



October 30, 2022

Submitted electronically to: OASH-ORI-Public-Comments@hhs.gov

Dr. Wanda K. Jones, Acting Director
Office of Research Integrity
1101 Wootton Parkway, Suite 240
Rockville, MD 20852

RE: Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct

Dear Dr. Jones:

COGR (Council on Governmental Relations) and ARIO (Association of Research Integrity Officers) submit this letter in response to the Office for Research Integrity's Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct published in the September 1, 2022, Federal Register. [\[87 FR 53750\]](#) (the "RFI"). COGR is an association of over 200 public and private United States research universities and affiliated academic medical centers and research institutes. ARIO is an association of research integrity officers (RIOs) and general counsel that shares best practices and strategies for handling research misconduct allegations and promoting ethical research. Both COGR and ARIO are concerned with the impact of federal regulations, policies, and practices on the performance of research conducted at their member institutions, and research integrity is one area of significant interest and expertise among COGR member institutions and ARIO members.

Ensuring the responsible and ethical conduct of research, free from fabrication, falsification, and plagiarism, is a primary responsibility and focus of every university that conducts research, regardless of funding source. Given the prominence of Public Health Service (PHS) funding for so much of the research that is conducted at many United States universities and the fact that current regulations have been in place since 2005, universities have had ample opportunity to see how the Public Health Service (PHS) Policies on Research Misconduct at [42 CFR Part 93](#) ("Research Misconduct Policies") work in practice. Accordingly, we appreciate the Office of Research Integrity's (ORI) solicitation of stakeholder input as it contemplates changes to the Research Misconduct Policies, and we hope that this RFI will serve as the beginning of continuing dialog with the research community regarding any such changes.

We also point out that for over 20 years there has been a federal-wide research misconduct policy promulgated by the White House Office of Science and Technology Policy (OSTP).¹ Universities rely upon such federally harmonized approaches to promote compliance and minimize administrative burden, and we urge ORI to use its review process as an opportunity to work with other federal research funding agencies toward harmonization of research misconduct policies. Of course, consistency as a singular goal may produce either consistently bad or consistently good outcomes. Thus, any harmonization efforts should focus on identifying/developing requirements that effectively provide for the review of research misconduct allegations in a manner that is fair to the parties and does not unnecessarily burden the institutions charged with administering the process. In this regard, given that both NIH and the National Science Foundation (NSF) have had long-standing research misconduct regulations,² consideration should be given to comparing how each agency's regulatory framework has worked in practice and using this information in developing any new, harmonized regulatory model.

Our specific comments are organized below under each question posed in the RFI, and they are presented in order of the regulations at 42 CFR Part 93 to which they pertain. At the beginning of each response, we have included a bulleted list of the main points addressed. Note, that our comments do not encompass every section or aspect of the regulations at 42 CFR Part 93, but rather focus on our primary concerns.

QUESTION 1: WHICH SECTION(S) SHOULD BE CHANGED OR AUGMENTED WHEN REVISING 42 CFR PART 93? WHY? HOW SHOULD THE SECTION(S) BE CHANGED OR AUGMENTED?

- a. *42 CFR §93.105, Time limitations, including the interplay of this section with §93.310(h), Pursue leads and §93.316, Completing the research misconduct process*

Major Topics Addressed in this Response:

- Provide institutions with more discretion to terminate proceedings at assessment or inquiry
- Retain health or safety of public exception at §93.105(b)(2)
- Delete or substantively revise the subsequent use exception at §93.105(b)(1)
- Set clear limitations on the phrases “pursue diligently all significant issues and leads discovered” in §93.310(h) and “pursue diligently all significant issues” in §93.316(a)

One of the most important recommendations that we offer in this letter is for ORI to rethink the provisions of §93.105, §93.310(h) and §93.316 as they pertain to the scope of inquiries/investigations and the circumstances under which an inquiry or investigation may be

¹ [65 Fed. Reg. 235 \(Dec. 6, 2000\)](#).

