

Human Research News

June 21, 2023

1) Impact of the end of the COVID-19 Public Health Emergency on some Human Subjects Research

- On May 11, 2023, the COVID-19 Public Health Emergency (PHE) officially ended. During the emergency, the FDA allowed the use of drugs, biologics and devices that had not gone through the usual amount of clinical testing to be used under the temporary approval known as an [Emergency Use Authorization](#). When human subjects research using drugs, biologics, and/or devices with EUA status were reviewed, the IRB treated those drugs, biologics, and/or devices as approved.
- With the end of the public health emergency, [the status of these drugs, devices, and/or biologics may change](#). If they do, the IRB may need to re-review their use in human subjects research as “test articles” (depending on the status of the research project). If this is your situation, please review the FDA guidance on the transition (link above).
- If you have an investigator-initiated trial and you have FDA questions, please consult with the UCLA CTSI office of FDA affairs fdaconsults@mednet.ucla.edu for guidance on how to proceed. If the status of your drug, biologic, and/or device, used in human subjects research *will* change, please reach out to your OHRPP administrator for consultation on what, if anything, needs to be submitted to the IRB to address this change.
- With the end of the public health emergency, UCLA Health data releases for COVID related research projects will follow the standard data release process. Please refer to <https://ctsi.ucla.edu/researcher-resources/pages/datarequests> for more information.

2) Updated UCOP Guidance on Retention of Signed Informed Consent Forms

- [RPAC Records Retention Guidance](#) includes a new section on “Investigator Records” that explains that investigators have a responsibility to retain signed consent forms. This section includes a table of required retention periods for signed consent forms.
- Required retention periods may vary depending on the research sponsor and researchers are advised to check with their sponsoring agency to verify the length of time required for record retention.

3) Reminder - Clinical Research Volunteers

- For Investigators who wish to use clinical research volunteers, please ensure that you follow instruction #4 of the UCLA Health volunteer office [guidelines](#). Following their guidelines requires that you complete the IRB application in a specific way. Please ensure you review the guidelines in advance of submitting your IRB application to reduce delays in the process of volunteer office approval.
- If you have any questions, please reach out to the UCLA Health volunteer office at CRV@mednet.ucla.edu

4) OHRPP's Office Hours

- [Register once](#) to join any Thursday session:

Upcoming Office Hours:

- June 22, 2023, at 2pm
- July 6, 2023, at 2pm

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