

Reporting Research Events
and
Non-compliance in Human Subjects Research

NCI Friday Training Session
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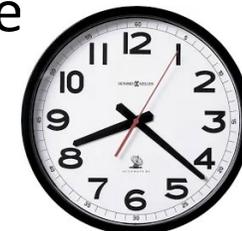
Learning Objectives

- Review terminology related to event reporting
- Describe Principal Investigator event reporting responsibilities
- Understand the workflow for submission of reportable events to the NIH IRB and non-NIH Reviewing IRBs
- Apply the knowledge gained to case examples

Policy 801 Terminology: Reportable Event

Reportable Event: An event that occurs during the course of human subjects research that requires notification to the IRB

- For the purposes of this policy, reportable events include the following:
 - Unanticipated problems involving risks to subjects or others (also referred to as UPs)
 - Non-compliance (including major protocol deviations and non-compliance that is not related to a protocol deviation)
 - Deaths related or possibly related to research activities
 - New information that might affect the willingness of subjects to enroll or continue participation in the study
- All events except deaths need to be reported to the NIH IRB **within 7 calendar days** when NIH is the Reviewing IRB (also known as the IRB of Record)
- Deaths that are possibly, probably or definitely related to the research must be reported to the NIH IRB **within 24 hours**



Unanticipated Problems



A **UP** is an event that meets **all** of the following:

1. Unexpected
2. Related or possibly related
3. Places subjects or others at a greater risk of harm

PI's will not need to make decisions related to seriousness of the event

When NIH is the Reviewing IRB, **UPs** must be reported to the NIH IRB using the Reportable Event Submission Form (REF) in iRIS **within 7 calendar days** unless the event is a **death that also meets the criteria for a UP** in which case it must be reported within **24 hours**.



Policy 802 Terminology: Non-compliance

Non-Compliance: Failure of investigator(s) to follow the applicable laws, regulations, or institutional policies governing the protection of human subjects in research or the requirements or determinations of the IRB, whether intentional or not

- When NIH is the Reviewing IRB, **non-compliance** (*including major protocol deviations and NC not related to protocol deviations*) needs to be reported to the IRB using the Reportable Event Form (REF) within **7 calendar days**



Policy 801 Terminology: Protocol Deviation

Protocol Deviations are a Subset of non-compliance

A Protocol Deviation (PD): any change, divergence, or departure from the IRB-approved research protocol

- **Major Deviations:** Deviations from the IRB approved protocol that have, or may have the potential to, negatively impact, the rights, welfare or safety of the subject, or to substantially negatively impact the scientific integrity or validity of the study
- **Minor Deviations:** Deviations that do not have the potential to negatively impact the rights, safety, or welfare of subjects or others, or the scientific integrity or validity of the study

PI's do not need to make decisions related to seriousness of the event

- When NIH is the Reviewing IRB, **major PDs** must be reported to the IRB using the Reportable Event Submission Form (REF) **within 7 calendar days**
- **Minor PDs are to be reported in aggregate at the time of continuing review (CR)**





Protocol Deviations: Major vs. Minor

Major Deviations

- Failing to obtain legally effective consent prior to initiating research procedures (including failure to obtain signed consent when required)
- Medication errors, such as administering the wrong study drug to a participant or the wrong dose of the right study drug
- Failing to conduct a study procedure or administer a study assessment that was meant to assess the safety of the individual's continuation in the study
- Changes necessary to eliminate apparent immediate hazards to a participant or others
- Informed consent obtained by someone other than individuals authorized by the IRB to obtain informed consent
- Enrollment of a participant who did not meet all inclusion/exclusion criteria
- Performing a study procedure that has not been approved by the IRB
- Failure to report an Unanticipated Problem to the IRB and/or sponsor of the study
- Study visit conducted outside the required timeframe that, in the opinion of the investigator, may impact the safety of the participant
- Failure to follow the IRB-approved safety monitoring plan
- Implementation of recruitment procedures that have not been IRB-approved

Protocol Deviations: Major vs. Minor

Minor Deviations

- Completing a study visit outside of the required timeframe when, in the opinion of the investigator, there are no safety implications
- Use of an expired consent form in which the information contained is not substantively different than the currently approved consent, unless the deviation occurs repeatedly
- Minimal over-enrollment
- A signed copy of the consent form was not given to the participant
- Documentation deficiencies in the consent form such as:
 - A missing investigator signature;
 - The participant signs the consent form but does not print their name in the signature block. *Note: A participant who does not sign and date the consent form prior to the initiation of research is considered a **major** deviation*

NONCOMPLIANCE

A: Minor deviations

- PK blood draw 10 minutes outside of time window
- Study visit occurs outside required time-frame when, in the opinion of the investigator, there are no safety implications

B: Major deviations

E.g.

- Enrollment of a participant who did not meet all inclusion/exclusion criteria
- Failure to obtain informed consent prior to initiating research procedures
- Failure to conduct a study assessment meant to assess subject safety

C: Other Noncompliance

E.g.

- Failure to promptly notify the NIH IRB when an enrolled subject becomes a prisoner, and the study had not been previously approved for inclusion of prisoners
- Failure to obtain a reliance agreement for a non-NIH AI prior to that AI conducting HSR on a new NIH protocol

All events in A + B + C represent noncompliance. Only events in B or C need to be reported to the NIH IRB in an expedited time frame.

Additional Reportable Events

- When NIH is the Reviewing IRB, the following reporting timeframes also apply for submission of the REF in iRIS:

➤ New information that might affect the willingness of subjects to enroll or continue participation in the study must be reported to the NIH IRB within **7 calendar days**



➤ Deaths that are at least possibly related (meaning either possibly, probably or definitely related) to the research protocol must be reported to the NIH IRB within **24 hours** if they occur on a study overseen by the NIH IRB or if they occur at an NIH site



➤ For FDA regulated studies, investigators are also required to report events to the study sponsor as described in the protocol and to immediately (i.e., no longer than 10 days) report SAEs or Unanticipated Adverse Device Effects (UADEs) to the study sponsor



Research Compliance & Review Committee (RCRC)

For protocols under review by the NIH Intramural IRB, the RCRC will:

- Be a duly convened NIH IRB
- Have stable membership including IRB members who are experienced clinical researchers
- Review events submitted via REF to determine if they constitute serious and/or continuing non-compliance
- Focus on adequacy of the proposed corrective action
- Provide consistency in determinations



RCRC Determinations of Non-compliance

Serious non-compliance

- Non-compliance, whether intentional or not, that results in harm or otherwise materially compromises the rights, welfare and/or safety of the participant

OR

- Non-compliance that materially affects the scientific integrity or validity of the research may be serious NC , even if it does not result in direct harm to research subjects

(continued)

RCRC Determinations of Non-compliance

Continuing non-compliance

- A pattern of recurring non-compliance that either has, or if continued may, in the IRB's judgment, result in harm to participants or otherwise materially compromise the rights, welfare and safety of participants, or affect the scientific integrity of the study or validity of the results
- The pattern may comprise repetition of the same non-compliant action(s), or different non-compliant events
- Such non-compliance may be unintentional (e.g. due to lack of understanding, knowledge, or commitment), or intentional (e.g. due to deliberate choice to ignore or compromise the requirements of any applicable regulation, organizational policy, or determination of the IRB)

OR

Non-compliance that is neither serious nor continuing

When NIH is Relying on External (non-NIH) Reviewing IRB

- External IRB policies for event reporting apply
 - PI must report to external IRB in compliance with *their* policies
 - External IRB makes determinations of serious/continuing NC, and UPs
- If the event occurred at an NIH site, duplicate reporting to NIH within the same NIH IRB timeframe is required
- If the Reviewing IRB makes a determination of serious and/or continuing non-compliance regarding an NIH investigator, then, even if the determination has already been provided to OHSRP either directly or via the NIH Institutional Official (IO)/designee, the NIH PI /designee must report this in iRIS **within 7 calendar days** of any member of the research team being notified of the determination by the Reviewing IRB
- The regulatory responsibility for reporting to federal agencies lies with the Reviewing IRB unless otherwise specified in the reliance agreement
- Additional reporting may also be required as specified by an NIH Institute/Center (IC) or other NIH policy



The Reportable Event Form



From IRB application

1.5 * Report Version

- Initial Report
- Follow-Up Report

1.6 Is a non-NIH IRB the Reviewing IRB?

Note: The following comes from the Study Application

- Yes
- No

1.7 IRB of Record

Note: The following comes from the Study Application.

Non-NIH IRB:

1.8 * Has this Event been Reported to the Reviewing IRB?

- Yes
- No

1.9 * Has the Reviewing IRB Made a Formal Determination?

- Yes
- No

Please submit a follow-up report as soon as the IRB's determination becomes available.

1.15 * Description of Subject

Does this Event Apply to a Single Subject?

- Yes
- Not Applicable (more than one subject is involved or subject information is unknown)

If Yes, enter Subject's details below

Subject ID	Sex	Age	Unit	Diagnosis
<p>(Do Not Use Medical Record Number)</p> <input type="text" value="00X0099"/>	<p><input type="radio"/> Male</p> <p><input checked="" type="radio"/> Female</p> <p><input type="button" value="Clear"/></p>	<p>(Only use numeric values)</p> <input type="text" value="4"/>	<p><input type="radio"/> Month (s)</p> <p><input checked="" type="radio"/> Year (s)</p> <p><input type="button" value="Clear"/></p>	<p>* Don't use Acronyms</p> <input type="text" value="enter diagnosis here"/>

If the subject is enrolled on any other studies, list the protocol number(s) here:
(If applicable, submit a separate report form for each protocol listed)

1.17 * How would you classify this Event?

(Select one)

- Unanticipated Problem
- Death
- Non-compliance (including protocol deviations)
- New information, other than Unanticipated Problem, that might affect the willingness of subjects to enroll or continue participation in the study

1.17 * How would you classify this Event?

(Select one)

- Unanticipated Problem
- Death
- Non-compliance (including protocol deviations)
- New information, other than Unanticipated Problem, that might affect the willingness of subjects to enroll or continue participation in the study

1.18 * Is this Problem "Unexpected"?

(click on the question mark on the right side to display definitions)

(i.e., event not described in protocol, consent, or Investigator Brochure)

- Yes
- No

Please explain:

1.19 * Is this problem related or possibly related to participation in the research?

(click on the question mark on the right side to display definitions)

- Yes
- No

Please explain:

1.20 * Does the problem suggest the research places subjects or others at a greater risk of harm than was previously known or recognized?

(click on the question mark on the right side to display definitions)

- Yes
- No

Please explain:

1.17 * How would you classify this Event?

(Select one)

- Unanticipated Problem
- Death
- Non-compliance (including protocol deviations)
- New information, other than Unanticipated Problem, that might affect the willingness of subjects to enroll or continue participation in the study

1.21 * Is the Death at least Possibly Related to the Research?

If the death is possibly, probably or definitely related to the research, select "yes."

- Yes
- No

Provide a detailed description of the death, include all relevant clinical information.

1.17 * How would you classify this Event?

(Select one)

- Unanticipated Problem
- Death
- Non-compliance (including protocol deviations)
- New information, other than Unanticipated Problem, that might affect the willingness of subjects to enroll or continue participation in the study

Select the type of Non-compliance: (click on the question mark on the right side to display definitions)

- Protocol Deviation
- Other

1.22 * Does the event have the potential to substantially negatively impact the scientific integrity or validity of the study?

- Yes
- No

Please explain:

1.23 * Does the event have the potential to negatively impact the rights, welfare or safety of the participant(s)?

- Yes
- No

Please explain:

1.24 Is this an Interventional/Observational/Expanded Access Protocol?

Note: The following comes from the Study Application.

- Observational Study
- Interventional or Clinical Trial
- Expanded Access

1.26 * Observational Trial

How many participants are currently enrolled?

How many participants have completed the study?

From IRB
application

1.24 Is this an Interventional/Observational/Expanded Access Protocol?

Note: The following comes from the Study Application.

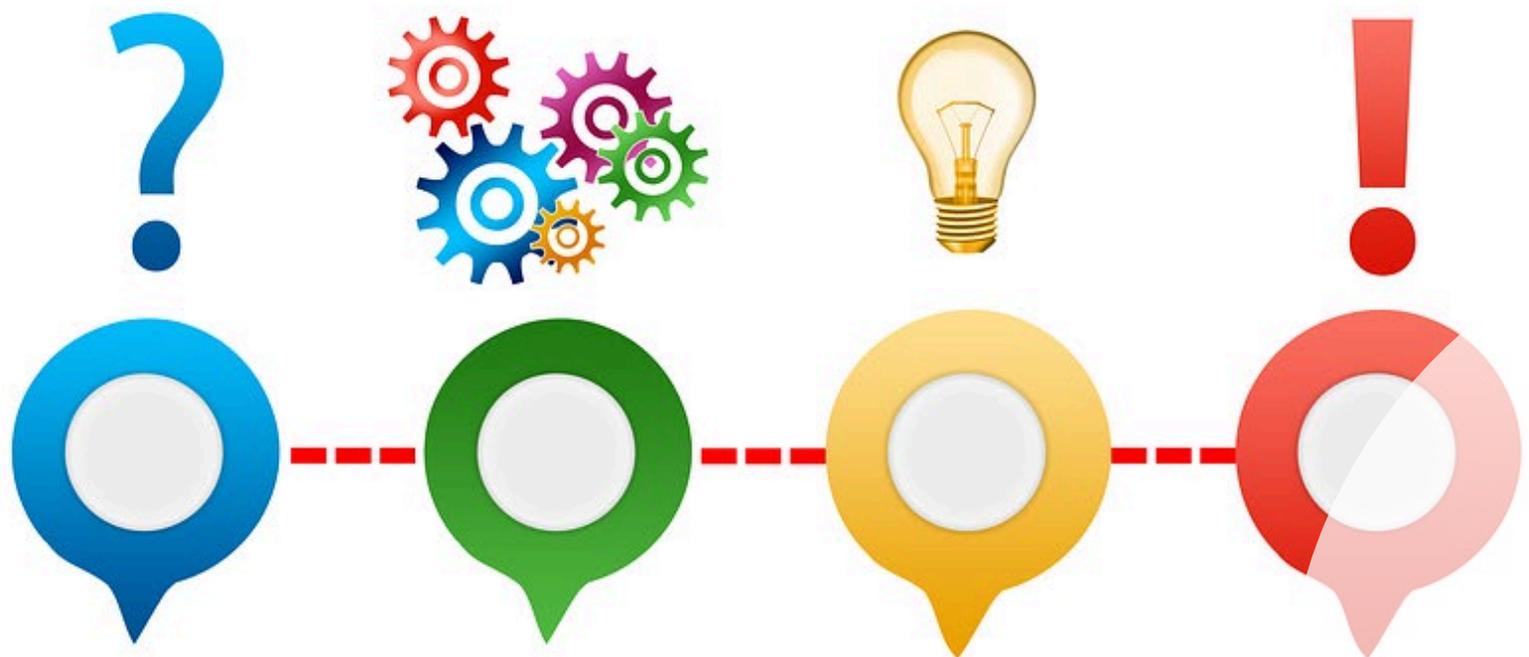
- Observational Study
- Interventional or Clinical Trial
- Expanded Access

1.25 * Interventional Trial or Expanded Access

How many participants still receiving study intervention?

How many participants completed study interventions but remain in follow up?

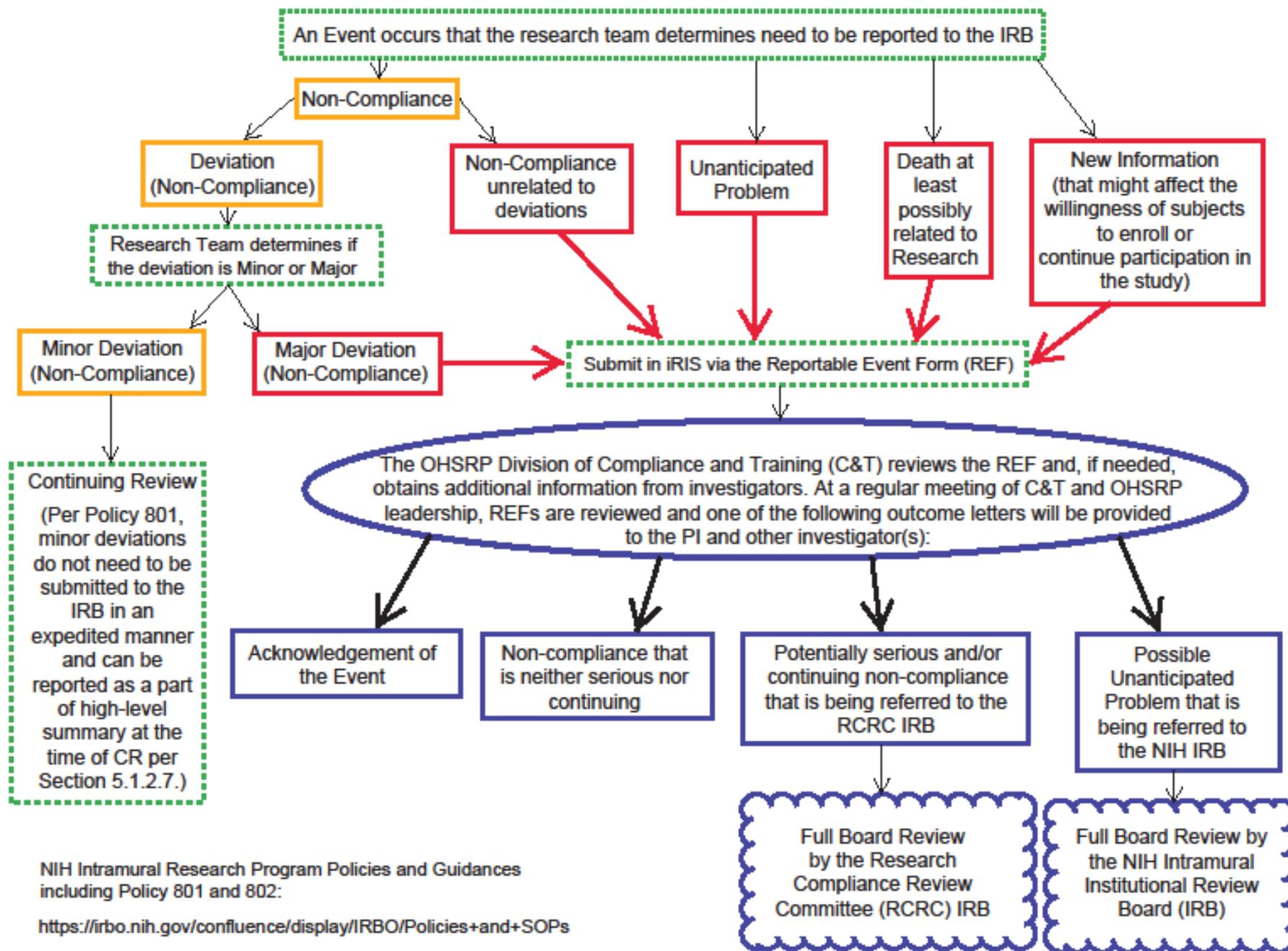
How many enrolled but not yet receiving study interventions?



