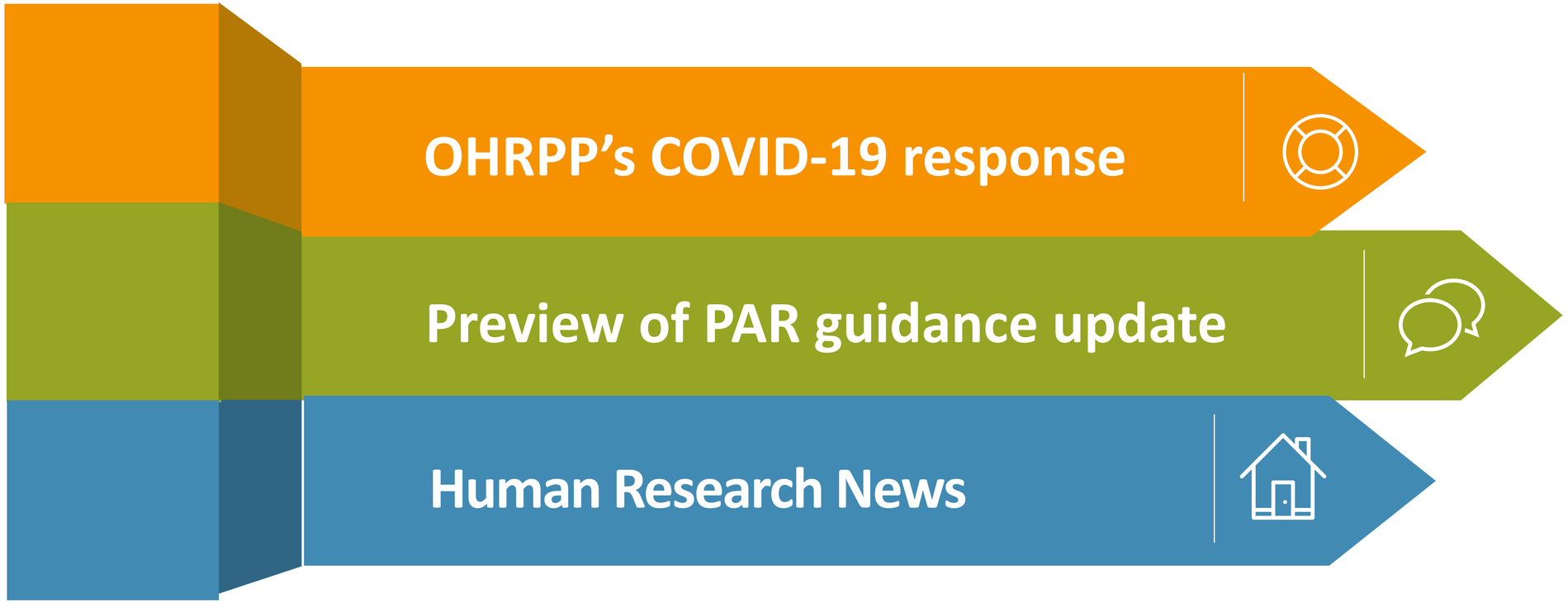
UCLA Research Administration

# OHRPP Updates

April 9, 2020

# OHRPP Updates



# OHRPP and COVID-19

## COVID-19 Policy for Human Subjects Research:

- **Policy is *temporary* (effective from March 16, 2020 until revoked)**
- **Applies to all human subjects research under the auspices of UCLA**
  - Conducted by faculty, staff, or students in their UCLA-affiliated capacity
  - Campus, UCLA Health locations, and off-campus

# OHRPP and COVID-19

## COVID-19 Policy for Human Subjects Research:

- In-person research visits **should NOT be conducted** unless ***the specific research visit provides an immediate benefit to a participant's health and/or well-being***

# OHRPP and COVID-19

## COVID-19 Policy for Human Subjects Research:

- ***It is the responsibility of the PI to assess whether a specific in-person research visit provides an immediate benefit to the participant's health and/or well-being in light of the changed circumstances with COVID-19***
  - *The IRB will **not** make these assessments for currently approved research*
  - *The investigator should document in a note to file their assessment of the above criteria*

# OHRPP and COVID-19

## COVID-19 Policy for Human Subjects Research:

- **Those procedures that can be moved to remote may be changed to remote *without prior IRB review* as long as:**
  1) *The change to remote does not impact the safety of participants;*
  2) *The change does not compromise the integrity of the data;*

  *AND*

  3) *The change would not affect subjects' willingness to participate*

- ***Note these change to remote procedures as COVID-19 related deviations in the deviation log submitted at continuing review (if remote procedures are not in approved protocol)***

# OHRPP and COVID-19

## COVID-19 Policy for Human Subjects Research:

- ***For study procedure changes that don't meet the criteria on the previous slide, there are 2 pathways:***

  1) ***Submit an amendment and secure IRB approval in advance of the change***

     - *Consult with your OHRPP Administrator to determine if review can happen before the change needs to be implemented*

