Environmental Protection Agency (EPA) Research: IRB Reviewer Checklist

The following is a checklist of requirements for ORI/IRB use to facilitate review of human subject research supported by the EPA and research in which the intent is submission of data to the EPA.

Instructions: Review and check to indicate criteria have been considered and/or are met for items applicable to the proposed research.

PROTOCOL INVOLVES INTENTIONAL EXPOSURE RESEARCH

(a study where the exposure experienced by the subject would not have occurred but for the human subject's participation in the study. This includes any research in which the subject's exposure is artificially manipulated or controlled).

☐ Not Applicable (skip answering "intentional exposure" questions; proceed to "observational research" section)

1) EPA Subpart B prohibits intentional exposure research, under all circumstances, in children and women who are pregnant or nursing. All circumstances include studies involving controlled exposures to neutral substances (such as clean, filtered air), foods, pesticides, or therapeutic drugs. This prohibition is absolute and does not incorporate reference to either risk level or potential benefit.

☐ Not Applicable (Intentional Exposure Research Protocol does not include children or women who are pregnant or nursing.)

2) EPA 2013 Subpart K Final Rule involving Intentional Exposure to Pesticides - Applies to all other adults (non-pregnant, non-nursing) and includes no provision of consent by a legally authorized representative in research involving intentional exposure to a pesticide.

☐ Not Applicable (does not involve intentional exposure to pesticides)

For research involving intentional exposure to pesticides:

☐ Protocol includes no plans for enrolling subjects who cannot consent on their own behalf and consent form does not include signature line for a subject's legally authorized representative; AND

☐ Consent identifies pesticide and nature of pesticidal function. Consent includes unforeseeable risks such as risk to embryo or fetus should subject become pregnant.

PROTOCOL INVOLVES OBSERVATIONAL RESEARCH

(Any research that does not involve intentional exposure. Studies that involve naturally occurring environmental exposures may meet the regulatory definition of observational research)

☐ Not Applicable (skip answering for populations listed below)

1) Observational Research with Pregnant Women/Fetuses:

☐ Not Applicable

For Observational Research Involving Pregnant Women or Fetuses:

☐ There is direct benefit to the woman or the fetus, OR

☐ In the absence of direct benefit, the risk is no greater than minimal to the fetus and the research is important for biomedical knowledge which cannot be obtained in any other manner.

2) Observational Research with Children:

EPA does not permit observational research that is greater than minimal risk when there is no direct benefit to the child. Also, EPA does not recognize the "minor increase over minimal risk".

☐ Not Applicable (research is not greater than minimal risk or does not involve children)

For observational research involving children that does involve greater than minimal risk but presenting the prospect of direct benefit to the individual participants the following must be met and documented:

☐ 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; AND

☐ Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

Source:

40 CFR 26 Subpart B, C, D (https://ecfr.federalregister.gov/current/title-40/chapter-I/subchapter-A/part-26), 2013 EPA Final Rule ((https://www.govinfo.gov/content/pkg/FR-2013-02-14/html/2013-03456.htm)

Updated 9/10/2020