NCI Specific
Examples

Reportable Events Flow Sheet Summary

Updated 1/28/2020



NIH Intramural Research Program Policies and Guidances including Policy 801 and 802:

<https://irbo.nih.gov/confluence/display/IRBO/Policies+and+SOPs>



Consent Issues Example 1:

During an audit, it was discovered that there was no copy available of a signed consent document.

Major Deviation

- Things to consider:
 - Was there good documentation of the consent process in the medical record?
 - Was the team able to contact the participant and have the participant confirm that they provided consent?
 - Was the participant able to send a copy of their signed consent to the research team?
 - What test or procedures were performed on the participant?
 - Was the participant's data entered into the research database?
 - What is the status of the samples and data if consent could not be obtained?

Consent Issues Example 2:

The protocol states that a copy of the signed consent document should be given to the participant. During an audit, it was discovered that there was no documentation that this action was performed on three patients.

Minor Deviation

- Things to consider:
 - Per Policy 801, minor deviations do not need to be submitted to the IRB in an expedited manner and can be reported as a part of high-level summary at the time of CR per Section 5.1.2.7.

Consent Issues Example 3:

During an audit, it was discovered that there was no copy available of a signed consent document. There is no documentation in CRIS about the consent process and the participant has since been lost to follow-up. The research studies performed on the participant include: 5 bone marrow biopsies, multiple blood tests, and two PET scans. The research team indicates that they would like to use the data in their publication.

Major Deviation

- Things to consider:
 - Reconsider what should be done with any collected samples/data.

Note: This event would likely be referred to the RCRC for Full Board IRB Review.

Consent Issues Example 4:

The short form consent process was not used for a German speaking participant. Though the participant understands some conversational English, they usually request an interpreter and German is their documented preferred language. The long form English version of the informed consent form was used.

Non-compliance that is not a protocol deviation

- Things to consider:
 - Was there an interpreter present during the consent process?
 - What information was documented in the consent note in CRIS?
 - What research tests or procedures were performed on the participant?
 - What happened to any research samples/data that were collected?

Note: This event would likely be referred to the RCRC for Full Board IRB Review.

Consent Issues Example 5:

The Investigator who obtained consent from one participant was not listed as an Associate Investigator on the protocol.

Major Deviation

- Things to consider:
 - Did the investigator had received training on the protocol?
 - Did the investigator complete training per OHSRP Policy 201: Education Program?
 - Why was the Investigator not listed as an AI?
 - Was the Investigator an NIH Investigator?

Personally identifiable information Breach Example:

An unencrypted email was sent to an outside physician that contained the participant's first name and date of birth.

Non-compliance that is not a protocol deviation

- Things to consider:
 - All potential or actual PII breaches must be reported to the NIH Privacy Office through the Incident Response Team (IRT).
 - Report to the IRT by emailing IRT@nih.gov or calling the Incident Response Team Hotline at 301-881-9726. Also notify the IC Privacy Coordinators.
 - The IRT will do an evaluation and notify you of their risk assessment. This assessment must be provided to the IRB.

Note: The IRT report is used by OHSRP leadership in determining severity of noncompliance.

Eligibility Issues Example 1:

During a review, it was discovered that one of the enrolled participants met one of the protocols exclusion criteria at enrollment. He did not have the correct genetic mutations required by the study inclusion criteria.

Major Deviation

- Things to consider:
 - Was there an evaluation of where the participant is in their therapy and if changes need to be made? (ex: cancel if still pre-treatment, change to SOC, etc.)
 - How does this event affect the participant's safety and treatment outcome?
 - How does this impact the scientific integrity or validity of the study?

Note: This event would likely be referred to the RCRC for Full Board IRB Review.

Eligibility Issues Example 2:

During a review, it was discovered that one of the tests/procedures required to determine eligibility was not performed. The test that was not performed was a biopsy to confirm disease or disease status.

Major Deviation

- Things to consider:
 - What research procedures/interventions have been performed on this participant?
 - How does this event affect the participant's safety and treatment outcome?
 - How does this impact the scientific integrity or validity of the study?

Procedures/Tests Examples:

The protocol requires that Test A to be performed, and Test A was missed or was performed outside of the protocol required window.

Minor Deviation -vs- Major Deviation

Quick Definition Review:

- Major Deviations - Deviations from the IRB-approved protocol that have, or may have the **potential** to, negatively impact, the rights, welfare or safety of the subject, or to substantially negatively impact the scientific integrity or validity of the study.
- Minor Deviations - Deviations that do not have the **potential** to negatively impact the rights, safety, or welfare of subjects or others, or the scientific integrity or validity of the study.

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*Reportable Events Related
to Protocol
Testing/Procedures
Exercise*



Procedures/Tests Examples (Continued):

1. The protocol specified that a follow-up survey be performed at the 6-month follow-up visit. Some of the questions were not answered by several of the participants, but the scientific integrity of the study was not affected.

Minor Deviation

2. The participant missed his one-month post gene therapy visit during which important safety testing was required. He did not return to NIH until his two-month visit.

Major Deviation

3. The protocol specifies that a follow-up survey be performed at the 6-month follow-up. The survey was not performed on any of the participants and contained information needed to address the protocol's primary objective.

Major Deviation

Procedures/Tests Examples (Continued):

4. The protocol indicated a 6-month timepoint visit that includes: a physical assessment, blood work, and disease staging. Due to a communication error, only labs were drawn. The participant completed the rest of the exams during a 9-month visit.

Major Deviation

5. The one-month echocardiogram was missed. A major toxicity of the IND product is cardiotoxicity. The next NIH timepoint was not until two-months when the oversight was noted.

Major Deviation

6. A research biopsy was not performed at the two-month visit. The participant declined the procedure. The sample was not a safety assessment nor was it required to address the primary objective of the protocol nor safety of the participant.

Minor Deviation

Procedures/Tests Examples (Continued):

7. A protocol requires post-therapy LFTs and creatinine to monitor for risk of renal and hepatotoxic side effects. Samples were not drawn, and the participant traveled home without this testing.

Major Deviation

8. Research blood was drawn on an adult patient per the protocol instructions; however, since this participant is on multiple protocols, the total amount drawn over eight weeks exceeded the NIH policy limits*.

Non-compliance that is not a protocol deviation

- * The amount of blood that may be drawn from adult patients and volunteers (i.e., those persons 18 years of age or older) for research purposes shall not exceed 10.5 mL/kg or 550 mL, whichever is smaller, over any eight week period.



Reporting Issues Example 1:

During the screening process, incidental findings were discovered that could affect the participant's health. These findings were not conveyed to the participant.

Major Deviation

- Things to consider:
 - Was the participant ever informed of the findings?
 - Was the participant ever contacted and their current health status determined?
 - How was the participant's health and safety affected by the delay?
 - Was a participant complaint generated by this delay? Does the participant need to be referred to the OHSRP?

Reporting Issues Example 2:

An SAE that also qualified as a UP was reported to the sponsor but was not reported to the IRB within the protocol required window. The event was reported to the IRB 3 months late, and six participants were treated during that time period with no updates to the consent document.

Major Deviation

- Things to consider:
 - Should enrollment or treatment of participants be halted until determinations on both the UP and the non-compliance are made?

Note: This event would likely be referred to the RCRC for Full Board IRB Review.

Study Treatment Issues Example 1:

The protocol specifies that chemotherapy be given intravenously. Due to a shortage in the pharmacy, the oral version of the chemotherapy was administered. The equivalence of the IV and oral version is unknown.

Major Deviation

- Things to consider:
 - Has this happened before and could it happen again?
 - If the PI does not want the protocol to be amended to have both options, is there a plan in place to prevent this in the future?

Study Treatment Issues Example 2:

A protocol requires administration of an investigational biologic product to treat multiple myeloma. This drug is manufactured by a non-NIH Sponsor. The Sponsor sends notice to all sites using this biologic to inform them that there was a potential mistake in the manufacturing process, and the strength of the drug given to each participant is uncertain. Some participants have had some response.

Unanticipated Problem

- Things to consider:
 - Letters and scripts informing participants of new risks or information need to be approved by the IRB and should be included in the submission.
 - The research team should keep up-to-date any new information from the Sponsor and update the IRB with any relevant changes.

Note: This event is likely to be forwarded to the NIH Intramural Research IRB for Full Board review. Additional details about the event may be requested that would help the IRB make their determination.

Study Treatment Issues Example 3:

At a participant's 2-month timepoint visit, their PET scan indicated that they had progressive disease. The participant was immediately started on standard of care therapy at NIH while still on protocol. The treatment protocol does not include standard of care therapy, and progressive disease is an off study criteria. (NIH Clinical Center specific)

Major Deviation

- Things to consider:
 - Why was the participant not taken off study prior to treatment with an alternative therapy that is not included in the protocol?

Study Treatment Issues Example 4:

One participant had three weeks of pancytopenia starting four days after gene therapy treatment. The consent mentions low counts but this is at a greater severity that was previously known and resulted in the need for additional intervention and an extended hospital admission.

Unanticipated Problem

- Things to consider:
 - Consider if the protocol and consent need to be amended based on this new information.

Note: This event will be forwarded to the NIH Intramural Research IRB for Full Board review. Additional details about the event may be requested that would help the IRB make their determination.

Study Treatment Issues Example 5:

A participant with progressive renal cell carcinoma was in between two cycles of protocol chemotherapy. The research team received an email from the her family that she was admitted to the hospital over the weekend and died. The family said that they were told that the participant died from an influenza infection. The PI reviewed the case and determined that the death was unrelated to research.

Does not need to be reported to the IRB via REF

- Things to consider:
 - The event would still be an SAE that will be reported to the IRB at time of CR.
 - If the home medical team provides NIH with records that change the PI's assessment of the event to at least possibly related to research, then the Death should be reported within 24 hours of receiving the additional information.

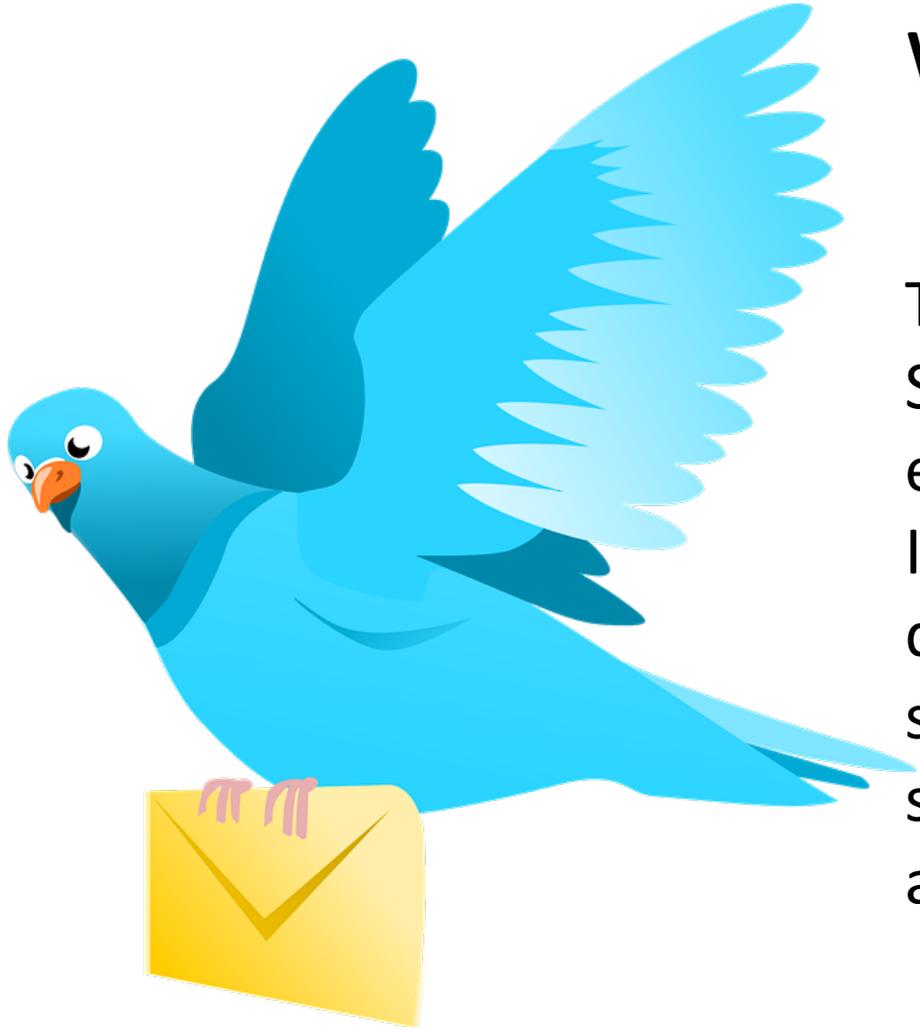
Study Treatment Issues Example 6:

