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Expression of Concern

Agency Information Collection Request; 30-Day Public Comment Request

A Notice by the Health and Human Services Department on 07/20/2026

Document Identifier: OS-0990-0279 · 91 FR 45279 · Document Number 2026-14537 · Pages 45279–45280

AGENCY: Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health (OASH), Office of the Secretary, HHS

[This comment addresses, inter alia, the purposes of the Paperwork Reduction Act at 44 U.S.C. 3501 and 5 CFR 1320.1; 45 CFR 46.107, 46.108(a)(2), 46.109(d), 46.115, and 46.501–46.505; 21 CFR 56.107 and 56.115; and the burden-estimation requirements at 44 U.S.C. 3506(c) and 5 CFR 1320.8]

Context

On July 20, 2026, the Department of Health and Human Services published a 30-day Paperwork Reduction Act notice announcing that OHRP and FDA have submitted to the Office of Management and Budget a request for reinstatement with changes of OMB No. 0990-0279, the HHS Registration of an Institutional Review Board Form. The single substantive change is the removal of the IRB membership roster from the registration form.

- **The full text of the Federal Register notice is below.**
- **The notice offers two justifications:** that removal constitutes "a burden reducing change," and that it "will align the IRB registration form with the 2018 Requirements at 45 CFR 46.103." We understand that the collection lapsed on June 30, 2025 and has been without valid OMB clearance for approximately fourteen months.
- **The public comment channel is reginfo.gov, not regulations.gov.** There is no public docket, no publicly visible comment record, and no mechanism by which one commenter can see another's submission. We observe that as of August 6, 2026 the Federal Register page recorded 321 page views.
- **GE2P2 Global's mission is to advance scientific rigor, ethical resilience, and integrity in research and evidence generation across the sciences**. Our standing posture is to [1] scrutinize closely any regulatory or administrative action that is potentially or demonstrably corrosive to the bulwark of norms, laws, regulations supporting human subjects protection, [2] to register and publish those instances and the associated assessment, and [3] to respond appropriately. In this sense, "corrosive" actions are not announced as such. They are, more typically, presented as modest, technical, and burden-reducing: their consequences are often cumulative, often fall on parties who are not counted as respondents, and become apparent only after a point at which they can readily be reversed. We assess the present notice to be an instance of that pattern – triggering this analysis and response.
- **Unlike most matters on which GE2P2 Global comments, this action has generated no discoverable public analysis.** We were unable to identify any journal commentary, professional-society statement, institutional guidance, or trade analysis addressing this change — notwithstanding that the same community responded promptly and in detail to OHRP's March 2026 revision of the Federalwide Assurance form. We therefore present original analysis which does not benefit from other, independent sources. of aligned sources. We note the absence of a public record as itself a matter of concern.

- **We supervised a structured inquiry using *Claude.ai* to assemble and verify the primary regulatory record**, the burden-estimate history across this docket, and the adjacent federal oversight literature. All primary sources are cited in the bibliography and are independently verifiable.
- **Our analysis identified thirteen concerns arising from this notice,** but we focus here only on those most substantive to our posture stated above. They are presented in three clusters: those bearing on human subjects protection, transparency and the evidence base; those bearing on the structural sequence of which this action forms part; and those bearing on administrative and procedural deficiencies in the instrument itself.

GE2P2 Global – Requested Actions

GE2P2 Global urges the Office of Management and Budget, OHRP, and FDA, in their respective capacities, to:

[1] decline to approve this Information Collection Request as submitted, pending correction of the record described below;

[2] analyze and publish the practical utility forgone — the first question the Paperwork Reduction Act requires — including the compliance-oversight and research uses of the IRB registry that OHRP has itself documented;

[3] retain collection of the IRB membership roster, which respondents are already required to prepare and maintain and which is submitted through an entirely electronic channel; and, if names are nonetheless to be removed, adopt as an irreducible minimum an attestation of compliance with 45 CFR 46.107 and 46.108(a)(2) at registration and renewal, together with aggregate member counts by category (scientist, nonscientist, unaffiliated) and by sex, published annually in machine-readable form. The software deployment the notice already contemplates is the occasion on which such a field can be added at negligible marginal cost, which is a direct answer to the fourth question on which comment is invited;

[4] obtain independent, external review and before implementation — which, absent SACHRP, now requires recourse to non-federal bodies — and disclose the relationship between this request and the March 2026 revision of the Federalwide Assurance form;

[5] correct and reconcile the burden estimate across the three notices in this docket, and isolate the burden actually attributable to roster removal;

[6] state publicly the disposition of roster records already held for approximately 4,988 registered IRBs; disclose how those records have been used and by whom, including the data requests OHRP reports having fulfilled for research about IRBs; and preserve the 2009–2026 composition series as a documented research dataset rather than permitting its destruction; and

[7] justify the prioritization of this particular burden reduction. OHRP conducts three to four routine inspections annually against approximately 2,300 IRBs, carries unimplemented GAO recommendations, and has sustained substantial loss of expert staff. The agency should explain why scarce clearance and software-development capacity is being applied to withdrawing a data element whose burden contribution is close to zero, in preference to the collections and functions on which its statutory responsibilities more evidently depend.

Contact: David R Curry, MS, President & CEO, GE2P2 Global Foundation, david.r.curry@ge2p2global.org

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Federal Register Notice [Full Text]

Agency Information Collection Request; 30-Day Public Comment Request

A Notice by the Health and Human Services Department on 07/20/2026
Document Identifier: OS-0990-0279 · 91 FR 45279 · Document Number 2026-14537 · Pages 45279–45280

AGENCY: Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health (OASH), Office of the Secretary, HHS

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on the ICR must be received on or before August 19, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice via www.reginfo.gov/public/do/PRAMain. Find this information collection by selecting “Currently under Review” and “Select Agency: Department of Health and Human Services”.

FOR FURTHER INFORMATION CONTACT: Natalie Klein, Natalie.Klein@hhs.gov or (240) 453-6900. If requesting information, please include the document identifier 0990-0279-30D and project title (Department of Health and Human Services (HHS) Registration of an Institutional Review Board Form) for reference.

SUPPLEMENTARY INFORMATION:

Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency’s functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Department of Health and Human Services (HHS) Registration of an Institutional Review Board Form.

Type of Collection: Reinstatement with changes OMB No. 0990-0279.

Abstract: The Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) are requesting reinstatement with changes for the Office of Management and Budget (OMB) No. 0990-0279, Department of Health and Human Services (HHS) Institutional Review Board (IRB) Registration Form. The previous information collection was approved by OMB on June 27, 2022, and expired on June 30, 2025. The request for reinstatement with changes involves implementing a burden reducing change. Specifically, OHRP is seeking to remove the IRB membership roster information collection from the IRB registration form. This change will align the IRB registration form with the 2018 Requirements at 45 CFR 46.103. The change, when implemented, is anticipated to result in a shorter, simplified IRB registration process for respondents. Updates to the software applications OHRP uses to manage IRB registration will be deployed to enable such changes.

The purpose of the form is to provide a simplified procedure for: (1) IRBs to satisfy the requirements for IRB registration at 45 CFR part 46, subpart E; and (2) IRBs in the United States (US) to satisfy the FDA requirements for IRB registration at 21 CFR 56.106. Institutions engaged in nonexempt human subjects research conducted or

supported by HHS, or another Common Rule department or agency, are required by the terms of the Federalwide Assurance (FWA) to rely upon only IRBs registered with OHRP for review of research to which the FWA applies. In this way, OHRP's FWA process, established pursuant to the requirements for assurances at 45 CFR 46.103, is linked to the regulatory requirements for IRB registration.

The respondents for this information collection are institutions or organizations operating IRBs that review human subjects research conducted or supported by HHS; or, in the case of FDA's requirements, each IRB in the United States that reviews clinical investigations regulated by FDA under sections 505(i) or 520(g) of the Federal Food, Drug and Cosmetic Act; and each IRB in the United States that reviews clinical investigations that are intended to support applications for research or marketing permits for FDA-regulated products. Many of the IRBs also review research conducted or supported by other Common Rule departments and agencies.

[Annualized Burden Hour Table: IRB Registration Form 0990-0279 · Institutions or Organizations that operate IRBs · 5,350 respondents · 1 response per respondent · 0.5 hours average burden per response · 2,675 total burden hours.]

The estimate of the number of respondents is based upon the current number of IRBs registered with HHS, approximately 4,988 (as of July 13, 2026), and projecting that the number of respondents may increase to 5,350. Of the approximately 4,988 registered IRBs, 100% submitted their registration information electronically. Of the 5,350 projected respondent IRBs, approximately 350 institutions or organizations are expected to submit IRB registration information for the first time, and nearly 5,000 institutions or organizations are expected to update or renew their existing IRB registration once each year. The burden is estimated to average 0.5 hours for both an initial IRB registration and for updating or renewing the registration of a previously registered IRB.

Catherine Howard, Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary. [FR Doc. 2026-14537 Filed 7-17-26; 8:45 am]

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GE2P2 Arguments/Concerns

Agency Information Collection Request; 30-Day Public Comment Request
Document Identifier: OS-0990-0279; 91 Fed. Reg. 45279 (July 20, 2026)

Arguments/concerns are presented in three clusters below, the most material first:

I. Consequences for human subjects protection, transparency, and the evidence base
II. Structural and cumulative context
III. Administrative, procedural, and record-keeping deficiencies

[See bibliography following for full citations under "documentary basis," and Appendix A for the burden series and selected full text]

I. Consequences for human subjects protection, transparency, and the evidence base

Concerns [A]–[F] address what the proposed removal costs, on whom those costs fall, and why they are not offset.

[A] Removal eliminates the only systematic basis for verifying statutory IRB composition requirements.

The composition requirements at 45 CFR 46.107 and 21 CFR 56.107 remain fully binding: at least five members of varying backgrounds; no IRB composed entirely of one profession; at least one member whose primary concerns are scientific and at least one whose primary concerns are nonscientific; at least one member not otherwise affiliated with the institution nor an immediate family member of someone so affiliated; and every nondiscriminatory effort to ensure that no IRB consists entirely of men or entirely of women. Sections 46.108(a)(2) and 46.115(a)(5), and 21 CFR 56.115(a)(5), continue to require that a current member list be prepared and maintained, identified by name, earned degrees, representative capacity, indications of experience, and any employment or other relationship with the institution — the fields bearing on conflict of interest. What ends is not the obligation but the federal collection of the record at registration and at triennial renewal. In particular, elimination of member qualification and sex data removes the only systematic means by which compliance with 46.107(b)–(d) can be assessed across the registry rather than one board at a time. The concern is amplified by the concentration of review under single-IRB requirements at 45 CFR 46.114(b) and the NIH single-IRB policy: the composition of a comparatively small number of boards now governs a large share of United States human subjects research.

Documentary basis: [7] 45 CFR 46.107, 46.108(a)(2), 46.115(a)(5); 21 CFR 56.107, 56.115(a)(5); 45 CFR 46.114(b); [8] Stidham (Jan/Feb 2024).

[B] The notice is silent on the practical utility of the collection it eliminates — utility OHRP has itself documented in print.

The Paperwork Reduction Act directs comment on "the necessity and utility of the proposed information collection." Where an agency proposes to cease collecting, the corresponding question is the utility forgone. The notice does not address it. OHRP has, however, addressed it elsewhere. Writing in NCURA Magazine in January 2024, a Program Specialist in OHRP's Division of Policy and Assurances stated that OHRP uses its IRB registry for compliance oversight activities, distribution of educational materials, and fulfilment of data requests for research about IRBs; that the registration form collects a membership roster; that the public may access some registration information online and request non-public registration information from OHRP; and that researchers have requested registration data in order to study the IRB enterprise, to the benefit of policymakers, institutions, and research participants. The same article confirms that removal will also eliminate collection of IRB member qualifications and sex. The agency has thus published a fuller and more candid account of this action than it has presented to OMB and to the public.

Documentary basis: [8] Stidham, NCURA Magazine (Jan/Feb 2024); [1] 91 FR 45279 (by omission).

[C] The change runs against standing federal recommendations to improve, not reduce, the evidence base on IRB effectiveness.

GAO-23-104721 made four recommendations, including that OHRP ensure the accuracy of data in its IRB registry, and, at Recommendation #4, that the Secretary ensures OHRP and FDA convene stakeholders to examine and implement approaches for measuring IRB effectiveness in protecting human subjects — expressly contemplating surveys of IRB members among such approaches. OHRP referred that recommendation to SACHRP, which delivered its response on October 19, 2023. A 2017 HHS Office of Inspector General report had earlier recommended that OHRP become more transparent about its compliance activities. Registry composition data is one of the few systematically collected inputs available to any such measurement effort, and the deficiency is longstanding: as Shamoo and Woeckner observed in 2006, there is no scientific data on the comparative quality of for-profit and non-profit IRBs, precisely because the framework discourages collection of the necessary information. Withdrawing composition data does not merely fail to advance these recommendations; it forecloses a line of inquiry the responsible agencies were directed to pursue.

Documentary basis: [9] GAO-23-104721; [10] SACHRP Recommendation, approved Oct. 19, 2023; [11] HHS OIG (2017), as reported at [12]; [17] Shamoo & Woeckner, PLoS Medicine (2006).

[D] The proposal does not eliminate burden; it transfers and multiplies it, disabling analysis of IRB composition and demographic trends.

The Paperwork Reduction Act measures burden borne by respondents — here, the institutions and organisations that operate registered IRBs. It does not measure burden imposed on anyone else. That convention conceals the principal practical effect of this proposal. At present, a researcher, policy analyst, accrediting body, or oversight authority seeking to examine IRB composition across the enterprise makes a single request to OHRP against a single standardised dataset; OHRP has confirmed that researchers do precisely this. Following removal, the same inquiry requires approach to as many as 4,988 institutions and organisations individually, each maintaining its roster in its own format under 45 CFR 46.108(a)(2), and none under any obligation to furnish it to anyone other than authorized representatives of the department or agency. What is presented as the saving of a half-hour per respondent is, in aggregate, the replacement of one tractable request with several thousand intractable ones.

For a substantial and growing share of the registered universe, the burden is not merely multiplied but rendered prohibitive. IRBs operated by private commercial entities are not subject to the Freedom of Information Act, and state open-records statutes reach only public institutions. For that sector the federal registry has been the sole systematic window onto board composition. It is the same sector that Senators Warren, Sanders and Brown asked the Government Accountability Office to examine in 2020, and on which GAO reported in 2023.

The temporal consequence is equally serious. Composition data has been collected through the registration system since 2009. Removal closes that series. Trend analysis of precisely the kind the field requires — the prevalence and persistence of genuinely unaffiliated members; the scientist and nonscientist balance; the sex distribution that 45 CFR 46.107(b) presupposes; and the comparative composition of institutional and independent boards — becomes impossible beyond the point of truncation, and no subsequent decision to resume collection can recover the interval. A modest administrative saving is thereby exchanged for the permanent loss of an evidentiary series that no other party is positioned to reconstruct.

Documentary basis: [7] 45 CFR 46.107(b), 46.108(a)(2), 46.115(b); 21 CFR 56.115(b); [8] Stidham (Jan/Feb 2024); [9] GAO-23-104721; [17] Shamoo & Woeckner (2006).

[E] Removal withdraws the basis on which investigators and participants can identify, question, or challenge the decision-makers who acted on them.

The concern at [D] is analytic and collective. This one is individual, and is not answered by aggregate reporting. Three regulatory provisions depend upon it being possible to know who sat on a given board.

First, 45 CFR 46.107(d) and 21 CFR 56.107(e) prohibit any member with a conflicting interest from participating in the initial or continuing review of a project, except to provide information the IRB requests. Section 46.108(a)(2) requires the member list to record each member's employment or other relationship with the institution — the field by which such an interest would be identified. Where no roster is collected and none is published, neither an investigator nor a participant can determine whether a conflicted member took part in the decision affecting them. The prohibition remains; the means of detecting its breach does not.

Second, 45 CFR 46.109(d) requires an IRB to notify investigators in writing of a decision to approve or disapprove, and, on disapproval, to state its reasons and give the investigator an opportunity to respond in person or in writing. That is the principal avenue of challenge available to a researcher whose protocol is refused. IRBs reviewing materially identical proposals reach materially different conclusions; an investigator responding to a refusal has a legitimate interest in knowing the composition and standing of the body refusing. A right to respond to a decision whose decision-makers are unidentified is attenuated.

Third, 45 CFR 46.115(a)(2) requires minutes recording attendance, the vote for, against and abstaining, the basis for requiring changes or disapproving research, and a summary of controverted issues. The record therefore exists — but under 46.115(b) it is reachable only by authorized representatives of the department or agency. Federal registration has been the one point at which composition was recorded outside that closed channel. Research participants, whose exposure to risk is the object of the entire apparatus, have no route to the identity of those who approved that exposure other than what the institution volunteers.

We recognise that this consideration stands in tension with the member-privacy interest acknowledged at [M]. The two are reconcilable: collection is not publication, and the question of what OHRP holds is separable from the question of what OHRP discloses and to whom. Ceasing to collect forecloses both, and forecloses the second by way of the first without ever addressing it.

Documentary basis: [7] 45 CFR 46.107(d), 46.108(a)(2), 46.109(d), 46.115(a)(2), 46.115(b); 21 CFR 56.107(e), 56.115(a)(5); [8] Stidham (Jan/Feb 2024).

[F] The oversight mechanism that would substitute for routine collection does not exist at the necessary scale.

Removing a data element from routine collection converts prospective, desk-level verification into retrospective, for-cause inspection. The Government Accountability Office has measured that capacity. In GAO-23-104721 (January 2023), issued at the request of Senators Warren, Sanders and Brown, GAO reported that OHRP officials aim to conduct three to four routine inspections annually, against approximately 2,300 United States IRBs overseen by HHS, and that neither OHRP nor FDA had conducted a risk-based assessment of its IRB inspection programme to determine whether an adequate number of IRBs is being inspected. Contemporaneous reporting establishes that OHRP's capacity has since contracted further, with an exodus of ethics expertise including the office's director. Three to four inspections per year is not a compensating control for the loss of a registry-wide data element. The notice does not identify any alternative mechanism, and does not appear to have considered whether one is required.

Documentary basis: [9] GAO-23-104721 (Jan. 17, 2023); [12] STAT (June 5, 2026); [13] STAT (Apr. 3, 2025).

II. Structural and cumulative context

Concerns [G]–[H] address the sequence of which this action forms part, and the absence of any body positioned to examine it.

[G] This is the fourth in a sequence of reductions to federal human subjects oversight effected through form revision rather than rulemaking.

Considered alone, roster removal is a modest administrative change. Considered in sequence, it is not. Within approximately eighteen months: SACHRP, the Secretary's standing advisory body on human research protections, was disbanded (March–April 2025); OHRP lost its director and a substantial share of its expert staff; the Federalwide Assurance form was revised effective March 2026 to remove the "check the box" option by which institutions voluntarily extended Common Rule protections — and with it OHRP's authority to evaluate

non-HHS-funded research at those institutions — and to eliminate the requirement that institutions designate one or more IRBs on the assurance; the Research Complaint Form was revised (91 FR 40546, July 2, 2026) to add elements requiring complainants to describe prior attempts at resolution and past submissions; and the IRB registration roster is now proposed for removal. Each step was framed as burden reduction. None proceeded by notice-and-comment rulemaking. Each attracted, at most, trade coverage. The cumulative effect is a material contraction of the federal human subjects oversight architecture accomplished through instruments that carry no obligation to analyse that effect.

Documentary basis: [5] OHRP FWA revision, OMB No. 0990-0278 (March 2026); [6] 91 FR 40546 (July 2, 2026); [13] STAT (Apr. 3, 2025); [12] STAT (June 5, 2026); [15] CITI Program (Mar. 2026); [16] Pearl IRB (Sept. 2025); [19] GE2P2 Global, Expression of Concern — Elimination of SACHRP (Apr. 23, 2025).

[H] No advisory or deliberative body now exists to examine the change before it takes effect.

Until March 2025, a proposal of this kind would have been susceptible to review by the Secretary's Advisory Committee on Human Research Protections — the body OHRP had itself asked, as recently as 2023, to advise on how IRB effectiveness should be measured, and which delivered that advice on October 19, 2023. SACHRP was disbanded before it could consider any of the four actions described at [G]. Its charter had been renewed on September 12, 2024 and would otherwise have run until October 1, 2026. GE2P2 Global documented that elimination at the time. The consequence is now concrete rather than abstract: a change with direct implications for the verification of statutory IRB composition requirements is proceeding to OMB with no federal advisory review, through a channel that generates no public docket, and has attracted no discoverable external analysis.

Documentary basis: [10] SACHRP Recommendation (Oct. 19, 2023); [13] STAT (Apr. 3, 2025); [14] HCCA, Report on Research Compliance (Jan. 2026); [19] GE2P2 Global, Expression of Concern — Elimination of SACHRP (Apr. 23, 2025).

III. Administrative, procedural, and record-keeping deficiencies

Concerns [I]–[K] address defects in the instrument itself and in the process by which it has been brought forward.

[I] The stated burden-reduction justification is contradicted by the agency's own published figures.

The notice characterizes roster removal as "a burden reducing change." The three notices in this docket do not support that characterization.

In 2022, with the roster collected, per-response burden for registration update and renewal was estimated at 0.50 hours. In the present notice, with the roster removed, per-response burden is estimated at 0.50 hours — identical. The apparent reduction from 6,175 to 2,675 total annual hours is produced almost entirely by re-counting responses per respondent from two to one and by consolidating the two-row burden table into one, neither of which bears any relation to the roster. The single line on which a reduction does appear — initial registration, from 0.75 to 0.50 hours — affects roughly 350 of 5,350 respondents, is not disaggregated, and is not attributed.

Further, the present estimate exceeds the agency's own 60-day estimate for the identical change by 618 hours, or thirty percent, without explanation of the reversal from 0.33 to 0.50 hours per response. An information collection request whose central justification is unsupported by its own arithmetic does not satisfy 44 U.S.C. 3506(c)(1)(A)(iv) or 5 CFR 1320.8(a)(4).

Two further points compound the defect. First, there was no material burden available to be relieved. Sections 46.108(a)(2) and 46.115(a)(5), and 21 CFR 56.115(a)(5), already require every respondent to prepare and maintain the member list; OHRP reports that 100% of registrations are submitted electronically. Submission was therefore the transcription of a record the respondent is independently obliged to hold, through a channel already automated. That is why the per-response figure does not move when the roster is withdrawn: the element removed was contributing almost nothing to begin with. Second, as set out at [D] and [E] above, even were a respondent-side saving demonstrated, it would be far exceeded by the burden transferred to every subsequent analyst of the field, and by the loss of the accountability functions that no aggregate substitute restores.

Documentary basis: [1] 91 FR 45279; [2] 90 FR 21784; [3] 87 FR 31569. See Appendix B, Table 1.

[J] The regulatory predicate is cited imprecisely; the roster was never a registration requirement.

The notice states that removal "will align the IRB registration form with the 2018 Requirements at 45 CFR 46.103." This conflates two distinct collections. The instrument at issue governs registration under 45 CFR part 46, subpart E, at 46.501–46.505. Section 46.502 enumerates the information that must be provided when registering an IRB — institutional and IRB identifiers, senior officer, contact person, chairperson, approximate protocol counts, and administrative full-time-equivalent positions. It has never required a membership roster, and subpart E has not been amended since its promulgation at 74 FR 2405 (January 15, 2009); the 2009 final rule described the registration information as comprising contact information, protocol counts, and IRB staffing. The 2018 change the notice invokes is the deletion of former 45 CFR 46.103(b)(3), which required assurances to include a detailed list of IRB members. That is the Federalwide Assurance collection, a separate ICR. The roster was accordingly a discretionary OHRP addition to the registration form. Its removal is lawful — we do not contend otherwise — but the notice defends a discretionary policy choice as though it were compelled by regulation, and thereby avoids the analysis such a choice requires.

Documentary basis: [1] 91 FR 45279; [4] 74 FR 2399, 2405 (Jan. 15, 2009); [7] 45 CFR 46.502; 45 CFR 46.103 (current).

[K] Silence on the disposition of existing records and on available substitutes — rationale not offered.

OHRP holds roster records for approximately 4,988 registered IRBs. The notice states only that "updates to the software applications OHRP uses to manage IRB registration will be deployed." It does not state whether existing roster data will be retained, archived under an applicable records schedule, or destroyed; nor whether previously collected rosters will remain available on request, as OHRP has previously advised they are.

Nor does the notice consider any substitute. At least two are available at negligible marginal burden: an attestation of compliance with 45 CFR 46.107 and 46.108(a)(2) at registration and renewal, and aggregate member counts by category and by sex. A functionally similar substitution is already in practice — the Duke University Health System IRB replaced public roster posting with a compliance assurance statement effective March 1, 2026 — which demonstrates that the choice before OMB is not between the roster and nothing.

We acknowledge, finally, two genuine considerations favoring change, neither of which the notice advances: that roster fields are difficult to keep current and that stale rosters degrade registry accuracy, a concern GAO has substantiated as to other registry fields; and that public identification of IRB members carries real risk, which has led institutions to restrict disclosure.

Both are legitimate. Neither supports ceasing collection. The first argues for a simpler, more maintainable data element; the second argues for collecting without publishing. Removal is the response to neither. The rationale actually offered — burden reduction — is the one the agency's own figures do not support.

Documentary basis: [1] 91 FR 45279; [8] Stidham (Jan/Feb 2024); [9] GAO-23-104721; [18] Duke University Health System IRB notice (effective Mar. 1, 2026).

The statutory frame

GE2P2 Global supports the IRB registration and assurance system, and supports the removal of genuinely unnecessary federal paperwork. Our concern is not that OHRP proposes to simplify a form. It is that the simplification proposed defeats the statute under which it is brought.

The Paperwork Reduction Act is not a burden-reduction statute simply. Its purposes at 44 U.S.C. 3501 include, at (1), minimizing paperwork burden; but also, at (2), ensuring the greatest possible public benefit from and maximizing the utility of information created, collected, maintained, used, shared and disseminated by or for the Federal Government; at (4), improving the quality and use of Federal information to strengthen decision making, accountability, and openness in Government and society; and at (11), improving the accountability of OMB and all Federal agencies to Congress and to the public for implementing the information collection review process.

OMB's own implementing regulation states both objects in a single sentence: 5 CFR 1320.1 provides that the part is designed to reduce, minimize and control burdens and maximize the practical utility and public benefit of the information created, collected, disclosed, maintained, used, shared and disseminated by or for the Federal government.

The notice invokes the first purpose as though it were the whole of the Act. Every concern below is directed to the proposition that the collection OHRP proposes to discontinue serves purposes (2), (4) and (11), that the notice does not analyse those purposes at all, and that the burden relied upon under purpose (1) is, on the agency's own record, close to zero — because respondents are already required to hold the information in question.

Documentary basis: 44 U.S.C. 3501(1), (2), (4), (11); 5 CFR 1320.1; [7] 45 CFR 46.108(a)(2), 46.115(a)(5).

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Bibliography of Key Sources

Primary Federal Register and information-collection record

[1] Department of Health and Human Services. *Agency Information Collection Request; 30-Day Public Comment Request* (Notice), 91 Fed. Reg. 45279 (July 20, 2026). Document Identifier OS-0990-0279; OMB No. 0990-0279. https://www.federalregister.gov/documents/2026/07/20/2026-14537/agency-information-collection-request-30-day-public-comment-request

[2] Department of Health and Human Services. *Agency Information Collection Request; 60-Day Public Comment Request* (Notice), 90 Fed. Reg. 21784 (May 21, 2025). [Type of collection: Revision. Estimated 2,057 total annual burden hours.] https://www.federalregister.gov/d/2025-09001

[3] Department of Health and Human Services. *Agency Information Collection Request; 30-Day Public Comment Request* (Notice), 87 Fed. Reg. 31569 (May 24, 2022). [Type of collection: Reinstatement without change. Estimated 6,175 total annual burden hours; roster collected.] https://www.federalregister.gov/d/2022-11064

[4] Office for Human Research Protections. *Institutional Review Boards: Registration Requirements* (Final Rule), 74 Fed. Reg. 2399, 2405 (Jan. 15, 2009). [Establishing 45 CFR part 46, subpart E; registration information described as contact information, approximate protocol counts, and IRB staffing.]

[5] Office for Human Research Protections. *Revisions to the Federalwide Assurance Form*, OMB No. 0990-0278 (implemented March 2026). Electronic Submission System notices and Assurance Process FAQs. https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/assurance-process/index.html [Removal of the voluntary "check the box" election and of the requirement that institutions designate an IRB on the FWA.]

[6] Department of Health and Human Services. *Agency Information Collection Request — OHRP Research Complaint Form* (Notice), 91 Fed. Reg. 40546 (July 2, 2026). [Conforming amendments to the FWA revision; two new elements on complainants' prior resolution attempts and past submissions.]

[7] 44 U.S.C. §§ 3501, 3506(c), 3512; 5 C.F.R. §§ 1320.1, 1320.8, 1320.10, 1320.11; 45 C.F.R. §§ 46.103, 46.107, 46.108(a)(2), 46.109(d), 46.114(b), 46.115(a)(2), 46.115(a)(5), 46.501–46.505; 21 C.F.R. §§ 56.106, 56.107, 56.115(a)(5).

Agency and federal oversight-body analyses

[8] Stidham, Michael (Program Specialist, Division of Policy and Assurances, OHRP). "Why Should IRBs Report Protocol Data Accurately in the IRB Registry?" *NCURA Magazine*, Jan/Feb 2024, p. 58.

https://www.hhs.gov/sites/default/files/ncura-magazine.pdf [Principal and originating source for concern [C]: documents registry use for compliance oversight, education, and research about IRBs; confirms roster removal will also eliminate member qualification and sex data.]

[9] U.S. Government Accountability Office. *Institutional Review Boards: Actions Needed to Improve Federal Oversight and Examine Effectiveness*, GAO-23-104721 (Jan. 17, 2023; publicly released Feb. 16, 2023). https://www.gao.gov/products/gao-23-104721 [Requested by Senators Warren, Sanders and Brown. Four recommendations; OHRP conducts 3–4 routine inspections annually against ~2,300 U.S. IRBs; no risk-based assessment of inspection programme.]

[10] Secretary's Advisory Committee on Human Research Protections. *SACHRP Recommendation on GAO-23-104721*, approved October 19, 2023. https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-a-october-19-2023-letter/index.html [Prepared at OHRP's request, addressing GAO Recommendation #4 on measuring IRB effectiveness.]

[11] Department of Health and Human Services, Office of Inspector General (2017). [Recommending greater OHRP transparency regarding compliance activities and increased independence and resources; as reported at

Contemporaneous reporting and professional analysis

[12] Molteni, Megan. "Tiny HHS office tasked with protecting research participants' safety is running on fumes." *STAT*, June 5, 2026. https://www.statnews.com/2026/06/05/hhs-cuts-office-human-research-protections-running-on-fumes/ [OHRP capacity; 2017 OIG recommendation; FY2026 budget proposal.]

[13] Molteni, Megan. "Federal advisory panel on ethical, legal issues in human health research disbanded." *STAT*, April 3, 2025. https://www.statnews.com/2025/04/03/hhs-advisory-committee-human-research-protections/ [SACHRP dissolution; OHRP oversight of 13,000+ institutions.]

[14] Defino, Theresa. "In First Project, NACHRP — Successor to SACHRP — Tackles Oversight After 'Unchecking the Box.'" *Report on Research Compliance* 23, no. 1 (January 2026), Health Care Compliance Association. [Formation of the National Committee for Human Research Protections; OHRP staffing losses.]

[15] CITI Program. "OHRP Updates the FWA: Key Changes Explained" (March 2026). https://about.citiprogram.org/blog/ohrp-updates-the-federalwide-assurance-fwa-key-changes-explained/ [FWA burden figures; note that some state protections, e.g. Virginia, were tied to the "check the box" election.]

[16] Pearl IRB. "OHRP's Proposed Changes to the Federalwide Assurance Form: An Update" (September 2025). https://www.pearlirb.com/ohrps-proposed-changes-to-the-federalwide-assurance-form-an-update/ [Enumerates the four proposed FWA changes.]

Adjacent literature and institutional practice

[17] Shamoo, Adil E., and Elizabeth Woeckner. "Research Ethics Boards: No Data on Quality of For-Profit or Non-Profit IRBs." *PLoS Medicine* 3, no. 10 (2006). DOI: 10.1371/journal.pmed.0030459. [On the structural absence of data permitting assessment of IRB quality.]

