scientific information, conference planning and implementation may still proceed. However, rather than being designated a Consensus Development Conference, the conference will be designated as a State of the Science Conference. *NIH State of the Science Conferences and Workshops* generally adhere to the NIH CDC format because the process is useful for evaluating complex issues. Usually, speakers present findings or perspectives on the issue. The public is invited to address questions to the speakers, and policy implications may be discussed. A report of the findings can emerge in one of a variety of formats including publication in a clinical or scientific journal. The Web site for the State of the Science Statements can be found at: odp.od.nih.gov/consensus/ta/talist.htm.

Although it is difficult to quantify their impact, the NIH Consensus Statements and State of the Science Statements are intended to influence important public health discussions on topics affecting or broadly applying to a significant number of people. The severity of the problem (morbidity and mortality) and the feasibility of intervention are key considerations. For example, the program has had measured success in influencing reimbursement policy and specialty organization policy, thereby indirectly affecting physician behavior. Each conference is jointly sponsored and administered by one or more ICs of NIH and by OMAR. Depending on the topic, other Federal agencies with biomedical components may join in sponsoring a CDC. In conjunction with each conference, the Agency for Health Care Research and Quality (AHRQ) provides a systematic review of the literature on the conference topic through one of its Evidence-Based Practice Centers.

Both the Consensus Statements and the State of the Science Statements are independent reports of the convened panel; none are policy statements of the NIH or the Federal Government. However, NIH funds and disseminates the Consensus Reports, and considers these Statements to be subject to OMB's higher standard of substantial reproducibility. These Statements meet the OMB's quality standards because of the balanced, rigorous, and systematic procedures that OMAR has in place to develop them. The panel makes available the evidence on which the Consensus Statement is based. If consensus cannot be achieved, minority or alternative views are included. The systematic literature review conducted by AHRQ is published with their explicit methods. The reports are peer-reviewed by expert panels, and posted on the Internet for at least one month for public comment.

d. Health, Safety, and Environmental Information

To make environmental health research findings more applicable to human risk assessment, NIH works in partnership with the CDC and the EPA to develop better ways to monitor and assess human exposure to specific chemicals. One of our most visible publications is the Report on Carcinogens (RoC), a congressionally mandated document that lists agents, substances, mixtures or exposure circumstances that are known or reasonably anticipated to be human carcinogens, and to which a significant number of persons residing in the United States are exposed. Responsibility for producing this report has been delegated to the National Toxicology Program (NTP) and the Director NTP also serves as the Director, NIEHS, NIH.[6] The RoC is a composite of Summary Profiles that describes the carcinogenicity, exposure, and regulatory information for each listing with relevant tables and appendices. Substances, agents, mixtures or exposure circumstances that are being considered by the NTP for possible listing or de-listing in the RoC (referred to as nominations) are evaluated by a review process

consisting of sequential reviews by distinct scientific review committees -- two Federal scientific review groups and one nongovernmental scientific peer-review body. External peer review of the nominations is performed by a subcommittee of the NTP Board of Scientific Counselors in open, public meetings. Publicly available, peer-reviewed technical reports are the primary sources of data used in the preparation of the Background Documents for each specific nomination.

Continuing opportunities for public comment and participation are an integral part of the process. The recommendations of the three (3) scientific review groups are published in the *Federal Register*, NTP newsletters and web pages and other appropriate publications to solicit final public comment and input for nominations. The recommendations and all public comments are provided to the NTP Executive Committee, who reviews this information and provides the Director, NTP with their recommendations. All recommendations and public comments are then reviewed by the Director, NTP, who forwards the final draft of the Report that contains his recommendations to the Secretary, HHS for the listings or de-listings in the RoC. Upon review and approval by the Secretary, HHS, and submission to Congress, a notice of the RoC publication, indicating all newly listed or de-listed agents, substances, mixtures or exposure circumstances is published in the Federal Register, NTP newsletters and web pages and other appropriate publications.

