OREGON CLINICAL & TRANSLATIONAL Research Institute

OHSU

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

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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

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

Subject Injury Identification Exercise

Is it subject injury?

- Clinical trial of investigational chemotherapy in cancer usually treated with tyrosine kinase inhibitor
  - Disease progression?
  - Anticipated side effect of research medication the same as tyrosine kinase inhibitor side effect?
  - Unanticipated side effect of research medication the same as tyrosine kinase inhibitor side effect?
  - Anticipated side effect of research medication different than expected tyrosine kinase side effect?
  - Unanticipated side effect of research medication different than expected tyrosine kinase side effect?

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Exercise Answers

Clinical trial of investigational chemotherapy in cancer usually treated 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

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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 contract officer)
  - OHSU personnel caused the injury (OHSU pays for the injury)

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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.

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

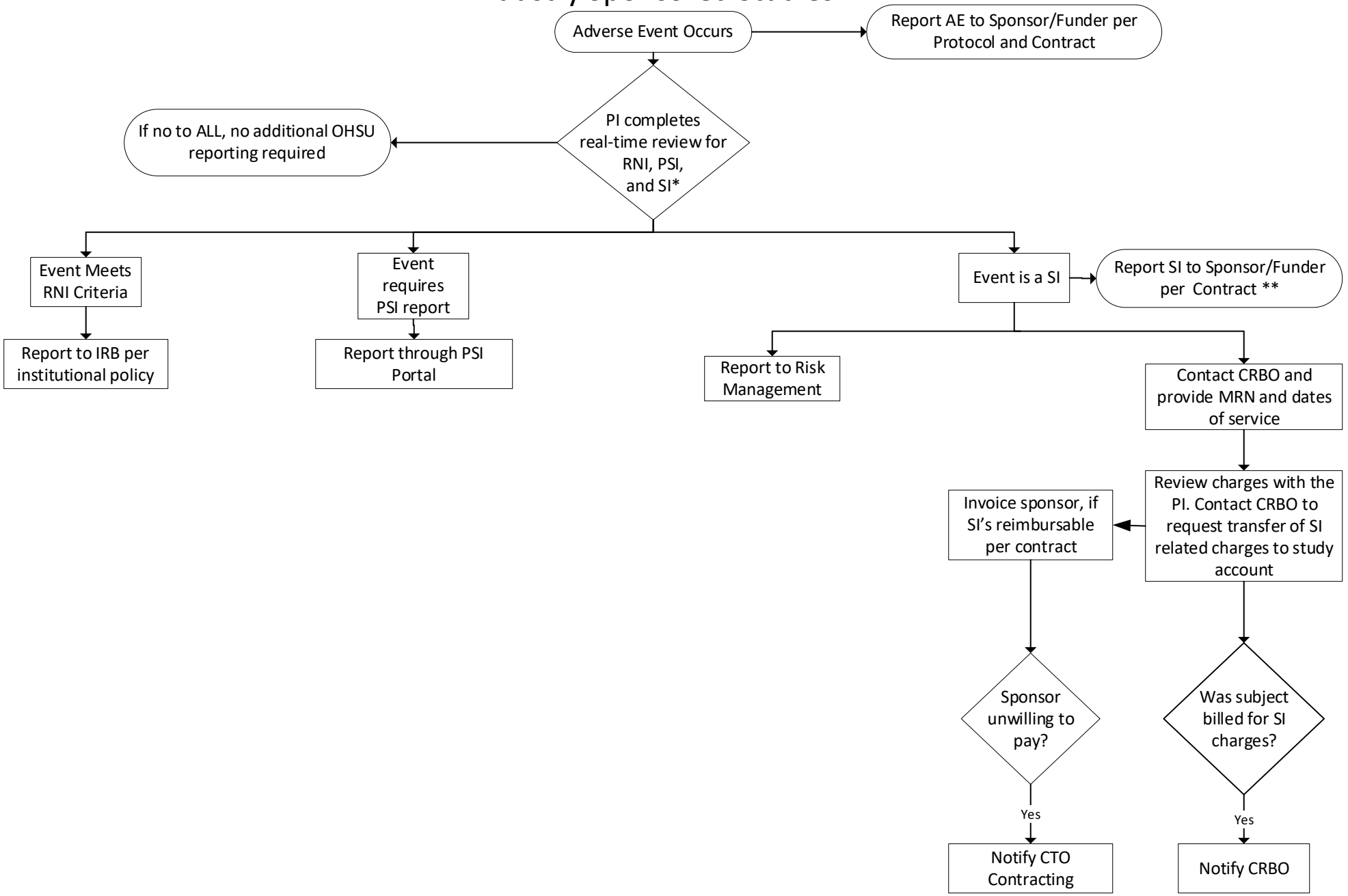
Sponsors and Boilerplate Liability Language in Consent:

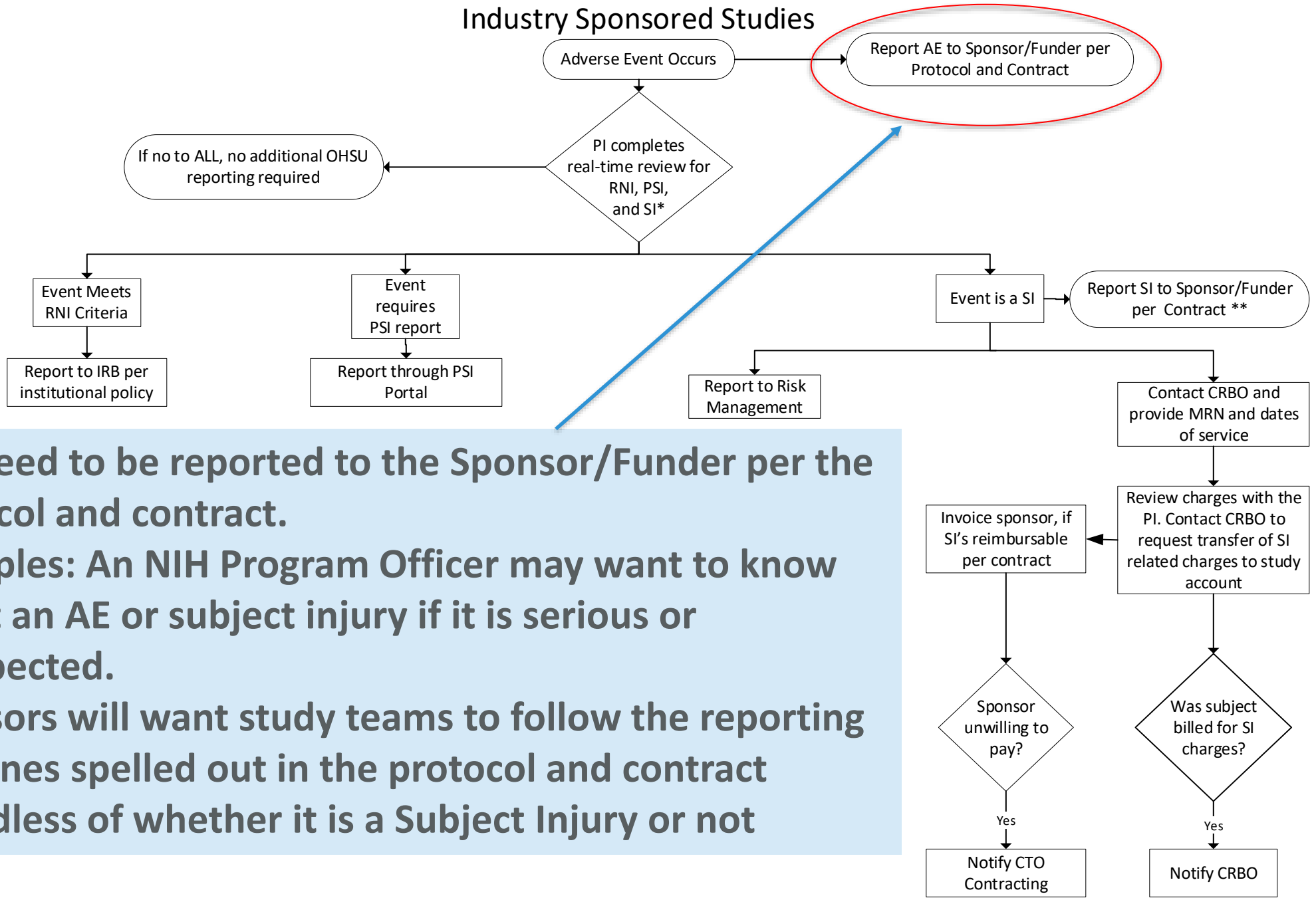
- Don't negotiate the liability language!
- Do not edit the boilerplate language without prior IRB approval.
- Do not insert unallowed limitations (exculpatory)
  - Cannot predicate payment for injury on following instructions
  - Can't include time limits for identification of the injury
- Inform sponsors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

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)

Industry Sponsored Studies



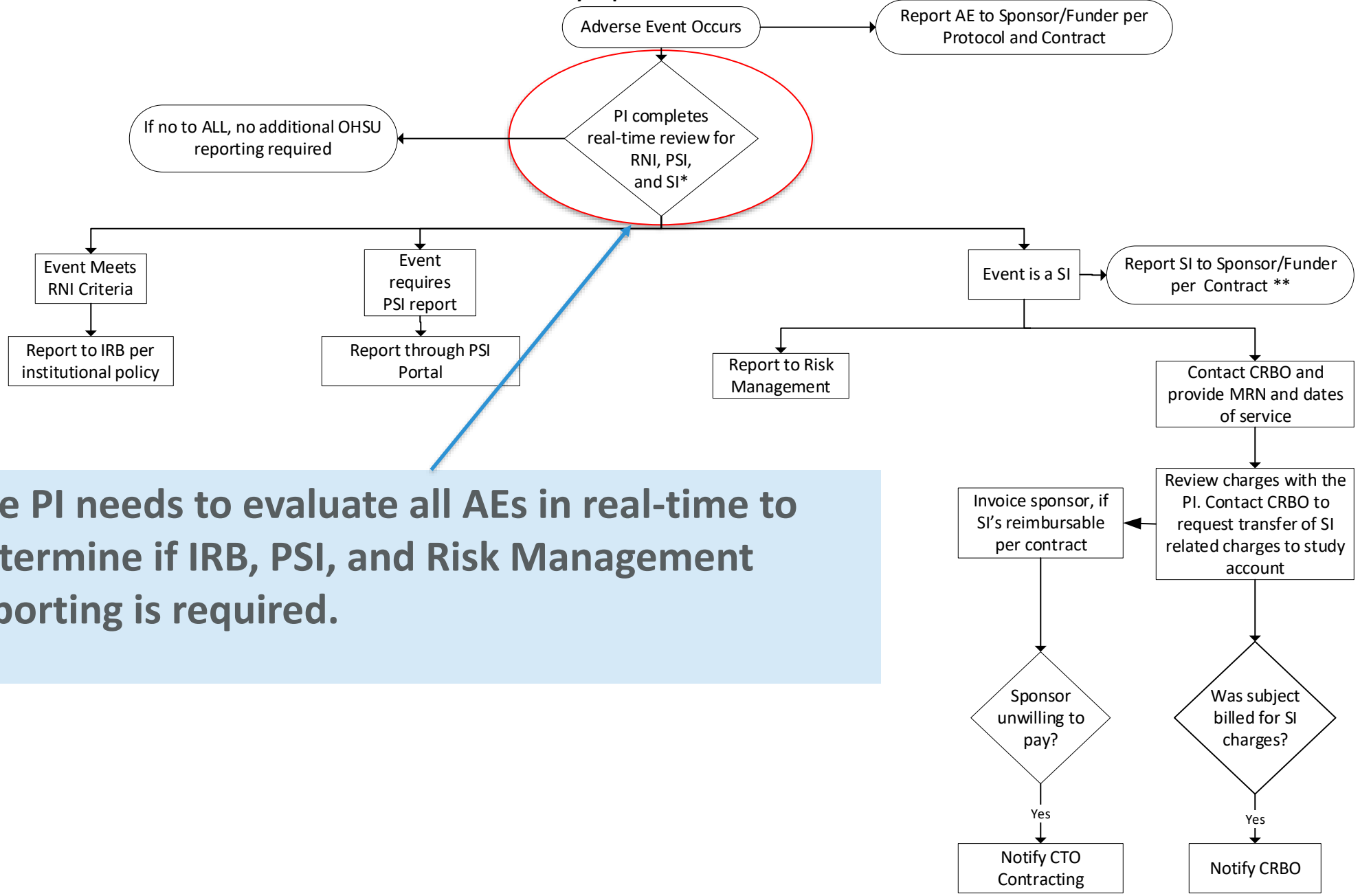


AEs need to be reported to the Sponsor/Funder per the protocol and contract.

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

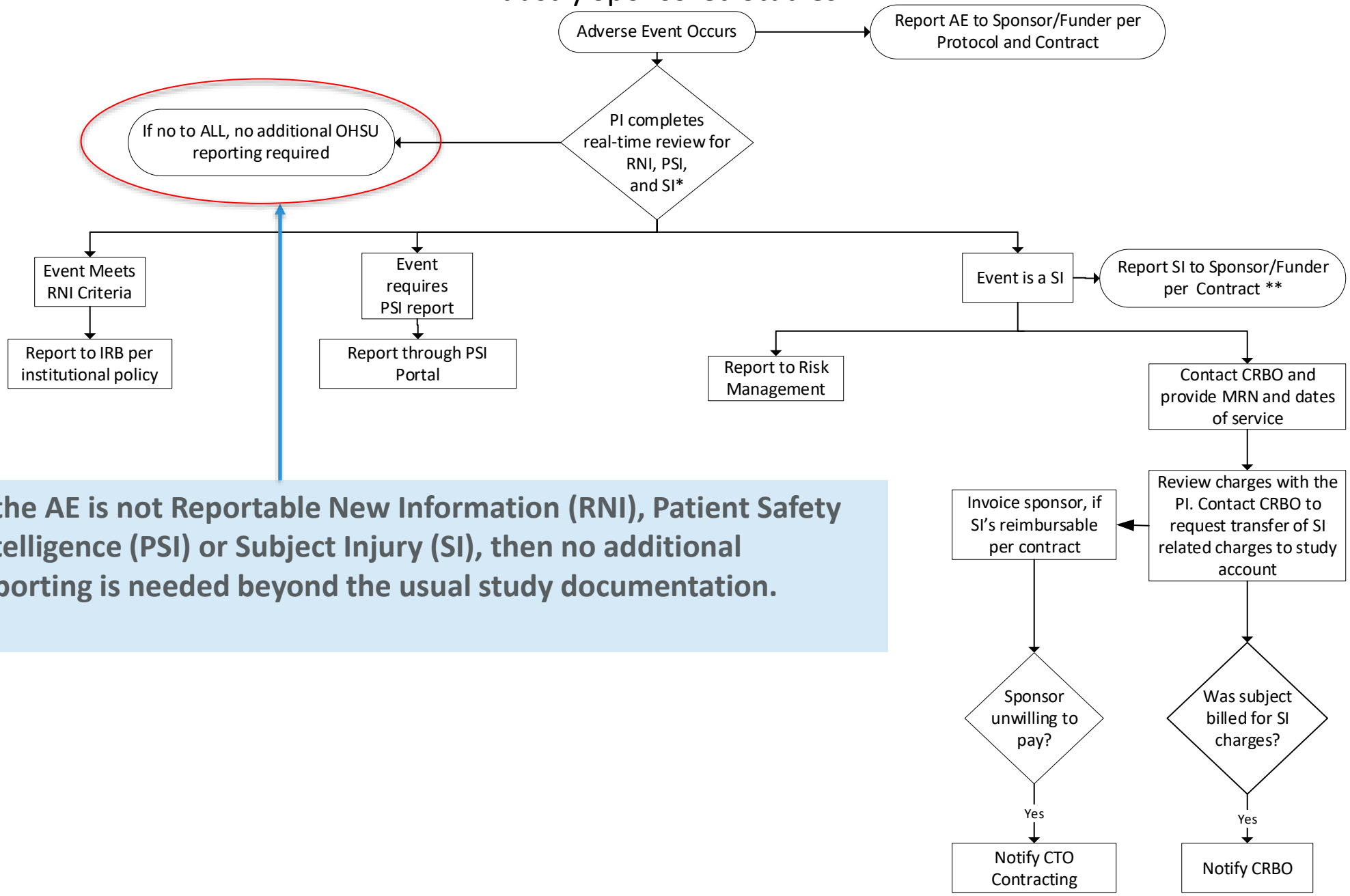
Sponsors will want study teams to follow the reporting timelines spelled out in the protocol and contract regardless of whether it is a Subject Injury or not

Industry Sponsored Studies



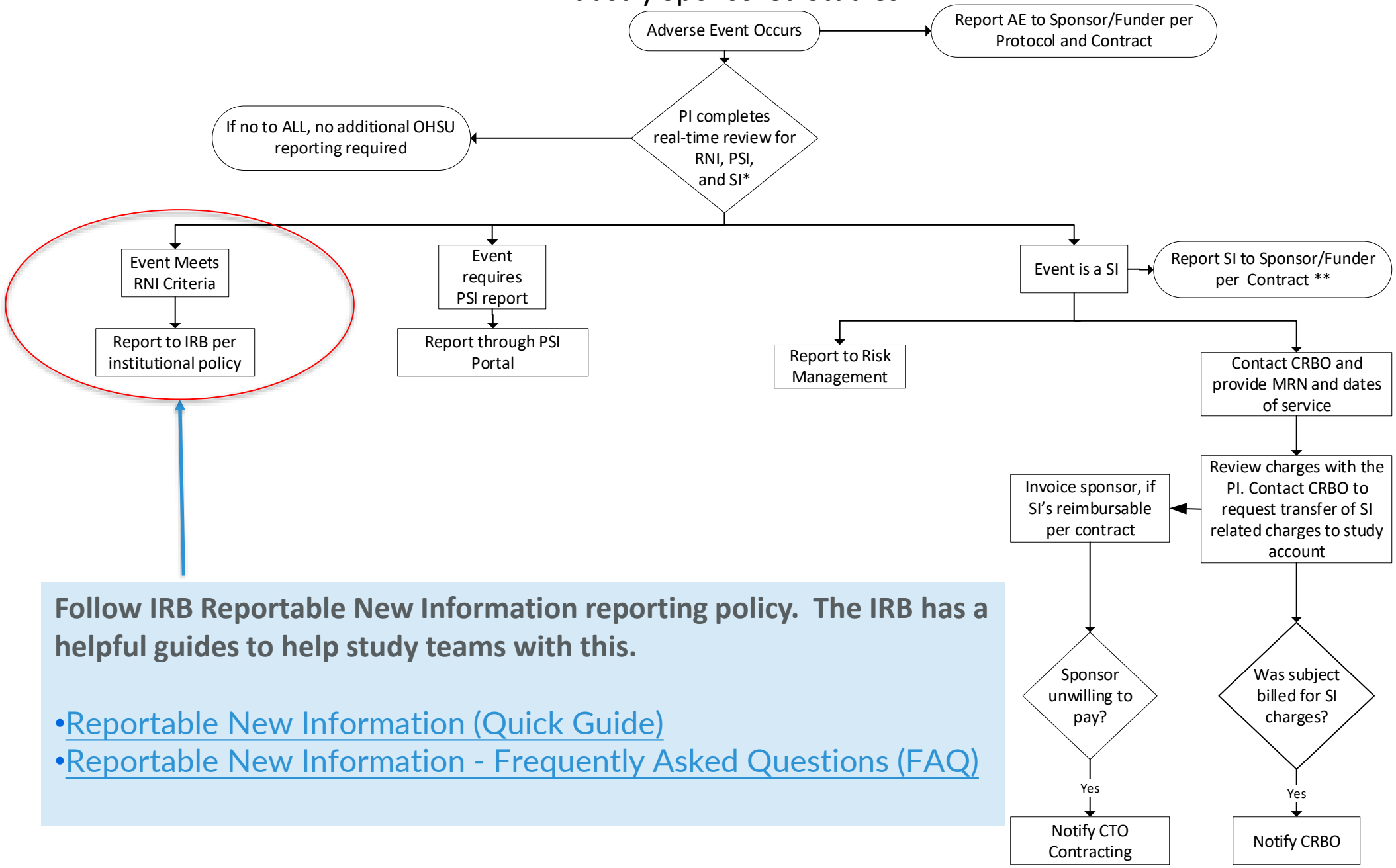
The PI needs to evaluate all AEs in real-time to determine if IRB, PSI, and Risk Management reporting is required.

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.

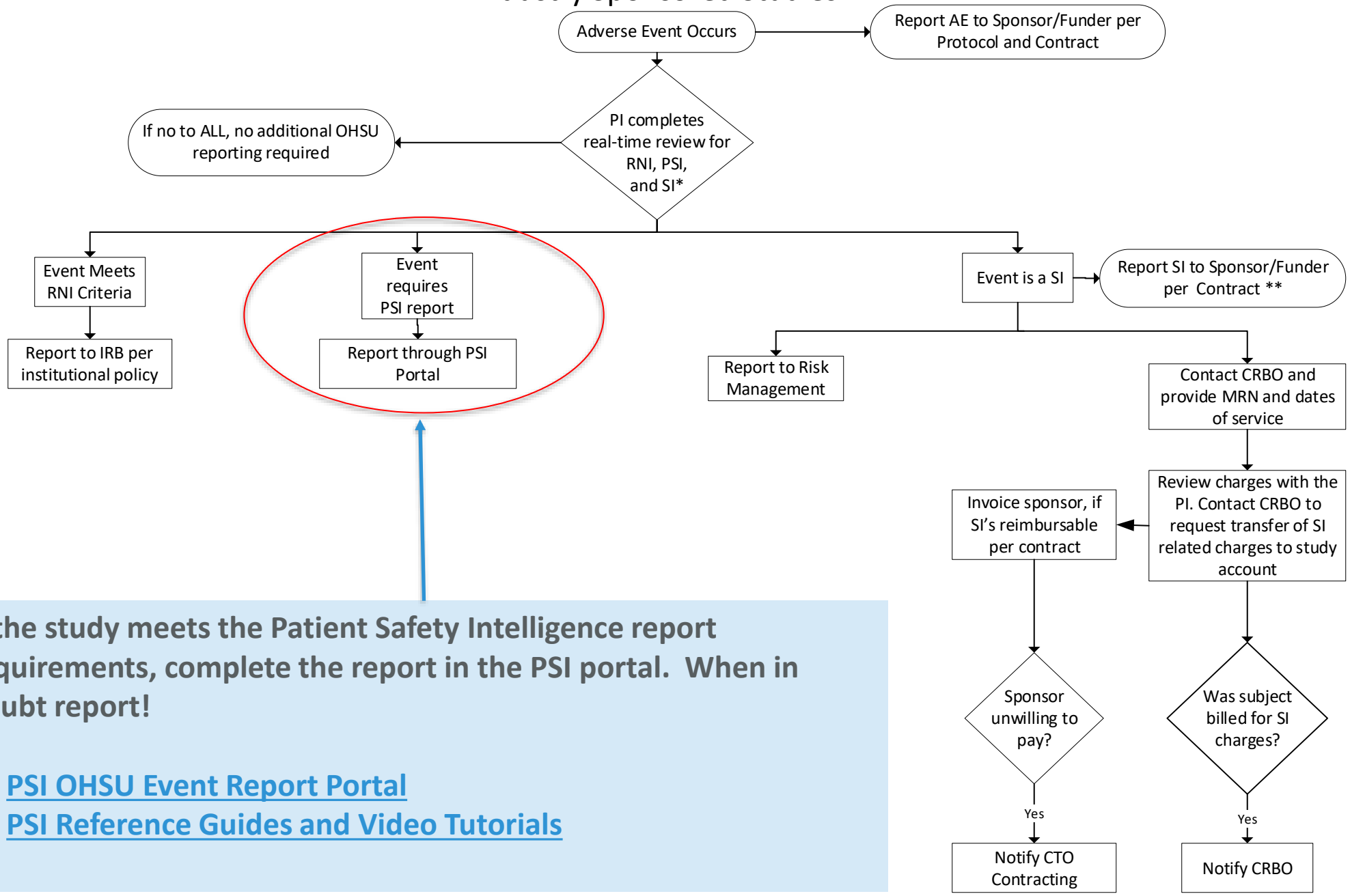
Industry Sponsored Studies



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

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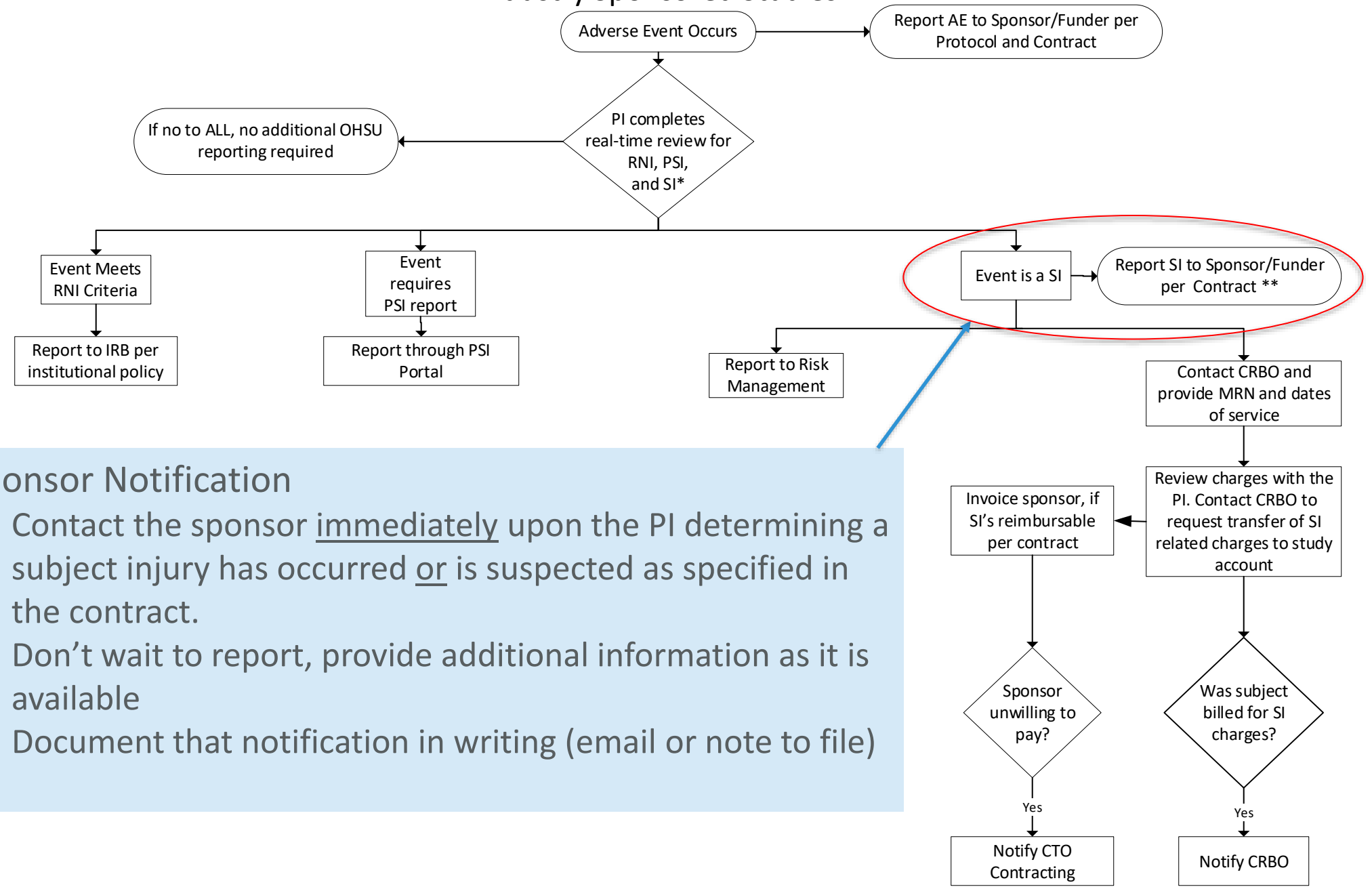
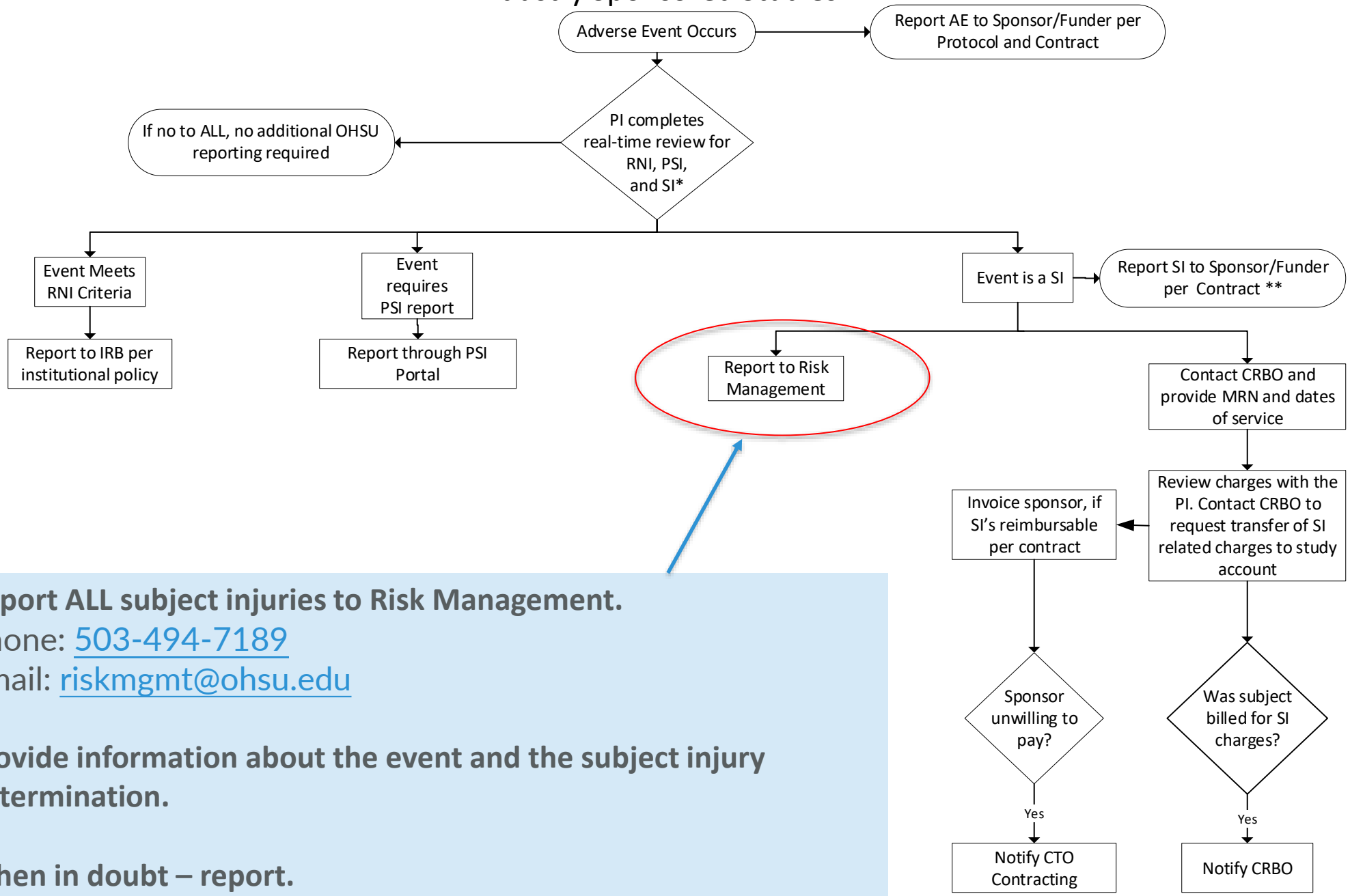


Sponsor Notification

- 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.

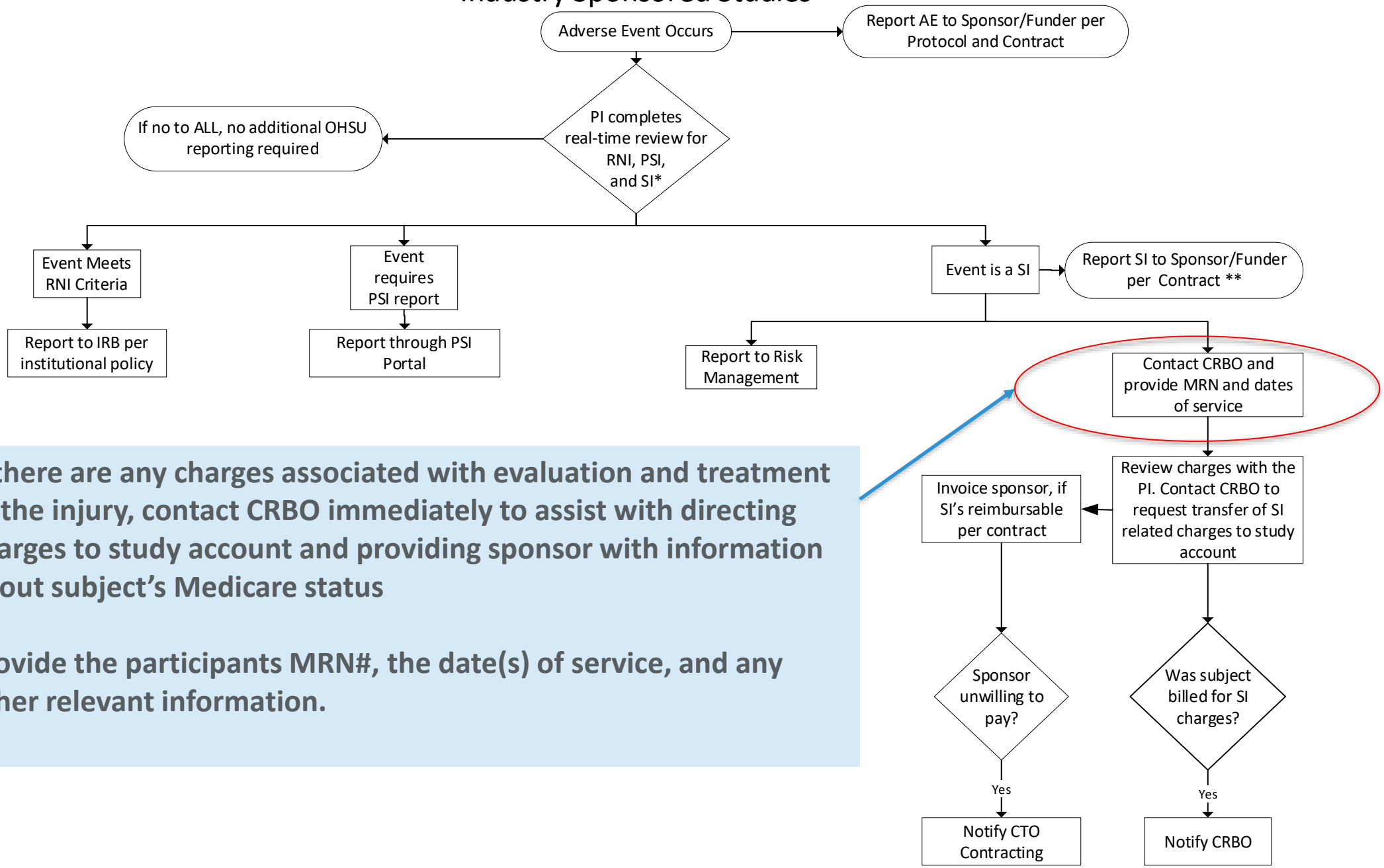
Phone: 503-494-7189

Email: riskmgmt@ohsu.edu

Provide information about the event and the subject injury determination.