[18] Duke University Health System IRB. "DUHS IRB Roster & Address Update" (effective March 1, 2026). https://irb.duhs.duke.edu/news/duhs-irb-roster-address-update [Replacement of public roster posting with a Compliance Assurance Statement, citing accuracy, burden, and risk to members from public identification.]

[19] GE2P2 Global Foundation. *Expression of Concern: HHS — Elimination of SACHRP (Secretary's Committee on Human Research Protections)*, April 23, 2025. https://ge2p2-center.net/expressions-of-concern/expression-of-concern-hhs-elimination-of-sachrp-secretarys-committee-on-human-research-protections-23-april-2025/

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Appendix A — Burden Series and Selected Full Text

Table 1. Estimated annual burden across the three notices in Docket OS-0990-0279

Federal Register notice	Roster collected?	Respondents	Responses per respondent	Hours per response	Total burden hours
87 FR 31569 (24 May 2022)	Yes	5,650 / 350	2 / 2	0.50 / 0.75	6,175
90 FR 21784 (21 May 2025) — 60-day	No	5,350 / 350	1 / 2	0.33 / 0.50–0.33	2,057
91 FR 45279 (20 July 2026) — 30-day	No	5,350	1	0.50	2,675

Note: per-response burden for registration update and renewal is 0.50 hours in 2022, with the roster collected, and 0.50 hours in 2026, with the roster removed. The reduction in total hours between 2022 and 2026 is attributable principally to the change in responses per respondent from two to one, and to consolidation of the two-row table into one. The 2026 estimate exceeds the agency's own 2025 estimate for the identical change by 618 hours (+30.0%).

Michael Stidham, Office for Human Research Protections
"Why Should IRBs Report Protocol Data Accurately in the IRB Registry?" NCURA Magazine, Jan/Feb 2024, p. 58 *[Excerpts]*

The author, writing as a Program Specialist in OHRP's Division of Policy and Assurances, records that OHRP uses its IRB registry for compliance oversight activities, for distribution of educational materials, and to fulfil data requests supporting research about IRBs, and that the registration form approved under OMB No. 0990-0279 collects a membership roster alongside protocol counts. He notes that accurate registry data informs OHRP's compliance efforts and thereby supports an effective and trustworthy system of human research protections; that some registration information is publicly accessible and non-public information may be requested from OHRP; and that researchers have sought registration data in order to study the IRB enterprise, to the benefit of policymakers, institutions and research participants. He further records that OHRP was then prioritising the removal of the membership roster from the registration form, that this would also eliminate collection of IRB member qualifications and sex, and that the requirements at 45 CFR 46.108(a)(2) and 46.115(a)(5) to prepare and maintain a current member list would continue to apply.

U.S. Government Accountability Office, GAO-23-104721
Institutional Review Boards: Actions Needed to Improve Federal Oversight and Examine Effectiveness (Jan. 17, 2023) [Summary of relevant findings]

Undertaken at the request of Senators Warren, Sanders and Brown, the report examined the composition of the IRB market and federal oversight of IRBs. GAO found that HHS oversees approximately 2,300 United States IRBs through routine and for-cause inspections, that OHRP officials aim to conduct three to four routine inspections annually, and that FDA conducted an average of 133 inspections annually between fiscal years 2010 and 2021. Neither agency had performed a risk-based assessment of its IRB inspection programme to determine whether an adequate number of IRBs are inspected. GAO made four recommendations, including that the agencies conduct annual risk assessments, that the accuracy of protocol data in OHRP's IRB registry be ensured, and — at Recommendation #4 — that the Secretary ensure OHRP and FDA convene stakeholders to examine and implement approaches for measuring IRB effectiveness in protecting human subjects, expressly including surveys of IRB members among the approaches contemplated. OHRP referred Recommendation #4 to SACHRP, which approved its response on October 19, 2023. SACHRP was disbanded in March–April 2025.

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GE2P2 Global is an integrated non-profit foundation/501[c]3 and public benefit corporation affiliate founded in 2016 to advance scientific rigor, ethical resilience, and integrity in research and evidence generation across the sciences — informing governance, policy, and practice.

The Foundation has a strong record of responding to public comment and public consultation opportunities globally to strengthen and refine the development of laws, regulations, standards, policies, and guidance, and in support of other deliberative processes involving scientific rigor, research ethics and integrity. These calls are issued from organizations in the United Nations system, multilateral agencies, governments and country regulatory bodies, non-governmental organizations, civil society organizations, academic institutions, professional societies, and commercial organizations.

This Expression of Concern is one of a series where the Foundation takes note of and urges mitigating responses to actions taken by organizations as listed above which we assess to challenge, compromise or confound scientific rigour, ethics, or integrity.

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