Protection of Human Research Subjects

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Action

Final rule.Summary

On January 19, 2017, the Environmental Protection Agency (EPA), acting in concert with other agencies, promulgated revisions to the “Common Rule.” EPA's codification of these revisions is in 40 CFR part 26, subpart A. These revisions went into effect on July 19, 2018, and compliance with the new provisions was required beginning on January 21, 2019. In addition to the core protections found in the Common Rule, EPA has promulgated regulations that are specific to ***research*** involving human ***subjects*** conducted or sponsored by EPA or submitted to EPA for regulatory purposes. The revisions to the Common Rule create discrepancies within some of these EPA-specific regulations. This final rule harmonizes the EPA-specific regulations with revisions to the Common Rule in order to resolve those discrepancies.Dates

This rule is effective on September 23, 2019.Addresses

The docket for this action, identified by docket identification (ID) number EPA-HQ-ORD-2018-0280, is available at *https://www.regulations.gov* or at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in the EPA WJC West Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20004. The Public Reading Room is open from 8:30 a.m to 4:30 p.m , Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.For* Further Information Contact

Tom Sinks, Director, Office of Science Advisor, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460 (Mail Code: 8105R); telephone number: 202-564-3099; email address: *sinks.tom@epa.gov* Supplementary InformationI. General InformationA. Does this action apply to me?

This action is directed to the public in general. This action may, however, be of particular interest to those who conduct human ***research*** on substances regulated by EPA. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions

regarding the applicability of this action to a particular entity, consult the person listed under FOR FURTHER INFORMATION CONTACT.B. What action is the Agency taking?

The Agency is finalizing the amendments to its human studies rules as proposed in December 2018 (83 FR 62760) (FRL-9987-01-ORD). These amendments include the following:

Revisions to regulatory citation references in subparts C and D; Harmonization, where appropriate, of language in subpart K with revisions in subpart A due to revisions to the Common Rule, 82 FR 7149 (January 19, 2017); and Correction of a typographical error in subpart M.

C. What is the Agency's authority for taking this action?

These amendments are authorized under the following legal authorities. The amendments to subparts C and D, which relate to ***research*** conducted or sponsored by EPA are authorized pursuant to 5 U.S.C 301. The amendments to subparts K and M, which govern third-party ***research*** involving intentional human exposure to pesticides or to other substances where such ***research*** is used for purposes of pesticide decision-making are authorized under sections 3(a) and 25(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C 136a(a) and 136w(a), and section 408(e)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C 346a(e)(1)(C).

In response to a comment received, the Agency is clarifying that it is not relying on the section 201 of the Department of the Interior, Environment, and Related Agencies Appropriations Act, 2006, Public Law 109-54 (“2006 Appropriations Act”) as authority for this rulemaking. The reference to the 2006 Appropriations Act included in the preamble to the December 2018 proposed rule was to explain in part the authority for EPA's initial promulgation in 2006 of its rules governing ***research*** with human ***subjects*** beyond the provisions contained in the Common Rule, including the subparts being updated herein. As noted in the Agency's Response to Comments Document prepared as part of the record for the 2013 revisions to EPA's human studies rule, the Agency has determined that the 2006 Appropriations Act is no longer in effect and does not provide authority for new regulatory provisions. See *https://www.regulations.gov*, in Docket No. EPA-HQ-OPP-2010-0785, document number 38.II. Background

As discussed in the preamble to the proposed rule, on January 19, 2017, several federal departments and agencies, including EPA, adopted revisions to the provisions of the Common Rule, a set of regulations intended to create a uniformity across the federal government for the protection of human ***subjects*** involved in ***research***. See 82 FR 7149 (January 19, 2017). Those revisions, which were intended to “modernize, strengthen, and make [the Common Rule] more effective”, established new requirements for the informed consent process; allowed the use of broad consent (i.e , seeking prospective consent to unspecified future ***research***) from a ***subject*** for storage, maintenance, and secondary ***research*** use of identifiable private information and identifiable biospecimens; established new exempt categories of ***research*** based on their risk profile; required the use of a single institutional review board (IRB) for U.S -based cooperative ***research***; and removed the continuing review requirement for certain ***research***, in addition to making minor changes intended to improve the clarity and accuracy of the rule. Id. at 7150. EPA's codification of the Common Rule provisions is located in 40 CFR part 26, subpart A. Compliance with these revisions was required starting on January 21, 2019. See 83 FR 28497.