IND bb5485 is being used in several multicenter international trials. NCI is site 201 for trial BGX555. The NCI study team receives an IND Safety Report that states that one participant had a seizure and encephalopathy that is possibly related to bb5485. The participant was in France and was on trial BGX999. These are not side effects listed on the consent for BGX555 and participants are still being treated at the NCI site.

New Information that might affect the willingness of a subject to enroll or remain in the study

- Things to consider:
 - Consider if the protocol and consent need to be amended based on this new information.

Understanding IND Safety Reports



What is an IND Safety Report?

These are reports that are sent out by a Sponsor/Manufacturer that relay adverse events that are possibly related to an Investigational New Drug (IND). These events did not necessarily occur on your particular study and/or site. These reports are usually sent by email or through a web-based portal and can often lack full context of the event.

Understanding IND Safety Reports (Continued)



When would you submit an IND Safety Report to the NIH IRB???

- You would submit an IND Safety report to the NIH IRB via a Reportable Event Form (REF) if the event that occurred also meets the definition of an Unanticipated Problem. (NIH IRB Policy 801 - Reporting Research Events: Section 4.10 and Section 5.1.2.3)
- If the event is not an Unanticipated Problem but could be considered “New Information that might affect the willingness of a subject to enroll or remain in the study”, the event should also be reported via a REF. (NIH IRB Policy 801 - Reporting Research Events: Section 5.1.2.5)
- Do not submit the report if one of the above two criteria are not met. If the Sponsor is insisting, please refer them to Policy 801. The Sponsor may require you to keep some documentation of the PI’s assessment of each report you receive.

Understanding IND Safety Reports (Continued)

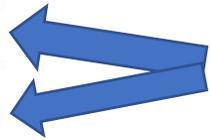


When do I consider an IND Safety Report to be an Unanticipated Problem?

- For the full definition of an Unanticipated Problem, please refer to the NIH IRB Policy 801 Section 4.10: “Unanticipated Problem Involving Risks to Subjects or Others”.
- If the sponsor is requiring a protocol amendment or changes to consent as a result of the event, it is likely that the event meets the definition of an Unanticipated Problem or New Information that might affect the willingness of subjects to enroll or continue participation in the study.
- The FDA also released a Guidance titled [“Adverse Event Reporting to IRBs — Improving Human Subject Protection: Guidance for Clinical Investigators, Sponsors, and IRBs”](#).



IRBO Home
OHSRP
NIH iRIS
For Participants
For PIs and Study Teams
For IRB Members
IRBO News
Templates and Forms
Policies and SOPs
Training and Education
IRBO Admin Information
IRB Reorganization Initiative
NIH IRB Meeting Calendar
Other Resources
Contact Us



The NIH Intramural Institutional Review Board

For Participants



What to consider before you agree to participate in a research study and other resources.

For Participants

For PIs and Study Teams



Find tools, checklists, E-IRB video tutorials and FAQs to help navigate the IRB review process.

For PIs and Study Teams

- [Public Health Emergency Research Review Board \(PHERRB\)](#).
- Investigators who receive NIH Extramural Research Grants, also known as "grantees", should contact the [NIH Office of Extramural Research \(OER\)](#).

For IRB Members



Find review checklists, guidance, and IRB meeting dates to help you serve as an IRB member.

For IRB Members

Policy/Guidance/Memos & Slides are Posted

- **Policy 801 and associated guidance and memos:**
<https://irbo.nih.gov/confluence/display/IRBO/Policies+and+SOPs>
- **Slides:** <https://irbo.nih.gov/confluence/display/IRBO/Training+and+Education>
(under Presentations, see *The OHSRP Education Series Presentation: 2019 NIH Intramural Research Program New Policies: Reporting Research Events and Non-compliance in Human Subjects Research*)

Thank You!

Questions?

OHSRP: 301-402-3444

IRB@od.nih.gov

IRBO Home Page: <https://irbo.nih.gov/confluence/display/IRBO/Home>