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?
      □ Yes  □ No  □ N/A
      • 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

   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: