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PEER REVIEW OF RESEARCH AND SCIENTIFIC PROGRAMS

Sections:

Attachment: TOOLS AND ADDITIONAL RESOURCES

1. PURPOSE AND SCOPE

This policy provides general guidance on the requirements for external peer review of all extramural and intramural research at the Centers for Disease Control and Prevention (CDC)[2]. This policy also includes external peer review of scientific programs and public health practice (non-research) conducted by the CDC (see Section 5, Item A).

2. BACKGROUND

The concept of peer review is strongly accepted by the scientific community. Peer review provides confidence that funding for research and scientific programs supports the most meritorious ideas and projects.

Peer review is critical to enable CDC to achieve greater and more effective public health impact. Peer review activities relate directly to two strategic imperatives: effective public health research and accountability. The critical review of research and scientific programs based on the principles of merit will enable CDC to maintain progress in achieving its health protection goals.

Since 1994, the Office of Management and Budget (OMB) has expected federal agencies engaged in research and development activities to enhance the utilization of merit review with peer review for competitive selection of projects and programs. In January 2002, OMB issued "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies" (See Section 5, Item B). The guidelines establish that technical information subjected to formal and independent external peer review is presumptively objective. Operating Divisions (OPDIVs) of the Department of Health and Human Services (HHS), including CDC, is subject to these guidelines. This updated policy supports

[1] This policy has been revised to update CDC Operational Policy format, CDC nomenclature, and links to references provided in the policy.
[2] References to CDC also apply to the Agency for Toxic Substances and Disease Registry (ATSDR).

and is governed by Code of Federal Regulations Title 42 Part 52 (42 CFR 52, Grants for Research, see Section 5, Item C); Awarding Agency Grants Administration Manual (AAGAM), see Section 5, Item D; and HHS Grants Policy Directives, see Section 5, Item E.

3. POLICY

All research and scientific programs conducted or funded by CDC are subject to periodic external peer review as described below.

A. Research

1) Extramural Research

All extramural research applications submitted to CDC are required to go through external peer review by a Federal Advisory Committee, except in justified emergency situations. In such situations, the Center, Institute, and Office (CIO) director must submit written justification requesting an exception from this policy. Approval is granted by the CDC Office of the Associate Director for Science (OADS) or their designee in consultation with the CDC Procurement and Grants Office (PGO).

This policy applies to extramural research funded by grants or cooperative agreements, including institutional awards to research centers that support centralized resources and facilities shared by extramural investigators conducting research.

2) Intramural Research and Scientific Programs

Scientific programs (including research and non-research, and intramural and extramural activities), conducted or funded by CDC are subject to external peer review for scientific and technical quality. CIO directors are encouraged to implement a strategic and flexible approach to external peer review of scientific programs so that it effectively addresses specific program needs. For example, a CIO may elect to conduct peer review arranged by total portfolio, individual project studies, organizational structure, or cross-cutting topic. Core service activities, such as animal laboratory facilities or clinical pathology laboratories, may be subject to accreditation or audit review and also require peer review. At the discretion of the CIO, other core service activities may also benefit from periodic external audits and/or program reviews.

B. Peer Review Requirements

External peer review of research and non-research activities is a rigorous process that identifies strengths, weaknesses, gaps, redundancies and research or program effectiveness to provide a basis for informed decisions regarding scientific direction, scope, prioritization, and financial stewardship. Specific procedures for each type of review are referenced in the appropriate sections below.

1) Extramural Research

Extramural research typically undergoes sequential peer review. The first-level review is conducted by a panel of experts for the purpose of evaluating the scientific and technical merit of research applications. The second-level review involves a separate senior

advisory panel whose purpose is to evaluate the preliminary recommendations (merit evaluations and rankings) from the first-level review in the context of program relevance or priorities, policy considerations, and fiscal capacity.

Procedures to conduct peer review of new extramural research applications and continuation awards can be found in the CDC Handbook for Peer Reviewers (see Section 5, Item F).

2) Intramural Research and Scientific Programs

Peer review of intramural research and scientific programs must address program quality, approach, direction, capability, and integrity. In addition, at the request of the CIO, external peer reviewers may also address mission relevance and impact of scientific programs. Peer reviews may be conducted by Boards of Scientific Counselors (BSCs), Special Emphasis Panels (SEPs), or other "ad hoc" groups. If reviewers are recruited on an ad hoc basis, outside of a Federal Advisory Committee Act (FACA) committee, they must provide individual and independent comments of findings, and consensus decisions must be avoided (See Section 5, Items G-I).

Peer review of intramural research and scientific programs can be accomplished through a variety of mechanisms. The approach used for peer review may consist of portfolio or program review of major research topics, of work conducted in discrete organizational units, or review of single studies. Reviews may be conducted on site, by mail, by telephone conference, or by any other means that effectively supports the

3) Contract Administration

The contract administration process, including selection criteria and review, is regulated by the FAR (Federal Acquisition Regulations, see Section 5, Item J). Contract proposals are evaluated in a two-step process. The first step is a review conducted by a technical evaluation panel (TEP) of experts organized according to scientific disciplines or specialty research area. Chartered FACA committees, comprised of external members, may also be utilized to conduct technical evaluations of contract proposals. The second step is a review conducted by the contracting officer, the project officer, and the TEP, if needed, to determine the competitive range and negotiation of best and final offers. The contract award is made by the Procurement and Grants Office (PGO), contracting officer in consultation with the CIO director or his/her designee.

Task orders (TOs) are also used to authorize work required under a contract. Because the FAR do not regulate selection criteria and review of TOs, CDC can determine procedures provided each applicant is given a fair opportunity to be considered. Task orders will be reviewed and selected using existing PGO guidance and procedures.

For specific guidance related to Peer Review of Research Contracts, please consult with PGO.

4. RESPONSIBILITIES

A. Centers, Institute, and Offices (CIOs)

The Directors of CIOs are responsible for the implementation of this policy and annual reporting of planned and completed peer review activities to the CDC Office of the Associate Director for Science (OADS). An optional template for summarizing key findings from peer review is available from OADS. CIOs have responsibility for managing BSCs that are established at the CIO level, and to ensure that these BSCs are available to support peer review for any Center or Division that is located within the CIO.

In coordination with CDC's Federal Advisory Committee Management Officer, the CIO will ensure that reviews are conducted by experts external to CDC, not affiliated with the program and without conflict of interest.

B. CDC Associate Director for Science

The CDC Associate Director for Science is responsible for providing overall guidance, as needed, to CIOs to implement and to assess the utility, and effectiveness of the peer review process.

The CDC Associate Director for Science, in consultation with the Procurement and Grants Office, when appropriate, is responsible for granting exclusions to this policy.

C. CDC Federal Advisory Committee Management Officer

CDC's Federal Advisory Committee Management Officer, in coordination with CIOs, will ensure that reviews are conducted by experts external to CDC, not affiliated with the program and without conflict of interest.

D. CDC Procurement and Grants Office

The roles and responsibilities of CDC's Procurement and Grants Office as they relate to this policy are outlined in the Peer Review Manual (See Section 5, Item F), Awarding Agency Grants Administration Manual Chapter 1.04.1.04 (See Section 5, Item D), and Chapter 1.04 of the HHS Grants Policy Directive (See Section 5, Item E).

E. CDC Management Analysis and Services Office

The roles and responsibilities of CDC's Management Analysis and Services Office as they relate to this policy are outlined in the Federal Advisory Committee Management Handbook (See Section 5, Item K) and the Special Emphasis Panel Guide (See Section 5, Item L).

5. REFERENCES

A. Policy for Distinguishing Public Health Research and Public Health Nonresearch http://isp-v-maso-apps.cdc.gov/Policy/Doc/policy557.pdf.

B. Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies http://www.whitehouse.gov/omb/fedreg/final_information_quality_guidelines.html.

C. Code of Federal Regulations Title 42 Part 52 (42 CFR 52) http://www.access.gpo.gov/nara/cfr/waisidx_03/42cfr52_03.html.

D. Awarding Agency Grants Administration Manual http://intranet.hhs.gov/abouthhs/administrative/grantsinfo/awarding_agency/.

E. HHS Grants Policy Directives http://www.hhs.gov/asfr/ogapa/aboutog/ogpoe/gpdhome.html.

F. CDC Handbook for Peer Reviewers http://intranet.cdc.gov/od/oads/osq/extramural_research/pdf/CDC_Reviewer_Handbook_Revised022011.pdf.

G. Federal Advisory Committee Management - CDC Intranet http://intranet.cdc.gov/maso/cmppa/faca.htm.

H. Federal Advisory Committee Management – Internet https://intranet.cdc.gov/ocoo/services/federal-advisory-committees/

I. Federal Advisory Committee Act http://www.gsa.gov/portal/content/100916.

J. Federal Acquisition Regulations http://www.acquisition.gov/far/index.html.

K. Federal Advisory Committee Management Handbook https://www.gsa.gov/cdnstatic/FACAFinalRule_R2E-cNZ_0Z5RDZ-i34K-pR.pdf

L. Special Emphasis Panel (SEP) Guide http://intranet.cdc.gov/maso/cmppa/pdfs/sepguide.pdf.

6. ABBREVIATIONS AND ACRONYMS

BSC – Board of Scientific Counselors
CDC – Centers for Disease Control and Prevention
CIO – Centers, Institutes, and Offices
DHHS – Department of Health and Human Services
EISC – CDC Excellence in Science Committee
FACA – Federal Advisory Committee Act
FAR – Federal Acquisition Regulations
NIH – National Institutes of Health
OADS - Office of the Associate Director for Science
OMB – Office of Management and Budget
OPDIV – Operating Division
PGO – Procurement and Grants Office
R & D – Research and Development
TEP – Technical Evaluation Panel
TO – Task Order

6. DEFINITIONS

Boards of Scientific Counselors (BSCs) – BSCs are FACA committees established to advise the Secretary, HHS, and the Director, CDC concerning strategies and goals for programs and research within the CIOs conduct peer review of scientific programs and monitor the overall strategic direction and focus of the CIO.

CDC Staff – For the purpose of this policy, CDC staff refers to full-time equivalents (FTEs).

Dissemination – The process of opening a subject for widespread debate or discussion.

External Peer Review – The process includes independent assessment of research and scientific programs by experts who are external to CDC. Reviewers must provide written assurance that their reviews are free of real or perceived conflicts of interest. Peer review addresses scientific technical quality and, as appropriate, assesses mission relevance, impact, and direction.

Federal Advisory Committee Act (FACA) of 1972 (Public Law 92-463) – Government advisory committees are formally established through FACA (See Section 5, Item I).

Non-research (Public Health Practice) – Non-research activities include surveillance, specialized investigations, public health program, services and response, and program evaluation. Similarly, reporting the results of these activities is also considered non-research. The primary intent of non-research is to prevent or control disease or injury and improve health, or to improve a public health program or service for a population.

Non-research Support Activities – Non-research activities may also include support activities that serve the needs of either research or public health practice and that are subject to accreditation, audit, or performance review. These support activities might include:

- Laboratory animal facilities
- Core clinical, pathology, and analytical chemistry laboratories
- Mathematical and statistical services
- The conduct and administration of peer review activities

Research – Research is a systematic investigation, including development, testing, and evaluation, that is designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered non-research for other purposes.(See Section 5, Item A). Decisions regarding whether a project is research or non-research should be based on guidance in the CDC Human Subjects Research document "*Policy for Distinguishing Public Health Research and Public Health Nonresearch"* (See Section 5, Item A).

- **Extramural Research** – Research activities funded through an assistance mechanism (i.e., grant or cooperative agreement).
- **Intramural Research** – Research activities directed by CDC or funded through an acquisition mechanism (i.e., contract). It does not include research funded through an assistance mechanism as defined above.

Scientific Program – For the purpose of this policy, the term "scientific program" includes, but is not necessarily limited to, intramural and extramural research and non-research (e.g., public health practice, core support services). Peer review of a scientific program may address 1) single or multiple activities, 2) a portfolio of organizational units or cross-cutting topics that relate to a unit's work, or 3) multiple organizational units at CDC.

ATTACHMENT: TOOLS AND ADDITIONAL RESOURCES

A template for summarizing and reporting key findings from peer reviews and guidance and resources on establishing and conducting external peer reviews have been compiled by OADS and are available on the OADS intranet site at:

http://intranet.cdc.gov/od/oads/osq/science_review/policy_guidance/index.htm