When in doubt – report.

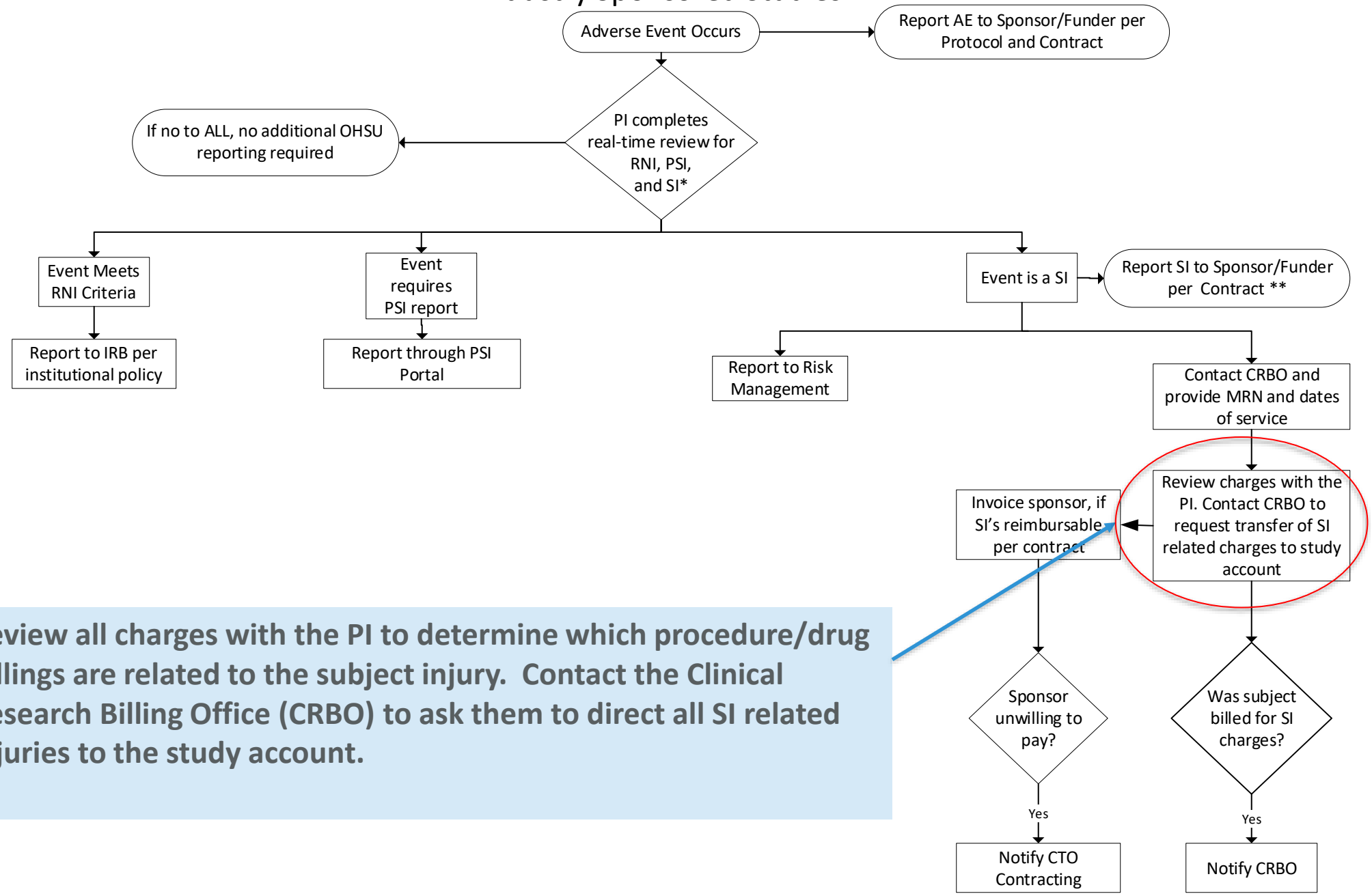
Industry Sponsored Studies



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.

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 injuries to the study account.

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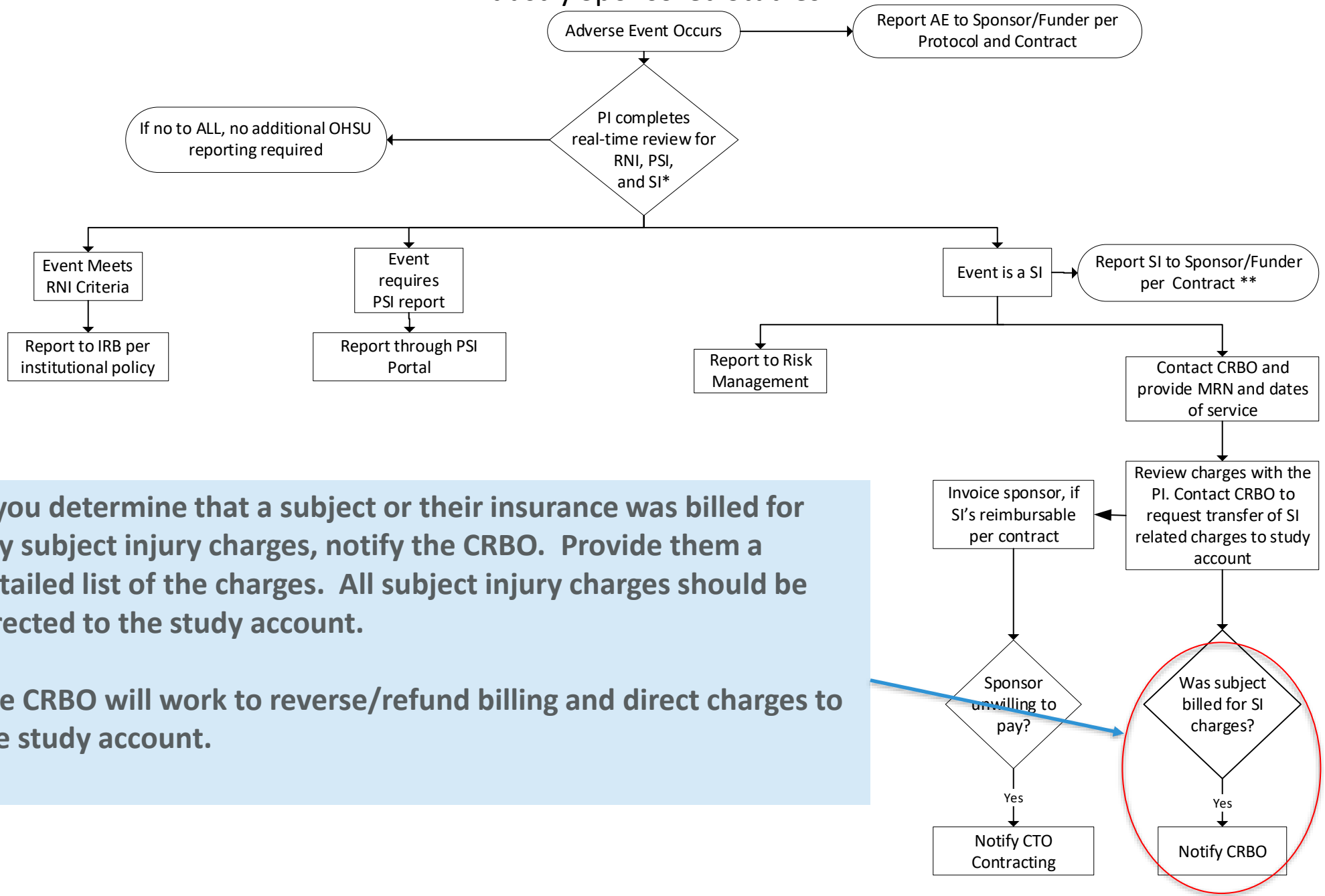
Industry Sponsored Studies



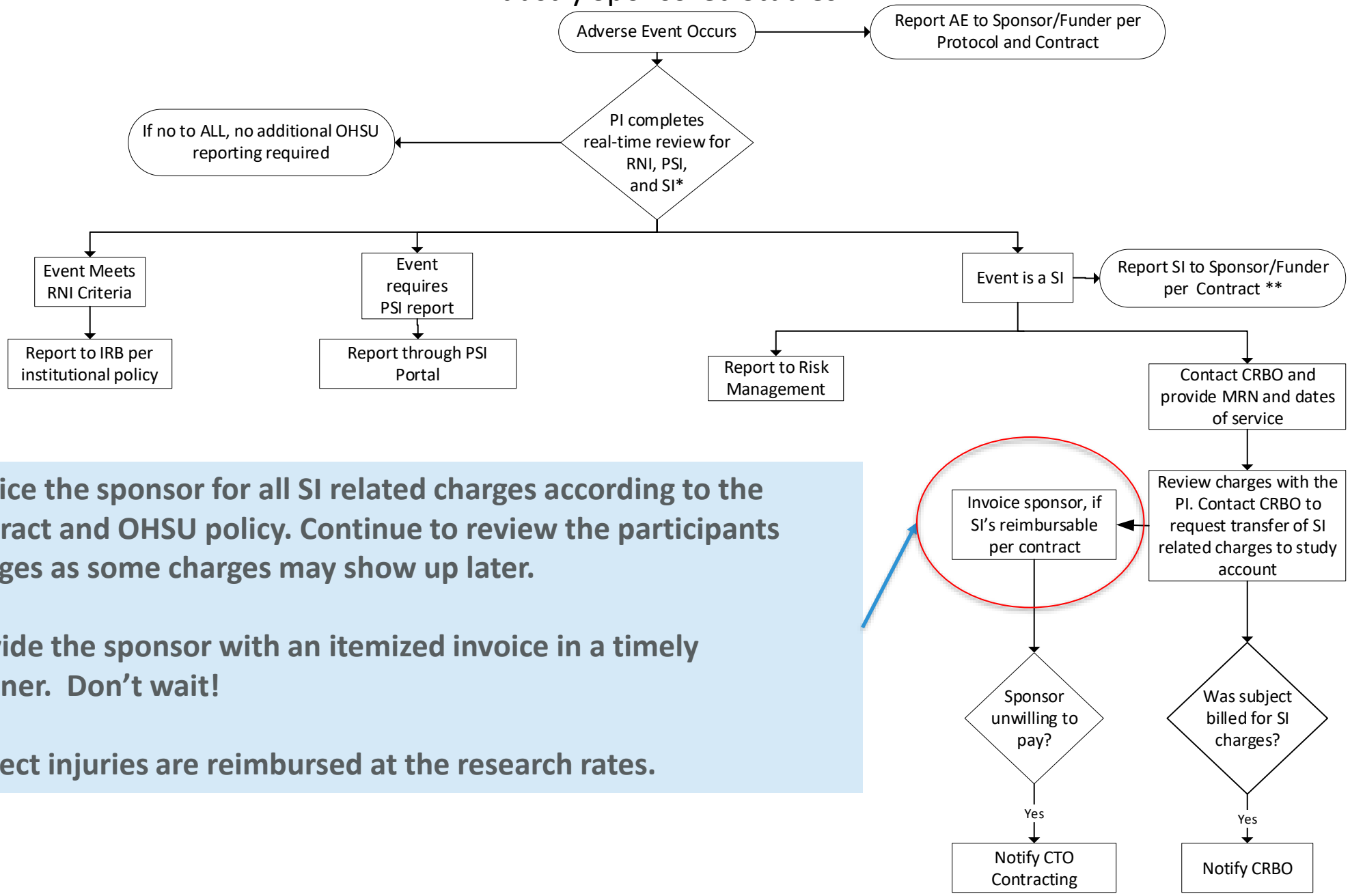
If you determine that a subject or their insurance was billed for any subject injury charges, notify the CRBO. Provide them a detailed list of the charges. All subject injury charges should be directed to the study account.

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

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

Industry Sponsored Studies



Invoice the sponsor for all SI related charges according to the contract and OHSU policy. Continue to review the participants charges as some charges may show up later.

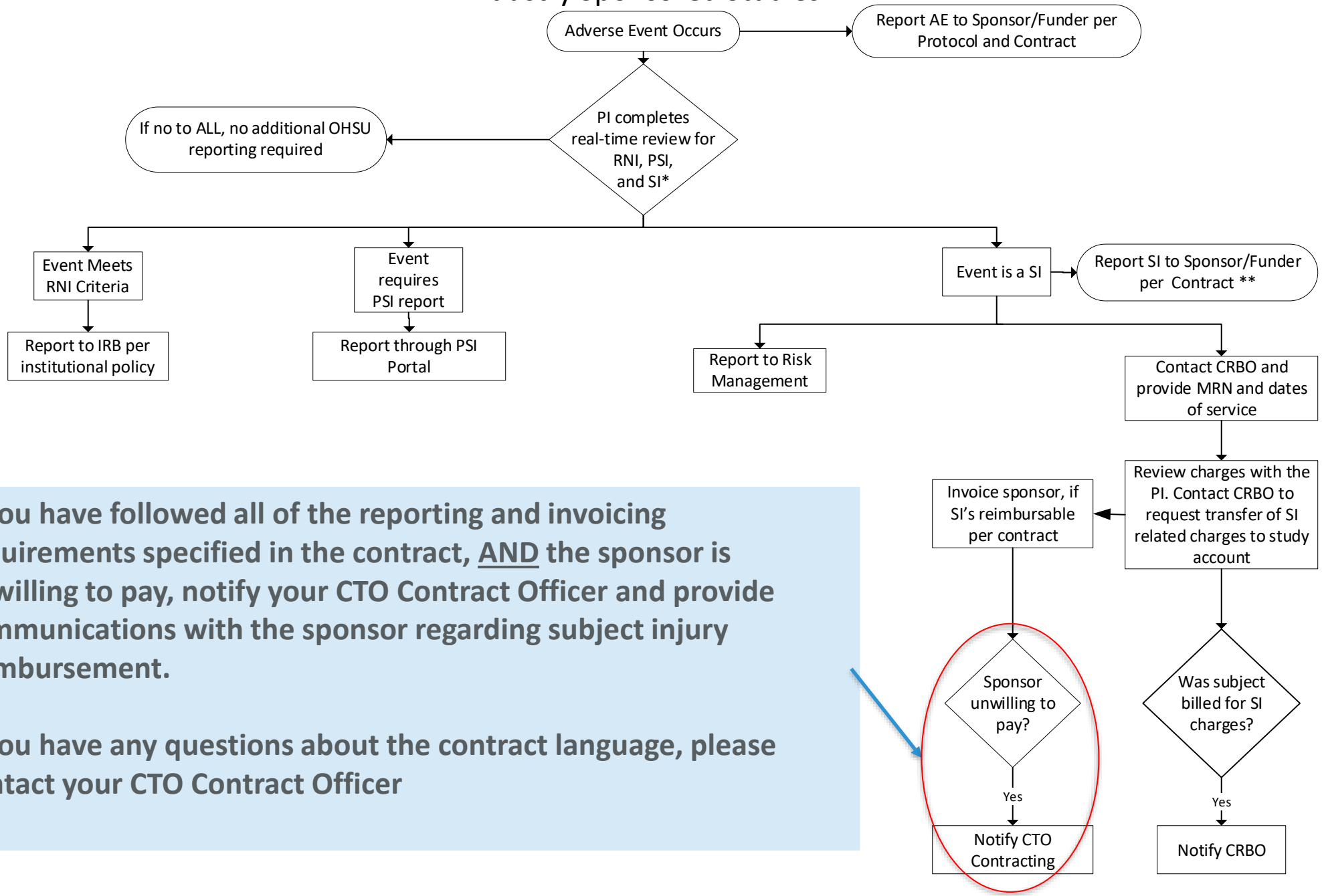
Provide the sponsor with an itemized invoice in a timely manner. Don't wait!

Subject injuries are reimbursed at the research rates.

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

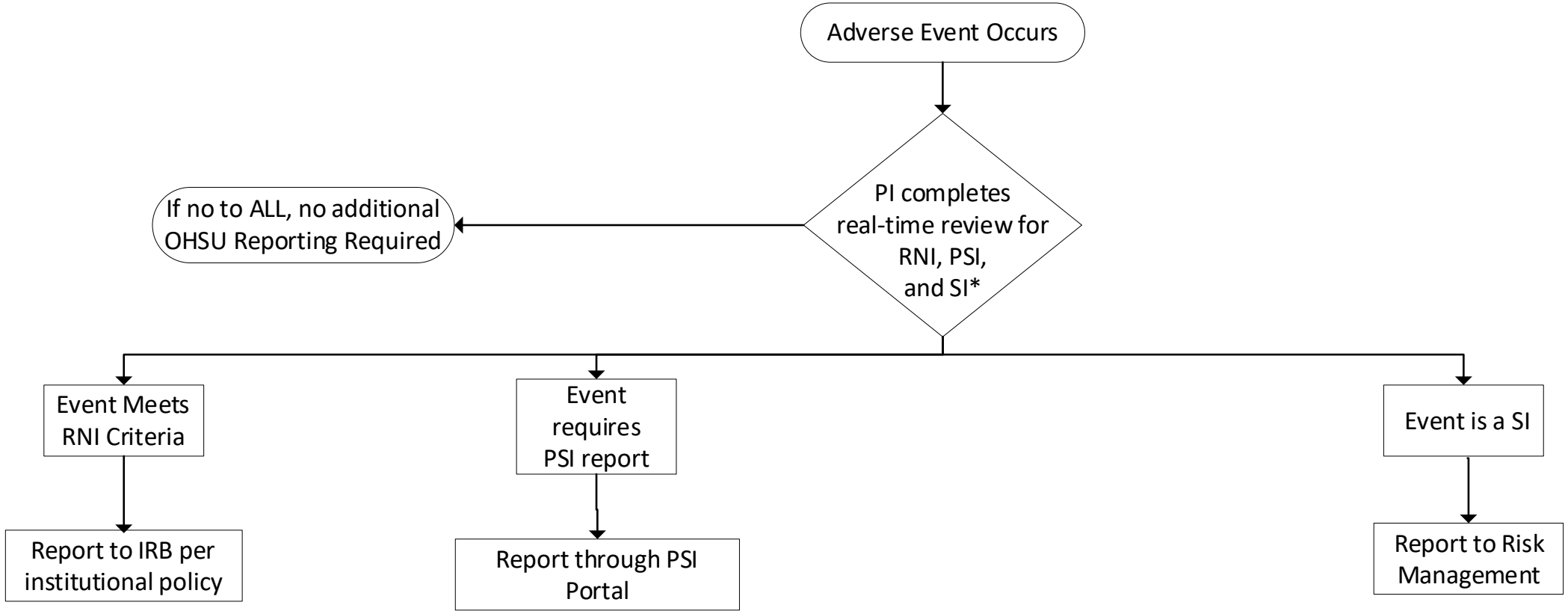
Industry Sponsored Studies



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

If you have any questions about the contract language, please contact your CTO Contract Officer

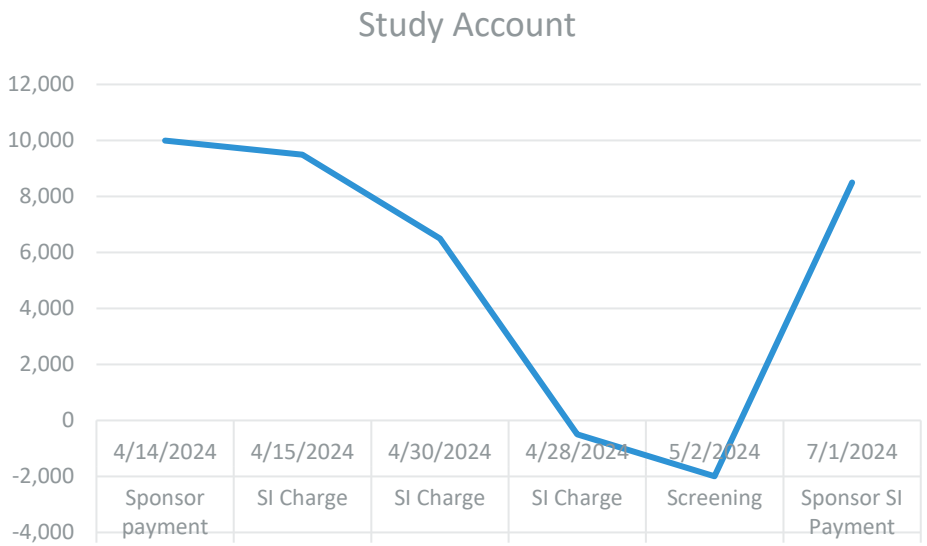
Non-Industry and Investigator Initiated Studies



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.

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.

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: Kristen Baptiste, CTO Manager
  - Consent questions: Contact your IRB Specialist
  - RNI questions: Contact your IRB Specialist
  - Risk – riskmgmt@ohsu.edu, 503-494-7189
- Subject Injury eLearning –in Compass

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Thank You