In addition to the provisions of the subpart A, EPA's regulations governing human studies ***research*** include several additional subparts at 40 CFR 26, including subparts B through D, which govern ***research*** conducted or sponsored by EPA involving pregnant or nursing women and children, and subparts, K through Q, which govern third-party pesticide ***research*** involving intentional exposure of human ***subjects*** and EPA's reliance on ***research*** involving intentional exposure of human ***subjects***. In particular, EPA's provisions in subpart K, which govern the conduct of pesticide-related third-party ***research*** involving intentional exposure of human ***subjects***, borrowed heavily from the Common Rule provisions based on the Agency's conclusion that it would be appropriate to apply ethical standards to third-party ***research*** that were equivalent to the protections for human ***subjects*** participating in ***research*** conducted or sponsored by EPA. See 70 FR 53838, 53845 (September 12, 2005).III. The Final Rule

EPA is finalizing revisions to its human studies regulations as proposed. As discussed in the preamble to the proposed rule, these revisions include updating numerical references in subparts C and D to accurately refer to exemption text in subpart A and to eliminate language concerning tribal laws that is no longer necessary due to the revisions in subpart A. These revisions are necessary to ensure that the exemptions will apply as intended to ***research*** conducted or sponsored by EPA and avoid unnecessary confusion about the applicability of tribal law.

In addition, this final rule also includes revisions as proposed to subpart K to harmonize, as appropriate, language governing third-party ***research*** with the revisions in subpart A and to clarify the timing and applicability of these revisions. These revisions are important to encourage equivalency in protections of human ***subjects*** between ***research*** conducted or sponsored by federal departments and agencies and third-party ***research***, wherever appropriate. Furthermore, the harmonization of provisions allows investigators and IRBs to follow equivalent or similar standards for regulating the ethical conduct of ***research*** involving human ***subjects***, regardless of who conducts that ***research***. Consistency in standards will result in greater clarity and less regulatory burden as well as less potential for confusion and misapplication of standards for the regulated community.

Finally, EPA is correcting a typographical error in subpart M, as discussed in the preamble.IV. Public Comments on the Proposed Amendments

Public comments on the proposed rule are discussed here, in general terms, along with EPA's response to the comments. EPA received a total of nine public comments during the 60-day comment period. All comments were submitted by individuals, two self-identified and seven anonymous. The docket (ID Number EPA-HQ-ORD-2018-0280) includes all the comments submitted to EPA on the proposed amendments.A. Comments on Proposal To Maintain Exemptions Limiting the Application in ***Research*** Involving Children

One commenter described the changes concerning Subpart D the commenter considers necessary (1) to maintain access to the exemptions integrated by reference and the provision limiting the application (of exemptions) in ***research*** involving children; (2) to withdraw the clarification concerning preemption of tribal laws; and (3) to comprise reference to the new general provisions in the Common Rule. EPA agrees that these changes are necessary and, indeed, are reflected in the revisions to Subpart D as proposed.B. Comments on the Legal Authority of the Rule

One person commented on references to the 2006 Appropriations Act in the preamble to the proposal and in the regulatory citation to legal authorities. As explained above, this final rulemaking is being promulgated under 5 U.S.C 301, FIFRA sections 3(a) and 25(a), and FFDCA section 408(e)(1)(C), not the 2006 Appropriations Act. The commenter asserts that changes to the authorities citation in the regulatory text are necessary to enable the Agency to make potential, future revisions to part 26. The Agency disagrees that the authority citation needs to be revised in this action in order to facilitate future revisions, as such questions can be taken up in relevant future actions. As explained above, this action is limited to revisions in subparts C, D, K, and M; changes that may impact other subparts of part 26 or part 26 more broadly are considered to be beyond the limited scope of the revisions in this rulemaking.C. Comments on the Requirement for Mixed-Gender, Professionally Diverse IRBs

One commenter drew attention to the proposed changes in Subpart K to harmonize IRB membership requirements with those in the revised Common Rule (Subpart A). As noted in the comment, the revised Common Rule removes the language that had been found in 40 CFR 26.107(b), requiring that “[e]very nondiscriminatory effort . . . be made to ensure that no IRB consists entirely of men or entirely of women, including the IRB's consideration of qualified persons of both sexes, so long as no selection is made on the basis of gender” and prohibiting IRBs from consisting entirely of members of one profession. The commenter expressed concern that because third-party ***research subject*** to subpart K may be more likely to be conducted overseas and ***subject*** to IRB review outside the United States than ***research*** conducted or sponsored by EPA, it is appropriate to retain the pre-2018 Common Rule language in 26.1107(b), rather than harmonize with the revised Common Rule language, in order to ensure that the same membership diversity continue to be required of the overseas IRBs.

EPA disagrees with the comment that IRB membership requirements for IRBs that review third-party ***research subject*** to subpart K warrant a divergence from the harmonization objectives of this action. EPA acknowledges that

some ***research*** ***subject*** to subpart K may be conducted overseas and ***subject*** to the membership requirements and foreign procedures of international IRBs. EPA already has provisions in place that permit EPA to approve of the use of the foreign procedures in lieu of the procedural requirements in subpart K upon determining that those procedures are at least as protective as EPA's regulations. See 40 CFR 26.1603(f). Under this current language, EPA may approve ***research*** conducted in a foreign country that does not meet the current diversity requirements in 26.1107(b), as long as it determines the protections are at least equivalent to EPA's procedures for protecting human ***subjects***. In that way, EPA does not view the revisions to the membership diversity requirements concerning gender and professional diversity as likely to meaningfully impact the integrity of the IRB reviews and approvals for ***research*** conducted overseas that is ***subject*** to subpart K. In any event, if EPA determines that the membership of the overseas IRB is so deficient that EPA cannot support a determination that the protections afforded by the foreign procedures are at least equivalent to subpart K, EPA would not be required to approve of the use of those procedures.

