

Comments / questions on OMB 0925-0761;
Proposed Collection: 30-Day Comment Request;
National Cancer Institute (NCI) Generic
Clearance for Application Information From
Fellows, Interns, and Trainees

Author: Anonymous

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1 Introduction

Motivation to comment occurred because some individuals were known who have cancer in church prayer groups. The notice was browsed as well as the ICR Documents. These were read for miscellaneous possible improvements. The comments are basic as there is no experience. While there is a little bit of verbiage, the comments / questions were intended to be easy. If something is not useful, no response is needed. A bunch of the verbiage is just supporting content.

2 Background

The first comments are simple edits or questions about the notice - references, procedure, and word definitions. Some of these comments would only apply if the notice extended again in the future. Other comments are on application process like having State employment system available as a backup. The last comments encourage plain language since exact goals were not listed. Some portion of content goes to the web, a perspective of those outside of NIH who depend on plain language.

3 Analysis - notice

3.1 regulation references 1

Location for comment is ICR Supporting Statement A, A.1 Circumstances Making the Collection of Information Necessary

Reference to 42 USC 285 for Nat. Cancer Inst. (NCI) was observed. Assuming CFR mediates between an agency and the USC, is a CFR reference preferred over USC? When a USC reference is used, is it practical to include a description that it is used temporarily until a CFR update completes? This resulted from independent reference search which found a CFR reference first, even if it is not the right reference - 42 CFR Chapter I, Subchapter E Fellowships, Internships, Training.

3.2 regulation references 2

Location for comment is the *Need and Use of Information Collection*:

Can the IC notice's content directly copy or link from the NCI Fiscal Year 2026 Annual Plan and Professional Judgment Budget Proposal or National Cancer Plan / Optimize the Workforce? Potentially less paperwork as the paragraph count decreases.

3.3 regulation review procedure

Location for the comment is the context.

Would putting the information collection in the CFR allow its review concurrent with periodic updating to avoid more extensions in the Fed Register? The CFR reference which might allow it is listed below:

- 1 CFR General Provisions

- Chapter I Administrative Committee of the Federal Register
- Subchapter C Special Editions of the Federal Register
- Part 8 Code of Federal Regulations
- 8.3 Periodic updating [at least once each calendar year]

3.4 word definition - research

Location for comment is Need and Use of Information Collection and Supporting Statement A

The words **research** and **cancer research** were observed to vary in definition (across the community) with some examples listed below. Would a stable definition minimize risk of unplanned variation of research positions? The definition may be more important if it does not derive from organizational structures. For example, a CalHHS was found in California, but it did not have a CalNIH and CalNCI equivalent to your agency. Instead ARTICLE 1 (below) was observed to give breast cancer to the University and ARTICLE 2 (below) gave research to the State Department of Health Services (estimated to be renamed Department of Health Care Services).

- 42 CFR 93.232 Research means a systematic experiment, study, evaluation, demonstration, or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) by establishing, discovering, developing, elucidating, or confirming information or underlying mechanisms related to biological causes, functions, or effects; diseases; treatments; or related matters to be studied.
- NCI EVS Explore Code - C16199 Cancer Research Systematic investigation into the causes of cancer and development of strategies for prevention, diagnosis, treatment, and cure.
- California Health and Safety Code, Div 103, Part I, Chapter 2
 - ARTICLE 1. The Breast Cancer Research Program 104145(b)(1) Breast cancer research includes, but is not limited to, research in the fields of biomedical science and engineering, the social, economic and behavioral sciences, epidemiology, technology development and translation, and public health.
 - ARTICLE 2. The Cancer Research Act of 1997 104181(c)(1) "Cancer research" is research with respect to the cause and prevention, cure, diagnosis, and treatment of cancer, including, but not limited to, intramural and extramural research in the fields of biomedical science and engineering, economics, epidemiology, diet and lifestyle, public health, and technology development and translation, with emphasis on noninvasive treatments.

Do varying definitions increase the possibility of NCI taking on activities another agency might have lead? Supporting Statement A (A.3) said Most programs are developing an electronic application system, if one is not already in place. Are tech agencies or tech departments able to minimize NIH tech

burden? Also observed was NCI's opportunity for Alleviating Financial Toxicity for Cancer Survivors and Caregivers in the Highlighted Scientific Opportunities in Cancer Research. Are financial offices and financial departments able to minimize NIH burden?

4 Analysis - personnel

The comment location is the context and considering States as backup application systems.

Would the total paperwork just shuffle, or would it be less if part of the research positions are hired by another organization? The high school opportunity observed in *Need and Use of Information Collection* may have already been demonstrated by a State according to page 37 of the Connecticut Cancer Plan 2021-2026. Can States take away some of the collection burden? (29 USC Chapter 4B, Sec. 49g. State plans)?

Would there be confidence a State can provide a backup application system if they included Supporting Statement Attachment 3 - Application Example in their plan? An example plan is California's 2024-2027 Unified Strategic Workforce Development Plan, but it was unclear if Attachment 3 was there, at least by the table of contents.

5 Analysis - plain language

The comment location is again the context and encouraging plain language, since specific goals were not observed.

5.1 plain language - basic biology

From the perspective of believing in the bible creation account, it was not 100 percent certain that cell and tissue biology can be modeled and simulated like other man-made products. No scriptures were remembered against it. A non expert might quickly experience a desire for plain language in modeling and simulation when 5% of the verbiage (estimated) in research reports contains unknown words. Also, experts in different fields might have trouble connecting if they also don't know all of the words. Some old ebooks written by experts were listed below to identify statements encouraging improvement to basic biology (plain language) for models and descriptions. Does it matter as an institute goal?

- Catalyzing Inquiry at the Interface of Computing and Biology
 - 5.1 ON MODELS IN BIOLOGY. *one excerpt* Human comprehension of biological systems is limited, among other things, by that very complexity and by the problems that arise when attempting to dissect a given system into simpler, more easily understood components. This challenge is compounded by our current inability to understand relationships between the components as they occur in reality, that is, in the presence of multiple, competing influences and in the broader context of time and space.

- 5.2.10 In the words of Pollard, "Any cellular process involving more than a few types of molecules is too complicated to understand without a mathematical model to expose assumptions and to frame the reactions in a rigorous setting." ...
- 5.2.12 ... Lander points out that molecular biologists traditionally have shied away from teleological matters, and that geneticists generally define function not in terms of the useful things a gene does, but by what happens when the gene is altered. However, as the complexity of biological mechanism is increasingly revealed, the identification of a purpose or a function of that mechanism has enormous explanatory power. That is, what purpose does all this complexity serve? ...
- 5.3 TYPES OF MODELS. [mentioned many models and ambiguity]
- Mathematics and 21st Century Biology. Offers 1. *Nature of the Field / What Makes Computational Biology Problems Hard?*
- Nanotechnology and Oncology
 - 3 Research and Development of New Cancer Nanomedicines Challenges and Solutions / BASIC BIOLOGY. *excerpt*: Improving our understanding of nanotechnology and how it can be applied to oncology rests, in part, on improving our understanding of basic biology and the pathogenesis of cancer, as well as biomarkers for cancer, some speakers noted. The dearth of good biomarker targets for prevention, diagnosis, prognosis, treatment, and monitoring is currently a limitation on development of nanomedicine for oncology and more generally. For nanomedicines for cancer prevention, for example, there needs to be a better understanding of what a precancerous lesion is, Dr. Hawk noted, and improved sensitivity and specificity of the technologies used to detect preinvasive neoplasia or early-stage cancer. Also needed are ways to identify populations at risk for prevention studies, and to identify meaningful endpoints for cancer prevention trials. There is great promise in measuring multiple biomarkers for early detection, but that promise remains a promise. It is not yet demonstrated, certainly, in the context of prevention, Dr. Hawk said.

5.2 plain language - tech

The Z-codes in the the pick list on the NIH Intramural Database (NIDB) at first glance did not look like plain language. Even if the public is not supposed to understand intramural (internal) codes, would definitions help internal? The plain language guide said to Choose your words carefully and maybe this includes pick list codes. There are many organizations and open source ways to improve HTML pick lists, so a specific improvement not attempted. If NIH has an internal procedure like having new hires memorize the Z-codes, the public would not know.

6 Recommendations

Consider the comments and questions. If something is helpful, please process. If it is not practical, it maybe skipped (author opinion) without any reply.

7 Conclusion

Obviously people are experiencing the cancer. Basic comments may be considered while research progress has not concluded. Basic comments have included edits to the notice, procedure, definitions, questions about State application systems, and encouraging plain language while other exact goals are unknown.