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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 26

[EPA–HQ–ORD–2018–0280; FRL-9987-01-ORD]

RIN 2080-AA13

Protection of Human Research Subjects

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: On January 19, 2017, the Environmental Protection Agency (EPA), acting in concert with other agencies, promulgated revisions to the "Common Rule," which is based on regulations for the protection of human research subjects originally promulgated by the Department of Health and Human Services (HHS) that were then revised and jointly adopted by multiple departments and agencies that conduct or support research involving human subjects. EPA's codification of these revisions is in 40 CFR part 26, subpart A. These revisions will go into effect 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 a discrepancy within some of these EPA-specific regulations. This proposed action is to harmonize the EPA-specific regulations with revisions to the Common Rule in order to resolve those discrepancies.

DATES: Comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-ORD-2018-0280, at http://www.regulations.gov. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from Regulations.gov. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (i.e. on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit http://www2.epa.gov/dockets/commenting-epa-dockets.

FOR FURTHER INFORMATION CONTACT: Tom Sinks, Director, Office of Science Advisor, Environmental Protection Agency, 1200 Pennsylvania Ave. N.W., Washington, D.C. 20460 (Mail Code: 8105R); telephone number: 202-560-3099; email address: sinks.tom@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. 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 proposing to amend subparts C, D, K, and M of its regulations relating to human research. These changes are intended to correct regulatory citation references in subparts C and D that have been rendered ineffective by the revisions to the Common Rule, 82 FR 7149 (Jan. 19, 2017), codified by EPA at 40 CFR part 26, subpart A, and to harmonize language in subpart K with those revisions, where appropriate. Finally, there is a single typographical error in subpart M that should be corrected while this action is being undertaken.

Subparts C and D refer back to provisions in the Common Rule codified at subpart A, and, in light of the revisions to the Common Rule, several numerical citations (i.e., regulatory reference numbers) in subparts C and D are no longer accurate and need to be updated.

Subpart K, in establishing a process for review of third-party research involving intentional exposure of human subjects, borrows heavily from the provisions contained in the previous version of the Common Rule. The proposed amendments would allow the Agency to align subpart K with the revised Common Rule and maintain consistency of Institutional Review Board (IRB) review between agency-conducted or agency-sponsored human research and third-party human research.

Failure to resolve these discrepancies will create confusion and, more seriously, potential compliance and/or legal liabilities for researchers, institutions, and sponsors who must follow EPA regulations. In the absence of the proposed revisions to EPA-specific subparts, there will effectively be two conflicting sets of regulations to follow, once the Common Rule changes are reflected in subpart A and compliance is required. These changes will reduce regulatory burdens and potential confusion among the regulated community about which standards to apply by

enhancing consistency among those standards. In addition, as discussed in the final rule amending the Common Rule, the proposed amendments would enhance protections for human subjects and improving consistency means that similar protections for human subjects apply, regardless of who is conducting the study.

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

The proposed rule described in this document is authorized under provisions of the following statutes that EPA administers. The proposed amendments to EPA's codification of the Common Rule and other provisions regarding first- and second-party research are authorized pursuant to 5 U.S.C. 301; the underlying Common Rule also cites to 42 U.S.C. 300v-1(b) as authority for the revisions to the Common Rule provisions. The proposed amendments to regulations governing 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 the following statutory provisions. Section 3(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizes EPA to regulate the distribution, sale, or use of any unregistered pesticide in any State "[t]o the extent necessary to prevent unreasonable adverse effects on the environment" (defined at FIFRA section 2(bb), in pertinent part, as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide"). 7 U.S.C. 136a(a) and 136(bb). In addition, section 25(a) of FIFRA authorizes EPA to "prescribe regulations to carry out the provisions of [FIFRA]." *Id*. at § 136w(a). Section 408(e)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FFDCA) authorizes the Administrator to issue a regulation establishing "general procedures and requirements to implement [Section 408]." 21 U.S.C. 346a(e)(1)(C).

EPA has also used the authority provided in section 201 of the Department of the Interior, Environment, and Related Agencies Appropriations Act, 2006, Public Law 109-54 (2006

Appropriations Act) to promulgate the subparts B through Q of EPA's regulations at part 26. Pub. L. No. 109-54, § 201, 119 Stat. 499, 531 (Aug. 2, 2005). In the 2006 Appropriations Act, Congress directed EPA to promulgate a rule on "third-party intentional dosing human toxicity studies for pesticides . . .", prohibiting the use of pregnant women, infants or children as subjects, consistent with the principles proposed in the 2004 report of the National Academy of Sciences on intentional human dosing and the principles of the Nuremberg Code, and establishing an independent Human Subjects Review Board. *Id*.