In addition, for the same reasons that were stated in the preamble to the Common Rule, EPA views the language in 26.107(a), which requires members to have varying backgrounds and such diversity of the members, including gender, as to promote respect for its advice, and in the revised 26.107(b), which requires IRBs to consist of at least one member whose primary concerns are scientific and one member whose primary concerns are nonscientific, to be sufficient to accomplish the same goal of diversity in IRB membership. See 82 FR 7149, 7203 (January 19, 2017). To the extent EPA considers the gender and professional diversity of an international IRB to be relevant to whether that IRB has protections in place that are at least equivalent to EPA's protections, EPA is not required to accept the use of those foreign procedures. For the rest of the third-party studies ***subject*** to subpart K, e.g , those conducted within the United States and reviewed by domestic IRBs, EPA sees no reason to deviate from the overall goal of harmonizing IRB requirements to reduce the potential for confusion and regulatory burden caused by conflicting requirements. Consequently, EPA is harmonizing 26.1107 with the revised language in 26.107 as proposed.D. Request for Extension of the Comment Period

One commenter requested an extension of the comment period, but EPA did not do so. There were relatively few comments submitted, most supported the rulemaking, and the one commenter that requested additional time appeared to be concerned about issues that were not only outside the scope of this rulemaking, but primarily concerned with another federal agency.E. Other Comments

The remaining comments were either supportive of the proposed amendments or were beyond the scope of this rule; as such, they provided no basis for any changes to the rule as proposed.V. Conclusion

EPA received relatively few comments on the proposed rule. EPA considered the comments but ultimately concluded that none raised any issues that merit any change to the amendments as proposed. Accordingly, EPA is finalizing the amendments as proposed for the reasons stated herein.VI. FIFRA Review Requirements

In accordance with FIFRA section 25(a), EPA has submitted a draft of the rule to the FIFRA Scientific Advisory Panel (SAP), the Secretary of Agriculture (USDA), and appropriate Congressional Committees. The SAP waived its review on May 20, 2019. USDA responded on June 4, 2019 and had no substantive comments on the proposal. Both responses are in the docket for this rulemaking.VII. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.A*. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

Because OMB considered this rulemaking to be a significant regulatory action when EPA issued its proposal, the Notice of Proposed Rule Making was reviewed by OMB under Executive Order 12866. Any changes made in response to OMB recommendations have been documented in the docket for this rulemaking as required by the Executive Order. After the proposed rule, OMB changed its determination to non-significant. This rule is expected to result in no more than de minimis costs since its purpose is to resolve internal discrepancies created by the recent revision to the Common Rule to avoid confusion, and potential compliance issues for researchers, institutions and

sponsors who must follow EPA regulations.B. Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs

This action is not an Executive Order 13771 regulatory action because this action is not significant under Executive Order 12866.C. Paperwork Reduction Act

This action does not impose any new information collection burden that would require additional review or approval by OMB under the Paperwork Reduction Act (PRA), 44 U.S.C 3501 et seq. OMB previously approved the information collection requirements contained in the existing regulations at 40 CFR part 26 under OMB Control No. 2070-0169.D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA.

The Agency has not identified any small entities ***subject*** to the requirements in this proposal, but it is possible that some small pesticide registrants may initiate ***research subject*** to EPA's Human Studies rule. The Agency has determined that impacted small entities, if any, may experience an impact of 0.02% as indicated in the “Economic Analysis of Final Rule: Protections for Human ***Research*** Participants” (January 12, 2006). The Agency does not have any information to support revising that analysis.E. Unfunded Mandates Reform Act

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C 1531-1538, and does not significantly or uniquely affect small governments.F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. This action is not expected to have substantial direct effects on Indian Tribes, will not significantly or uniquely affect the communities of Indian Tribal governments, and does not involve or impose any requirements that affect Indian Tribes. Thus, Executive Order 13175 does not apply to this action.H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2-202 of the Executive Order. This action is not ***subject*** to Executive Order 13045 because it does not concern an environmental health risk or safety risk. This action is not ***subject*** to Executive Order 13045 because it does not establish an environmental standard intended to mitigate health or safety risks. EPA's regulations governing ***research*** involving human ***subjects*** applies to the conduct and review of ***research*** involving intentional exposure of human ***subjects***, and prohibits the conduct of or EPA reliance on any such ***research*** involving ***subjects*** who are children, or pregnant or nursing women. These provisions remain in effect and would not be affected by the amendments.I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a “significant energy action” because it is not likely to have any effect on the supply, distribution, or use of energy.J. National Technology Transfer and Advancement Act

This action does not involve any technical standards.K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

This action does not entail special considerations of environmental justice-related issues as delineated by Executive Order 12898. The strengthened protections for human ***subjects*** participating in covered ***research*** established in the 2006 rule would not be altered by these amendments.L. Congressional Review Act (CRA)

This action is ***subject*** to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a “major rule” as defined by 5 U.S.C 804(2).List of ***Subjects*** in 40 CFR Part 26

Environmental protection, Administrative practice and procedures, Human ***research***, Pesticides and pests.Dated: July 3, 2019.Andrew R. Wheeler,Administrator.

Therefore, 40 CFR chapter I is amended as follows:Part 26 Protection of Human SubjectsRegulatory Text

1. The authority citation for part 26 continues to read as follows:Authority:

5 U.S.C 301; 7 U.S.C 136a(a) and 136w(a)(1); 21 U.S.C 346a(e)(1)(C); sec. 201, Pub. L. 109-54, 119 Stat. 531; and 42 U.S.C 300v-1(b).

2. Amend § 26.301 by revising paragraphs (b) and (c) to read as follows:§ 26.301 To what does this subpart apply?

* * * * *

(b) The exemptions at § 26.104(d) are applicable to this subpart.

(c) The provisions of § 26.101(c) through (m) are applicable to this subpart.

* * * * *

3. Amend § 26.401 by revising paragraphs (a) and (b) to read as follows:§ 26.401 To what does this subpart apply?

(a) This subpart applies to all observational ***research*** involving children as ***subjects***, conducted or supported by EPA. This includes ***research*** conducted in EPA facilities by any person and ***research*** conducted in any facility by EPA employees.

(b) Exemptions at § 26.104(d)(1) and (d)(3) through (8) are applicable to this subpart. The exemption at § 26.104(d)(2) regarding educational tests is also applicable to this subpart. However, the exemption at § 26.104(d)(2) for ***research*** involving survey or interview procedures or observations of public behavior does not apply to ***research*** covered by this subpart, except for ***research*** involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

* * * * *§ 26.402[Amended]Regulatory Text

4. Amend § 26.402 by removing paragraph (g).

5. Amend § 26.406 by revising the last sentence of paragraph (a) to read as follows:§ 26.406 Requirements for permission by parents or guardians and for assent by children.

(a) * * * Even where the IRB determines that the ***subjects*** are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with § 26.116(e).

* * * * *

6. Revise subpart K, consisting of §§ 26.1101 through 26.1125, to read as follows:Subpart K—Basic Ethical Requirements for Third-Party Human ***Research*** for Pesticides Involving Intentional Exposure of Non-Pregnant, Non-Nursing AdultsSec.26.1101To what does this subpart apply?26.1102Definitions.26.1103-26.1106[Reserved]26.1107IRB membership.26.1108IRB functions and operations.26.1109IRB review of ***research***.26.1110Expedited review procedures for certain kinds of ***research*** involving no more than minimal risk, and for minor changes in approved ***research***.26.1111Criteria for IRB approval of ***research***.26.1112Review by institution.26.1113Suspension or termination of IRB approval of ***research***.26.1114Cooperative ***research***.26.1115IRB records.26.1116General requirements for informed consent.26.1117Documentation of informed consent.26.1118-26.1122[Reserved]26.1123Early termination of

research.26.1124[Reserved]26.1125Prior submission of proposed human ***research*** for EPA review.Subpart K—Basic Ethical Requirements for Third-Party Human ***Research*** for Pesticides Involving Intentional Exposure of Non-Pregnant, Non-Nursing Adults§ 26.1101To what does this subpart apply?

(a) Except as provided in paragraph (c) of this section, this subpart applies to all ***research*** initiated on or after September 23, 2019 involving intentional exposure of a human ***subject*** to:

(1) Any substance if, at any time prior to initiating such ***research***, any person who conducted or supported such ***research*** intended either to submit results of the ***research*** to EPA for consideration in connection with any action that may be performed by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C 136-136y) or section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C 346a), or to hold the results of the ***research*** for later inspection by EPA under FIFRA or section 408 of FFDCA; or

(2) A pesticide if, at any time prior to initiating such ***research***, any person who conducted or supported such ***research*** intended either to submit results of the ***research*** to EPA for consideration in connection with any action that may be performed by EPA under any regulatory statute administered by EPA other than those statutes designated in paragraph (a)(1) of this section, or to hold the results of the ***research*** for later inspection by EPA under any regulatory statute administered by EPA other than those statutes designated in paragraph (a)(1) of this section.

(b) For purposes of determining a person's intent under paragraph (a) of this section, EPA may consider any available and relevant information. EPA must rebuttably presume the existence of intent if:

(1) The person or the person's agent has submitted or made available for inspection the results of such ***research*** to EPA; or

(2) The person is a member of a class of people who, or whose products or activities, are regulated by EPA and, at the time the ***research*** was initiated, the results of such ***research*** would be relevant to EPA's exercise of its regulatory authority with respect to that class of people, products, or activities.

(c) Unless otherwise required by the Administrator, ***research*** is exempt from this subpart if it involves only the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens from previously conducted studies, and if these sources are publicly available or if the information is recorded by the investigator in such a manner that ***subjects*** cannot be identified, directly or through identifiers linked to the ***subjects***.

