eIRB Upgrade:
Reportable New Information (RNI)

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IRB’s Regulatory Requirements

• Certain federal requirements regarding:
  ▪ Unanticipated Problems Involving Risks to Subjects or Others
  ▪ Serious or Continuing Noncompliance
  ▪ Suspension or Termination of IRB approval

• IRB must be made aware of any new information that affects the criteria for approval.
Reportable New Information (RNI)

- Protocol Deviations (PDs)
- Unanticipated Problems (UPs)
- Certain kinds of modifications (ex: DSMC reports)
## Main Differences

<table>
<thead>
<tr>
<th>Will no longer be reportable</th>
<th>New reportable items (sort of)</th>
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<tr>
<td>Deviations that are not due to any action or inaction of the researchers AND did not increase risk to subjects</td>
<td>Audit and monitoring reports with any deficiencies</td>
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Submit RNI within **5 business days** of becoming aware of the event/issue.
Rationale for Changes

• PD vs. UP is not a regulatory distinction
• No need to know about things that were “out of your control” — unless increased risk of harm
• Helps identify Continuing Noncompliance early
• Streamline reporting of audit/monitoring findings
• Standardize reporting timelines
Timing

• Concurrent with eIRB Upgrade (Summer 2015)
• Study enters new system = follow new policy
**Policy Details**

Four main categories of RNI:

- Potential UPs
- Written Reports
- PDs / Non-compliance
- Other
Policy Details: Potential UPs

- UP = “Unanticipated Problems Involving Risks to Subjects or Others”
- Report the following:
  - Any new or increased risk related to the research
  - SUSARs, IND safety reports, and adverse events that require a change to the protocol or consent
  - Unanticipated Adverse Device Effect
  - Unauthorized disclosure of confidential subject information
**New Risks**

- Identified from **any source** (specific event, new IB, publications, safety reports, etc.)

- Must be
  - Previously **unanticipated**
  - AND
  - **Related** to the research

- Does **NOT** include:
  - Events not related to the research
  - Anticipated events
Example – New Risk?

A study in college students involves completion of a survey asking questions about early childhood experiences. During the completion of the survey, one student subject has a reaction of intense sadness and depressed mood that resolved without intervention after a few hours. The protocol and informed consent document for the research did not describe any risk of such negative psychological reactions. Upon further evaluation, the investigator determines that this resulted from certain survey questions that triggered the subject’s repressed memories of physical abuse as a child. The investigator had not expected that such reactions would be triggered by the survey questions.
Unauthorized Disclosure

• Any disclosure about a subject made in violation of
  ▪ applicable law, regulation, or policy, or
  ▪ the approved study protocol.

• Not just PHI!

• If PHI or other institutionally protected information is released, IPS Office must be notified.
Policy Details: PDs / Noncompliance

• **Protocol deviation** = deviation from approved protocol
• **Noncompliance** = failure to follow the regulations or the requirements or determinations of the IRB
• Report these **only if** they:
  ▪ Harmed a subject or placed a subject at risk of harm; or
  ▪ Occurred due to the action or inaction of the investigator or research staff and **may represent** Serious or Continuing Noncompliance; or
  ▪ Were made without IRB approval to eliminate an immediate hazard to a subject.
Action or Inaction of Researchers

• Researchers did something noncompliant
  Researchers failed to do something that was required

• Not due to action or inaction of researchers:
  ▪ MRI machine broke
  ▪ Commercial lab lost samples
  ▪ Subject went on vacation during visit window
**Serious or Continuing Noncompliance**

- **Serious** Noncompliance = may adversely affect the rights and welfare of subjects

- **Continuing** Noncompliance =
  - A pattern of Noncompliance that is likely to continue without intervention, or
  - Failure to work with the IRB to resolve Noncompliance

- Examples:
  - Unapproved research
  - Procedures without consent
  - Recurrence of a problem after education / corrective action
Example – Report Noncompliance?

A revised consent form is approved by the IRB. The next 10 subjects who enroll in the study are asked to sign the outdated version of the consent form.

• What if there are no differences between the old and new forms?
• What if the only difference is the addition of a blood draw?
• What if there are differences in risks?
• Does the number of subjects affected matter?
**Policy Details: Written Reports**

- **Regardless of findings:** Audits, inspections, or formal inquiries by a federal agency

- **If any deficiencies noted/changes required:**
  - Audits or inspections by any internal or external entity
  - Study monitoring reports
  - DSMB/C letters

- **Any finding of Noncompliance** by any entity
Policy Details: Other

• Significant or unresolved subject complaint
• Suspension or premature termination by the sponsor, investigator, or institution
• Incarceration of a subject in a research study not approved to involve prisoners
• State medical board or hospital Medical Staff actions against a study team member
Example #1 – Report?

A subject enrolled in a clinical trial evaluating a new investigational agent for osteoarthritis develops severe abdominal pain and nausea one month after randomization. Subsequent evaluation reveals gastric ulcers. The protocol and consent indicated that the there was a 10% chance of developing mild to moderate gastritis and a 2% chance of developing gastric ulcers. The investigator concludes that the subject’s gastric ulcers resulted from the research intervention. A review of data on all subjects enrolled so far reveals that the incidence of gastritis and gastric ulcer are within the expected frequency.
Example #1

- The occurrence of gastric ulcers – in terms of nature, severity, and frequency – was expected
- Not a potential UP
- Not a PD, noncompliance, written report, or other

Do Not Report RNI
Example #2 – Report?

A subject received in the mail a study survey that included questions about illegal drug use. The subject hand-wrote her name on it, even though the protocol stated that the survey document would not identify the subjects. The subject completed half of it and stored it in her purse. She was subsequently arrested for drug possession. When her belongings were searched, the survey, with her responses that identified her as a drug user, was discovered by police. The study protocol was not approved to include prisoners.
Example #2

- Potential UP
  - Did not anticipate police finding the survey
  - Related to study
  - Could harm subject – incriminating evidence

- PD/Noncompliance
  - Name on survey – not researchers’ fault, but...
  - Subject harm

- Other – unexpected incarceration

Report RNI
Do you need to do a mod?

RNIs do not process study document changes!

Mod required for:

• Consent updates
• Protocol changes
• New IB (needs to be part of final documents)
• Documents you need “approved”
What does the IRB do with your report?

- IRB determines if it represents a UP, S/CN, or Susp/Term
- If yes, full board review (with mod, if applicable)
- Full board determines actions needed to protect subjects
- IRB determines if reportable to federal agencies and/or institutional officials

*Note* – you may also need to report to sponsor and/or FDA.
Continuing Review

• New information that does not require prompt reporting via RNI is submitted at continuing review.
• Includes:
  ▪ AEs that are not potential UPs
  ▪ PDs that do not meet RNI requirements
  ▪ DSMC reports – no changes or concerns
  ▪ Audit reports with no findings
  ▪ Most subject withdrawals, resolved minor complaints
• New Continuing Review Form in development
Relying on an External IRB

• Reporting depends on the arrangement with the external IRB
• Refer to external IRB’s policies and procedures
• Consult IRB office for guidance on what to report and to whom
RNI Submission Form in New eIRB
Mark your calendars!

Visit our website for more information:
www.ohsu.edu/researchintegrity