



OHRPP Updates

February 13, 2020

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New OHRPP QIU staff



Preview of PAR guidance update

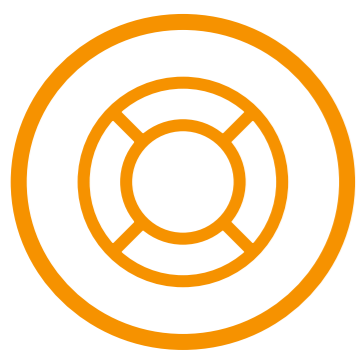


Learn at Lunch



OHRPP Training & HRN





New OHRPP Quality Improvement Unit Staff

Tiffany Rose, Sr. Analyst, QIU

- Previously worked at USC
- Started last week

Anya Rosensteel, Sr. Analyst, QIU

- Internal OHRPP promotion
- Starts next week



PARs – a snapshot of what's been submitted

There's a lot of noise

Average > 3000/yr.



That's more than
58 a week.

Average 100 SSEs/yr.



Many are not urgent

> 10% IBs



Investigator's brochures
are managed
differently than
all other study
documents

> 5% external AEs



Many of these are
follow-ups with no
substantive update



Revised PAR Guidance - Goals

Goals:

- 1.** To ensure the IRB receives everything that they need to meet regulatory and compliance oversight functions.
- 2.** To stop submission of materials the IRB does not need to receive in order to reduce the burden on:
 - **The IRB**, especially the Chairs, reviewing and making determinations on unnecessary submissions/duplicate submissions
 - **OHRPP staff** processing unnecessary submissions/duplicate submissions
 - **Researchers and their proxies** submitting/responding to queries on unnecessary submissions



Revised PAR Guidance – purpose of PARs

Type of Application	Purpose of the application
Post approval report application	<p>The PI provides information <i>relevant to the ongoing conduct of the research</i>:</p> <ol style="list-style-type: none">1) After-the fact reporting for deviations necessary to eliminate immediate hazards to participants2) Urgent safety information that may suggest an unexpected change to the risks or benefits of the research3) Events/information related to non-compliance that could rise to the level of serious or continuing non-compliance4) Complaints about the research



PARs – Regulatory requirements

IRBs are required (under [45 CFR 46.108\(a\)\(4\)](#) &/or [21 CFR 46.108\(b\)](#)) to make determinations on events/incidents/new information (when appropriate) related to conduct of the research at the site(s) under that IRB's jurisdiction and report those to the relevant regulators (OHRP &/or FDA) in a timely fashion:

1. Unanticipated Problems Involving Risks to Subjects or Others
2. Serious non-compliance
3. Continuing non-compliance
4. Suspension of the research by the IRB
5. Termination of the research by the IRB



PAR guidance – what's changed

GENERAL:

- The guidance is *more specific* (what we do and don't want to be submitted via PAR) to help limit submissions to what is necessary for the IRB to review
 - Examples for *biomedical* and *social/behavioral* research have been added throughout
- For reports/information we will no longer receive via PAR, *instructions are provided on what to do with them.*



PAR guidance – what's changed

GENERAL (cont.):

- **Definitions** have been **re-organized** (in order of complexity/severity) and **updated** (for UAP, serious non-compliance and continuing compliance) to conform to UCOP definitions.
 - These are the definitions we are asking reviewers/IRBs to use when making these determinations
- **Remove the term “violation”** throughout the document, as we want to **encourage investigators to report relevant deviations** and it is not a term used in the regulations.



PAR guidance – what's changed

GENERAL (cont.):

- Clarify that ***this guidance is only for IRB reporting*** and that ***other entities may have other requirements***
- ***Add subtypes of categories*** under PI reporting responsibilities in sub-headers (***indexed***)
- Add AAHRPP standards reference, update reference links, and add ICH-GCP references
- Simplify the ***IRB responsibilities and procedures section*** (to reflect Chair/designee triage)



PAR guidance – what's changed

ADVERSE EVENTS:

- **Limit initial reports of external AEs** to only ones **where the local PI is certain** it meets all three criteria (serious, related, and unexpected)
 - Necessary as there is a “don't know” option in webIRB for the question regarding seriousness of event
- **Limit follow-up reports for external AEs** to only those that provide information that the event is now **of greater severity than initially reported.**



PAR guidance – what's changed

DSMB REPORTS:

- Only reports that indicate the DSMB *has a concern* about the research or that indicate the DSMB has *suspended or terminated the research* should be submitted
- DSMB reports that indicate the study may “continue as planned” should no longer be submitted



PAR guidance – what's changed

SAFETY REPORTS:

- PARs are now specifically designated as the mechanism for submitting required *progress reports for IDEs, treatment IDEs, and HUDs* to comply with these FDA regulations
 - [21 CFR 312.53\(c\)\(1\)\(vii\)](#)
 - [21 CFR 312.66](#)
 - [21 CFR 812.150\(a\)\(1\)](#)

- *Investigator's brochures/device brochures* will only be submitted via Initial application and Amendment applications moving forward



PAR guidance – what's changed

SAFETY REPORTS (cont.):

- Notification to the IRB of the *use of the short form process* will now be made in the Amendment application submitted to provide the IRB with the fully translated consent document (to reduce the number of IRB submissions necessary to successfully complete the short form checklist)
- Include a place for investigators to submit *“self-assessment”* forms – a new component of the forthcoming post-approval monitoring program of the QIU



PAR guidance – what's changed

SINGLE SUBJECT EXCEPTIONS:

- Single Subject Exceptions are now limited to *only inclusion/exclusion criteria variance* on treatment studies where there is a time constraint that would make submission/processing of an Amendment application not a plausible mechanism.
- Specific *details/justification needed* for the IRB chair/designee to consider a SSE are now described
- Additional guidance is included for the investigator/clinician to *consider expanded access options* as well.



PAR guidance – what's changed

DEVIATIONS:

- Provide *updated content to be included in the log of deviations* (submitted at CR or kept in study records for no CR studies)
- Clarify that *all* research-related *breaches of confidentiality* meet the threshold for reporting
- Put the *responsibility to notify the IRB of non-compliance trends* on the Principal Investigator



PAR guidance – what's changed

DEVIATIONS (cont.):

- Provide guidance on *root causes analyses and CAPA plans* for research deviations that meet the threshold for reporting
- Include directions to *consult with campus and/or health system compliance offices* for specific types of reportable deviations.
- Include that *OHRPP QIU may open complaint PARs* for complaints that come directly to the OHRPP office



PAR guidance – what's changed

SINGLE IRB/RELIANCE PARS:

- Guidance for submission (or not) of PARs under sIRB (*reviewing* and *relying*) is now provided
- Throughout the document, “*internal*” events are defined as happening *at sites under the responsibility of a UCLA IRB* (to help investigator better understand what actions the IRB may take when other sites rely on the UCLA IRB)



PAR guidance – rollout

Related guidance and other documents will be updated:

- Decision Trees
- IRB Review Type - Amendments to Previously Approved Research
- Complaints, Concerns and Suggestions, and Reports of Undue Influence Regarding the Conduct of Human Participants Research
- Noncompliance and Allegations of Noncompliance Regarding the Conduct of Human Subjects Research
- Research Involving Non-English Speaking Research Participants
- CHECKLIST FOR USING THE “SHORT FORM” METHOD OF CONSENT FOR NON-ENGLISH SPEAKING RESEARCH PARTICIPANTS
- Protocol Violation, Deviation, or Incident Summary Log



PAR guidance – rollout

Guidance Documents will be made available to stakeholders:

- On OHRPP website

Updates announced:

- Via Human Research News

Trainings provided to:

- CRU (hem/onc coordinators)
- All researchers (at least 2 general sessions)
- Specific department trainings *as requested*
- IRB Chairs
- OHRPP staff



PAR guidance – rollout

webIRB revisions (*in development*):

- Automated functions will be added to support the guidance
 - Auto-acknowledgement of some AEs
- Change to document management (for IBs)
- We hope these will roll out a few weeks after the guidance goes live

“Learn at Lunch” Series



February 25, 2020, Noon-1pm

“Single IRB mandate and Reliance”

Presenter: *Kristin Craun*, Director UCLA OHRPP

Location: [CHS 17-323](#)

“Learn at Lunch” Series

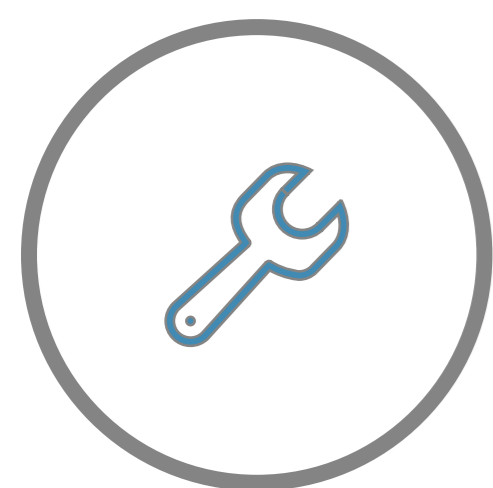


Upcoming presentations:

March: Expanded Access, Emergency Use, HUD, and Right To Try

April: Post Approval Reporting

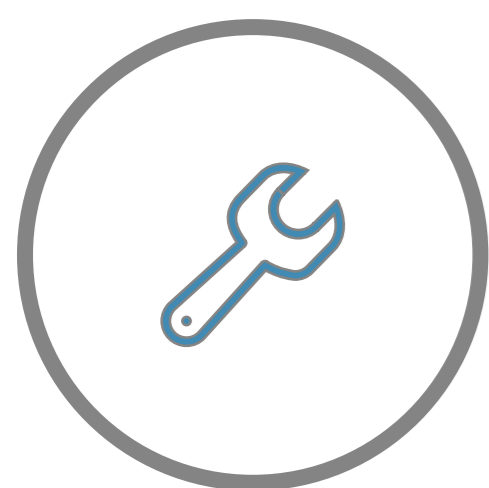
OHRPP Training Opportunities



- ✓ OHRPP Quality Improvement Unit *will come to your division/department for IRB-related training, customized to your needs.*
- ✓ Please suggest Learn at Lunch series topics

➤ *To request a custom training or suggest a Learn at Lunch topic, please contact: OHRPP Assistant Director, Education & Quality Improvement [Moore Rhys](#) (310) 794-6339*

Reminder - Subscribe to Human Research News



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- ***To subscribe, send an email (blank subject and body) to: investigators-l+subscribe@lists.ucla.edu***

Any Questions?

Contact Information

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<http://ora.research.ucla.edu/ohrpp>

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