(d) The EPA Administrator retains final judgment as to whether a particular activity is covered by this subpart and this judgment shall be exercised consistent with the

ethical principles of the Belmont Report.

(e) Compliance with this subpart requires compliance with pertinent Federal laws or regulations that provide additional protections for human ***subjects***.

(f) This subpart does not affect any state or local laws or regulations (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe) that may otherwise be applicable and that provide additional protections for human ***subjects***.

(g) This subpart does not affect any foreign laws or regulations that may otherwise be applicable and that provide additional protections to human ***subjects*** of ***research***.

(h) Notwithstanding paragraph (a) of this section, nothing in this section alters the previous obligation to comply with EPA regulations in this subpart that governed ***research*** involving intentional exposure of human ***subjects*** initiated prior to September 23, 2019 and that were in effect and applicable to such ***research*** at the time it was initiated.§ 26.1102Definitions.

(a) Administrator means the Administrator of the Environmental Protection Agency (EPA) and any other officer or employee of EPA to whom authority has been delegated.

(b) Common Rule refers to the Federal Policy for the Protection of Human ***Subjects*** as established in 1991 and codified by EPA and 14 other Federal departments and agencies (see the Federal Register issue of June 18, 1991 (56 FR 28003)) and its subsequent revisions as adopted by EPA and other federal departments and agencies (see the Federal Register issue of January 19, 2017 (82 FR 7149)). The Common Rule contains a widely accepted set of standards for conducting ethical ***research*** with human ***subjects***, together with a set of procedures designed to ensure that the standards are met. Once codified or adopted by a Federal department or agency, the requirements of the Common Rule apply to ***research*** conducted or sponsored by that Federal department or agency. EPA's codification of the Common Rule appears in 40 CFR part 26, subpart A.

(c) Federal department or agency refers to a federal department or agency (the department or agency itself rather than its bureaus, offices or divisions) that takes appropriate administrative action to make the Common Rule applicable to the ***research*** involving human ***subjects*** it conducts, supports, or otherwise regulates (e.g , the U.S Department of Health and Human Services, the U.S Department of Defense, or the Central Intelligence Agency).

(d)(1) Human ***subject*** means a living individual about whom an investigator (whether professional or student) conducting ***research***:

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens, or

(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

(2) Intervention includes both physical procedures by which information or biospecimens are gathered (e.g , venipuncture) and manipulations of the ***subject*** or the ***subject***'s environment that are performed for ***research*** purposes.

(3) Interaction includes communication or interpersonal contact between investigator and ***subject***.

(4) Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g , a medical record).

(5) Identifiable private information is private information for which the identity of the ***subject*** is or may readily be ascertained by the investigator or associated with the information.

(6) An identifiable biospecimen is a biospecimen for which the identity of the ***subject*** is or may readily be ascertained by the investigator or associated with the biospecimen.

(e) Institution means any public or private entity or agency (including federal, state, and other agencies).

(f) IRB means an institutional review board established in accord with and for the purposes expressed in this part.

(g) IRB approval means the determination of the IRB that the ***research*** has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

(h) Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the ***research*** are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(i) Person means any person, as that term is defined in FIFRA section 2(s) (7 U.S.C 136), except:

(1) A Federal agency that is ***subject*** to the provisions of the Federal Policy for the Protection of Human ***Subjects*** of ***Research***, and

(2) A person when performing human ***research*** supported by a federal agency covered by paragraph (i)(1) of this section.

(j) Pesticide means any substance or mixture of substances meeting the definition in 7 U.S.C 136(u) (Federal Insecticide, Fungicide, and Rodenticide Act, section 2(u)).

(k) ***Research*** means a systematic investigation, including ***research***, development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute ***research*** for purposes of this subpart, whether or not they are considered ***research*** for other purposes. For example, some demonstration and service programs may include ***research*** activities.

(l) ***Research*** involving intentional exposure of a human ***subject*** means a study of a substance in which the exposure to the substance experienced by a human ***subject*** participating in the study would not have occurred but for the human ***subject***'s participation in the study.

(m) Written, or in writing, for purposes of this subpart refers to writing on a tangible medium (e.g , paper) or in an electronic format.§ § 26.1103-26.1106[Reserved]§ 26.1107IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of ***research*** activities that are presented for its approval. The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human ***subjects***. The IRB shall be able to ascertain the acceptability of proposed ***research*** in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews ***research*** that involves a category of ***subjects*** vulnerable to coercion or undue influence, such as prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of ***subjects***.

(b) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

(c) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(d) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(e) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.§ 26.1108IRB functions and operations.

(a) In order to fulfill the requirements of this subpart each IRB shall:

(1) Have access to meeting space and sufficient staff to support the IRB's review and recordkeeping duties;

(2) Prepare and maintain a current list of the IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications or licenses sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution, for example, full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant;

(3) Establish and follow written procedures for:

(i) Conducting its initial and continuing review of ***research*** and for reporting its findings and actions to the investigator and the institution;

(ii) Determining which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since previous IRB review;

(iii) Ensuring prompt reporting to the IRB of proposed changes in ***research*** activity, and for ensuring that investigators will conduct the ***research*** activity in accordance with the terms of the IRB approval until any proposed changes have been reviewed and approved by the IRB, except when necessary to eliminate apparent immediate hazards to the ***subject***.

