitations (exculpatory)
  - Cannot predicate payment for injury on following instructions
  - Can't include time limits for identification of the injury
- Inform sponsors that the boilerplate language is required
- Contact the IRB early if the sponsor has issues with using OHSU boilerplate language

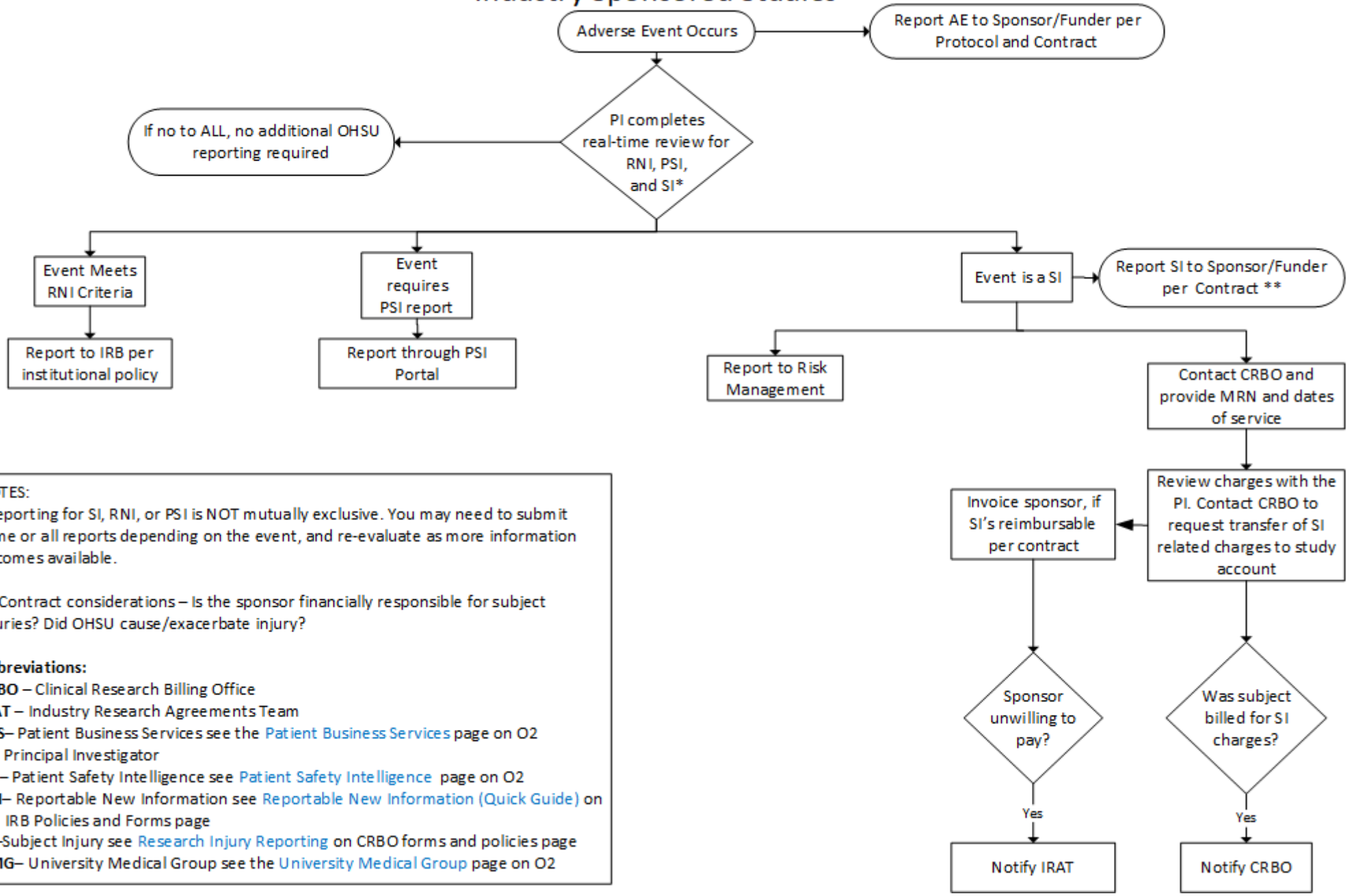
OHSU

Subject Injury Contract Language

- Cannot bill injuries to insurance
- Cannot include failure to follow instructions
- Injuries treated at other facilities: Can't limit reimbursement to only injuries treated at OHSU
- Reimbursement rates: Sometimes identified in the contract, OHSU bills the sponsor for injuries treated at OHSU at the DHHS negotiated research rate (does not apply to outside facilities)
- Can't exclude anticipated risks, e.g., risks noted in consent form or IB
- Attribution: The sponsor cannot control the determination of whether an adverse event is an injury (conflict of interest)
- Timelines for sponsor reporting can be included in contracts, but must begin upon OHSU becoming aware of the injury (e.g., no limit on the subject identifying the injury)

OHSU

Industry Sponsored Studies

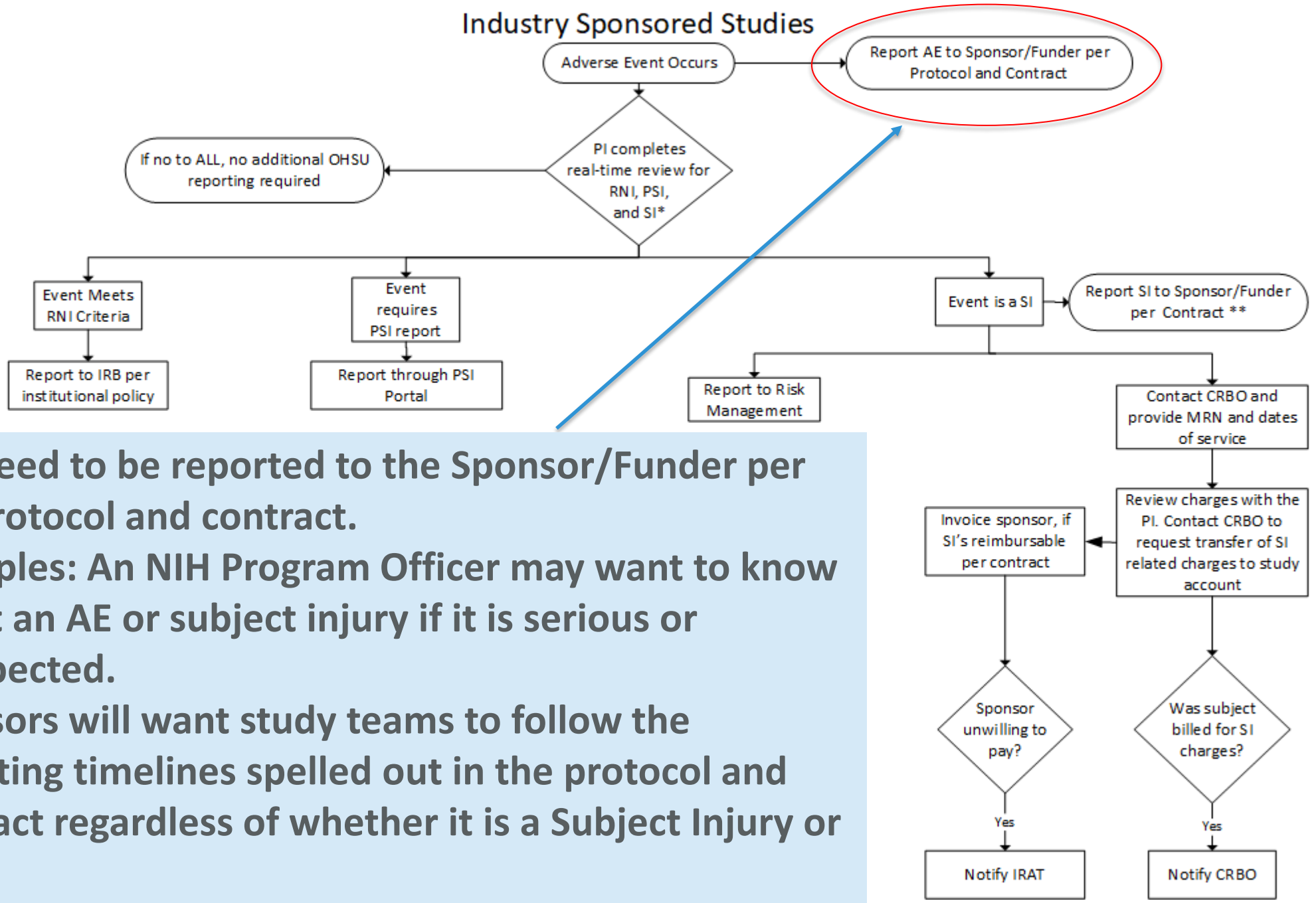


NOTES:
*Reporting for SI, RNI, or PSI is NOT mutually exclusive. You may need to submit some or all reports depending on the event, and re-evaluate as more information becomes available.

** Contract considerations – Is the sponsor financially responsible for subject injuries? Did OHSU cause/exacerbate injury?

Abbreviations:
CRBO – Clinical Research Billing Office
IRAT – Industry Research Agreements Team
PBS– Patient Business Services see the Patient Business Services page on O2
PI– Principal Investigator
PSI– Patient Safety Intelligence see Patient Safety Intelligence page on O2
RNI– Reportable New Information see Reportable New Information (Quick Guide) on the IRB Policies and Forms page
SI –Subject Injury see Research Injury Reporting on CRBO forms and policies page
UMG– University Medical Group see the University Medical Group page on O2

OHSU

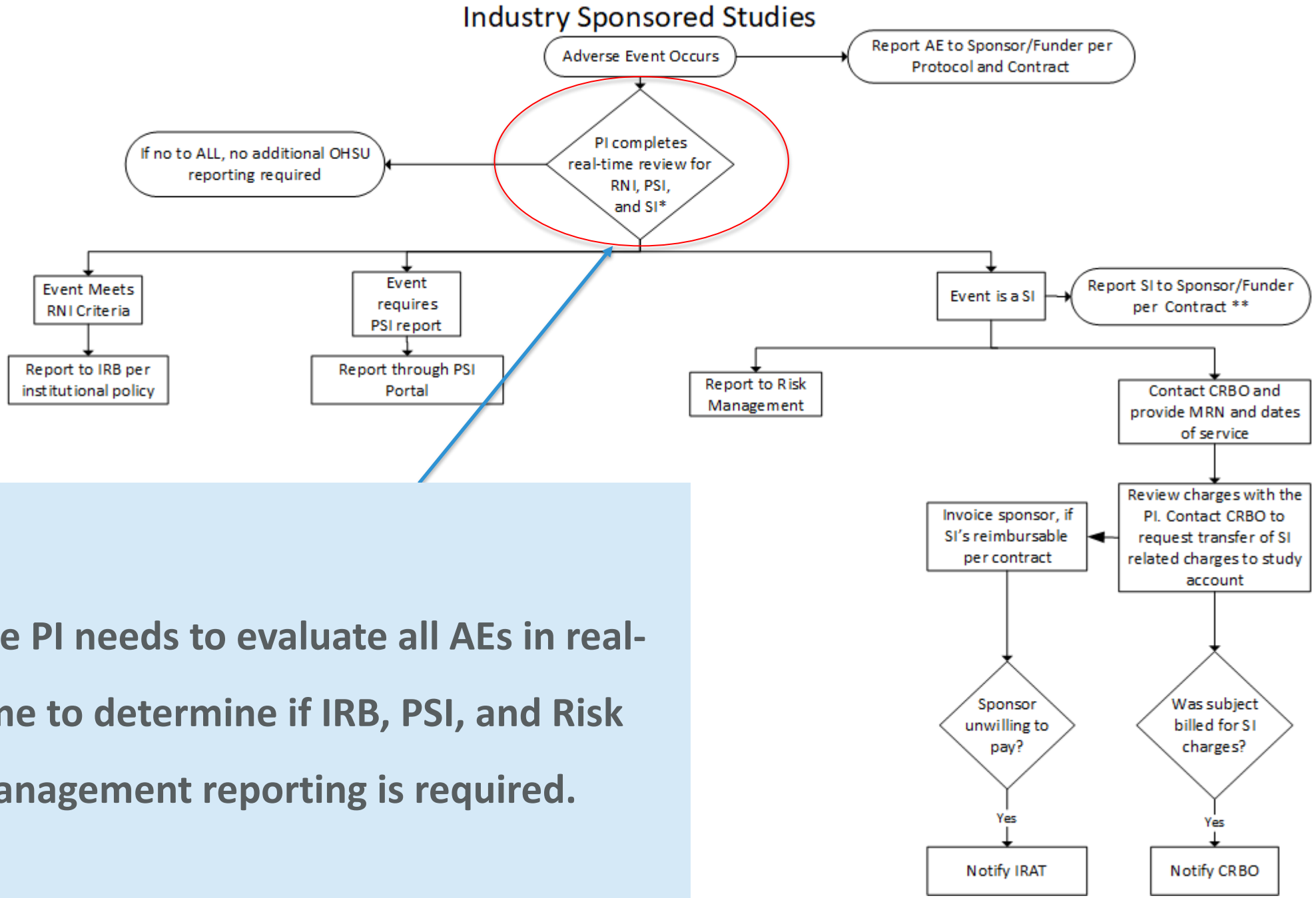


AEs need to be reported to the Sponsor/Funder per the protocol and contract.

Examples: An NIH Program Officer may want to know about an AE or subject injury if it is serious or unexpected.

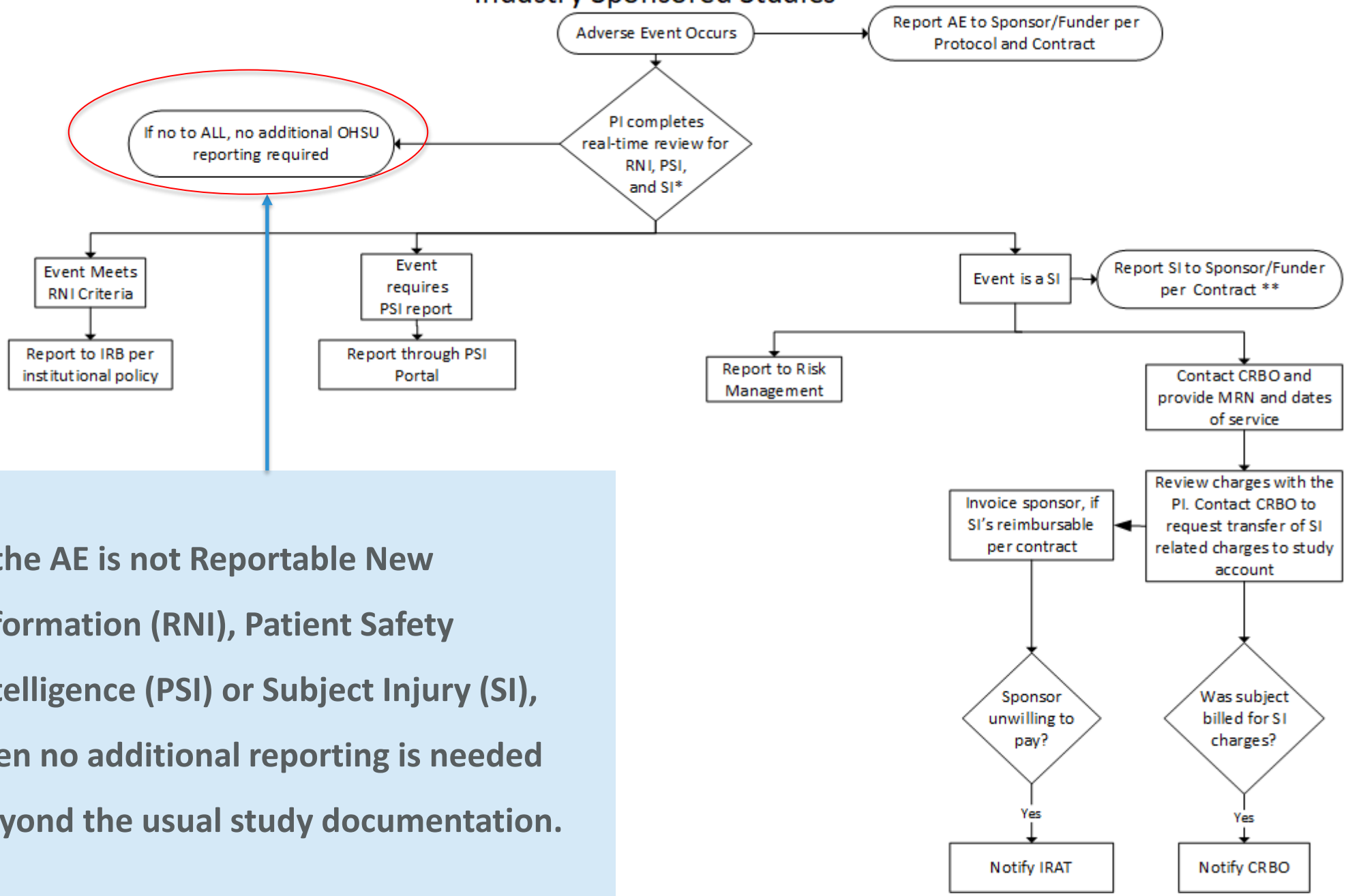
Sponsors will want study teams to follow the reporting timelines spelled out in the protocol and contract regardless of whether it is a Subject Injury or not

OHSU



The PI needs to evaluate all AEs in real-time to determine if IRB, PSI, and Risk Management reporting is required.

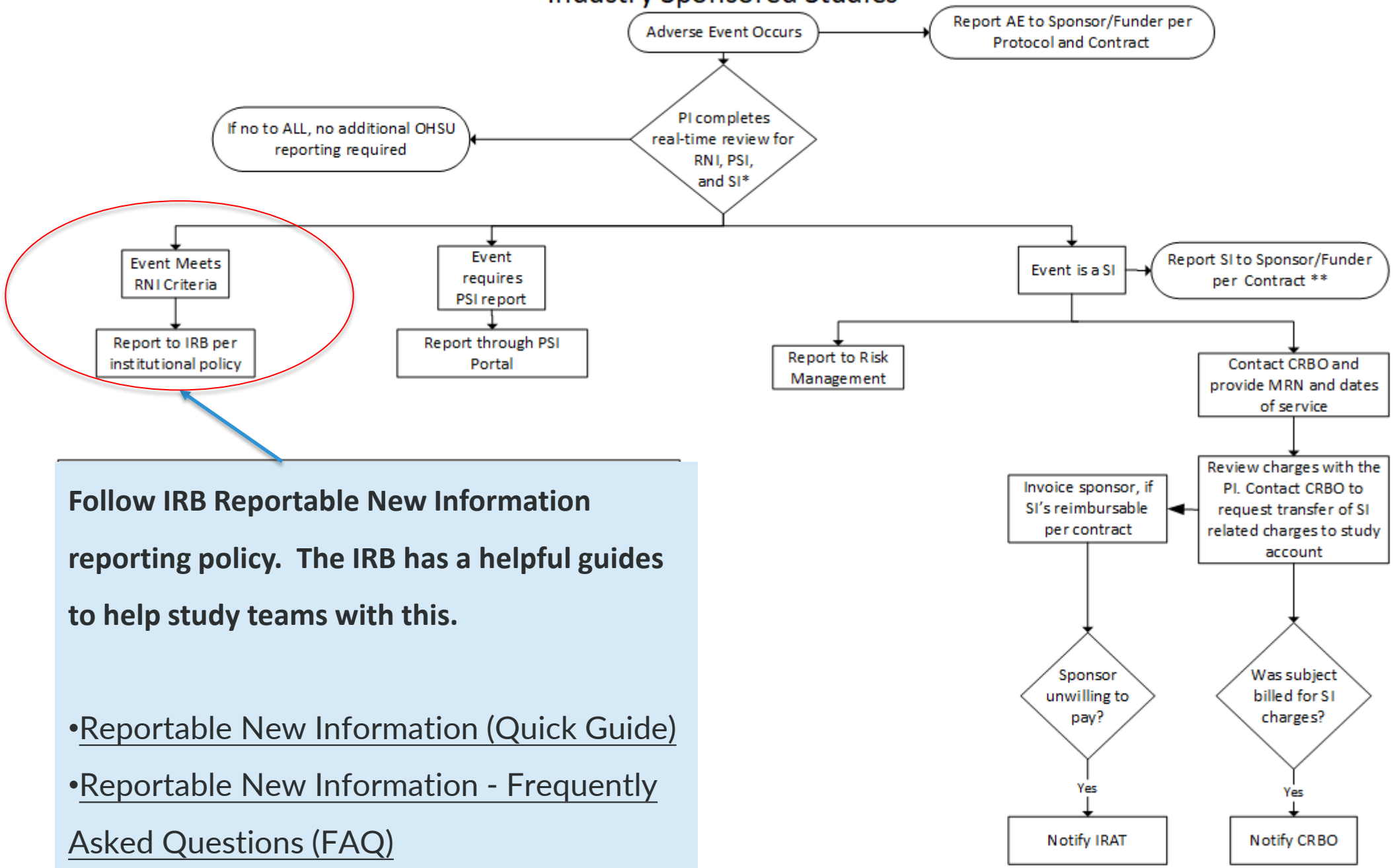
Industry Sponsored Studies



If the AE is not Reportable New Information (RNI), Patient Safety Intelligence (PSI) or Subject Injury (SI), then no additional reporting is needed beyond the usual study documentation.

OHSU

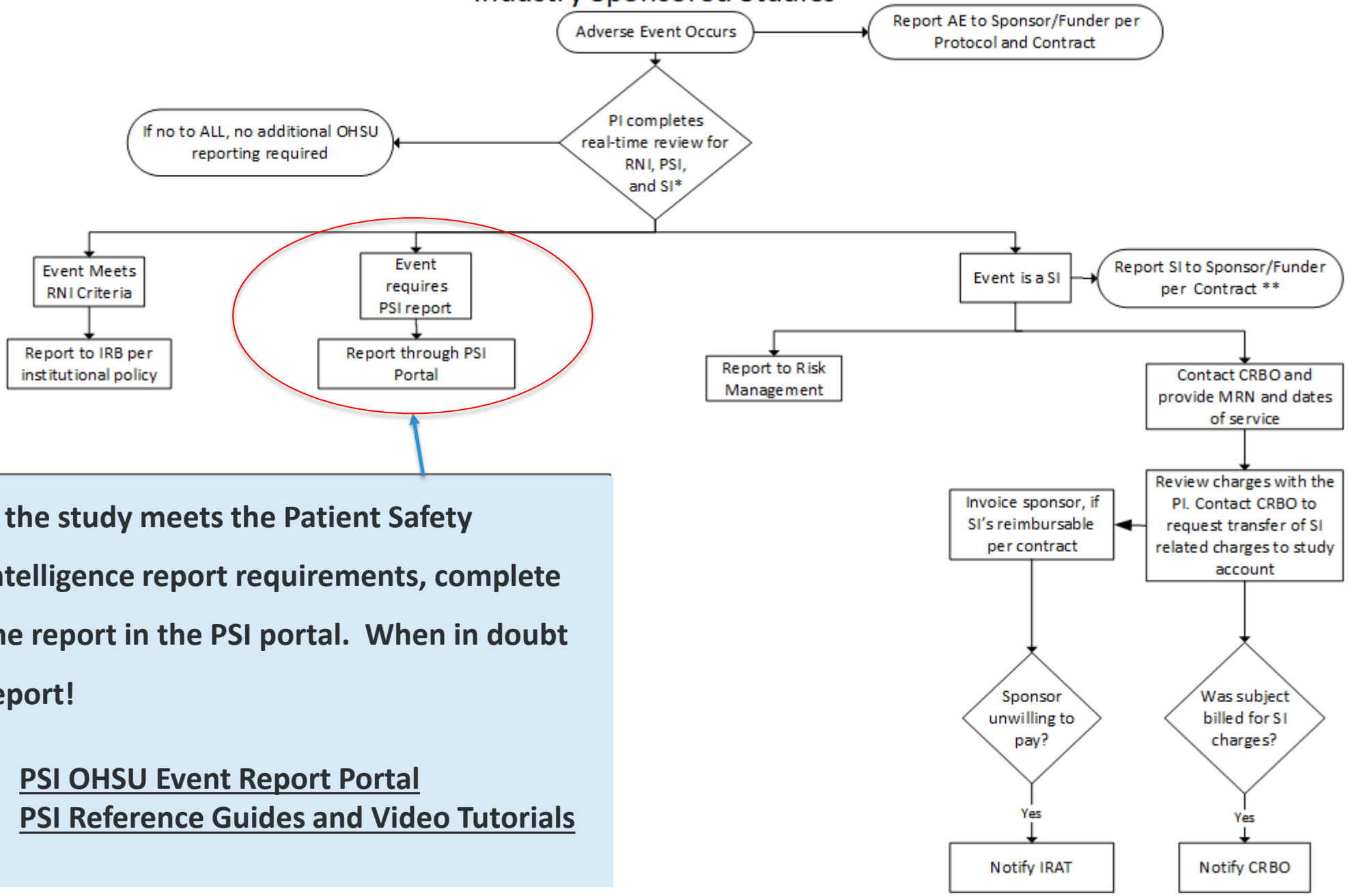
Industry Sponsored Studies



Follow IRB Reportable New Information reporting policy. The IRB has a helpful guides to help study teams with this.

- Reportable New Information (Quick Guide)
- Reportable New Information - Frequently Asked Questions (FAQ)

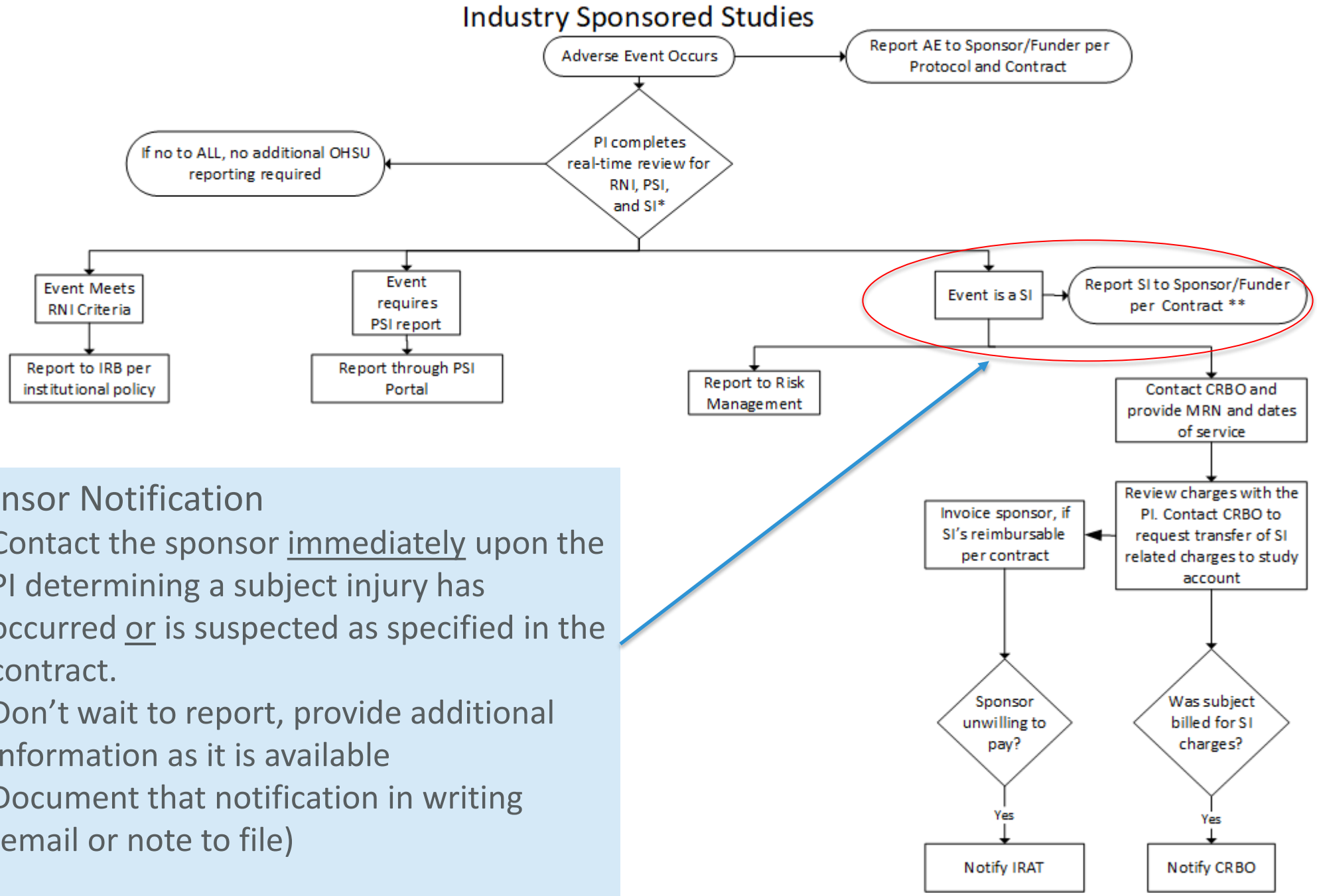
Industry Sponsored Studies



If the study meets the Patient Safety Intelligence report requirements, complete the report in the PSI portal. When in doubt report!

- **PSI OHSU Event Report Portal**
- **PSI Reference Guides and Video Tutorials**

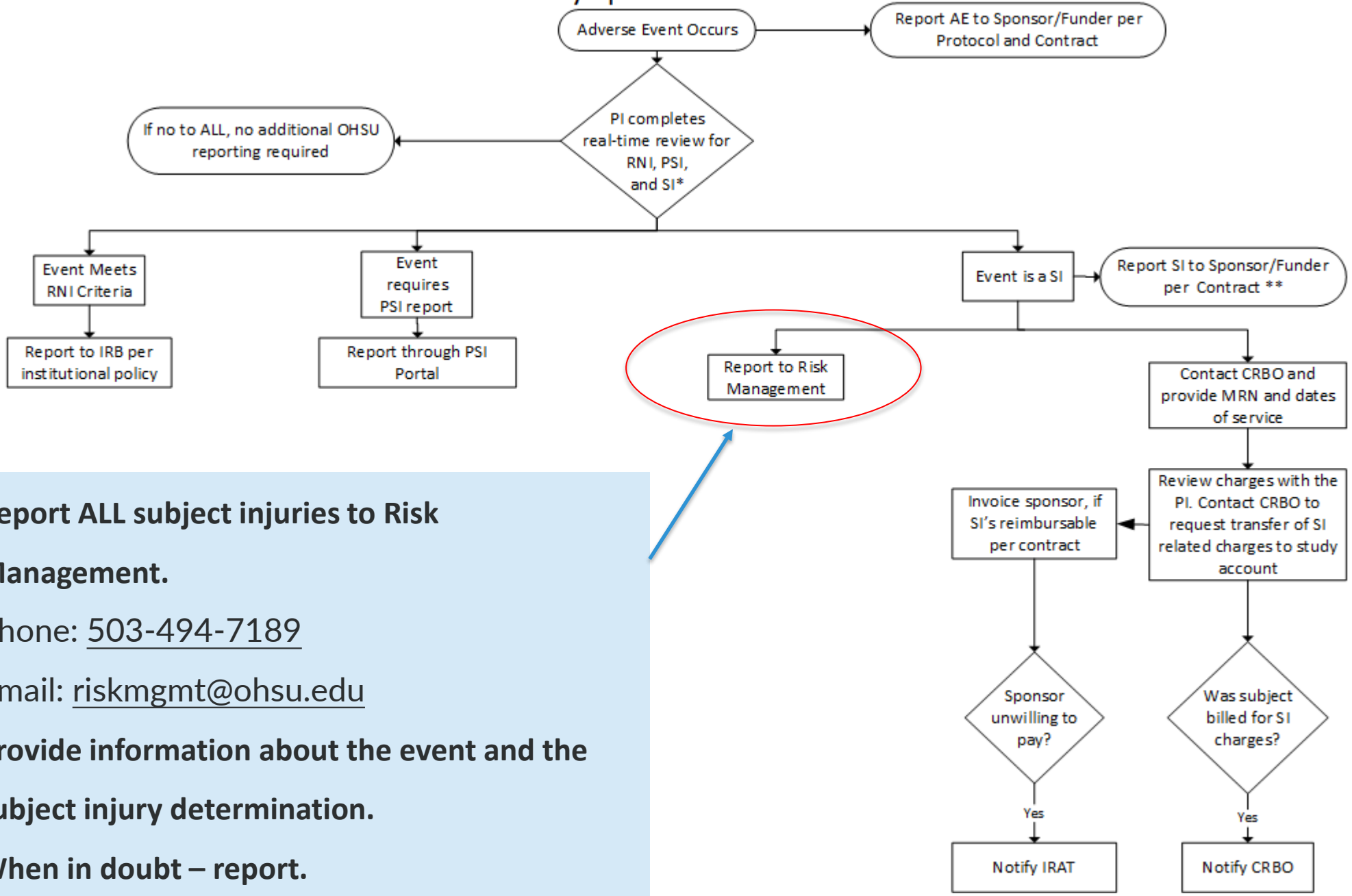
OHSU



Sponsor Notification

- Contact the sponsor immediately upon the PI determining a subject injury has occurred or is suspected as specified in the contract.
- Don't wait to report, provide additional information as it is available
- Document that notification in writing (email or note to file)

Industry Sponsored Studies



Report ALL subject injuries to Risk Management.

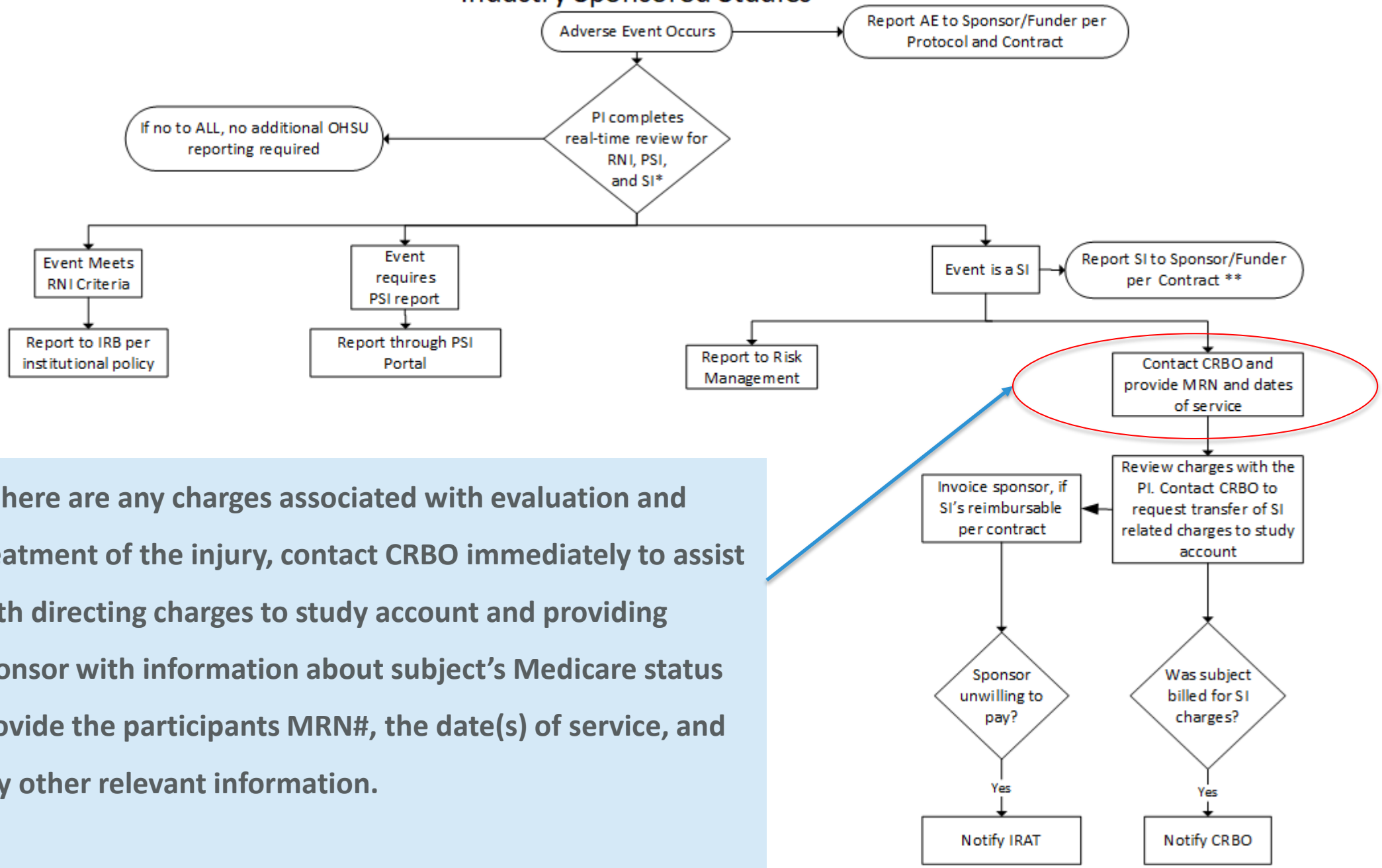
Phone: 503-494-7189

Email: riskmgmt@ohsu.edu

Provide information about the event and the subject injury determination.

When in doubt – report.

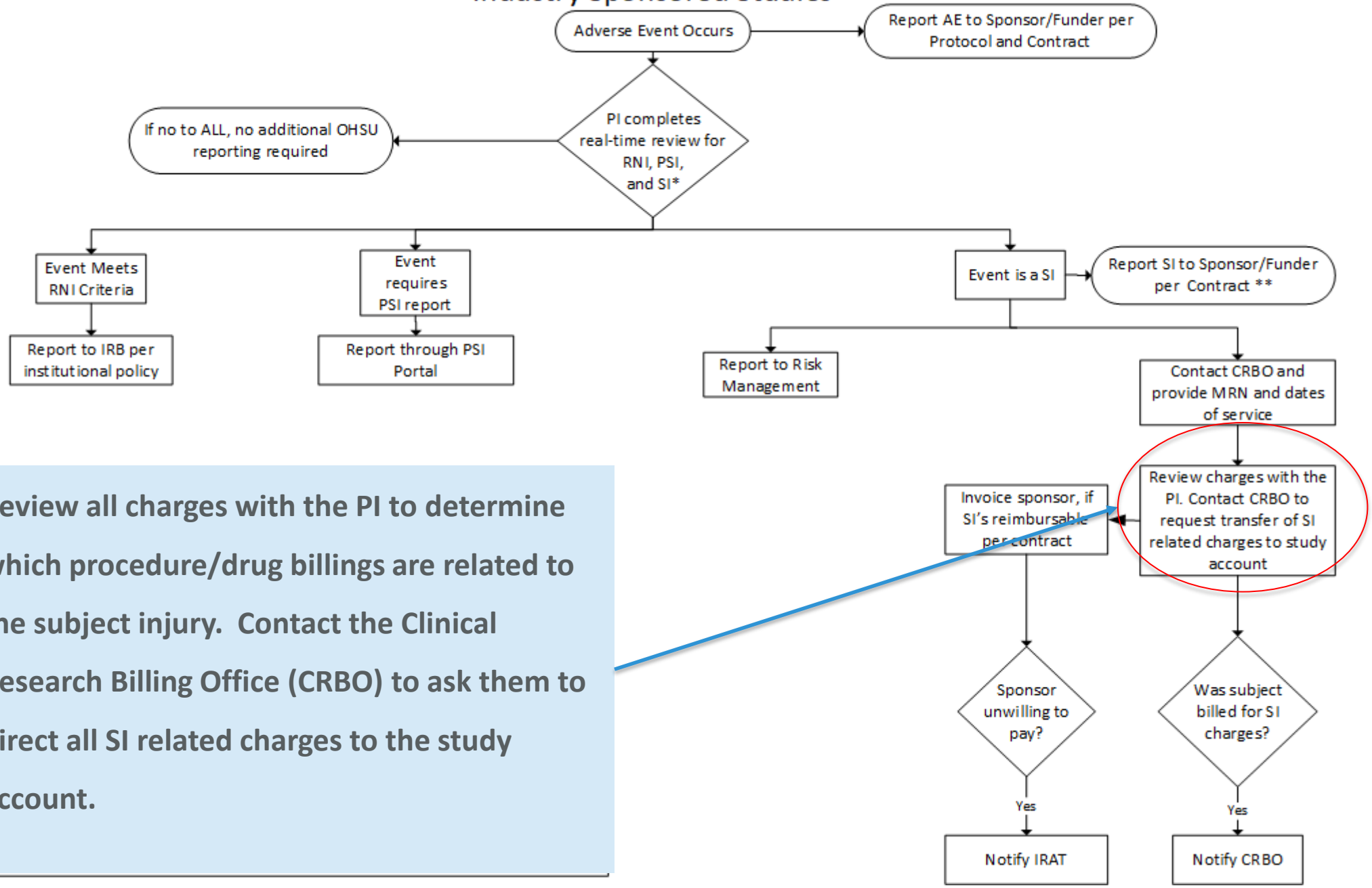
Industry Sponsored Studies



If there are any charges associated with evaluation and treatment of the injury, contact CRBO immediately to assist with directing charges to study account and providing sponsor with information about subject's Medicare status Provide the participants MRN#, the date(s) of service, and any other relevant information.

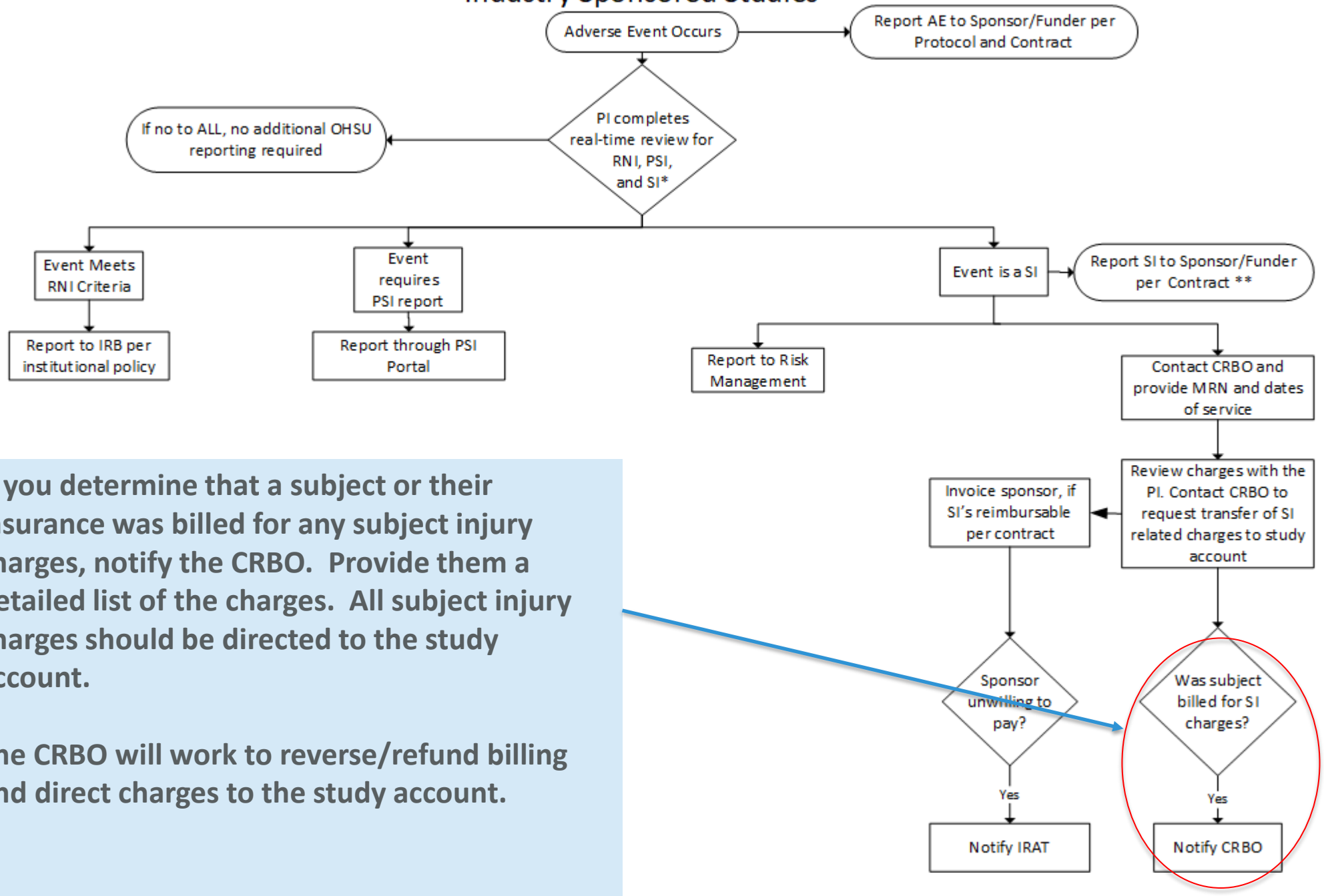
OHSU

Industry Sponsored Studies



Review all charges with the PI to determine which procedure/drug billings are related to the subject injury. Contact the Clinical Research Billing Office (CRBO) to ask them to direct all SI related charges to the study account.

Industry Sponsored Studies



If you determine that a subject or their insurance was billed for any subject injury charges, notify the CRBO. Provide them a detailed list of the charges. All subject injury charges should be directed to the study account.

The CRBO will work to reverse/refund billing and direct charges to the study account.

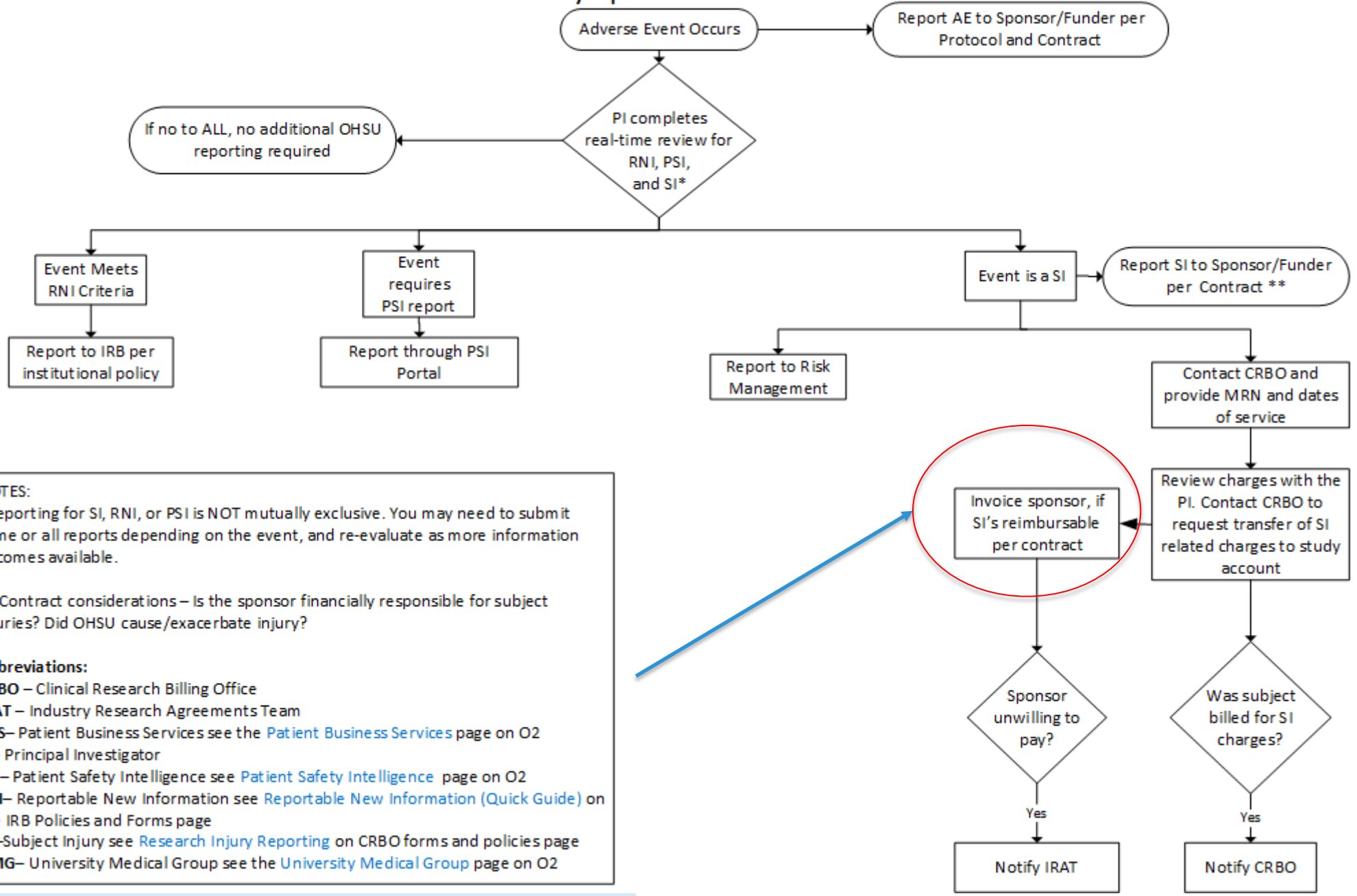
OHSU

Directing Subject Injury Cost to Study Account

- Direct all charges for SI treatment and evaluation to the study account
  - OHSU evaluation and treatment:
    - CRBO contacts PBS/UMG to direct charges to the study account
  - If SI evaluated and/or treated at outside facility:
    - Study team requests copy of bill from facility
    - Forwards bill and Accounts Payable disbursement form to Accounts Payable disbursements@ohsu.edu
    - Accounts payable will pay the external facility from the OGA study account
    - Note: Research Rates don't apply – we don't negotiate prices with outside facilities.
  - If subject paid for evaluation and/or treatment out of pocket:
    - Study team asks subject to provide copy of bills, then study team sends a request to Accounts Payable to pay the subject from OGA study account
  - If the subject's insurance has been billed:
    - CRBO work to reverse/refund billing and directed to the study account

OHSU

Industry Sponsored Studies



NOTES:
*Reporting for SI, RNI, or PSI is NOT mutually exclusive. You may need to submit some or all reports depending on the event, and re-evaluate as more information becomes available.

** Contract considerations – Is the sponsor financially responsible for subject injuries? Did OHSU cause/exacerbate injury?

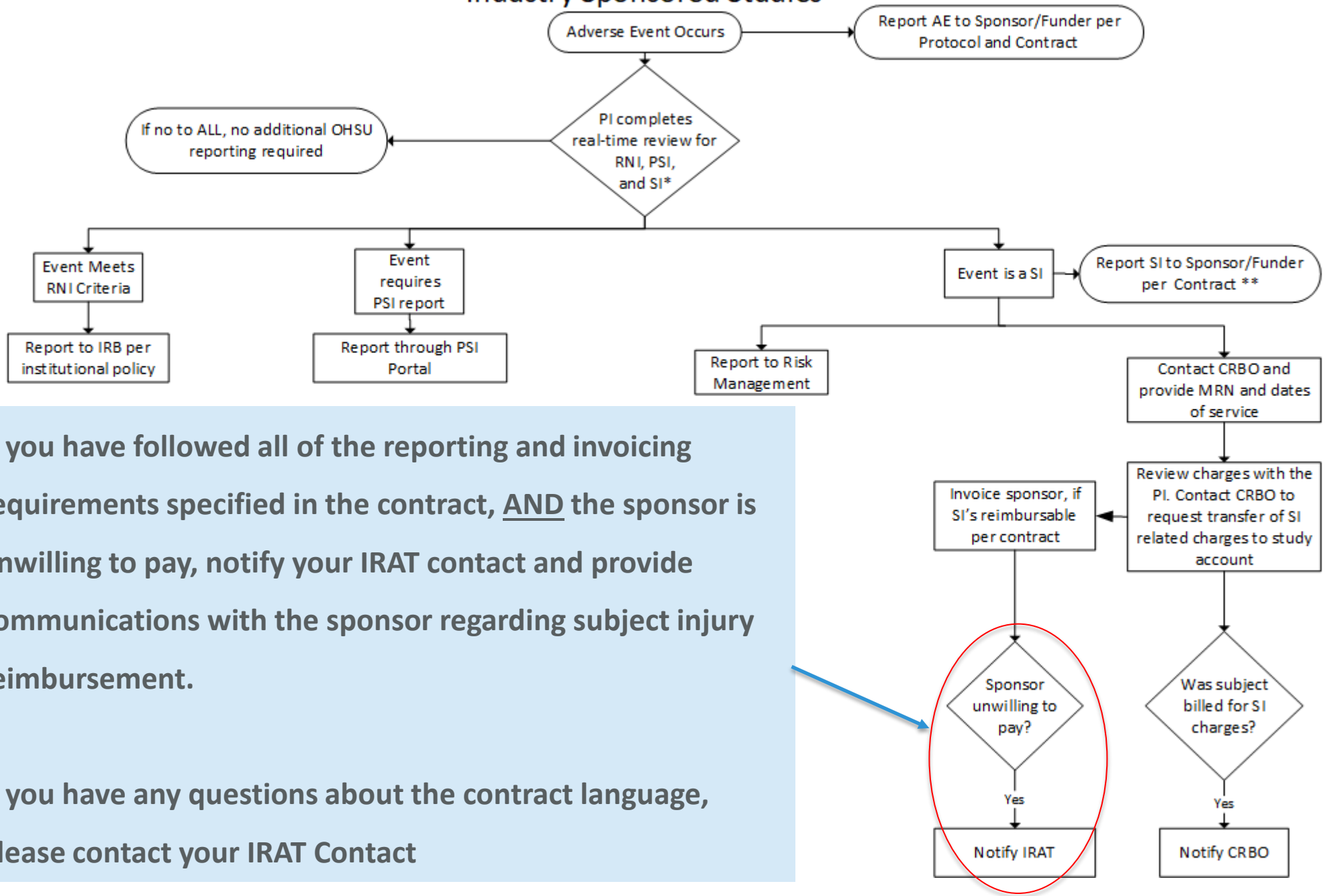
Abbreviations:
CRBO – Clinical Research Billing Office
IRAT – Industry Research Agreements Team
PBS– Patient Business Services see the Patient Business Services page on O2
PI– Principal Investigator
PSI– Patient Safety Intelligence see Patient Safety Intelligence page on O2
RNI– Reportable New Information see Reportable New Information (Quick Guide) on the IRB Policies and Forms page
SI –Subject Injury see Research Injury Reporting on CRBO forms and policies page
UMG– University Medical Group see the University Medical Group page on O2