  OR

  2) **Enact the change *in advance of IRB review* *only if the deviation is necessary to avoid apparent immediate hazard to participants***

     - *Submit PAR notification within 3 business days after the deviation per the PAR Guidance*

# OHRPP and COVID-19

## Additional Resources:

- **FDA Guidance on conduct of clinical trials of medical products during COVID-19 pandemic**
  - Includes guidance on acceptable methods of obtaining consent during COVID-19 medical isolation
- **OHRPP COVID-19 FAQ**
  - Please send in your questions if they haven't yet been answered in the FAQ

# Revised PAR Guidance

## *Goals of the revised PAR Guidance:*

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
   - **OHRPP staff** processing unnecessary submissions
   - **Researchers and their proxies** submitting/responding to queries on unnecessary submissions

# PAR guidance – what's changed

- 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 will receive via PAR, ***instructions are provided on what to do with them***.

# PAR guidance – what's changed

- ***Remove the term "violation"*** throughout the document, as we want to ***encourage investigators to report relevant deviations***
  - "Violation" is ***not*** a regulatory term

- Clarify that ***this guidance is only for IRB reporting*** and that ***other entities may have other requirements***

# PAR guidance – what's changed

## ADVERSE EVENTS:

- ***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

## OTHER REPORTS:

- ***Investigator's brochures/device brochures*** will NO LONGER be submitted by PAR
  - submitted via initial application and amendment application only

# 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 authorizing a Single Subject Exception are now described

# PAR guidance – what's changed

## DEVIATIONS:

- 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

- Include directions to ***consult with campus and/or health system compliance offices*** for specific types of reportable deviations.

# PAR guidance – what's changed

**SINGLE IRB/RELIANCE PARS:**

- Guidance for submission (or not) of PARs under sIRB is now provided for both when
  - The UCLA IRB is ***reviewing*** on behalf of other institutions
  - The UCLA IRB is ***relying*** on the review of another IRB

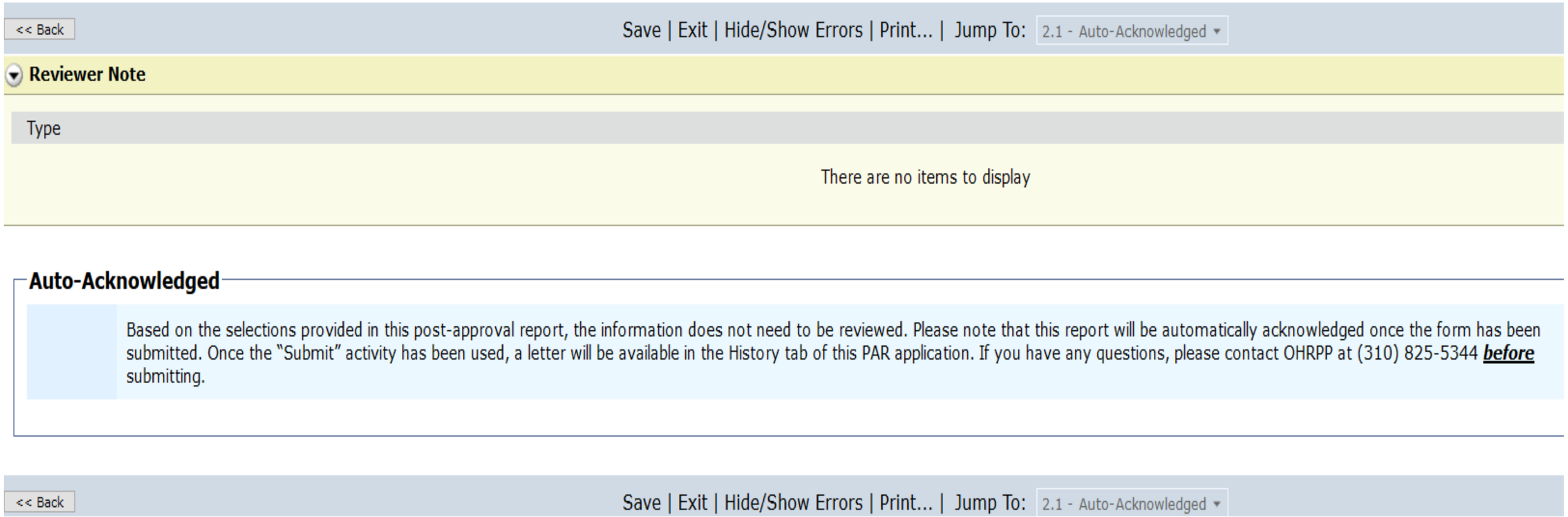
# PAR guidance – rollout

**webIRB revisions:**

- Revised questions and answer choices in line with revised guidance

- ***Automated functions*** have been added to support the guidance
  - Auto-acknowledgement of AEs that don't meet the criteria

# PAR guidance – rollout



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# Any Questions?

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