

## Checklist: Additional Requirements for Research Supported by the Environmental Protection Agency (EPA) (version date: May 9, 2019)

**Note:** The Environmental Protection Agency (EPA) IS a [signatory to the Revised Common Rule](#), which took effect January 21, 2019.

For more information see: <https://www.epa.gov/osa/harmonizing-epa-human-subjects-research-regulations-revised-common-rule>

### Researcher Responsibilities

Researchers are responsible for communicating with their EPA Program Officer to ensure that all EPA requirements are met prior to starting an IRB approved study.

**EPA HUMAN SUBJECTS RESEARCH REVIEW:** All human subjects research (HSR) conducted or supported by EPA must be approved by the EPA Human Subjects Research Review Official (HSRRO) as compliant with EPA Regulation [40 CFR 26](#) (Protection of Human Subjects) or be determined to be exempt research before the research can begin.

#### WHAT NEEDS EPA HSRRO REVIEW?

The following projects or activities require review by the EPA HSRRO:

- Y All agreements in which support for projects meeting the regulatory definition of research with human subjects is anticipated at any time during the period of support
- Y All projects conducted or supported by EPA that meet the regulatory definition of research with human subjects
- Y If requested, the EPA HSRRO may also review any project that plans to collect data from or about humans in order to assist with the determination of whether or not the project meets the regulatory definition of research with human subjects

#### WHEN IS EPA HUMAN SUBJECTS REVIEW REQUIRED?

- Y **For Support Agreements:** Before the agreement signed by UCLA OCGA.
- Y **For Projects:** After the UCLA IRB has approved the project but before the project begins
- Y **Not Yet Supported:** Researchers are required to apply EPA human subjects regulations to all research where there is the *intent* to submit a request for EPA support.

### UCLA IRB Responsibilities

The UCLA IRB is responsible for ensuring that EPA requirements are met prior to approving EPA-supported human subjects research.

#### EPA PROHIBITED RESEARCH

- Y Research involving intentional exposure of pregnant women or children to any substance regulated by the EPA is prohibited and may not be approved by the IRB.

## INTENTIONAL EXPOSURE

- Y Research involving intentional exposure of non-pregnant, non-nursing adults must comply with the provisions of [40 CFR 26](#).

## OBSERVATIONAL RESEARCH:

- Y The UCLA will apply [40 CFR 26](#) and [45 CFR 46 Subpart B](#) when reviewing observational research involving pregnant women and fetuses.
- Y The UCLA IRB will approve observational research involving children that does not involve greater than minimal risk only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in 26.406.
- Y The UCLA IRB will approve observational research involving children that involves greater than minimal risk but presenting the prospect of direct benefit to the individual participants if the IRB finds and documents that:
  - The intervention or procedure holds out the prospect of direct benefit to the individual participant or is likely to contribute to the participant's well-being.
  - The risk is justified by the anticipated benefit to the participants.
  - The relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches.
  - Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in [40 CFR 26.406](#).

## Regulations and References

- Protection of Human Subjects - [40 CFR 26](#)
- [EPA Basic Information About Human Subjects Research](#)
- [Project Review by the EPA Human Subjects Research Review Official](#)

## Questions

If you have questions regarding EPA requirements, please contact the relevant [IRB Administrator](#) or Director. Click [here](#) for contact information.

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### Change history:

2019/5/9: Updated EPA links, added reference to Revised Common Rule, replaced Director name & contact information with link to Leadership contact information.