2019 NIH Intramural Research Program New Policies: Reporting Research Events and Non-compliance in Human Subjects Research

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Why are we revising the NIH Human Research Protection Program (HRPP) event reporting policies?

- To streamline the reporting process
- Improve consistency in reporting research related events across the NIH Intramural Research Program (IRP)
- Decrease unnecessary reporting
- Align the IRP's reporting with that of the extramural community

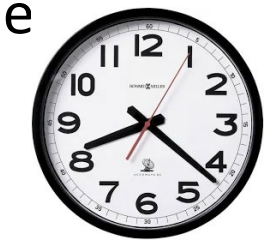
Learning Objectives

- Review terminology related to event reporting
- Describe Principal Investigator event reporting responsibilities
- Discuss updates to these NIH Policies
  - *Reporting Research Events* (Policy #801)
  - *Non-compliance in Human Subjects Research* (Policy #802)
- Review the workflow for submission of reportable events to the NIH IRB and non-NIH Reviewing IRBs
- Explain the roles of the following entities in the process of review of event reports
  - NIH Research Compliance Review Committee (RCRC)
  - OHSRP office of Compliance and Training
  - NIH Intramural IRB

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



Policy 801 Terminology: Unanticipated Problem

An unanticipated problem (UP): an event that meets **all** of the following 3 criteria:

- **Unexpected** in terms of nature, severity, or frequency given (a) the research procedures described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied, and
- It is **related or possibly related** to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research), and
- Suggests that the research **places subjects or others (**which may include research staff, family members or other individuals not directly participating in the research) **at a greater risk of harm** (including physical, psychological, economic, or social harm) than was previously known or expected

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**.

Unanticipated Problem: Example #1

- A subject with seizures was enrolled in a randomized, Phase 3 clinical trial comparing a new investigational anti-seizure agent to a standard, FDA-approved anti-seizure medication
- The subject was randomized to the group receiving the investigational agent
- One month after enrollment, the subject was hospitalized with severe fatigue and, on further evaluation, was noted to have severe anemia (hematocrit decreased from 45% pre-randomization to 20%)
- Further hematologic evaluation suggested an immune-mediated hemolytic anemia
- The known risk profile of the investigational agent does not include anemia, and the IRB-approved protocol and informed consent document for the study do not identify anemia as a risk of the research

Unanticipated Problem: Example #2

- A clinical study was evaluating the safety and efficacy of a new oral agent administered daily for treatment of severe psoriasis unresponsive to FDA-approved treatments
- A study subject developed severe hepatic failure complicated by encephalopathy one month after starting the oral agent
- The known risk profile of the new oral agent prior to this event included mild elevation of serum liver enzymes in 10% of subjects receiving the agent during previous clinical studies, but there was no other history of subjects developing clinically significant liver disease
- The IRB-approved protocol and informed consent document for the study identified mild liver injury as a risk of the research
- The investigators identified no other etiology for the liver failure in this subject and attributed it to the study agent

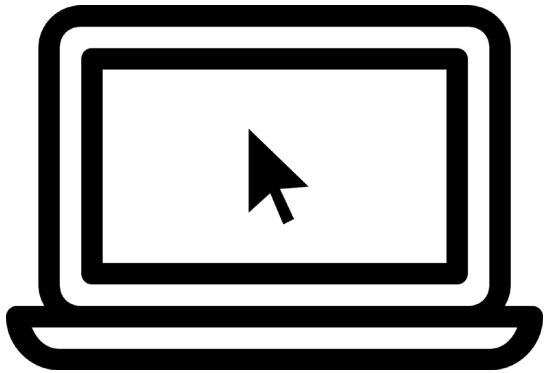
Unanticipated Problem: Example #3

- Subjects with coronary artery disease presenting with unstable angina were enrolled in a multicenter clinical trial evaluating the safety and efficacy of an investigational vascular stent
- Based on prior studies, the investigators anticipated that up to 5% of subjects receiving the investigational stent would require emergency coronary artery bypass graft (CABG) surgery because of acute blockage of the stent
- The risk of needing emergency CABG surgery was described in the IRB-approved protocol and informed consent document
- After the first 20 subjects were enrolled, the DSMB monitoring the clinical trial conducted an interim analysis as required by the IRB-approved protocol, and noted that 10 subjects needed emergency CABG surgery soon after placement of the investigational stent
- The DSMB concluded that the rate at which subjects needed to undergo CABG greatly exceeded the expected rate and communicated this information to the investigators

Unanticipated Problem: Example #4

- An investigator conducting behavioral research collected individually identifiable sensitive information about illicit drug use and other illegal behaviors by surveying college students

- The data were stored on a laptop computer without encryption, and the laptop computer was stolen from the investigator's car on the way home from work



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

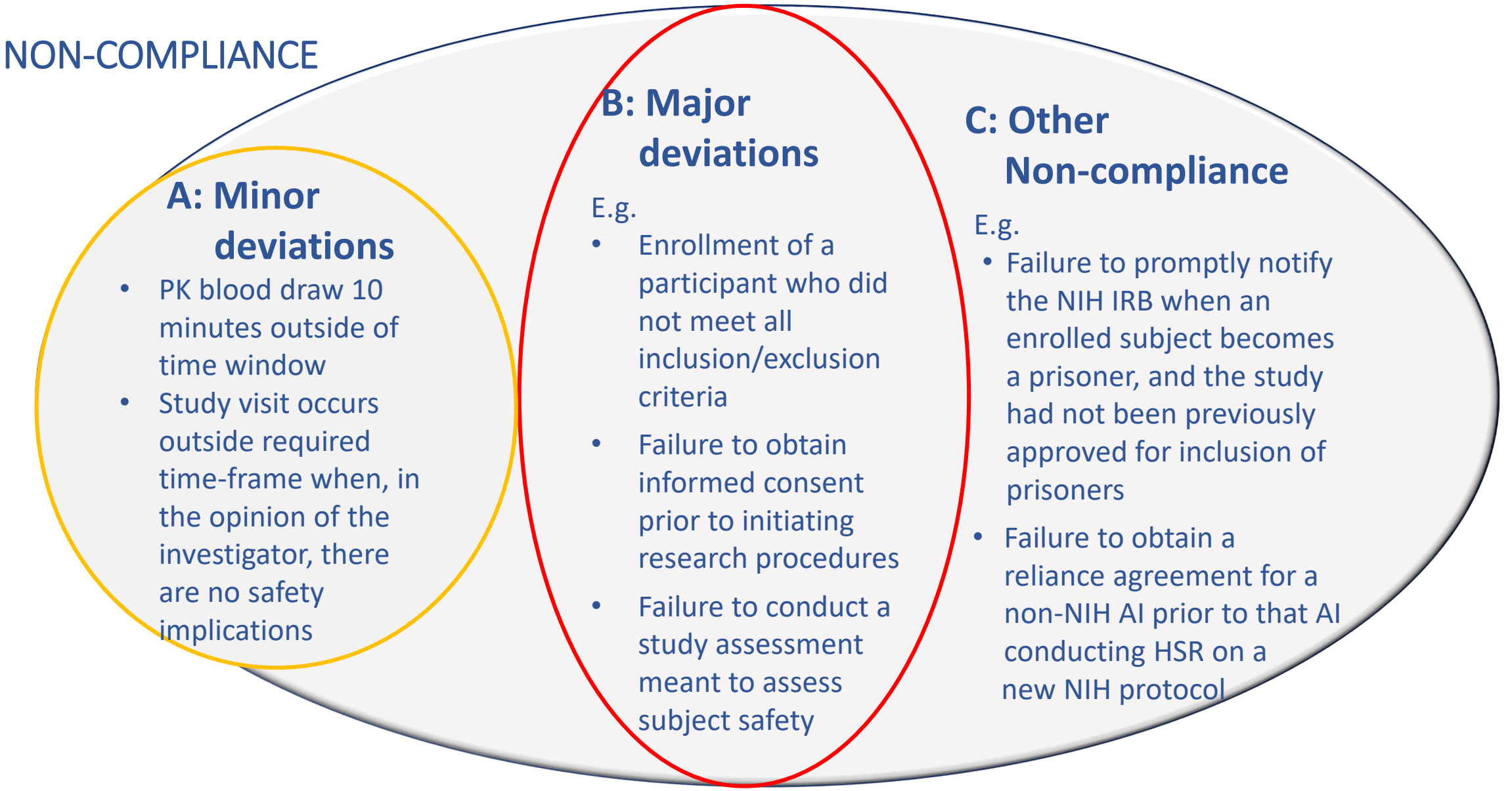
Major Deviations

- Failing to obtain legally effective consent prior to initiating research procedures (including failure to obtained 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 that does not sign and date the consent form prior to the initiation of research is considered a* ***major*** *deviation*



All events in A + B + C represent non-compliance. 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

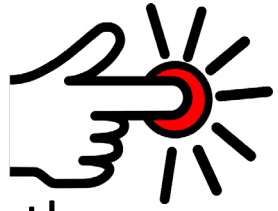
What needs to be reported in an *expedited* manner to NIH IRB when NIH is the Reviewing IRB?

	Report within 24 hours	Report within 7 calendar days
Unanticipated problems (UPs)		X
Non-compliance including major protocol deviations and NC not related to a protocol deviation		X
New information that might affect willingness of subjects to enroll or continue participation		X
Deaths possibly, probably or definitely related to research	X	

What needs to be reported *at Continuing Review* when NIH is the Reviewing IRB?

	Report at the time of CR
High level, aggregate summary of major and minor protocol deviations	X
Summary of non-compliance reported to the IRB that was not related to a protocol deviation	X
High level, aggregate summary of UPs	X
Adverse Events (AEs) including Serious Adverse Events (SAEs) that are not UPs (use a narrative summary statement indicating whether these events were within the expected range such as *"Adverse events have occurred at the expected frequency and level of severity.")*	X

Process once the Reportable Event Form is submitted



Once all NIH IRBs have been consolidated, the REF submission will be routed to the OHSRP office of Compliance and Training for the following actions:

- In consultation with the OHSRP Director, IRBO Director, and/or Executive Chair, determine if any reported event requires immediate action to protect the rights, safety or welfare of research subjects and if so, communicate such actions to the Principal Investigator and the IRB
- After discussion with OHSRP leadership, REFs that describe potential UPs (including deaths that are possible UPs) or new information that may affect subjects' willingness to participate will be scheduled for review by the convened NIH Intramural IRB
- Schedule REFs that report events constituting possible serious and/or continuing non-compliance for review of the Research Compliance Review Committee (RCRC)
- Provide a letter to the PI that relates the outcome of the REF review
- Submit reports of events that are required by federal regulation to be reported to OHRP and, as applicable, FDA

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 or continuing

Reporting by whom to whom

PI reports the following in iRIS* using the REF and will choose **one** of the following that best represents the event:

- Possible or definite Unanticipated Problem
- Non-compliance (major protocol deviations or other NC that is not a PD)
- New information affecting subjects' willingness to participate
- Research related deaths

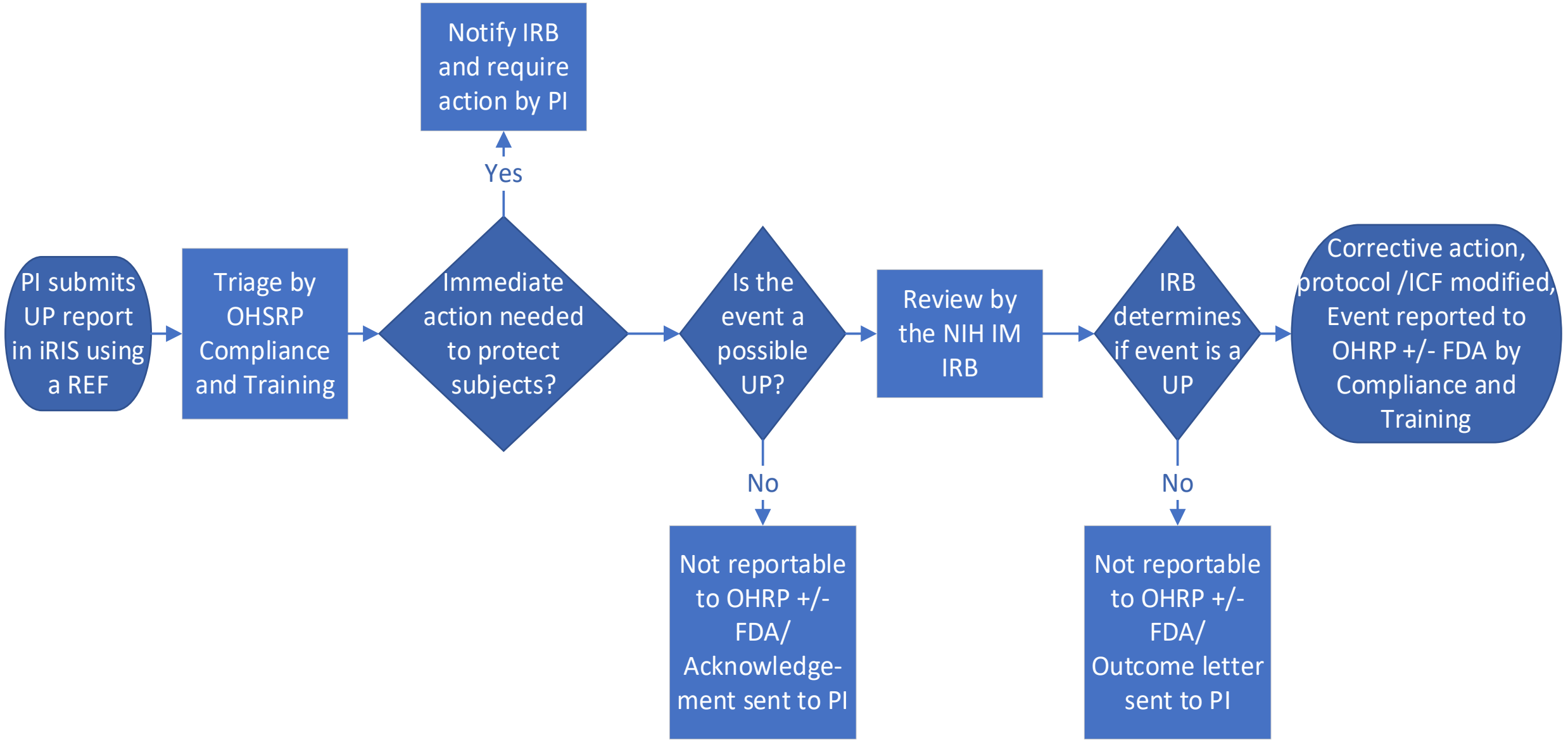
OHSRP office of Compliance and Training reports the following IRB determinations to OHRP and, as applicable, FDA:

- Findings of serious and/or continuing NC
- UPs
- IRB suspension or termination of a research protocol