² NSF Research Misconduct Policies ([45 CFR Part 689](#)).

closed. ORI has interpreted these provisions to greatly expand the scope of investigations beyond what the allegations and evidence suggest. Institutions recognize that they may uncover additional instances of research misconduct during their review of initial allegations, and they take seriously their obligations to conduct a robust review. However, an overly broad scope may require universities to spend countless hours attempting to locate and assess information about rarely cited publications, unfunded proposals, unpublished research activities, and laboratory research records many years after their creation. This problem is compounded, and raises key process fairness concerns, when the respondent and/or key witnesses have left the institution and cannot be located or remain non-responsive to requests for information. Requiring institutions to allocate scarce institutional resources to these frequently fruitless tasks hampers institutional efforts to address new or higher-impact concerns, as well as to conduct preventative and educational activities. For these reasons, and other factors detailed below, we urge ORI to take the following actions to better enable institutions to prioritize their activities in the review of the research misconduct matters to optimize the ultimate goals of fair proceedings and meaningful correction of the scientific record:

- (1) Provide institutions with discretion to terminate research misconduct proceedings at assessment or inquiry based on factors including, but not limited to the following items³:
 - Scope of the allegations
 - Respondent’s status/non-status as an active researcher in the U.S.
 - Institution’s inability, after diligent efforts, to establish any factual basis that supports culpability of a respondent
 - Impact of the questioned research on federal funding (e.g., was funding awarded based on questioned research) and the public scientific record (e.g., was the questioned research limited to the lab, did it result in a publication, and was that publication highly cited)
 - Impact of the questioned research on public health or safety (e.g., does the questioned research impact practices that could influence public health and safety)
 - Impact of the questioned research on the research record (e.g., has or will the research record be corrected).
- (2) Retain the health or safety of the public exception at §93.105(b)(2), while deleting the subsequent use exception at §93.105(b)(1). If the subsequent use exception is retained, ORI should revise the exception to make clear that it applies only to the citation, republication, or use of the questioned data, or the conclusions or results derived from the questioned data.
- (3) Clarify that the phrase “pursue diligently all significant issues and leads discovered” in §93.310(h) and the phrase “pursue diligently all significant issues” used in §93.316(a) are

³ See, also, comments below concerning §93.307(d).

limited to issues and leads the institution discovers from evidence and testimony obtained during the inquiry or investigation, and that any review of a researcher's publications and proposals is limited to those implicated by such allegations/evidence.

Per §93.105(a), the Research Misconduct Policies apply to “research misconduct occurring within six years of the date HHS, or an institution receives an allegation of research misconduct.” Sequestering the evidence and identifying witnesses necessary to substantiate allegations becomes more difficult with the passing of each year after the questioned event occurs, and beyond six years, it may become exceedingly difficult, thus raising questions of fair process for the respondent. Further, application of this limitation is complicated by the “subsequent use exception” detailed at §93.105(b)(1). The broad and vague language of this exception states that the “respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the citation, republication or other use for the potential benefit of the respondent of the research record that is alleged to have been fabricated, falsified, or plagiarized.” Given that the definition of “research record” in §93.224 includes research proposals, many, if not all, of which will include citations to a respondent's entire body of research work, the “exception” ends up swallowing the rule. Additionally, the lack of any firm time limitation sends institutions on time-consuming and expensive historical “paper chases,” combing through ancient computers, lab instruments, file cabinets, and document storage facilities for data associated with papers that were published decades ago. Frequently, these data are no longer technically accessible (e.g., equipment or software that is no longer supported, damaged computers), or it has been lost or destroyed, and in many cases any information that is obtained through these pursuits does little to contribute to the advancement of a case.

Section §93.310(h) requires institutions to “pursue diligently all significant issues and leads discovered that are determined relevant to the investigation.” The Research Misconduct Policies do not define the term “significant issues and leads,” but on its face, this term indicates that institutions should follow the evidence they have discovered in the investigation. ORI's guidance on the scope of research misconduct,⁴ however, goes beyond the plain language of §93.310(h) and calls for institutions to perform “a cursory review of other papers and grant applications within the six-year time limitation (§93.105(a)) to eliminate the possibility of any additional instances of research misconduct.” First, the notion of a “cursory” review to “eliminate” the possibility of additional instances of research misconduct is unrealistic in cases in which images must be analyzed or figures compared from one publication to the next. Second, ORI calls for this review even though there may be no evidence or allegations to suggest that the papers contain fabrication, falsification, or plagiarism. In other words, ORI considers the mere existence of any paper or proposal authored during the six-year period to constitute a “significant issue or lead discovered” that must be pursued. Moreover, when ORI's interpretation of §93.310(h) is considered in connection with the subsequent use exception under §93.105(b)(1), the scope of the investigation

⁴ [ORI, Scope of Research Misconduct \(May 27, 2021\).](#)

can quickly become limitless, imposing a tremendous burden on the investigating institution, and causing the respondent to undergo a lengthier investigation that may be completely unwarranted by the actual evidence.

COGR and ARIO strongly support the need to ensure that the scientific record is correct, and we advocate for prioritizing institutional resources to investigating allegations and leads from actual evidence because they present a greater likelihood of producing dispositive conclusions that lead to appropriate retractions and other corrections. For similar reasons, we also encourage limiting the investigation to a reasonable number of years for which data, reliable testimony, and other evidence can be obtained and accurately assessed. Importantly, this approach also supports the rationale behind “statutes of limitations”: to refrain from putting a respondent in the position of defending against allegations that are so old the respondent can no longer obtain the evidence or witnesses necessary to refute the allegations. At a minimum, ORI should develop criteria that would enable institutions to limit the review of additional papers or grant applications in research misconduct proceedings, to those that have a significant potential impact on the field, the funding agency, and/or public health and safety. Requiring unlimited review of *all* papers and grant applications in a researcher’s body of work (especially those over six-years old) without regard to their scientific impact/value or the nature of the evidence results in institutions diverting scarce time and resources away from more important and productive pursuits such as the review of other, more serious misconduct concerns and/or educational and preventative efforts. Additionally, in many cases, there often are alternative methods to address concerns subsequent to the proceedings through communications with authors and journals concerning correction of the scientific record.

Finally, we also recommend that the “health or safety of the public exception,” in §93.105(b)(2) be retained, so that ORI maintains the ability to require an institution to look beyond the six-year limitations period in the most important cases concerning research with major public impacts.

b. §93.104, Requirements for findings of research misconduct

Major Topics Addressed in this Response:

- Define all state-of-mind terms used in the Research Misconduct Policies.

The requirement for a finding of research misconduct set forth in §93.104, includes an intent requirement, i.e., that the misconduct be committed “intentionally, knowingly, or recklessly.” The determination of the intent of the respondent in performing activities that may constitute research misconduct is vital, yet, surprisingly, none of these terms are defined under Subpart B, the Research Misconduct Policy’s definitions section.

Although the terms “intentionally,” “knowingly,” and “recklessly,” may be commonly used in legal settings, the committees of scientists that review research misconduct cases are generally not

familiar with how these terms are used to frame intent. Additionally, as a matter of fundamental fairness, these terms should be defined in the regulations to ensure the respondent fully understands the allegations against them and to promote their consistent application in proceedings. Accordingly, COGR and ARIO urge ORI to amend the regulations to include a definition of each of these terms and to provide guidance to the community that includes examples illustrating the differences among the terms and discussing common situations in which they apply.

c. **93.108, Confidentiality**

Major Topics Addressed in this Response:

- Clarify the “need to know principle” in §93.108 to address:
 - Multiple entities involved in research misconduct proceedings;
 - Institution that hires a researcher during the conduct of a proceeding; and
 - Communications with journals.

Section 93.108 states as follows:

Disclosure of the identity of respondents and complainants in research misconduct proceedings is limited, to the extent possible, *to those who need to know* consistent with a thorough, competent, objective, and fair research misconduct proceeding, and as allowed by law. . . . *(Emphasis added).*

COGR and ARIO recognize the potential damage that unproved allegations of research misconduct may cause to a researcher’s reputation, and we fully support strong regulations to ensure that the confidentiality of research misconduct proceedings is maintained. Yet, we are also cognizant of the fact that increasingly research misconduct proceedings, including interviews of witnesses, sequestration of evidence, and inquiry and investigation proceedings, span multiple institutions inside and outside of the United States. In these circumstances, it can be extremely difficult to determine who falls into the scope of “those who need to know.” Should ORI proceed with changes to the Research Misconduct Policy, we urge it to consider updating this section on confidentiality to expressly acknowledge that a research misconduct proceeding may involve multiple entities, i.e., “to those who need to know consistent with a thorough, competent, objective and fair research misconduct proceeding, *that may involve multiple entities and require communications among those entities . . .*”

The “need to know principle” also frequently arises when a respondent departs for employment at another institution during the misconduct proceedings. Institutions have no desire to interfere with a respondent’s employment. Yet circumstances often require that the institution that initiated the proceedings communicate with the respondent’s new employer to carry out the proceeding (e.g., need for additional testimony or sequestration of additional data). To facilitate such

communications, we recommend that ORI clarify that the phrase “those who need to know” may include the Research Integrity Officer, or other institutional officials, at the institution that employs the respondent, if the respondent ceases employment with the institution conducting the research misconduct proceedings during the process.

Finally, we believe that ORI also should consider providing guidance concerning the applicability of the “need to know” principle in the context of communications with journals. Correction of the scientific record is at the core of research misconduct proceedings, yet the confidentiality provisions do not explicitly address communications between the institution conducting the proceeding and journals that review and publish affected manuscripts. ORI should make clear that during the conduct of research misconduct proceedings, journals may be considered as having a “need to know” if substantive fact-finding has confirmed that data underlying materials provided to the journal are unreliable/inaccurate/false; provided, however, that communications should separate the matters of data reliability/accuracy/veracity from the issue of culpability until the proceedings on that issue have concluded. Being able to take this action when the need arises will allow for speedier correction of the scientific record.

d. §93.307(d) Criteria Warranting an Investigation

Major Topics Addressed in this Response:

- Limit the criteria for proceeding to an investigation in §93.307(d) to circumstances in which there is reasonable basis for:
 - Finding the allegation falls under definition of research misconduct; and
 - Allegation has substance; and
 - Allegation does not stem from honest error or difference of opinion

This section states that an investigation is warranted if there is:

- (1) A reasonable basis for concluding that the allegation falls within the definition of research misconduct under this part and involves PHS supported biomedical or behavioral research, research training, or activities related to that research or research training as provided in §93.102; and
- (2) Preliminary information-gathering and preliminary fact-finding from the inquiry indicates that the allegation may have substance.

The use of the term “may have substance” in subsection (2) is so broad that it prevents the closing at inquiry of many cases that should not proceed to investigation because a realistic evaluation of the evidence demonstrates that it will be insufficient to support a finding of research misconduct after investigation. Although a “reasonable basis” is required for finding that the allegation falls within the definition of research misconduct, there is no similar requirement of reasonableness for

the evidence gathered at the inquiry stage. Yet, a vast amount of evidence is collected and reviewed at the inquiry stage because of rigorous sequestration requirements. Despite this fact, mandating only that an allegation *may have* substance often propels an inquiry with even minimal evidence into the investigation stage. It also requires an investigation even when sufficient evidence from preliminary information-gathering and preliminary fact-finding demonstrates that an honest error or mistake occurred. Rather than compel institutions to continue with investigations in virtually all these types of cases, COGR and ARIO urge ORI to revise this provision as follows (changes shown in ***bold italicized text***) to (a) incorporate a “reasonableness” standard in both prongs of the test for moving to investigation; and (b) add a new provision to expressly recognize that an investigation is not warranted if preliminary information and fact-finding demonstrate credible evidence of honest error or a difference of opinion as a defense to the allegations:

- (2) Preliminary information-gathering and fact-finding from the inquiry provides a ***reasonable basis*** for concluding that the allegation has substance; ***and***
 - (3) Preliminary information-gathering and fact-finding from the inquiry provide credible evidence that the allegations do not stem from honest error or a difference of opinion.
- e. ***§93.307(g), Inquiry report and §93.311(a) Time limit for completing an investigation***

Major Topics Addressed in this Response:

- Eliminate 60-day deadline for inquiry in §93.307(g)
- Eliminate 120-day deadline for investigation in §93.311(a)
- Acknowledge that the timeline depends on facts and circumstances of each case and replace each deadline with a requirement for the institution and ORI to develop a schedule for completion of the inquiry/investigation
- Acknowledge extensions may be granted per reasonable request and progress reports may be required.

Section 93.307(g) states that the time for completion of the inquiry is 60 days from the date of initiation, and §93.311(a) states that the time for completing an investigation is within 120 days of its initiation. Each of these timelines is an arbitrary number that applies regardless of the nature of the case and neither has proved to be a realistic estimate of the time required to conduct an inquiry or investigation. In fact, many investigations may take a year or more to complete, and ORI has addressed this issue by granting extensions in response to institutional requests.

The time required to conduct either an inquiry or investigation is completely dependent upon the individual circumstances of the case and calculating this time is complex. Accordingly, rather than attempt to determine a specific completion period that applies in all cases, COGR and ARIO suggest that in the case of inquiries, ORI require institutions to diligently pursue their conduct,

while affording the institution the discretion to set its own timetable based on the circumstances of the case. In the case of investigations, we suggest that the current 120-day deadline be deleted, and the institution propose, for ORI's acceptance, a schedule for the completion of the investigation, with full recognition by the institution and ORI that this schedule may require adjustment as circumstances develop. Below, suggested revised provisions are set forth:

§93.307(g): Time for completion: The institution must undertake and diligently conduct the inquiry and complete it within a reasonable time based on the facts and circumstances of the case. In the event ORI reasonably believes that the inquiry is not being conducted diligently, it may require the institution to provide a progress report that describes remaining steps and an estimate of the time by which the inquiry will be completed, with follow-up reports, as necessary.

§93.311(a), Time limit for completing an investigation: An institution must diligently conduct the investigation and complete all aspects of the investigation (including conducting the investigation, preparing the report of the findings, providing the draft report for comment in accordance with §93.312, and sending the final report to ORI under §93.315) within a reasonable time based on the facts and circumstances of the case. At the beginning of the investigation, the institution shall provide ORI, for ORI's approval, a tentative schedule indicating when the investigation will be completed. Recognizing that the complexity of research misconduct proceedings makes it difficult to predict a completion date, ORI may grant an institution one or more extension(s) of the investigation period, based on written request(s) of the institution that identifies reasonable facts and circumstances supporting the extension. In the event ORI reasonably believes that the investigation is not being conducted diligently, it may require the institution to provide a progress report that describes remaining steps and an estimate of the time by which the investigation will be completed, with follow-up reports, as necessary.

QUESTION 2: WHICH SECTION(S) SHOULD BE RETAINED AS IT CURRENTLY IS IN [42 CFR PART 93](#)? WHY?

42 CFR §93.103, Research Misconduct

Major Topics Addressed in this Response:

- Do not expand definition of “research misconduct” under §93.103 to address:
 - Behaviors encompassed under scientific or research integrity.
 - Misconduct beyond falsification, fabrication, or plagiarism
- Reconsider the current definition of “plagiarism” under §93.103(c).

A key provision of the current Research Misconduct Policies that should remain unchanged is the definition of the term “Research Misconduct,” which is limited to “fabrication, falsification, or

plagiarism [FFP] in proposing, performing, or reviewing research, or in reporting research results.” The term research misconduct should not be replaced by or conflated with the terms “research integrity” or “scientific integrity,” each of which encompass a more diverse array of behaviors and threats, including bias, reproducibility, and data security.⁵ The process set forth in the Research Misconduct Policies for examining and adjudicating allegations of “research misconduct” is tailored to examining allegations of FFP and would be unwieldy when applied to broader terms. Rather, the concepts of “research integrity” or “scientific integrity,” should continue to be addressed through separate requirements such as those pertaining to training in the responsible and ethical conduct of research.⁶

Along the same lines, we contend that the definition of research misconduct should not be altered to incorporate behavior beyond FFP. For example, certain individuals and groups recommend that behavior such as failure to disclose “foreign research ties” should be investigated as “research misconduct.”⁷ Similarly, some individuals/groups believe that sexual harassment should be treated as research misconduct.⁸ We strongly disagree. Institutions have developed mature programs to meet the requirement for handling allegations of research misconduct that include elements specifically developed for scientists to effectively review claims of fabrication, falsification, or plagiarism. These programs include elements such as sequestration of evidence and consideration of whether there has been a significant departure from the scientific standards of the relevant research community, and these processes that would be ineffective and inappropriate for the assessment of other types of allegations.

We fully support steps already taken to improve related reporting, investigation, and sanctions for research security concerns, harassment, and bullying. However, we firmly believe that these activities should *not* be reviewed under an investigational process that was specifically designed to examine accuracy of the scientific record. Instead, existing pathways designated for the investigation of malign foreign influence or sexual harassment should be utilized, as these processes were developed specifically for, and contain procedural protections that are unique to, these subject areas. Similarly, if the review of research misconduct allegations unearths evidence of harassment, undisclosed conflicts of interest, or other prohibited behaviors, referrals are made to the appropriate institutional officials/processes specifically designated for investigating those

⁵ See, e.g., National Science and Technology Council (STC), [Scientific Integrity Fast-Track Action Committee, Protecting the Integrity of Government Science \(Jan. 2022\)](#) at p. 1-2 (identifying principles of scientific integrity); [U.S. Dept. of Agriculture, Scientific Integrity and Research Misconduct webpage](#) (accessed Oct. 5, 2022) (identifying research misconduct as compromised subset of research integrity).

⁶ National Institutes of Health (NIH), [FY 2022 Updated Guidance: Requirement for instruction in the Responsible Conduct of Research \(NOT-22-055\) \(Feb. 17, 2022\)](#).

⁷ Mervis, J., [U.S. Scientists who Hide Foreign Ties Should Face Research Misconduct Sanctions, Panel Says, SCIENCE \(Dec. 11, 2019\)](#).

⁸ [Marin-Spiotta, E., Harassment Should Count as Scientific Misconduct, NATURE \(May 9, 2018\)](#); [Kuo, M., Scientific Society Defines Sexual Harassment as Scientific Misconduct, SCIENCE \(Sept. 20, 2017\)](#) (American Geophysical Union adopts policy that considers sexual harassment to be a type of scientific misconduct).

allegations. To do otherwise, risks running afoul of laws, regulations, policies, processes, and concerns specific to these areas.

Additionally, we believe that ORI should take this opportunity to reconsider its definition of plagiarism. Section 93.103(c) currently defines plagiarism as the "appropriation of another person's ideas, processes, results, or words without giving appropriate credit," yet the plagiarism of "ideas" is extremely difficult to prove (e.g., the accused may have access to many different public documents that would disprove a complainant's allegation of plagiarism of ideas). Similarly, ORI has recognized in guidance that collaborators' use of joint research without appropriate attribution is an authorship matter, as opposed to plagiarism. ORI should consider these concerns and address them through revisions to the definition.

QUESTION 3: WHICH SECTION(S) SHOULD BE CONSIDERED FOR REMOVAL WHEN REVISING 42 CFR PART 93? WHY?

Major Topics Addressed in this Response:

- Eliminate Subpart E and revise appeals process to call for direct appeal to the Assistant Secretary of Health.

COGR and ARIO advocate for eliminating the current Subpart E and replacing it with an appeals process that is simpler for respondents to navigate. Currently, Subpart E calls for a hearing before an administrative law judge (ALJ), who makes a recommendation to the Assistant Secretary for Health (ASH). The ASH may modify or reject the ALJ's decision if it is found to be arbitrary and capricious or clearly erroneous as detailed in §93.523. If debarment or suspension is part of the recommended administrative actions, the debarring official makes the final Department of Health and Human Services (HHS) decision on those actions.

A much simpler process would be to have a respondent direct their appeal to the ASH, who would review it and make a recommendation to the Secretary of HHS or the Deputy Secretary of HHS (or their designee), who would decide the appeal. This type of process is currently in use at the National Aeronautics and Space Administration,⁹ the National Science Foundation,¹⁰ the Veterans Administration,¹¹ and the Department of Defense,¹² and adopting this recommendation would align the HHS appeals process with that of other federal agencies.

⁹ [14 CFR §1275.108.](#)

¹⁰ [45 CFR §689.10.](#)

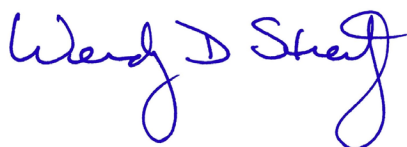
¹¹ Veterans Health Administration Directive 1058.02 (Jul. 10, 2020).

¹² [Dept. of Defense, Instruction 3.7 \(Oct. 15, 2018\).](#)

CONCLUSION

It is always good practice to periodically review regulations to determine whether changes need to be made to better achieve regulatory goals. COGR and ARIO support ORI in its efforts to undertake such a review of the Research Misconduct Policies, and we are grateful to ORI for not undertaking this review in a vacuum, but rather reaching out to the stakeholder community for input. We hope that the comments and recommendations set forth herein will assist ORI in its mission, and any questions regarding this transmittal may be directed to Kris West, COGR's Director for Research Ethics and Compliance at kwest@cogr.edu or to Lauren Qualkenbush at lhane@northwestern.edu on behalf of ARIO. We look forward to continuing the dialog with ORI on any proposed changes to the regulations at 42 CFR Part 93, and once again thank the agency for this opportunity to submit comments.

Sincerely,

A handwritten signature in blue ink that reads "Wendy D. Streit". The signature is fluid and cursive, with the first and last names being more prominent.

Wendy D. Streit
President, COGR

A handwritten signature in blue ink that reads "L M". The signature is very stylized and cursive, with the letters being large and flowing together.

Lauran Qualkenbush
President, ARIO