UCLA Research Administration
Human Research Protection Program

WORKSHEET: IRB Review of potential non-compliance

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: