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Elimination of Institutional Review Board (IRB) Review of Research Applications and Proposals: 2018 Requirements

NOTE: This guidance is consistent with the 2018 Requirements (the revised Common Rule) effective July 19, 2018.

Draft

This guidance, when finalized, will represent the Office for Human Research Protections's (OHRP's) current thinking on this topic. This guidance does not create or confer any rights for or on any person and does not operate to bind OHRP or the public. OHRP guidance should be viewed as recommendations unless specific regulatory requirements are cited. The use of the word "must" in OHRP guidance means that something is required under the Department of Health and Human Services (HHS) regulations at 45 CFR part 46. The use of the word "should" in OHRP guidance means that something is recommended or suggested, but not required. An institution may use an alternative approach if the approach satisfies the requirements of 45 CFR part 46. OHRP is available to discuss alternative approaches by telephone at 240-453-6900 or 866-447-4777, or by email at ohrp@hhs.gov.

Date: July 19, 2018

Scope:

This guidance document applies to nonexempt research involving human subjects that is conducted or supported by HHS. It provides guidance on the elimination of the requirement in the pre-2018 Requirements (45 CFR 46.103(f)), that each application or proposal for research undergo IRB review and approval as part of the certification process. This guidance also affirms the requirement in the 2018 Requirements for certification of each proposed research study prior to initiation.

Target Audience:

Institutions, IRBs, investigators, HHS funding agencies, and others that may be responsible for the review, conduct, or oversight of nonexempt research involving human subjects conducted or supported by HHS.

Regulatory Background:

The term "pre-2018 Requirements" in this document refers to the Common Rule as published in the 2016 edition of the Code of Federal Regulations (i.e., the Federal Policy for the Protection of Human Subjects, originally published on June 18, 1991 and subsequently amended on June 23, 2005).^[1]

The term "2018 Requirements" in this document means the Federal Policy for the Protection of Human Subjects requirements published in the Federal Register on January 19, 2017 (82 FR 7149) and further amended on January 22, 2018 (83 FR 2885) and June 19, 2018 (83 FR 28497).^[2] The 2018 Requirements may also be referred to as the "revised Common Rule."

The 2018 Requirements for the protection of human subjects at 45 CFR part 46 include several provisions pertinent to certification, including the following:

"Certification means the official notification by the institution to the supporting Federal department or agency component, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance." (45 CFR 46.102(a))

Note: The Federalwide Assurance (FWA) is the only type of assurance that OHRP approves.

"Certification is required when the research is supported by a federal department or agency and not otherwise waived under 45 CFR 46.101(i) or exempted under 45 CFR 46.104. For such research, institutions must certify that each proposed research study covered by the assurance and 45 CFR 46.103 has been reviewed and approved by the IRB. Such certification must be submitted as prescribed by the federal department or agency component supporting the research. Under no condition shall research covered by 45 CFR 46.103 be initiated prior to receipt of the certification that the research has been reviewed and approved by the IRB." (45 CFR 46.103(d)).

Guidance

Pre-2018 Requirements:

The pre-2018 Requirements at 45 CFR 46.103(f) require an institution with an approved assurance to certify to HHS that each application or proposal covered by an OHRP-approved assurance and by 45 CFR 46.103 has been reviewed and approved by the IRB – that is, the research grant application and/or proposal submitted to an HHS component. Such certifications must be submitted with the application or proposal or by such later date as may be prescribed by the department or agency to which the application or proposal is submitted (45 CFR 46.103(f) of the pre-2018 Requirements).

2018 Requirements:

The 2018 Requirements eliminate the requirement in the pre-2018 Requirements that grant applications or proposals for research undergo IRB review and approval for the purpose of certification. Experience suggests that review and approval of the application or proposal is not a productive use of IRB time. Elimination of that requirement is not expected to reduce protections for human subjects because the research study (e.g. a research protocol) would remain subject to the requirement for IRB review and approval, assuming that an HHS component funds the research.

The 2018 Requirements at 45 CFR 46.103(d) require certification when the research is supported by HHS, and applicability of the regulations is not otherwise waived under 45 CFR 46.101(i) or the study is not exempted under 45 CFR 46.104. For such research, institutions must certify that each proposed research study covered by an OHRP-approved assurance and by 45 CFR 46.103 has been reviewed

and approved by an IRB. Such certification must be submitted as prescribed by the federal department or agency component supporting the research. Under no condition shall research covered by 45 CFR 46.103 be initiated prior to receipt by HHS of the certification that the research has been reviewed and approved by the IRB.

Thus, for research to which the 2018 Requirements apply, the IRB must review and approve such research (e.g., a research protocol) for certification; however, the IRB no longer is required to review and approve the research grant application or proposal.

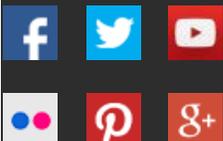
If you have specific questions about how to apply this guidance, please contact OHRP by phone at (866) 447-4777 (toll-free within the United States) or (240) 453-6900, or by e-mail at ohrp@hhs.gov.

[1] The pre-2018 Requirements can be viewed at the following Government Printing Office link: <https://www.gpo.gov/fdsys/pkg/CFR-2016-title45-vol1/pdf/CFR-2016-title45-vol1-part46.pdf> - PDF

[2] 82 FR 7149, available at: <https://www.gpo.gov/fdsys/pkg/FR-2017-01-19/pdf/2017-01058.pdf> - PDF, 83 FR 2885, available at: <https://www.gpo.gov/fdsys/pkg/FR-2018-01-22/pdf/2018-00997.pdf> - PDF, 83 FR 28497, available at <https://www.gpo.gov/fdsys/pkg/FR-2018-06-19/pdf/2018-13187.pdf> - PDF.

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