Sponsor Medicare Reporting Requirements (MMSEA)

- Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA)
- Mandatory reporting requirements for sponsors when they pay for the injury of a Medicare beneficiary
- Study team should coordinate with the CRBO for any information needed for MMSEA reporting
  - Email all inquiries to CRBO@ohsu.edu

OHSU

Industry Sponsored Studies

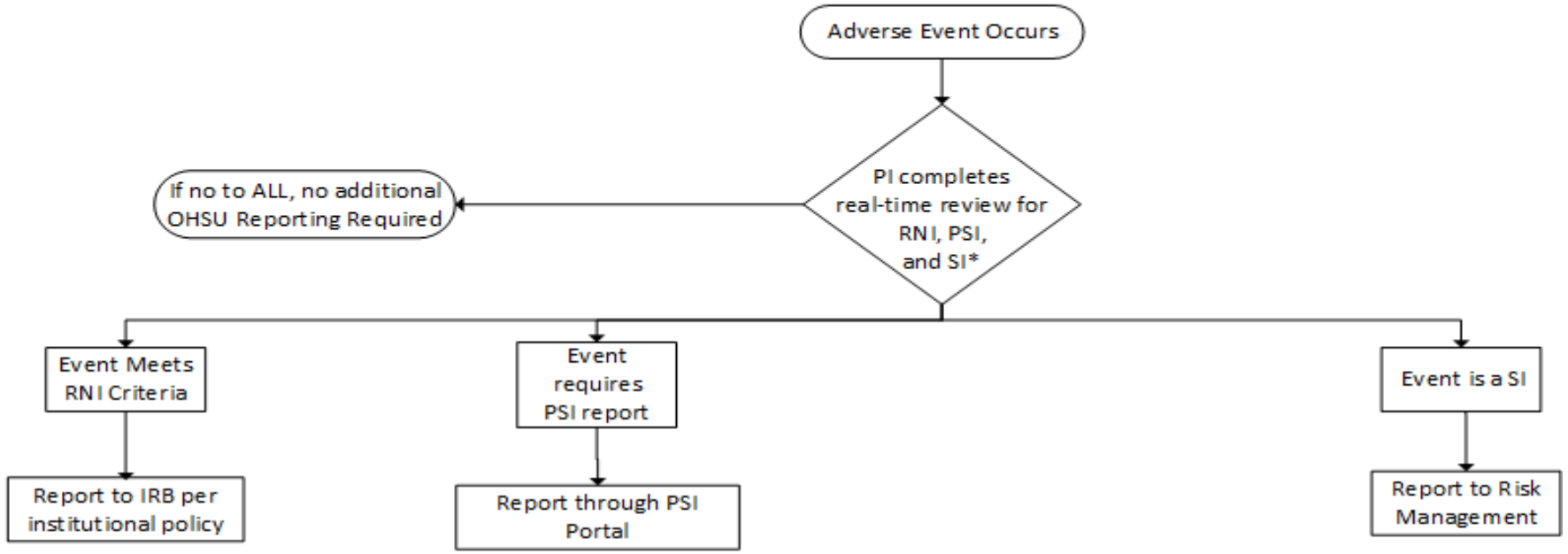


If you have followed all of the reporting and invoicing requirements specified in the contract, AND the sponsor is unwilling to pay, notify your IRAT contact and provide communications with the sponsor regarding subject injury reimbursement.

If you have any questions about the contract language, please contact your IRAT Contact

OHSU

Non-Industry and Investigator Initiated Studies

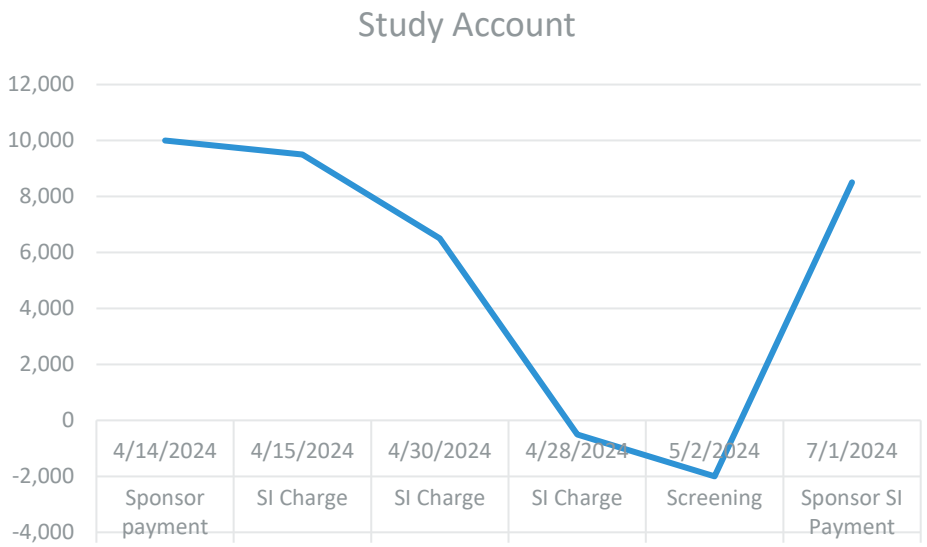


This is the same process we reviewed for industry sponsored clinical trials minus the contract and billing.

The NIH, OHSU, and most non-industry funders do not agree to pay for research subject injuries.

OHSU

Subject Injury Charges and Billing



- Subject Injury Charges will likely make your study account go into deficit.
- That's ok, the sponsor payments will fix this
- If there is a question about whether or not it is a subject injury, the CRBO will ask the Billing office to place a "Do Not Bill" (DNB) on the account(s) until the subject injury has been determined.

Subject Injury Scenario

- A patient enrolled in a clinical trial to evaluate a category B investigational pacemaker develops an implant site infection. Implant site infections are rare, but they do occur with marketed pacemaker implants.

- Is the implant site infection a subject injury?
- What type of OHSU report is required?

Subject Injury Scenario – New Information

- A patient enrolled in a clinical trial to evaluate a category B investigational pacemaker develops an implant site infection. Implant site infections are rare, but they do occur with marketed pacemaker implants.
- A week later the PI receives a letter from the study sponsor recalling the investigational pacemakers due to potential sterilization problems during the manufacturing process.

- Now is this a subject injury?
- Who needs to be notified?

OHSU

Resources

- Policies and Procedures
  - Links to all policies and procedures can be found on the Subject Injury Reporting Webpage https://o2.ohsu.edu/clinical-research-services/subject-injury-reporting
- Contact information
  - Billing questions: crbo@ohsu.edu
  - Contract questions: opamira@ohsu.edu
  - Consent questions: Contact your IRB Specialist
  - RNI questions: Contact your IRB Specialist
  - Risk – riskmgmt@ohsu.edu, 503-494-7189
- Subject Injury eLearning –in Compass

OHSU



Thank You