UCLA researchers are responsible for reporting to the IRB non-compliance that meets the threshold for reporting (see PAR Guidance) and IRB members share responsibility for ensuring that determinations of serious or continuing non-compliance are only found after following a consistent review process.

This worksheet guides review of non-compliance for both BIOMEDICAL/CLINICAL and SOCIAL/BEHAVIORAL RESEARCH.

Note: Throughout the form “Investigator” is used to indicate “Principal Investigator, all research personnel, and all who are delegated to perform research-related activities under this protocol at any site for which the UCLA IRB is the reviewing IRB.”

1. Is the event(s)/incident(s) non-compliance?
   a. Did the investigator fail to comply with an applicable law?
      □ Yes □ No □ Unclear
      If yes, which specific law(s):
   b. Did the investigator fail to comply with human subjects research regulations?
      □ Yes □ No □ Unclear
      If yes, which specific regulation(s):
   c. Did the Investigator fail to comply with institutional policies (including OHRPP guidance) relating to the protection of human subjects?
      □ Yes □ No □ Unclear
      If yes, which specific institutional policy(s):
   d. Did the Investigator fail to comply with the requirements of the IRB (approved IRB application or stipulations in the current approval notice)?
      □ Yes □ No □ Unclear
      If yes, which specific IRB requirement(s):
      ➢ Note: if the answer for any of a through d is “unclear”, please request additional information before making any non-compliance determinations.
   e. If any of the answers above are “unclear” what information is needed (from the investigator, another compliance office, and/or the OHRPP QIU) for the IRB to make a determination:
      ➢ Note: if the answer for all of a through d is “no,” stop here. There is no non-compliance.
      ➢ Note: if the answer for any of a through d is “yes” and none are “unclear,” there is non-compliance. Proceed to section 2.

2. Is the event(s)/incident(s) “continuing non-compliance”?  
   a. Is there a pattern of non-compliance?
      i. Are there four or more instances of the same or similar non-compliance events/incidents (in keeping with the definition of pattern from the PAR guidance)?
         □ Yes □ No □ Unclear
         AND
      ii. Did the non-compliance continue after it was brought to the attention of the PI?
         □ Yes □ No □ Unclear
Note: if the *answer for a i or ii is “unclear,”* please request additional information *before making a continuing non-compliance determination.*

iii. If any of the answers above are “unclear” *what information is needed* (from the investigator, another compliance office, and/or the OHRPP QIU (for-cause monitoring and/or research)) for the IRB to make a determination:

- Note: if the *answer for a i or ii is “no,”* there is no continuing non-compliance. Skip to section 3.
- Note: if the *answer for a i and ii is “yes,”* continue with b.

b. Does this pattern of non-compliance suggest an inability to comply with applicable laws, regulations, institutional policies, or the determinations of the IRB?  
☐ Yes ☐ No ☐ Unclear  
If yes, *what information has led you to believe* that the Investigator is unable to comply:

c. Does this pattern of non-compliance suggest an unwillingness to comply with applicable laws, regulations, institutional policies, or the determinations of the IRB?  
☐ Yes ☐ No ☐ Unclear  
If yes, *what information has led you to believe* that the Investigator is unwilling to comply:

- Note: if the *answer for b or c is “unclear,”* please request additional information *before making a continuing non-compliance determination.*

d. If any of the answers above are “unclear” *what information is needed* for the IRB to make a determination:

- Note: if the *answer for b and c is “no,”* there is no continuing non-compliance. Continue to section 3.
- Note: if the *answer for b or c is “yes” and neither are “unclear,”* there is continuing non-compliance. Continue to section 3.

3. **Is the event(s)/incident(s) “serious non-compliance”?**

a. Did the non-compliance *significantly and negatively impact the rights and/or welfare of participants?*  
☐ Yes ☐ No ☐ Unclear  
If yes, how were the rights of participant(s) impacted:

If yes, how was the welfare of participant(s) impacted:

b. Did the non-compliance *significantly and negatively impact the integrity of the data?*  
☐ Yes ☐ No ☐ Unclear  
If yes, how was the integrity of the data impacted:

- Note: if the *answer for a or b is “unclear,”* please request additional information *before making a serious non-compliance determination.*

c. If any of the answers above are “unclear” *what information is needed* for the IRB to make a determination:

- Note: if the *answer for a and b is “no,”* there is no serious non-compliance. Continue to section 4.
- Note: if the *answer for a or b is “yes” and neither are “unclear,”* there is continuing non-compliance. Continue to section 4.
4. **Is the remediation plan sufficient?**
   a. If the non-compliance is related to any of the following, has the relevant local privacy/compliance office participated in the development of the CAPA plan?
      - breach of confidentiality
      - failure to provide the California Research Participant's Bill of Rights
      - failure to obtain effective consent/parental permission for FERPA-covered educational records
      - failure to obtain effective HIPAA authorization
      □ Yes  □ No  □ N/A

   b. Has the Investigator or other stakeholder conducted a root cause analysis?  □ Yes  □ No
      If no, **is a root cause analysis needed at this time?**  □ Yes  □ No

   c. Is the corrective action plan sufficient to address the impact on relevant participants?
      □ Yes  □ No
      If no, what **additional corrective action** is needed:

   d. Is the preventive action plan sufficient to reduce the probability of this serious and/or continuing non-compliance from recurring?  □ Yes  □ No
      If no, what **additional preventive action** is needed: