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IRB GRAND ROUNDS

REPORTABLE NEW INFORMATION

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REPORTABLE NEW INFORMATION (RNI)



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ID	Name	Date Created	<input checked="" type="checkbox"/> Date Modified	State	Coordinator
RNI00000005	_IRBSubmission - Mon Sep 16 11:32:47 EDT 2013	9/16/2013 11:32 AM	9/16/2013 11:32 AM	Pre-Submission	
20130011	UIRB	9/13/2013 12:51 PM	9/16/2013 11:20 AM	Pre-Submission	
20130010	test	9/13/2013 11:37 AM	9/13/2013 4:16 PM	Pre-Submission	
20130009	eIRB	9/13/2013 8:53 AM	9/13/2013 1:39 PM	Clarification Requested (Pre-Review)	James Holland (irbc)
CR00000001	Continuing Review for Study 20130001	9/10/2013 6:24 PM	9/12/2013 11:46 AM	Pre-Submission	James Holland (irbc)
RNI00000001	RNI Validation Test	9/6/2013 2:45 PM	9/6/2013 2:45 PM	Pre-Submission	

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New: IRB Submission
When viewing items in your inbox or on the IRB Workspace, RNI Short Title will show up under the "Name" column

List date study team became aware of the RNI

Reportable New Information

1. **RNI short title:** (uniquely identify this new information report)

2. * **Date you became aware of the information:**

 

3. **Identify the categories that represent the new information:** (check all that apply)

- Risk:** Information that indicates a new or increased risk, or a safety issue. For example:
- a. New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor report, or investigator finding) indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk.
 - b. An investigator brochure, package insert, or device labeling is revised to indicate an increase in the frequency or magnitude of a previously known risk, or to describe a new risk.
 - c. Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol.
 - d. Protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm.
 - e. Complaint of a subject that indicates subjects or others might be at increased risk of

RNI includes unanticipated problems, newly identified risks, adverse events (unexpected and probably related), deviations and violations, audit or monitoring results, etc.

RNIs do not include expected or unrelated AEs, IND Safety Reports, Translations, Sponsor Letters without impact on risks, etc.

b. A harm is "**probably related**" to the research procedures if, in the opinion of the investigator, the research procedures more likely than not caused the harm.

- Non-compliance:** Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such non-compliance.
- Audit:** Audit, inspection, or inquiry by a federal agency.
- Report:** Written reports of study monitors.
- Researcher error:** Failure to follow the protocol due to the action or inaction of the investigator or research staff.
- Confidentiality:** Breach of confidentiality.
- Unreviewed change:** Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject.
- Incarceration:** Incarceration of a subject in a study not approved by the IRB to involve prisoners.
- Complaint:** Complaint of a subject that cannot be resolved by the research team.
- Suspension:** Premature suspension or termination of the research by the sponsor, investigator, or institution.
- Unanticipated adverse device effect:** Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

Important! Information that does not fit into one of the categories above does not need to be reported to the IRB as new information.

4. * **Briefly describe the new information:**

Summary of RNI

5. **In the PI's opinion:**

5. In the PI's opinion:

a. * Does this information indicate a new or increased risk, or a safety issue?

Yes No [Clear](#)

b. * Does the study need revision?

Yes No [Clear](#)

Select Yes or No based on PI's review of the RNI

c. * Does the consent document need revision?

Yes No [Clear](#)

If revisions are required, describe them above and submit a study modification for review.

6. Related Studies:

ID	Short Title	Investigator	State	IRB Office
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There are no items to display

You will be able to list as many studies as are affected. (E.g. PI is involved in multiple studies involving the same drug.)

7. Attach files containing supporting information:

Name

There are no items to display

Upload documents as appropriate

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RISK

- Information that indicates a new or increased risk, or a new safety issue. For example:
 - New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor report, or investigator finding) indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk.
 - An investigator brochure, package insert, or device labeling is revised to indicate an increase in the frequency or magnitude of a previously known risk, or describe a new risk
 - Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol
 - *Protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm*
 - Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm
 - Any changes significantly affecting the conduct of the research

HARM

- Harm experienced by a subject or other individual which, **in the opinion of the investigator**, is **unexpected** and **probably related** to the research procedures.
 - “**unexpected**” = specificity or severity is inconsistent with risk information previously reviewed and approved by the IRB in terms of nature, severity, frequency, and characteristics of the study population
 - “**probably related**” = the research procedures more likely than not caused the harm

NON-COMPLIANCE

- Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such non-compliance.
 - *Some protocol deviations fall into this category.*

AUDIT

- Audit, inspection, or inquiry by a federal agency and any resulting reports (e.g. FDA Form 483.)
- **Not to be used for Office for Research Compliance and Quality Assurance (RCQA) audits.**

REPORT

- Written reports of study monitors.
 - Monitoring reports from industry-sponsored studies are not generally required by the IRB.
 - May be required if the investigator is also sponsor.

RESEARCHER ERROR

- Failure to follow the protocol due to the action or inaction of the investigator or research staff.

CONFIDENTIALITY

- Breach of confidentiality.
 - May require additional action due to HIPAA and other applicable regulations.

UNREVIEWED CHANGE

- Change to the protocol taken without prior IRB review *to eliminate an apparent immediate hazard* to a subject.

INCARCERATION

- Incarceration of a subject in a study not approved by the IRB to involve prisoners.

COMPLAINT

- Complaint of a subject that cannot be resolved by the research team.

SUSPENSION

- Premature suspension or termination of the protocol by the sponsor, investigator, or institution.

UNANTICIPATED ADVERSE DEVICE EFFECT

- Unanticipated adverse device effect (any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death *was not previously identified in nature, severity, or degree of incidence in the investigational plan or application* (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.)

REPORTING TIMEFRAME

- Report the information items that fall into one or more of the following categories to the IRB within 10 business days using the RNI form.
- ***Information that does not fall under any of the categories does not require reporting to the IRB*.***

THINGS TO NOTE

- Ability to link RNI to multiple studies
- Ability to link RNI to prior submissions (initial vs. follow-up reports)
 - ‘Create Follow-On RNI’ activity from within previous RNI

CURRENT REPORTABLE EVENTS

- Internal SAEs
- Protocol Deviations/Study Violations
- **Study Exception Request**
- Unanticipated Problem (UPIRTSO)
- Notifications
- Updated Investigator Brochure/Package Insert
- **External SAE/IND Safety Report**
- DSMB, Sponsor or Other Reports
- Certificate of Confidentiality
- Translated Consent Forms
- **Notice of Grant Award**
- **Executed Clinical Trials Agreement**
- **Form 1572**

REPORTS AT THE TIME OF CONTINUING REVIEW

- Enrollment summaries
- Summaries of AEs not requiring prompt reporting
- Summaries of protocol violations that do not meet criteria
- Interim reviews/findings
- DSMB, grant progress, or other reports
- Sponsor letters, etc.

THANK YOU!



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