(4) Establish and follow written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the Environmental Protection Agency of:

(i) Any unanticipated problems involving risks to human ***subjects*** or others or any instance of serious or continuing noncompliance with this subpart or the requirements or determinations of the IRB; and

(ii) Any suspension or termination of IRB approval.

(b) Except when an expedited review procedure is used (see § 26.1110), an IRB must review proposed ***research*** at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the ***research*** to be approved, it shall receive the approval of a majority of those members present at the meeting.§ 26.1109IRB review of ***research***.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all ***research*** activities covered by this subpart.

(b) An IRB shall require that information given to ***subjects*** as part of informed consent is in accordance with § 26.1116 The IRB may require that information, in addition to that specifically mentioned in § 26.1116, be given to the ***subjects*** when, in the IRB's judgment, the information would meaningfully add to the protection of the rights and welfare of ***subjects***.

(c) An IRB shall require documentation of informed consent in accordance with § 26.1117

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed ***research*** activity, or of modifications required to secure IRB approval of the ***research*** activity. If the IRB decides to disapprove a ***research*** activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(e) An IRB shall conduct continuing review of ***research*** requiring review by the convened IRB at intervals appropriate to the degree of risk, not less than once per year, except as described in paragraph (f) of this section.

(f)(1) Unless an IRB determines otherwise, continuing review of ***research*** is not required in the following circumstances:

(i) ***Research*** eligible for expedited review in accordance with § 26.1110;

(ii) ***Research*** that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:

(A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or

(B) Accessing follow-up clinical data from procedures that ***subjects*** would undergo as part of clinical care.

(2) [Reserved]

(g) An IRB shall have authority to observe or have a third party observe the consent process and the ***research***.§ 26.1110Expedited review procedures for certain kinds of ***research*** involving no more than minimal risk, and for minor changes in approved ***research***.

(a) The Secretary of HHS, has established, and published as a notice in the Federal Register, a list of categories of ***research*** that may be reviewed by the IRB through an expedited review procedure. The Secretary will evaluate the list at least every 8 years and amend it, as appropriate after consultation with other federal departments and agencies and after publication in the Federal Register for public comment. A copy of the list is available from the Office for Human ***Research*** Protections, HHS, or any successor office.

(b)(1) An IRB may use the expedited review procedure to review the following:

(i) Some or all of the ***research*** appearing on the list described in paragraph (a) of this section, unless the reviewer finds that the study involves more than minimal risk.

(ii) Minor changes in previously approved ***research*** during the period for which approval is authorized.

(2) Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the ***research***, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the ***research***. A ***research*** activity may be disapproved only after review in accordance with the non-expedited procedure set forth in § 26.1108(b).

(c) Each IRB that uses an expedited review procedure shall adopt a method for keeping all members advised of ***research*** proposals that have been approved under the procedure.

(d) The Administrator may restrict, suspend, terminate, or choose not to authorize an institution's or IRB's use of the expedited review procedure for ***research*** covered by this subpart.§ 26.1111Criteria for IRB approval of ***research***.

(a) In order to approve ***research*** covered by this subpart the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to ***subjects*** are minimized:

(i) By using procedures that are consistent with sound ***research*** design and that do not unnecessarily expose ***subjects*** to risk, and

(ii) Whenever appropriate, by using procedures already being performed on the ***subjects*** for diagnostic or treatment purposes.

(2) Risks to ***subjects*** are reasonable in relation to anticipated benefits, if any, to ***subjects***, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the ***research*** (as distinguished from risks and benefits of therapies ***subjects*** would receive even if not participating in the ***research***). The IRB should not consider possible long-range effects of applying knowledge gained in the ***research*** (e.g , the possible effects of the ***research*** on public policy) as among those ***research*** risks that fall within the purview of its responsibility.

(3) Selection of ***subjects*** is equitable. In making this assessment the IRB should take into account the purposes of the ***research*** and the setting in which the ***research*** will be conducted. The IRB should be particularly cognizant of the special problems of ***research*** that involves a category of ***subjects*** who are vulnerable to coercion or undue influence, such as prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective ***subject***, in accordance with, and to the extent required by § 26.1116

(5) Informed consent will be appropriately documented in accordance with § 26.1117

(6) When appropriate, the ***research*** plan makes adequate provision for monitoring the data collected to ensure the safety of ***subjects***.

(7) When appropriate, there are adequate provisions to protect the privacy of ***subjects*** and to maintain the confidentiality of data.

(b) When some or all of the ***subjects*** are likely to be vulnerable to coercion or undue influence, such as prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these ***subjects***.§ 26.1112Review by institution.

Research covered by this subpart that has been approved by an IRB may be ***subject*** to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the ***research*** if it has not been approved by an IRB.§ 26.1113Suspension or termination of IRB approval of ***research***.

An IRB shall have authority to suspend or terminate approval of ***research*** that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to ***subjects***. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the Administrator of EPA.§ 26.1114Cooperative ***research***.

In complying with this subpart, sponsors, investigators, or institutions involved in multi-institutional studies may use joint review, reliance upon the review of another qualified IRB, or similar arrangements aimed at avoidance of duplication of effort.§ 26.1115IRB records.

(a) An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all ***research*** proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to ***subjects***.

(2) Minutes of IRB meetings, which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving ***research***; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities, including the rationale for conducting continuing review of ***research*** that otherwise would not require continuing review as described in § 26.1109(f)(1).

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members in the same detail as described in § 26.1108(a)(2).

(6) Written procedures for the IRB in the same detail as described in § 26.1108(a)(3) and (4).

(7) Statements of significant new findings provided to ***subjects***, as required by § 26.1116(c)(5).

(8) The rationale for an expedited reviewer's determination under § 26.1110(b)(1)(i) that ***research*** appearing on the expedited review list described in § 26.1110(a) is more than minimal risk.

(9) Documentation specifying the responsibilities that an institution and an organization operating an IRB each will undertake to ensure compliance with the requirements of this subpart.

(b) The records required by this subpart shall be retained for at least 3 years, and records relating to ***research*** which is conducted shall be retained for at least 3 years after completion of the ***research***. The institution or IRB may maintain the records in printed form or electronically. All records shall be accessible for inspection and copying by authorized representatives of EPA at reasonable times and in a reasonable manner.§ 26.1116General requirements for informed consent.

(a) General. General requirements for informed consent, whether written or oral, are set forth in this paragraph and apply to consent obtained in accordance with the requirements set forth in paragraphs (b) and (c) of this section. Except as provided elsewhere in this subpart:

(1) Before involving a human ***subject*** in ***research*** covered by this subpart, an investigator shall obtain the legally effective informed consent of the ***subject***.

(2) An investigator shall seek informed consent only under circumstances that provide the prospective ***subject*** sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.

(3) The information that is given to the ***subject*** shall be in language understandable to the ***subject***.

(4) The prospective ***subject*** must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

(5)(i) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective ***subject*** in understanding the reasons why one might or might not want to participate in the ***research***. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

(ii) Informed consent as a whole must present information in sufficient detail relating to the ***research*** and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective ***subject***'s understanding of the reasons why one might or might not want to participate.

(6) No informed consent may include any exculpatory language through which the ***subject*** is made to waive or appear to waive any of the ***subject***'s legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

(b) Basic elements of informed consent. In seeking informed consent the following information shall be provided to each ***subject***:

(1) A statement that the study involves ***research***, an explanation of the purposes of the ***research*** and the expected duration of the ***subject***'s participation, a description of the procedures to be followed, and identification of any procedures that are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the ***subject***;

(3) A description of any benefits to the ***subject*** or to others that may reasonably be expected from the ***research***;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the ***subject***;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the ***subject*** will be maintained;

(6) For ***research*** involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the ***research*** and ***research subjects***' rights, and whom to contact in the event of a ***research***- related injury to the ***subject***;

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the ***subject*** is otherwise entitled, and the ***subject*** may discontinue participation at any time without penalty or loss of benefits to which the ***subject*** is otherwise entitled; and

(9) One of the following statements about any ***research*** that involves the collection of identifiable private information or identifiable biospecimens:

(i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future ***research*** studies or distributed to another investigator for future ***research*** studies without additional informed consent from the ***subject***, if this might be a possibility; or

(ii) A statement that the ***subject***'s information or biospecimens collected as part of the ***research***, even if identifiers are removed, will not be used or distributed for future ***research*** studies.

(c) Additional elements of informed consent. One or more of the following elements of information, when appropriate, shall also be provided to each ***subject***:

(1) A statement that the particular treatment or procedure may involve risks to the ***subject*** (or to the embryo or fetus, if the ***subject*** may become pregnant) that are currently unforeseeable;

(2) Anticipated circumstances under which the ***subject***'s participation may be terminated by the investigator without regard to the ***subject***'s consent;

(3) Any additional costs to the ***subject*** that may result from participation in the ***research***;

(4) The consequences of a ***subject***'s decision to withdraw from the ***research*** and procedures for orderly termination of participation by the ***subject***;

(5) A statement that significant new findings developed during the course of the ***research*** that may relate to the ***subject***'s willingness to continue participation will be provided to the ***subject***;

(6) The approximate number of ***subjects*** involved in the study;

(7) A statement that the ***subject***'s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the ***subject*** will or will not share in this commercial profit;

(8) A statement regarding whether clinically relevant ***research*** results, including individual ***research*** results, will be disclosed to ***subjects***, and if so, under what conditions; and

(9) For ***research*** involving biospecimens, whether the ***research*** will (if known) or might include whole genome sequencing (i.e , sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

(d) Elements of broad consent for the storage, maintenance, and secondary ***research*** use of identifiable private information or identifiable biospecimens. Broad consent for the storage, maintenance, and secondary ***research*** use of identifiable private information or identifiable biospecimens (collected for either ***research*** studies other than the proposed ***research*** or non-***research*** purposes) is permitted as an alternative to the informed consent requirements in paragraphs (b) and (c) of this section. Broad consent is only permitted for the purposes mentioned and may not be substituted for the elements of informed consent in paragraphs (b) and (c) of this section, as required for the intentional exposure ***research subject*** to this subpart. If the ***subject*** is asked to provide broad consent, in addition to providing the informed consent required in paragraphs (b) and (c), the following shall be provided to each ***subject***:

(1) The information required in paragraphs (b)(2), (3), (5), and (8) and, when appropriate, (c)(7) and (9) of this section;

(2) A general description of the types of ***research*** that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of ***research*** conducted;

(3) A description of the identifiable private information or identifiable biospecimens that might be used in ***research***, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct ***research*** with the identifiable private information or identifiable biospecimens;

(4) A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for ***research*** purposes (which period of time could be indefinite);

(5) Unless the ***subject*** will be provided details about specific ***research*** studies, a statement that they will not be informed of the details of any specific ***research*** studies that might be conducted using the ***subject***'s identifiable private information or identifiable biospecimens, including the purposes of the ***research***, and that they might have chosen not to consent to some of those specific ***research*** studies;

(6) Unless it is known that clinically relevant ***research*** results, including individual ***research*** results, will be disclosed to the ***subject*** in all circumstances, a statement that such results may not be disclosed to the ***subject***; and

(7) An explanation of whom to contact for answers to questions about the ***subject***'s rights and about storage and use of the ***subject***'s identifiable private information or identifiable biospecimens, and whom to contact in the event of a ***research***-related harm.

(e) Screening, recruiting, or determining eligibility. An IRB may approve a ***research*** proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective ***subjects*** without the informed consent of the prospective ***subject***, if either of the following conditions are met:

(1) The investigator will obtain information through oral or written communication with the prospective ***subject***, or

(2) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

(f) Preemption. The informed consent requirements in this subpart are not intended to preempt any applicable Federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that require additional information to be disclosed in order for informed consent to be legally effective.

(g) Emergency medical care. Nothing in this subpart is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, state, or local law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe).

(h) Additional information for ***subjects*** when ***research*** involves a pesticide. If the ***research*** involves intentional exposure of ***subjects*** to a pesticide, the ***subjects*** of the ***research*** must be informed of the identity of the pesticide and the nature of its pesticidal function.§ 26.1117Documentation of informed consent.

(a) Informed consent shall be documented by the use of a written consent form approved by the IRB and signed (including in an electronic format) by the ***subject***. A written copy shall be given to the ***subject***.

(b) The informed consent form may be either of the following:

(1) A written informed consent form that meets the requirements of § 26.1116 The investigator shall give the ***subject*** adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the ***subject***.

(2) A short form written informed consent form stating that the elements of informed consent required by § 26.1116 have been presented orally to the ***subject***, and that the key information required by § 26.1116(a)(5)(i) was presented first to the ***subject***, before other information, if any, was provided. The IRB shall approve a written summary of what is to be said to the ***subject***. When this method is used, there shall be a witness to the oral presentation. Only the short form itself is to be signed by the ***subject***. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary must be given to the ***subject***, in addition to a copy of the short form.§ § 26.1118-26.1122[Reserved]§ 26.1123Early termination of ***research***.

The Administrator may require that any project covered by this subpart be terminated or suspended when the Administrator finds that an IRB, investigator, sponsor, or institution has materially failed to comply with the terms of this subpart.§ 26.1124[Reserved]§ 26.1125Prior submission of proposed human ***research*** for EPA review.

Any person or institution who intends to conduct or sponsor human ***research*** covered by § 26.1101(a) shall, after receiving approval from all appropriate IRBs, submit to EPA prior to initiating such ***research*** all information relevant to the proposed ***research*** specified by § 26.1115(a), and the following additional information, to the extent not already included:

(a) A discussion of:

(1) The potential risks to human ***subjects***;

(2) The measures proposed to minimize risks to the human ***subjects***;

(3) The nature and magnitude of all expected benefits of such ***research***, and to whom they would accrue;

(4) Alternative means of obtaining information comparable to what would be collected through the proposed ***research***; and

(5) The balance of risks and benefits of the proposed ***research***.

(b) All information for ***subjects*** and written informed consent agreements as originally provided to the IRB, and as approved by the IRB.

(c) Information about how ***subjects*** will be recruited, including any advertisements proposed to be used.

(d) A description of the circumstances and methods proposed for presenting information to potential human ***subjects*** for the purpose of obtaining their informed consent.

(e) All correspondence between the IRB and the investigators or sponsors.

(f) Official notification to the sponsor or investigator, in accordance with the requirements of this subpart, that ***research*** involving human ***subjects*** has been reviewed and approved by an IRB.

7. Revise § 26.1302 to read as follows:§ 26.1302Definitions.

The definitions in § 26.1102 apply to this subpart as well.[FR Doc. 2019-15665 Filed 7-22-19; 8:45 am]BILLING CODE 6560-50-P

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