II. Background

A. Common Rule

In 1991, 15 federal departments and agencies, including EPA, adopted a set of regulations intended to create a uniform body of regulations across the federal government for the protection of human subjects involved in research. *See* 56 FR 28003 (June 18, 1991). Patterned after the regulations originally promulgated by HHS under 45 CFR part 46, this set of regulations was titled the "Federal Policy for the Protection of Human Subjects" and is commonly referred to as the "Common Rule." The Common Rule regulations were subsequently promulgated into each federal department's or agency's own set of regulations and implemented, and are enforced at the individual department or agency level. EPA codified the Common Rule provisions at 40 CFR part 26, subpart A.

A number of changes in research involving human subjects have occurred since the Common Rule was initially adopted in 1991. In 2011, the Office of the Secretary of HHS, in coordination with the Executive Office of the President's Office of Science and Technology Policy, published an advance notice of proposed rulemaking, seeking comment on areas where revisions to the Common Rule might be warranted. *See* 76 FR 44512 (Jul. 26, 2011). Then in 2015, HHS and the other Common Rule agencies issued a notice of proposed rulemaking,

proposing and seeking comment on several potential regulatory revisions to the Common Rule. *See* 80 FR 53931 (Sept. 8, 2015).

On January 19, 2017, all Common Rule agencies and departments, including EPA, adopted several revisions intended to "modernize, strengthen, and make [the Common Rule] more effective". *See* 82 FR 7149 (Jan. 19, 2017). The preamble to the final rule noted that the revisions are "intended to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators." *Id*. In brief, the January 2017 revisions 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 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. There are currently 20 Federal agencies and departments that are signatories or have otherwise adopted the Common Rule.

The January 19, 2017 rule stated that its effective date and compliance date would be January 19, 2018, with the exception of one section (§ .114(b) (cooperative research)), which would have a compliance date of January 20, 2020. *Id*. at 7274. The effective date and January 19, 2018 compliance date were delayed until July 19, 2018, through an interim final rule. *See* 83 FR 2885 (Jan. 22, 2018). Further delay of the compliance date until January 21, 2019, was proposed in a notice of proposed rulemaking, *see* 83 FR 17595 (Apr. 20, 2018), and finalized on June 19, 2018. *See* 83 FR 28497.

B. EPA's Human Studies Subparts

In addition to the Common Rule (subpart A), EPA has adopted several additional subparts to the rule at 40 CFR 26 that provide enhanced protection for participants in human research conducted or supported by EPA, or certain types of third party research. These EPA-specific subparts were added in 2006 in response to a Congressional mandate. *See* EPA, Protections for Subjects in Human Research, 71 FR 6138 (Feb. 6, 2006). Specifically, Congress prohibited EPA use of certain appropriated funds until EPA issued a rule on the subject of EPA's acceptance, consideration, or reliance on third-party intentional dosing human toxicity studies for pesticides. Congress mandated three requirements for EPA's rule: (1) prohibit the use of pregnant women, infants or children as subjects; (2) be consistent with the principles proposed in the 2004 report of National Academy of Sciences "Intentional Human Dosing Studies for EPA Regulatory Purposes: Scientific and Ethical Issues" and the principles of the Nuremberg Code; and (3) establish an independent Human Subjects Review Board. *See* Pub. L. No. 109-54.

In accordance with that mandate, EPA created several regulatory subparts in addition to subpart A. Subparts B through D govern research conducted or sponsored by EPA involving pregnant or nursing women and children. Specifically, subpart B categorically prohibits any EPA-conducted or EPA-sponsored research involving intentional exposure to any substance of human subjects who are children or pregnant or nursing women; subparts C and D provide extra protections for pregnant women and for children who are the subjects of observational research conducted or supported by EPA.

EPA also created several subparts, K through Q, governing third-party pesticide research and EPA's reliance on research involving intentional exposure of human subjects. EPA concluded that it was appropriate to apply equivalent ethical standards to EPA-conducted and EPA-sponsored research, as well as to third-party research and thus in subpart K, extended the

Common Rule provisions to third-party human research involving intentional exposure of non-pregnant, non-nursing adults relevant to pesticide regulatory decision-making. *See* 70 FR 53838, 53845 (Sept. 12, 2005). EPA copied the requirements from the Common Rule into a new subpart K with a parallel numbering system to the Common Rule, making minor modifications that reflected the more limited set of human research subject to subpart K. For a discussion of those minor modifications, *see* 71 FR at 6147. The other subparts prohibited use of pregnant or nursing women or children as human subjects in third-party research involving intentional exposure (subpart L); established requirements for submission of information on the ethical conduct of completed human research (subpart M); established provisions to address noncompliance of an IRB or institution (subpart O); established a Human Studies Review Board (HSRB) and standards for EPA and HSRB review of proposed and completed research involving intentional exposure (subpart P); and standards for EPA reliance on such studies (subpart Q).

Additional modifications to subparts K through Q were made in 2013. Among those modifications were broadening its applicability to decision-making outside the scope of the pesticide laws and eliminating the option for a "legally authorized representative" to provide informed consent for a human subject within the context of third-party research involving intentional exposure to pesticides or submitted for pesticide decision making. *See* 78 FR 10538, 10538-39 (Feb. 14, 2013).

IV. Proposed Amendments and Request for Comment

This section of the preamble provides a description of the proposed changes to subparts C, D, K, and M. In sum, the rationale for revisions to subparts C, D, and K is to ensure consistency with the revisions to 40 CFR part 26, subpart A, i.e., the Common Rule; the rationale for the revision to subpart M is to correct a minor typographical error.

A. Harmonizing Subparts C and D with the Revised Common Rule

Subpart C: Subpart C, which sets forth additional protections for pregnant women and fetuses involved as subjects in observational research conducted or supported by EPA, refers back to subpart A in several provisions. First, the text at § 26.301(b) provides that the exemptions found in the Common Rule are applicable to the observational research studies covered by subpart C. The purpose of these exemptions is to provide a mechanism to allow for the conduct of research that is of such low risk that full IRB review and related processes are not warranted and would only serve to inhibit research without adding meaningful protections for human subjects. Recognizing this, the Common Rule pre-emptively identifies several categories of research (including much educational and social science research, simple surveys, and use of existing data or records) that are exempt from the full set of regulatory requirements that follow. In the revised Common Rule, the exempt categories were revised and expanded and moved to a different section number. Without a regulatory correction, EPA's regulations would no longer reference the section describing exempt research. Thus, a study involving an innocuous survey would no longer be eligible for exemption, and EPA researchers or grantees for such studies would need to comply with the full requirements of the Common Rule, in contrast to other federal agencies and grantees, which would be able to proceed with such research outside the scope of the Common Rule.

The second change required to subpart C is found in § 26.301(c), which refers back to the general provisions of the Common Rule. The revised Common Rule contains several new provisions, including a new reference to tribal laws in the preemption provision of the Common Rule found at § 26.101(f). EPA had initially added a provision to its subpart clarifying that tribal laws are not preempted, but this addition is no longer

necessary, with updates to the Common Rule. Specifically, the revised Common Rule provides that: "This policy 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*)." (Emphasis added). The italicized language is new, and renders redundant and unnecessary EPA's previous statement to the same effect. In addition, the Common Rule contains new provisions on the effective and compliance dates of the revised Common Rule and severability, that must also be included in subpart C for consistency in implementation.

Subpart D: Like subpart C, subpart D also incorporates by reference the exemptions found in subpart A. Specifically, § 26.401(b) lists the applicable exemptions in subpart A that are also applicable to subpart D. Unlike subpart C, however, subpart D, which provides additional protections for children involved as subjects in observational research conducted or supported by EPA, provides that the Common Rule exemption for research involving survey or interview procedures or observations of public behavior does not apply to research covered by subpart D, except in limited circumstances. Changes to the relevant section numbers are needed to preserve access to the exemptions incorporated by reference, as well as the provision limiting the application in research involving children. In addition, changes are needed to § 26.401(a) and (c), respectively, to remove the now-unnecessary clarification regarding preemption of tribal laws and to include reference to the new general provisions in the Common Rule, including the effective date information provision.

In practice, failing to amend subparts C and D, especially with respect to ensuring that the applicable exemptions in subpart A are accurately incorporated by reference, would greatly complicate the conduct of the above types of studies that have little to no risk, without

commensurate benefit for their subjects. It would also place EPA at odds with the scientists and institutions conducting EPA-sponsored research, and their IRBs that review the studies, all of whom will be applying the new Common Rule.

B. Harmonizing Subpart K with the Revised Common Rule

As noted above, when establishing new regulations for third-party research in 2006, EPA determined that it was appropriate to extend the Common Rule provisions to third-party research, so that equivalent ethical standards were applied to both research conducted and supported by EPA and by third parties. *See* 70 FR at 53845. At the same time, EPA narrowed the extension of the Common Rule provisions by limiting the scope of subpart K to third-party research involving intentional exposure of human subjects to pesticides and intended to be submitted to EPA under the pesticide laws and made minor modifications to those provisions to reflect the narrower scope of studies in subpart K. *See id*.

With the adoption of revisions to the Common Rule, EPA believes that many of the Common Rule revisions should again be extended to subpart K for the same reasons that EPA adopted Common Rule provisions for the original subpart K. The Common Rule amendments, as noted above, are intended to accommodate changes in the field of human research and to better protect human subjects, while facilitating research and reducing burden and delay. Those revisions can similarly apply to research subject to subpart K. EPA continues to believe that it is appropriate for third-party research to be held to equivalent ethical standards as research conducted or supported by EPA. In addition, EPA recognizes the efficiencies in having equivalent or similar standards for regulating the ethical conduct of research involving human subjects, regardless of who conducts that research, and the confusion that might arise if standards are different. Many investigators and their IRBs will be following the revised Common Rule in non-EPA research and in EPA-sponsored research. Increased variability in standards will likely

impose greater burden on the regulated community to keep straight and apply the different standards for review of 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.

Accordingly, EPA proposes to adopt the revisions finalized for the Common Rule in January 19, 2017, with a few exceptions that are not relevant or appropriate given the scope of subpart K. The same considerations that informed the original drafting of subpart K and the reasons for the 2013 revisions, as mentioned above, inform the harmonization of subpart K with the applicable provisions of the revised Common Rule. As with the original drafting of subpart K, there are some elements of the broader Common Rule that are not applicable to the particular subset of research subject to EPA's subpart K, and inclusion of these provisions would be confusing and problematic. These exceptions include definitions that did not apply to third-party studies; categories of exempt research that are not relevant to third-party studies; requirements for Federal Register notifications that would be redundant with the HSRB process; references to research involving pregnant women, fetuses or children that would not be allowed under subpart L; and provisions for alteration or waiver of informed consent. For various reasons, these provisions would generally not be appropriate or permissible for intentional exposure studies, so those provisions are not included in the proposed amendments to subpart K. EPA already determined that waiver of informed consent and consent by legally authorized representative are not appropriate for intentional exposure studies, nor would such studies be eligible for exemption, so these options are not offered under subpart K. *See* 71 FR at 6148; 76 FR at 5744-45.

EPA is proposing to adopt the broad consent provisions, which were newly added in the revised Common Rule, with a clarifying statement. There was concern that the Common Rule

reference to broad consent as an "alternative" to the informed consent requirements might lead to mistaken use as a replacement for, rather than an adjunct to, full informed consent. Because this would never be appropriate for an intentional exposure study of the type regulated under this EPA-specific subpart, a statement was added to clarify and confirm that the option to obtain broad consent for the limited purposes of storage, maintenance and secondary research use of identifiable private information or identifiable biospecimens is not a replacement for obtaining full informed consent for the primary research involving intentional exposure of a human subject that is subject to subpart K.

Another similarity with the Common Rule revisions is that EPA intends that the proposed amendments to subpart K to apply prospectively, i.e., to research subject to subpart K that is initiated after the final rule goes into effect. As such, EPA proposes to replace the date in section 26.1101(a) with the date the final rule becomes effective. This revision would not eliminate the prior obligation any third-party had to comply with subpart K if it was conducting or sponsoring research involving intentional exposure to human subjects covered by subpart K that was initiated prior to that date; such research would have had to comply with the EPA regulations in effect at the time the research was initiated. Clarity on this point is significant because, in contrast to other Common Rule agencies, EPA's regulations also require a retrospective analysis of completed research involving intentional exposure to human subjects before EPA may rely on any such research. Specifically, section 26.1705 of EPA's regulations applies to research that was subject to EPA's rules "at the time it was conducted" and requires that EPA determine, among other things, that certain completed research involving intentional exposure of human subjects was conducted in substantial compliance with "[a]ll applicable provisions of subparts A through L…." 40 CFR 26.1705. It is important to be clear about the scope of research subject to this retrospective review and to ensure that the research subject to the retrospective review is

evaluated under the appropriate standards. To avoid the misinterpretation that subpart K no longer applies to research initiated before the effective date of the final rule and to avoid the retrospective application of newer regulatory requirements, EPA is proposing to add a new paragraph (h) to § 26.1101, clarifying that research initiated before the effective date of the final rule would be subject to the standards of EPA's regulations that were in effect at the time the research was initiated.

C. Correcting Error in Subpart M

The existing text at 40 CFR 26.1302 reads, "[t]he definitions in § 26.102 apply to this subpart as well." EPA is proposing to amend this text to reference the definitions in subpart K, which are found at § 26.1102, instead of the definitions in subpart A, found at § 26.102. With the exception of subpart M, all EPA subparts from L to Q refer to the definitions in subpart K, which include terms necessary and relevant to these EPA-specific subparts. Subpart M was intended to reference the same set of definitions. *See* 71 FR at 6147 (indicating that definition in section 26.1102 was intended to apply to subpart M). This was a typographical error at the time of original drafting, which EPA is proposing to correct.

V. FIFRA Review Requirements

In accordance with FIFRA section 25(a), EPA has submitted a draft of the proposed rule to the FIFRA Scientific Advisory Panel (SAP), the Secretary of Agriculture (USDA), and appropriate Congressional Committees. The SAP waived its review on June 4, 2018. USDA responded on July 3, 2018 and had no substantive comments on the proposal. Both responses are in the docket for this rulemaking.

VI. 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

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. Any changes made in response to OMB recommendations have been documented in the docket for this rulemaking as required by the Executive Order.

The incremental costs of these proposed amendments both to industry and to EPA are expected to be negligible, including the costs to industry related to informed consent documentation and the cost to EPA of reviewing research submitted under the revised subpart K requirements. Entities who would be impacted by the proposed amendments have already been accounted for in previous economic analyses for the revised Common Rule and the 2006 and 2013 EPA rulemakings concerning human subjects research. EPA has not, therefore, prepared a new economic analysis for this rulemaking. The cost estimates for complying with the 2006 rule were incremental costs of $39,000 for industry and $808,000 for EPA (71 FR at 6166), and the costs for the 2013 amendments were estimated to be negligible (76 FR at 5751). The costs and benefits associated with implementing these proposed amendments, particularly those linked to IRBs, have already been captured by the economic analysis for the Common Rule. The costs for this rule include costs for some additional parties, i.e., third-party investigators, who may need to spend some time familiarizing themselves with the new requirements, but these costs will be negligible[11] and outweighed by the benefits to the regulated community of having consistent standards applied to third-party studies. In addition to providing equally protective ethical

[1] The revised Common Rule economic analysis, which included more revisions than proposed in this document, estimated that affected individuals would spend five hours to familiarize themselves with the changes. *See* 82 FR at 7238.

standards to the human subjects of third-party intentional exposure research, the benefits of greater consistency will improve efficiencies in the oversight and review of human research, improve understanding of the standards that apply, and reduce the potential for misapplication of standards. This proposal provides no basis on which to revise the cost estimates that were provided in the economic analysis for the 2006 rulemaking or those most recently provided in the 2013 renewal of the Information Collection Request (ICR) for the existing regulation at 40 CFR part 26.

B. Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs

This action is not expected to be subject to Executive Order 13771 because this proposed rule is expected to result in no more than *de minimis* costs.

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" (Jan. 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 proposed 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 proposed amendments.

List of Subjects in 40 CFR Part 26

Environmental protection, Administrative practice and procedures, Human research, Pesticides and pests.

Dated: November 16, 2018.

Andrew R. Wheeler,
Acting Administrator.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 26—[AMENDED]

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 (d)(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].

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).

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6. Revise subpart K, consisting of §§26.1101 through 26.1125, to read as follows:

PART 26 – PROTECTION OF HUMAN RESEARCH SUBJECTS

Subpart K - BASIC ETHICAL REQUIREMENTS FOR THIRD-PARTY HUMAN RESEARCH FOR PESTICIDES INVOLVING INTENTIONAL EXPOSURE OF NON-PREGNANT, NON-NURSING ADULTS

Sec.

26.1115 IRB records

26.1116 General requirements for informed consent

26.1117 Documentation of informed consent

26.1118-26.1122 [Reserved]

26.1123 Early termination of research

26.1124 [Reserved]

§26.1125 Prior submission of proposed human research for EPA review

§26.1101 To 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 [effective date for final rule] 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), 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 [effective date of final rule] and that were in effect and applicable to such research at the time it was initiated.

§26.1102 Definitions.

(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]

§26.1107 IRB 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.

§26.1108 IRB 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.

§26.1109 IRB 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.

§26.1110 Expedited 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.

§26.1111 Criteria 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.

§26.1112 Review 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.

§26.1113 Suspension 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.

§26.1114 Cooperative 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.

§26.1115 IRB 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.

§26.1116 General 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 paragraph (b) and (c), the following shall be provided to each subject:

(1) The information required in paragraphs (b)(2), (b)(3), (b)(5), and (b)(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.

§26.1117 Documentation 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]

§26.1123 Early 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]

§26.1125 Prior 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:

§ 26.1302 Definitions.

The definitions in § 26.1102 apply to this subpart as well.

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