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eIRB Changes

Incorporating new policies:

Reporting Unanticipated Problems and Adverse Events

Data & Safety Monitoring

Presented by:

Mindy Roberts, MA, CIP

Sr. Human Subjects Protections Analyst

Changes to eIRB

The DSMP Policy affects:

- Initial Review
  - A Monitoring Plan (DSMP) may be required
  - A Monitoring Entity may need to be designated
- Modifications
  - Includes the opportunity to change the DSMP or Monitoring Entity
- Continuing Review
  - Includes the opportunity to change the DSMP or Monitoring Entity
  - Studies may be required to submit a DSMP & designate a Monitoring Entity at the next Continuing Review
  - The new Annual Event Summary Form may be required

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DSMP Policy – Requirements

Type of Study			DSMP required ?	Monitoring Entity required?	Annual Event Summary Form required at Continuing Review?
Exempt			No	No	No
Expedited – Minimal risk	OHSU is the only site		No	Yes	No
	OHSU is the Coordinating Center, or Multi-site study		Yes	Yes	Yes
Full Board – Active studies	Actively enrolling		Yes	Yes	Yes
	No subjects enrolled yet, no new risks (Cat. 8b)		Yes	Yes	Yes
	Deemed minimal risk by Board (Cat. 9)	OHSU is the only site	No	Yes	No
		OHSU Coord. Center or Multi-site	Yes	Yes	Yes
Full Board – Closed to Enrollment	Subjects still in treatment		Yes	Yes	Yes
	Subjects only in long-term follow-up (Cat. 8a)		Yes	Yes	Yes
	Data Analysis only (Cat. 8c)		No	Yes	No

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DSMP Policy – Initial Review

A new Data Safety Monitoring Plan (DSMP) page has been added to the Initial Review Questionnaire.

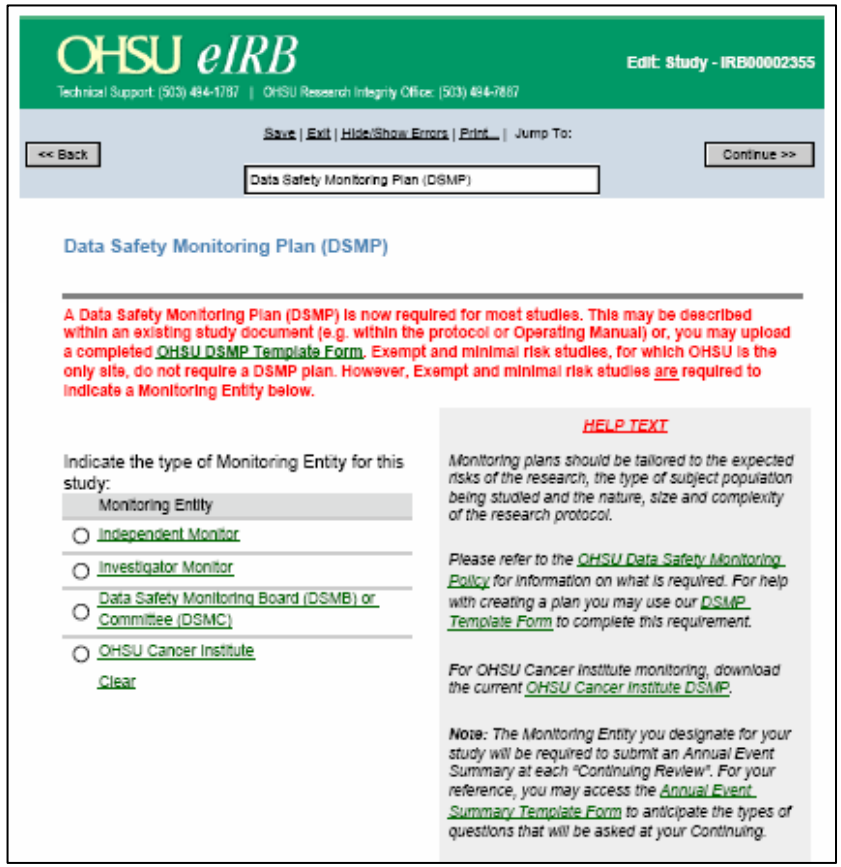
A DSMP may be required. The DSMP must include all required monitoring provisions as outlined in Section II:B of the *OHSU Data Safety Monitoring Policy*.

Indicate the location of the DSMP *in a Memo**:

- Within the protocol
- Within another document
- Uploaded as a stand-alone DSMP document

**The next eIRB development cycle will add a new question to this page of the IRQ. Until then, please capture this information in a memo.*

Indicate the type of Monitoring Entity. One of the four entities must be chosen. If OHSU Cancer Institute (OCI) is checked, download the OCI DSMP from the link within the help text.



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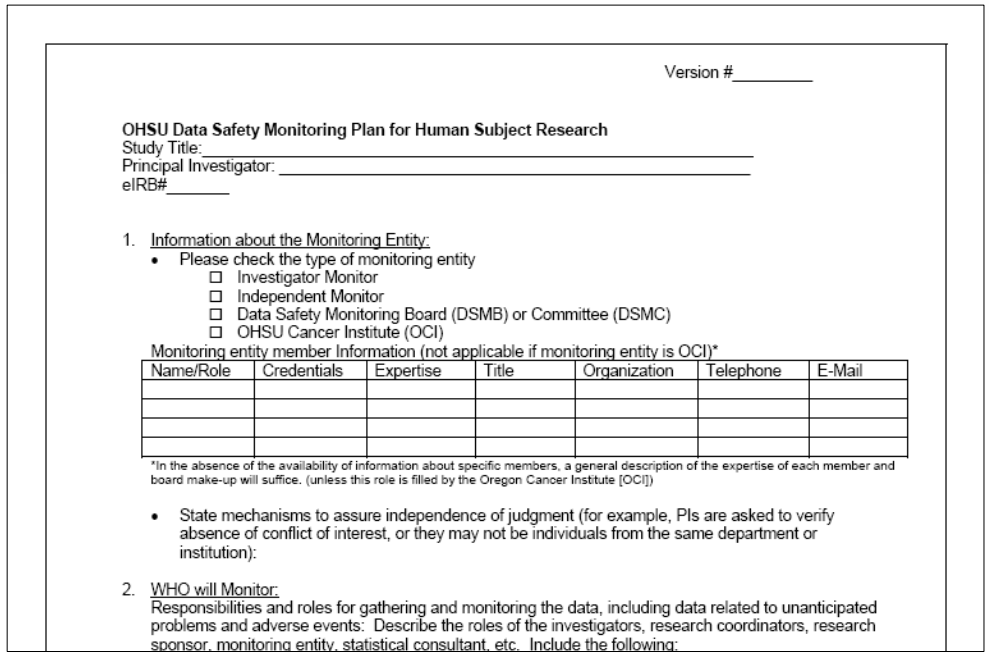
DSMP Policy – Initial Review cont.

If needed, an

OHSU DSMP Template

can be used as your plan.



Version #_____

OHSU Data Safety Monitoring Plan for Human Subject Research
Study Title:_____
Principal Investigator: _____
eIRB#_____

1. Information about the Monitoring Entity:
   - Please check the type of monitoring entity
     - ☐ Investigator Monitor
     - ☐ Independent Monitor
     - ☐ Data Safety Monitoring Board (DSMB) or Committee (DSMC)
     - ☐ OHSU Cancer Institute (OCI)

   Monitoring entity member Information (not applicable if monitoring entity is OCI)*

Name/Role	Credentials	Expertise	Title	Organization	Telephone	E-Mail

*In the absence of the availability of information about specific members, a general description of the expertise of each member and board make-up will suffice. (unless this role is filled by the Oregon Cancer Institute [OCI])

   - State mechanisms to assure independence of judgment (for example, PIs are asked to verify absence of conflict of interest, or they may not be individuals from the same department or institution):

2. WHO will Monitor:
   Responsibilities and roles for gathering and monitoring the data, including data related to unanticipated problems and adverse events: Describe the roles of the investigators, research coordinators, research sponsor, monitoring entity, statistical consultant, etc. Include the following:

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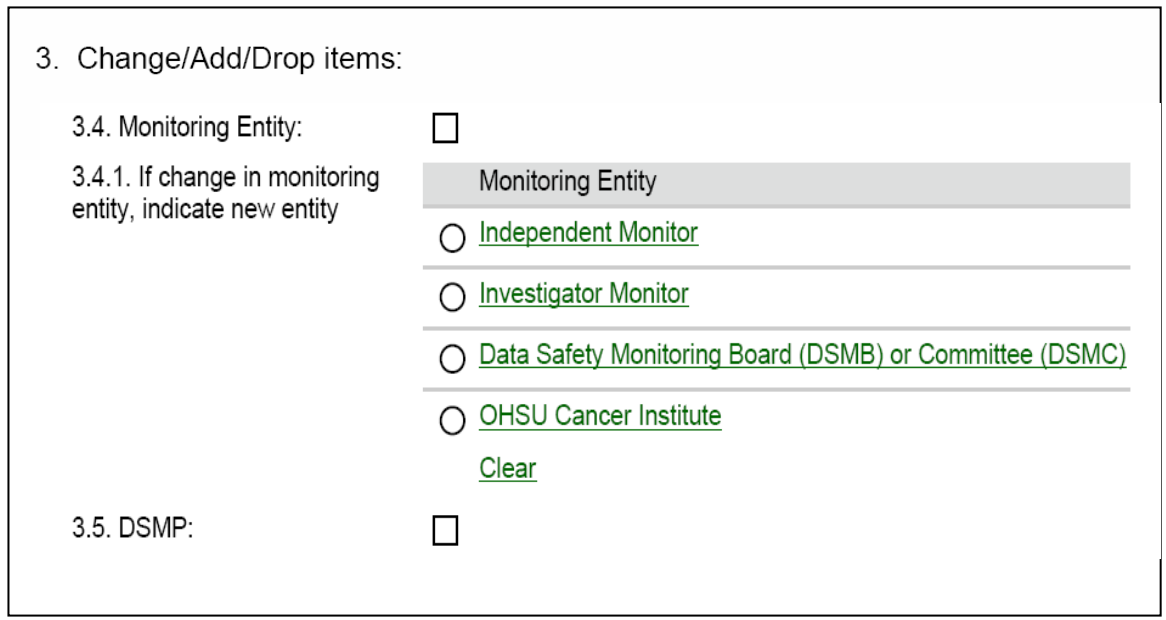
DSMP Policy - Modifications

New Modification questions:

The Monitoring Entity or DSMP can now be revised within a Modification. Choose from the four Monitoring Entity options.

If you are changing the Monitoring Entity, a revised DSMP is required.

Existing studies will not be required to designate a Monitoring Entity or outline a DSMP until Continuing Review.



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DSMP Policy – Continuing Review

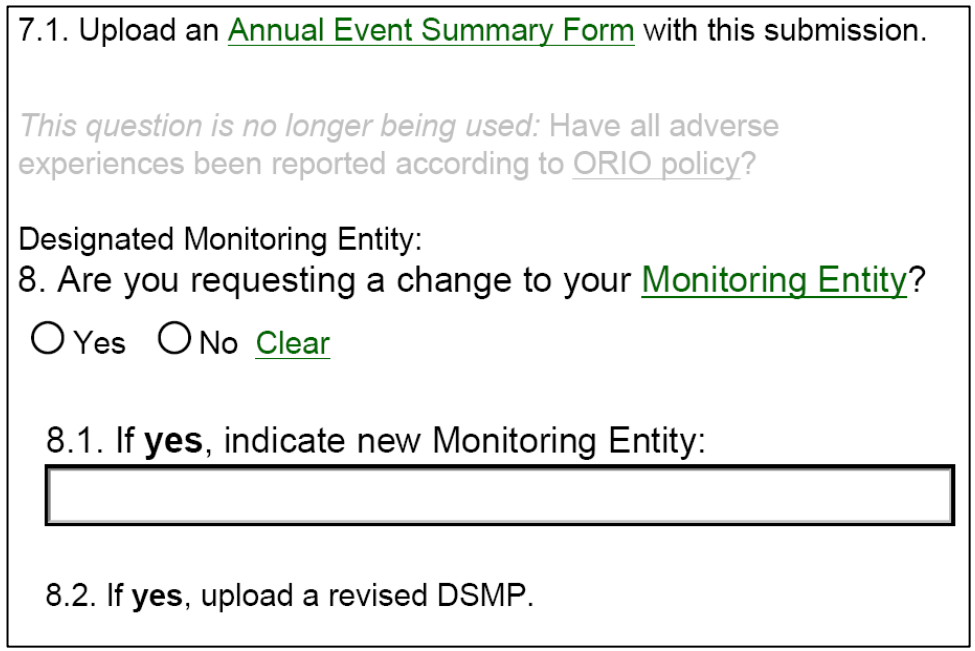
New Continuing Review questions:

The Monitoring Entity or DSMP can be revised within the Continuing Review.

If a Monitoring Entity has already been designated for your study, it will appear just above Q.#8 as the 'Designated Monitoring Entity'.

If an Entity has not been designated, and your type of study requires it, you must answer Q.8. & 8.1, and upload a DSMP.

The new Annual Event Summary Form may be required with your Continuing review.


7.1. Upload an Annual Event Summary Form with this submission.

This question is no longer being used: Have all adverse experiences been reported according to ORIO policy?

Designated Monitoring Entity:

8. Are you requesting a change to your Monitoring Entity?

○ Yes ○ No Clear

8.1. If **yes**, indicate new Monitoring Entity:

8.2. If **yes**, upload a revised DSMP.

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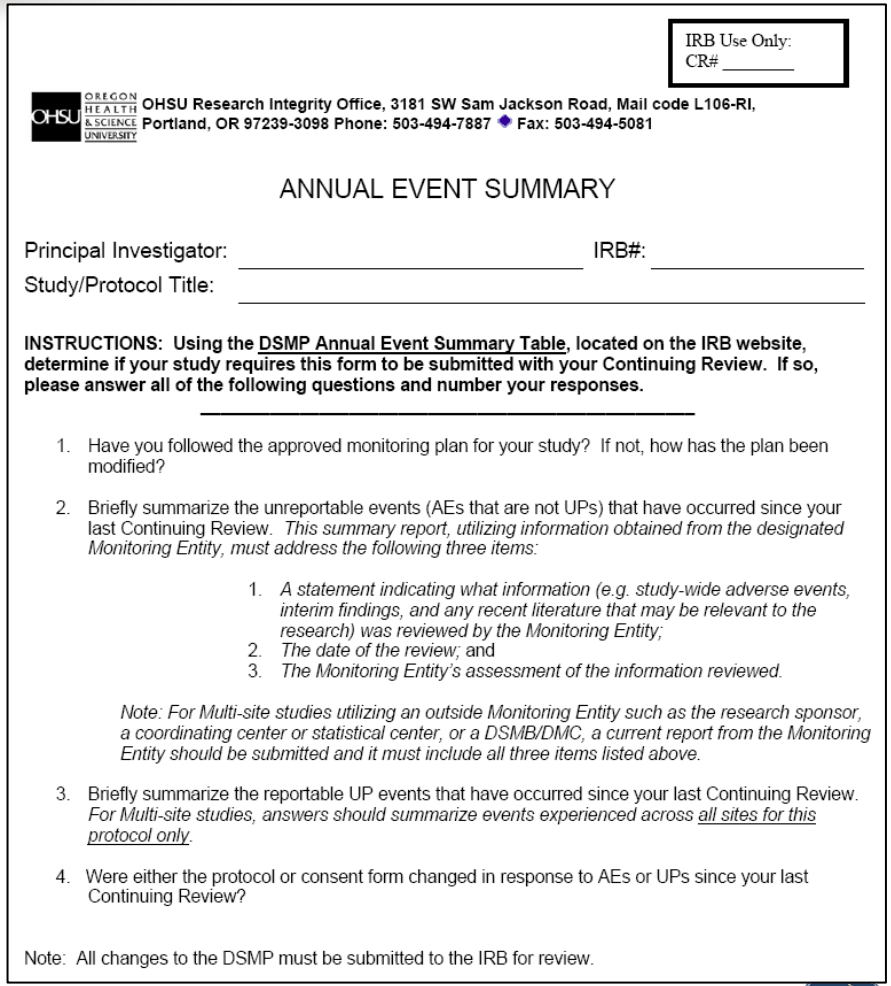
DSMP Policy – Continuing Review cont.

An Annual Event Summary Form may be required with your Continuing review submission.

This form will summarize events and actions since the last Continuing Review.

- *For studies using an Independent Monitor or DSMB/DMC as the Monitoring Entity, the annual progress report or other summary should be uploaded & results summarized in this form.*
- *If the Monitoring Plan or Entity has changed from the approved plan, indicate the changes under Q. #1.*



IRB Use Only:
CR# _____

OHSU Research Integrity Office, 3181 SW Sam Jackson Road, Mail code L106-RI,
Portland, OR 97239-3098 Phone: 503-494-7887 Fax: 503-494-5081

ANNUAL EVENT SUMMARY

Principal Investigator: _____ IRB#: _____

Study/Protocol Title: _____

INSTRUCTIONS: Using the DSMP Annual Event Summary Table, located on the IRB website, determine if your study requires this form to be submitted with your Continuing Review. If so, please answer all of the following questions and number your responses.

1. Have you followed the approved monitoring plan for your study? If not, how has the plan been modified?
2. Briefly summarize the unreportable events (AEs that are not UPs) that have occurred since your last Continuing Review. *This summary report, utilizing information obtained from the designated Monitoring Entity, must address the following three items:*
    1. *A statement indicating what information (e.g. study-wide adverse events, interim findings, and any recent literature that may be relevant to the research) was reviewed by the Monitoring Entity;*
    2. *The date of the review;* and
    3. *The Monitoring Entity's assessment of the information reviewed.*

    Note: For Multi-site studies utilizing an outside Monitoring Entity such as the research sponsor, a coordinating center or statistical center, or a DSMB/DMC, a current report from the Monitoring Entity should be submitted and it must include all three items listed above.
3. Briefly summarize the reportable UP events that have occurred since your last Continuing Review. *For Multi-site studies, answers should summarize events experienced across all sites for this protocol only.*
4. Were either the protocol or consent form changed in response to AEs or UPs since your last Continuing Review?

Note: All changes to the DSMP must be submitted to the IRB for review.

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Changes to eIRB

The UP Policy affects:

- Modifications
  - You can now indicate if a Modification is due to a UP report
- Continuing Review
  - The new Annual Event Summary Form may be required
    - Summarizes unreported AEs (Q.#2)
    - Summarizes reported UPs (Q.#3)
    - Indicates if changes have been made to documents (Q.#4)
- Reportable Events
  - Event(s) must fit into one of four categories to be considered "reportable"

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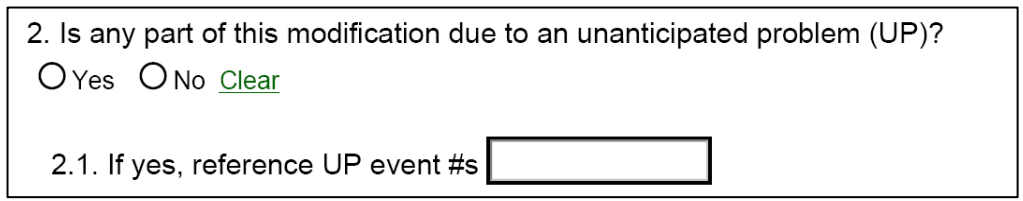
UP Policy - Modifications

New Modification question:

Modifications will now capture the UP event #, if applicable.



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UP Policy – Continuing Review

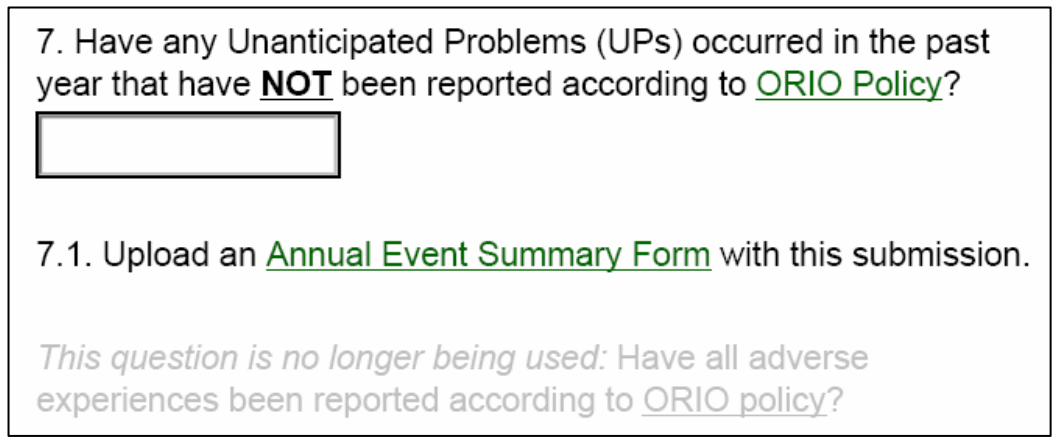
New Continuing Review questions:

Q. #7 asks if any UPs have ***not*** been reported.

- ✓ If new UPs are submitted simultaneously with the Continuing Review, indicate 'yes' for Q.#7.

The Annual Event Summary Form may be required for your study. This form will:

- ✓ Q. #2 - summarize unreported events (i.e. AEs that are not UPs)
- ✓ Q. #3 - summarize reported UP events
- ✓ Q. #4 - address changes to documents due to UPs



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UP Policy – Reportable Events

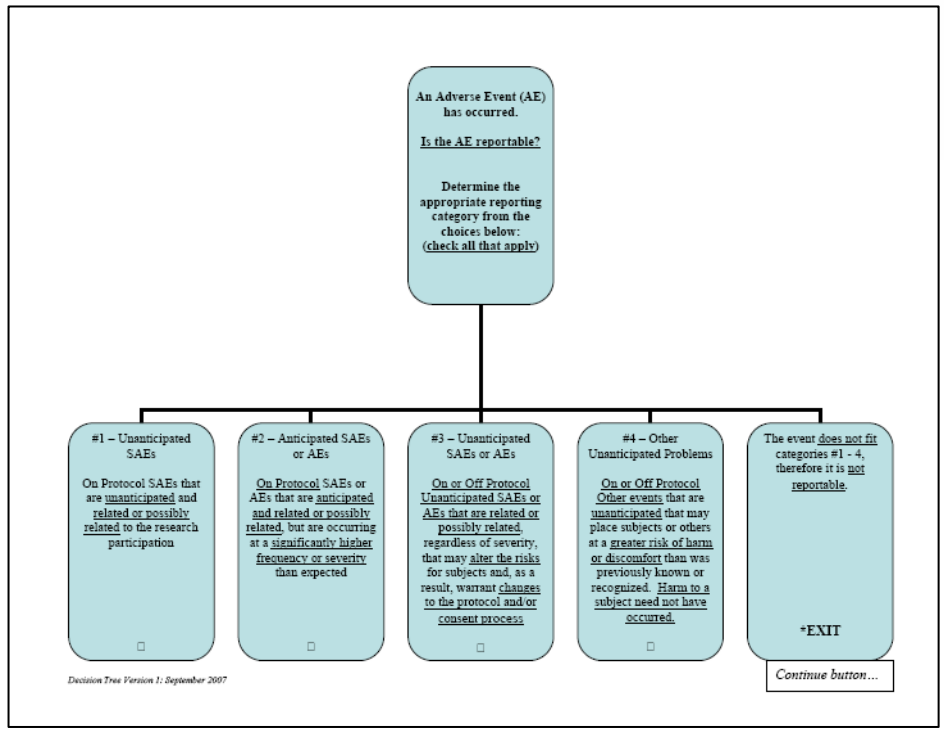
New Reportable Event questions:

An adverse event (AE) is considered reportable if it falls into any of the four reportable categories in the decision tree.

Use the checkbox to indicate the category that applies to the event. If submitting multiple events, indicate all categories that apply.

You can link to the UP Case Studies for examples of each category.

If an event does not fit into a category, it does not need to be reported to the IRB. Click EXIT.



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UP Policy – OHSU Category #1

Must fit all 4:

- On Protocol
- Serious Adverse Event
- Unanticipated
- Related or Possibly related

#1 – Unanticipated SAEs

On Protocol SAEs that are unanticipated and related or possibly related to the research participation

↑

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UP Policy – OHSU Category #2

Must fit all 4:

- On Protocol
- Anticipated
- Related or Possibly related
- Occurring at a higher frequency or severity

#2 – Anticipated SAEs or AEs

On Protocol SAEs or AEs that are anticipated and related or possibly related, but are occurring at a significantly higher frequency or severity than expected

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UP Policy – OHSU Category #3

Must fit all 3:

- Unanticipated
- Related or Possibly related
- May alter the risks and therefore warrants changes to the protocol or consent process

#3 – Unanticipated SAEs or AEs

On or Off Protocol Unanticipated SAEs or AEs that are related or possibly related, regardless of severity, that may alter the risks for subjects and, as a result, warrant changes to the protocol and/or consent process

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UP Policy – OHSU Category #4

Must fit all 3:

- Unanticipated
- "Other" events
- May place subjects or others at a greater risk of harm or discomfort

*Refer to UP Case Studies for specific examples of this category

#4 – Other Unanticipated Problems

On or Off Protocol Other events that are unanticipated that may place subjects or others at a greater risk of harm or discomfort than was previously known or recognized. Harm to a subject need not have occurred.

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UP Policy – Reportable Events cont.

New UP Report questions (page 1):

A new *Chair Use Only box* has been added.

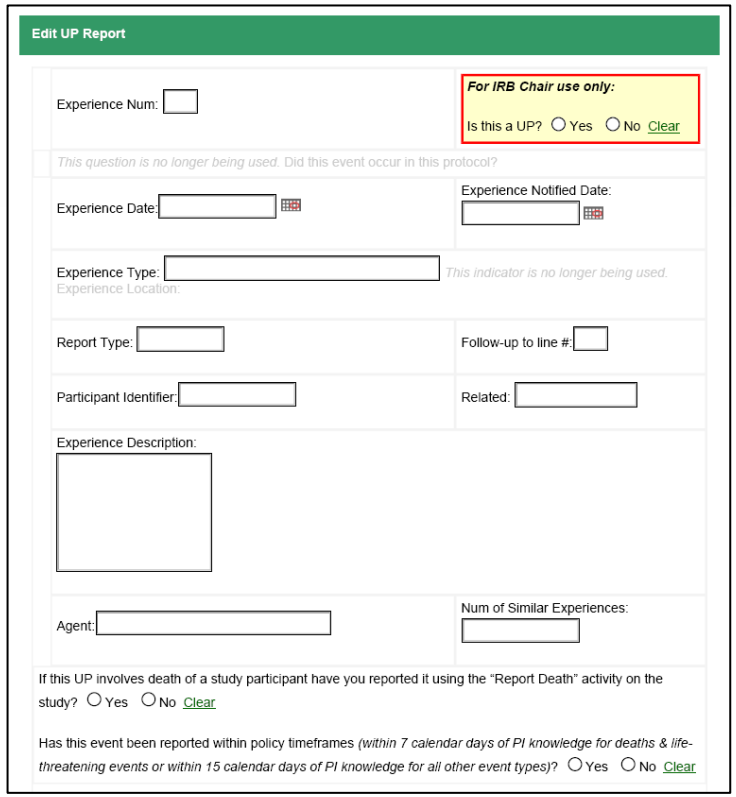
The 'Experience Type' now indicates:

- On protocol UP – OHSU subjects
- On protocol UP – Non-OHSU subjects
- Off protocol UP (using same drug or agent)
- Other UP

Indicate if the event was submitted according to the new policy timeframes.

- Within 7 calendar days of PI knowledge for deaths & life-threatening events considered to be UPs

- Within 15 calendar days of PI knowledge for all other events that are considered UPs



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UP Policy – Reportable Events cont.

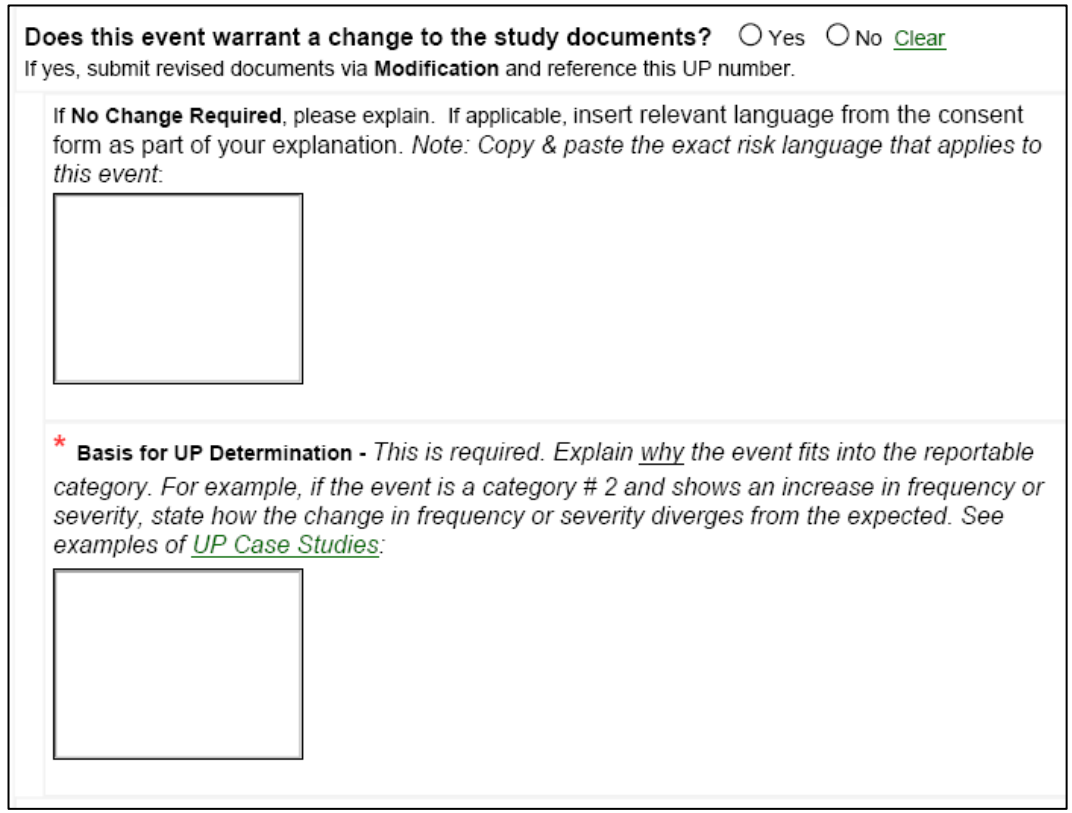
New UP Report questions (Page 2):

Questions are revised to capture changes to all documents, not just the consent form.

If no changes are submitted, this requires a full explanation along with copying relevant consent form language that may apply.

The Basis for UP Determination is required and must be thoroughly explained.

- *Refer to the UP Case Studies for examples.*



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Questions?

Next up:

UP Case Studies review

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UP Case Study Review

Reportable Categories:

1. On Protocol SAEs† that are unanticipated†† and related or possibly related to the research participation.

2. On Protocol SAEs or AEs that are anticipated and related or possibly related, but are occurring at a significantly higher frequency or severity than expected.

3. On or Off Protocol Unanticipated SAEs or AEs that are related or possibly related, regardless of severity, that may alter the risk to benefit ratio for the subjects and, as a result, warrant changes to the protocol and/or consent process.

4. Other Unanticipated Problems that are On or Off Protocol – Other events that are unanticipated that may place subjects or others at a greater risk of harm or discomfort than was previously known or recognized. Harm to a subject need not occur for an event to be an unanticipated problem.

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