CATEGORY: General Administration
CDC-GA-2002-09 (Formerly CDC-101)
DATE OF ISSUE: 9/27/2002; Revised 9/3/2008[1]
PROPONENT: Office of the Director, Office of the Chief Science Officer

PEER REVIEW OF RESEARCH AND SCIENTIFIC PROGRAMS

Sections:

Exhibit: **Documentation of Peer Review Form**

1. PURPOSE AND SCOPE

This updated policy continues to provide general guidance on the external peer review of all extramural and intramural research at the Centers for Disease Control and Prevention (CDC)[2] and augments the original policy to include 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 support 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, are subject to these guidelines. As of October 1, 2002, these guidelines mandate not only the need for peer review but also other quality control

[1] Policy revised to comply with HHS guidelines and to expand the scope of external peer review of research and scientific programs.
[2] References to CDC also apply to the Agency for Toxic Substances and Disease Registry (ATSDR).

processes to ensure utility and integrity of disseminated information. In addition, this updated policy supports 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.

In September 2002, CDC issued a policy "Peer Review of Research" (CDC-GA-2002-09). This policy established criteria and schedules to implement external peer review of all extramural and intramural research projects with initial review to be completed by October 1, 2007. This policy made CDC practices more consistent with other HHS OPDIVs such as the Agency for Healthcare Research and Quality (AHRQ) and the National Institutes of Health (NIH), and it increased CDC's visibility and credibility as a research-focused public health agency.

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 directors of coordinating centers (CC), coordinating offices (CO) or national centers (NC)[3] can request, with justification, an exclusion from this policy. Approval is granted by the CDC Chief Science Officer or his/her 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

As part of the Board of Scientific Counselors (BSC) administered review of scientific programs, all intramural research conducted by CDC must be externally peer reviewed for scientific and technical quality at least once every five years. (See Section B "Procedures" for more specific information on this review). CC/CO/NC should augment the program review with peer review of individual studies as appropriate. Major research studies must be reviewed at inception. These research studies are defined by the CC/CO/NC director or his/her designee, and are generally studies with large budget or staff commitments, or projects anticipated to produce findings of high importance or interest. For other research studies, peer review at the beginning of the study is at the discretion of the

[3] For ease of reference within policy documents, "center" will refer collectively to CDC's national centers, institute, and the Agency for Toxic Substances and Disease Registry (an independent Health and Human Services agency that is led by the CDC director and for which CDC provides administrative services).

CC/CO/NC director or his/her designee. When appropriate, due to potential impact or policy implications, the CC/CO/NC will also obtain external review of research study results prior to dissemination (e.g., journal peer review may fulfill this requirement).

- All research contracts with total direct costs of $100,000 or greater will be subject to peer review, except in justified emergency situations. In such situations, the CC/CO/NC, can request, with justification, an exclusion from peer review. This request can be granted by the CDC Chief Science Officer or his/her designee.

3) Scientific Programs

Scientific programs (including research and non-research), conducted or funded by CDC are subject to BSC administered, external peer review for scientific and technical quality at least once every five years. Directors of CC/CO/NC 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 CC/CO/NC 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 thus also require peer review. At the discretion of the CC/CO/NC, other core service activities may also benefit from periodic external audits and/or program reviews.

B. Procedures

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 for the conduct of peer review of new extramural research applications and continuation awards can be found in the Peer Review Manual (see Section 5, Item F).

2) Intramural Research and Scientific Programs

Board of Scientific Counselors -administered peer review of intramural research and scientific programs must address program quality, approach, direction, capability, and integrity. In addition, at the request of the CC/CO/NC, external peer reviewers may also address mission relevance and impact of scientific programs. The BSC may elect to utilize workgroups or subcommittees to assist in the review. A BSC peer review

may be augmented by other types of peer review as appropriate. For example, programs may wish to conduct ad hoc reviews of individual projects on a more frequent cycle than BSC reviews. Programs may also choose to use ad hoc reviews as background material for BSC peer review, (for example, to obtain highly specialized expertise needed to review specific projects). If reviewers are recruited on an ad hoc basis apart from a FACA committee, then reviewers must provide individual and independent comments, and consensus decisions must be avoided. (See Section 5, Items G-I)

Peer review of intramural research and scientific programs may be accomplished through a variety of mechanisms. The approach to 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 process of review.

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 is review 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 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 CC/CO/NC director or his/her designee.

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

For specific guidance related to peer review of research contracts, please consult directly with a Contracting Officer in PGO.

4. RESPONSIBILITIES

A. Coordinating Offices / National Centers

The Directors of CO / NC are responsible for the implementation of this policy and annual reporting of planned and completed peer review activities to the CDC Associate Director for Science (ADS). An optional template for summarizing key findings from peer review is available from the Office of the Chief Science Officer. Coordinating Offices and National Centers have responsibility for managing BSCs that are established at the CO/NC level.

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

B. Coordinating Centers

Coordinating Centers have responsibility for managing BSCs that are established at the CC level, and to ensure that these BSCs are available to support peer review for any NC that is located within the CC.

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

C. CDC Associate Director for Science

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

D. CDC Chief Science Officer

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

E. CDC Federal Advisory Committee Management Officer

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

F. 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).

G. 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. Guidelines for Defining Public Health Research and Public Health Non-Research
http://www.cdc.gov/od/science/regs/hrpp/researchDefinition.htm

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/grantsinfo/gpdstable.html

E. HHS Grants Policy Directives
http://intranet.hhs.gov/grantsinfo/gpdstable.html

F. CDC Peer Review Manual

G. Federal Advisory Committee Management – Internet
http://www.cdc.gov/maso/FACM/facmhome.htm

H. Federal Advisory Committee Act
http://www.gsa.gov/Portal/gsa/ep/contentView.do?contentType=GSA_BASIC&contentId=11635&noc=T

I. Federal Acquisition Regulations
http://www.arnet.gov/far/

J. CDC Federal Advisory Committee Management Handbook

K. Special Emphasis Panel (SEP) Guide

L. DHHS Project Officers' Contracting Handbook
http://www.knownet.hhs.gov/acquisition/bpostudenthandbook2.doc

M. National Institutes of Health. Office of the Director. NIH Manual Chapter 6315-1-Initiation, Review, and Evaluation, and Award of R&D Contract Projects

6. ABBREVIATIONS AND ACRONYMS

A. ADS – Associate Director for Science
B. AHRQ – Agency for Healthcare Research and Quality
C. BSC – Board of Scientific Counselors
D. CC/CO – coordinating center/coordinating office
E. CDC – Centers for Disease Control and Prevention
F. CSO – Chief Science Officer
G. DHHS – Department of Health and Human Services
H. EISC – CDC Excellence in Science Committee
I. FACA – Federal Advisory Committee Act
J. FAR – Federal Acquisition Regulations
K. NC – national center
L. NIH – National Institutes of Health
M. OMB – Office of Management and Budget

N. OPDIV – operating division
O. PGO – Procurement and Grants Office
P. R & D – research and development
Q. TEP – technical evaluation panel
R. TO – task order

7. DEFINITIONS

A. 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 CC/CO/NC, conduct peer review of scientific programs, and monitor the overall strategic direction and focus of the CC/CO/NC.

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

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

D. 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.

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

F. 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.

G. 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

1) laboratory animal facilities,

2) core clinical, pathology, and analytical chemistry laboratories,

3) mathematical and statistical services, and

4) the conduct and administration of peer review activities.

H. 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 B). Decisions regarding whether a project is research or non-research should be based on guidance in the CDC Human Subjects Research document "*Guidelines for Defining Public Health Research and Public Health Non-Research"* (See Section 5, Item B).

1) **Extramural Research.** Research activities funded through an assistance mechanism (i.e., grant or cooperative agreement).

2) **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.[4]

I. 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.

8. TOOLS AND ADDITIONAL RESOURCES

An optional template for summarizing key findings from peer review and resources on establishing and conducting external peer review, including case studies from CC/CO/NC have been compiled by the CDC Excellence in Science Committee (EISC) and will be available from the Office of the Chief Science Officer upon request.

[4] Decisions on whether a contract is research should be based on guidance in the DHHS Project Officers' Contracting Handbook (See Section 5, Item M) and the NIH Manual Chapter 6315-1- Initiation, Review, and Evaluation, and Award of R&D Contract Projects (See Section 5, Item N).