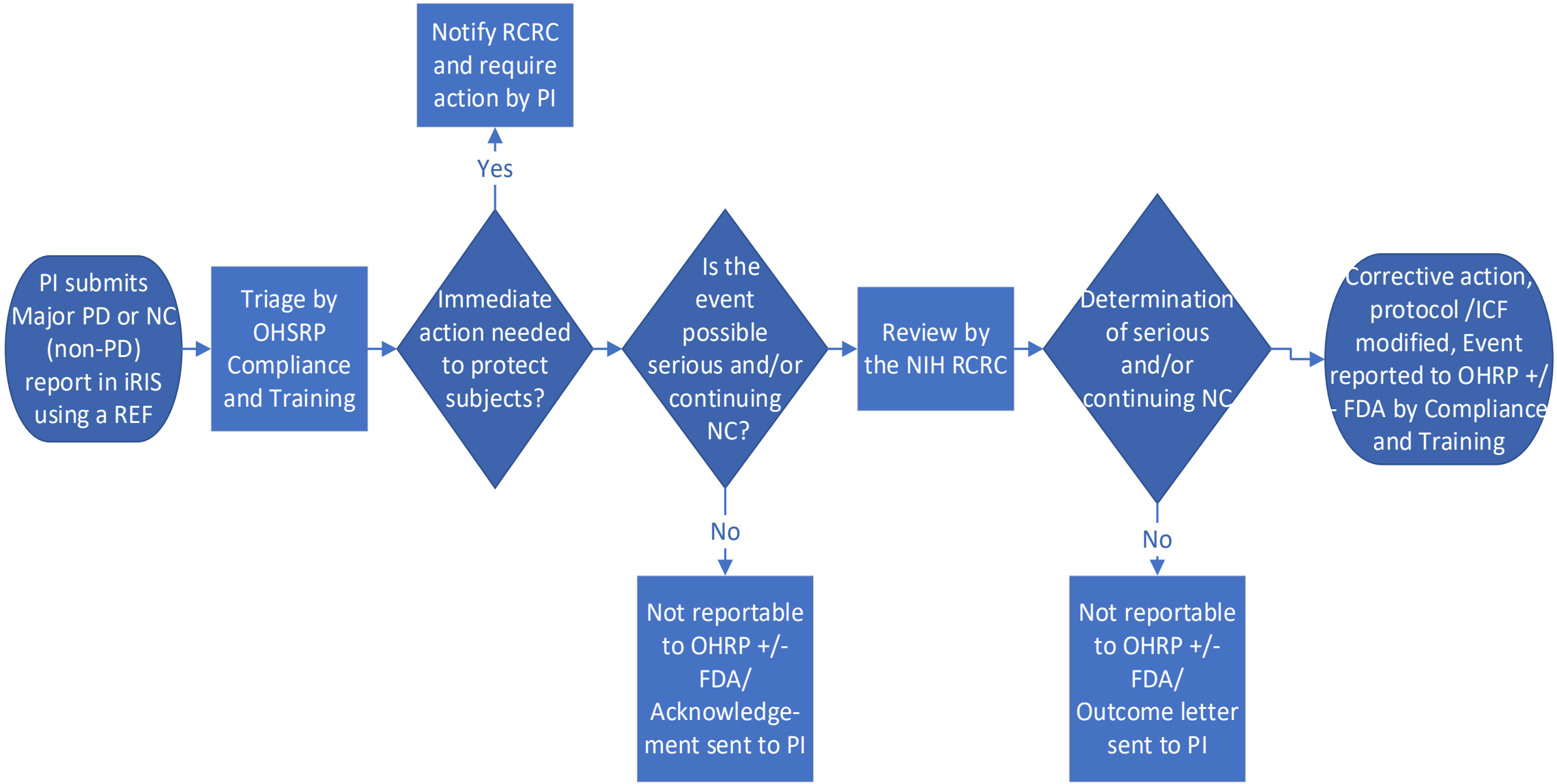
Additional reporting may also be required as specified by NIH Institute/Center (ICs) or other NIH policy.

*For FDA regulated studies, investigators are 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 UADEs to the study sponsor.

Unanticipated problem workflow



Non-compliance workflow



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

Summary of Changes

- New Reportable Event Form (REF)
- New reporting time frames
- New terminology for the following:
  - protocol deviations
  - serious non-compliance and continuing non-compliance
- PI will not be making decisions related to seriousness of the event
- PI will report event as one of the following:
  - UP
  - NC
    - If NC is selected, the PI will be asked to select PD or "Other"
    - If PD is selected, additional questions are asked, and guidance regarding which PDs need to be reported has been provided.
  - Death
  - New information that may impact subjects' willingness to participate

(Continued)

Summary of Changes (Continued)

- REFs submitted in iRIS for protocols overseen by the NIH IRB will be triaged by the office of Compliance and Training in consultation with OHSRP leadership
- Minor deviations will only be reported in summary at the time of CR
- Events that constitute possible serious and/or continuing NC will be reviewed by the Research Compliance Review Committee
- Other reportable events that require review by the NIH IM IRB will be put on the agenda for an upcoming meeting
- When NIH is not the Reviewing IRB but an event happens at an NIH site, the NIH investigator must submit events to the Reviewing IRB based on that IRB's policies and must also follow NIH policies for reporting events in iRIS

In the meantime…..

Transition Plan for Reporting Events to NIH IRB(s)

- Testing of the new REF is currently underway
- A compliance date for use of the REF is July 1st and will apply to all NIH investigators regardless of which IRB has oversight over their protocols
- Required reporting of research related events by the PI will follow policy 801
- REFs that relate to a protocol under oversight of an existing IC-specific IRB (NIAID, NCI, NIDDK/NIAMS etc.) should be submitted in iRIS using the existing process, and that IRB will be responsible for evaluation of these REFs

Transition Plan for Reporting Events to NIH IRB(s)

Once an IC specific IRB is rolled into the NIH IM IRB, all aspects of polices 801 and 802 will apply. Specifically:

- REFs will be sent, via iRIS, to the OHSRP office of Compliance and Training where they will be triaged
- If that office determines, with input and review by OHSRP leadership, that the event constitutes a possible UP or provides new information that might affect subjects' willingness to participate in the research, the REF will be reviewed at an upcoming meeting of the NIH IM IRB
- If the event represents possible serious and/or continuing non-compliance, the REF will be referred to the RCRC for review

The Reportable Event Form

1.6 * Report Version

- (•) Initial Report
- ( ) Follow-Up Report

1.7 Is a non-NIH IRB the Reviewing IRB?

- (•) Yes
- ( ) No

1.8 IRB of Record

Non-NIH IRB: Children's National Medical Center

1.9 Has this Event been Reported to the Reviewing IRB?

- (•) Yes
- ( ) No

1.10 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.

1.14 * Location of Problem

- ( ) NIH CC
- ( ) Other NIH site (specify)
- (•) Other (specify)

Other location, please specify:

Did this event occur to a subject enrolled onto this protocol by an NIH investigator?

- ( ) Yes
- ( ) No

1.16 * Description of Subject

Does this Event Apply to a Single Subject?

- (●) Yes
- ( ) Not Applicable (more than one subject is involved)

If Yes, enter Subject's details below

Subject ID	Sex	Age	Unit	Diagnosis
(Do Not Use Medical Record Number) 00X0099	( ) Male (●) Female Clear	(Only use numeric values) 4.00	( ) Month (s) (●) Year (s) Clear	* Don't use Acronyms enter diagnosis here

1.17 * Name the Event

(select all that apply)

- [ ] Specimen collection issue
- [ ] Informed consent issue
- [ ] Ineligible for enrollment
- [ ] Breach of PII
- [x] Other

If Other, *state in one or two words the nature of the event:*

Detailed Description of the Event: (*Include any relevant treatment, outcomes or pertinent history*):

1.18 * 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 * 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

1.19 * 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:

1.20 * 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:

1.21 * 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:

(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

1.22 Is the Death at least Possibly Related to the Research?

- ○ Yes
- ○ No

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

(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

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

- ◯ Yes
- ◯ No

Please explain:

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

- ◯ Yes
- ◯ No

Please explain:

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

- (●) Observational Study
- ( ) Interventional or Clinical Trial
- ( ) Expanded Access

1.27 Observational Trial

How many participants are currently enrolled?

[ ]

How many participants have completed the study?

[ ]

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

- ○ Observational Study
- ◉ Interventional or Clinical Trial
- ○ Expanded Access

1.26 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?

1.28 * Have Similar Events Occurred on this Protocol?

○ Yes ○ No

If yes, how many?

1.29 Describe What Steps have you Already Taken as a Result of this Event?

1.30 * What Additional Steps do you Plan to Take as a Result of the Event?

- ☐ No action required
- ☐ Amend consent (Separate amendment submission required)
- ☐ Amend protocol (Separate amendment submission required)
- ☐ Inform existing subjects (include example of information to be provided to subjects)
- ☐ Close the protocol (Separate closure submission required)
- ☐ Temporarily halt the protocol (Provide plan for management of enrolled subjects)
- ☐ Increase frequency/type of safety or other monitoring (Separate amendment submission required)
- ☐ Other corrective action

If other corrective action, please describe:

1.31 * In Addition to the IRB, this Event is also being Reported to:

(Select all that apply)

☐ IC Clinical Director

☐ Study Sponsor

Date reported to Sponsor:

☐ If Investigator-held IND/IDE, report to FDA

Date reported to FDA:

☐ Manufacturer

Date reported to Manufacturer:

Specify Manufacturer:

☐ Institutional Biosafety Committee

☐ Data Safety Monitoring Board

Date reported to Safety Monitoring Board:

Specify Monitoring Board:

☐ Safety Tracking and Reporting System (STARS)

☐ Radiation Safety Committee (RSC)

☐ Other

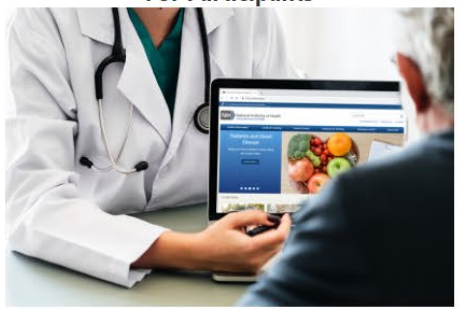
Other Specify:

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

- 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

For IRB Members

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

For IRB Members

NIH Intramural Research Program Policies

IRB Member and Staff Handbook

Introduction to the NIH Human Resource Protections Program

ⓘ The policies are being created, and we are continuing to add content to this page.

- Policy 102: HRPP Overview (in progress)
- Policy 103: Organization Structure (in progress)
- Policy 201: Education Program
  - Guidance on Policy 201
- Policy 801: Reporting Research Events
  - Memo Regarding Implementation of Policy 801
  - Reportable Events and Non-compliance Implementation Memo
  - Guidance for Reporting Research Events and Non-compliance
- Policy 802: Non-compliance in Human Subjects Research
  - Reportable Events and Non-compliance Implementation Memo
  - Guidance for Reporting Research Events and Non-compliance
- Current Policies and Procedures

U.S. Department of Health and Human Services | National Institutes of Health

NIH Office of Intramural Research
Institutional Review Board Office

Training and Education

- Training and Education
- Training and Education
  - Required Training
  - iRIS Training
  - IRB Member Training
  - Educational Seminars
  - Presentations
  - FAQs

Presentations

- Changes to the NIH IRBs and Common Rule (Power Point)
- Presentation to the IRB Staff: Using the Investigator Attestation (February 13, 2019) (PDF)
- The OHSRP Education Series Presentation: When IRB Approval is Necessary and How to Complete the New Investigator Attestation for Tech Transfer Agreements (March 18, 2019) (PDF)
  Videocast: https://videocast.nih.gov/summary.asp?Live=31618&bhcp=1 (NIH Only)
- Presentation to Tech Transfer: Tech Transfer's Role in the Use of the Investigator Attestation (March 19, 2019) (PDF)
- The OHSRP Education Series Presentation: Important Changes to Informed Consent: The Regs, the Policies, the Procedures and Forms, Oh My! (April 3, 2019) (PDF) videocast: https://videocast.nih.gov/summary.asp?Live=31785&bhcp=1 (NIH Only)
- The OHSRP Education Series Presentation 2019 NIH Intramural Research Program New Policies: Reporting Research Events and Non-compliance in Human Subjects Research (May 20, 2019) (PDF) videocast: https://videocast.nih.gov/summary.asp?Live=33168&bhcp=1 (NIH Only)
- The OHSRP Education Series Presentation: Exemptions from IRB Review and the Revised Common Rule: What Has Changed and What Has Stayed the Same? (June 13, 2019) (PDF)

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