It is important to note that the RoC does not present assessments of carcinogenic risks. Listing of substances in this Report, therefore, does not establish that such substances present carcinogenic risks to individuals in their daily lives. Such formal risk assessments are the purview of the appropriate Federal, State, and local health regulatory and research agencies. However, for each effluent, ambient, or exposure standard established by a Federal agency with respect to a listed substance, the RoC is required to state the extent to which, on the basis of available medical, scientific, or other data, the implementation of such standard decreases the risk to public health from exposure to the substance. This requires quantified information on the extent of protection from cancer that the public receives from established Federal standards. Only in a few instances, where studies of long-term human exposures and cancer incidence in restricted environments are available, can risk be estimated with complete confidence.

NIEHS and NTP procedures conform to accepted NIH scientific practices where quantitative and qualitative scientific conclusions are based on: (1) The best available science and supporting studies, particularly peer-reviewed studies, conducted in accordance with sound and objective scientific practices; and (2) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data). The NIEHS and NTP make every effort to ensure that the presentation and dissemination of information about environmental health is comprehensive, informative, and understandable.

Scientific results that can directly affect risk assessment and risk management activities are often published in the NIEHS journal *Environmental Health Perspectives* (EHP), but do not necessarily represent the viewpoints of NIEHS. EHP also publishes perspectives in the form of editorials, commentaries, reviews, and correspondence, as well as workshop summaries. Workshop summaries are reports by expert scientific committees that include reviews of existing information and that summarize research findings on specific topics, present new information, and

recommend methods, courses of action, or further research needs for the scientific community. All scientific articles, including workshop summaries, are subject to rigorous peer review. The criteria for publication are weighted toward scientific quality and environmental significance. A submission is assessed according to its originality, scientific merit, and experimental design; the manuscript is evaluated for its conciseness, clarity, and presentation. These standards are thus consistent with the requirement that the presentation of information on risk effects be comprehensive, informative, and understandable. EHP also addresses certain ethical problems during the review process and requires assurances that all human and animal subjects have been treated humanely and with regard for the alleviation of suffering. The review also considers scientific integrity as part of the process.

e. ***NIH Clearinghouse Information*** Clearinghouses often serve as the public's point of contact and access to information about IC programs, conferences, and research activities. At NIH, clearinghouses have been contracted to provide varying levels of service, including development and distribution of fact sheets, information packages, and publications; storage of materials; conducting outreach and promotion; and performing training and quality control for the clearinghouse staff. Some clearinghouses respond to inquiries about particular diseases or conditions, ranging from information about available patient and professional education materials to statistical data. Clearinghouses are challenged to ensure accuracy and reliability of information, while continually striving to improve performance and response times. Some clearinghouses also wrestle with how to determine which organizations are worthy of referral when customers need information that is not available at the clearinghouse and how to avoid implying endorsement. Clearinghouse inquiries may also be answered by searching the Combined Health Information Database (CHID), an NIH/CDC database that provides bibliographic references of both NIH and non-NIH materials on various health topics. This database represents a shared data archive, and as such is not covered by the new OMB guidelines.

The NIH Manual chapter 1183 requires that official materials or information prepared by any NIH component directly or through a contract must be sent for HHS clearance through the Editorial Operations Branch, using form HHS-615, Publication Planning and Clearance Request. This clearance requirement does not apply to publication of articles in journals. Information developed by a clearinghouse for an NIH IC is subject to the OMB Guidelines. See NIH Manual Chapter 1183 for further information regarding this requirement.

At NIH, there are essentially three types of materials being disseminated through information clearinghouses to the public: (1) Materials produced by NIH staff or contractors that undergo usual NIH review and approval processes; (2) materials produced by NIH grantees that are subject to policies and procedures in the Public Health Service (PHS) Grants Policy Statement; and (3) other materials not produced by NIH but available through libraries, whether in print or in electronic format, with appropriate

disclaimers attached. Virtually all NIH ICs direct their clearinghouses to distribute only materials produced by the IC or other NIH ICs or Federal agencies. Non-Federal materials typically undergo careful IC scientific review before they are authorized for dissemination by the clearinghouse, and those materials are accompanied by appropriate disclaimers.

3. Procedures to Ensure the "Integrity" of Information

NIH has developed World Wide Web (WWW) Guidance (April 15, 1998), which is available on the Internet (irm.cit.nih.gov/policy/guideli2.html). Each IC has a designated IC contact/reviewer for information and approvals related to developing Web pages and operating a new Web server. The list of IC contacts/reviewers is available on the Web (www.nih.gov/employee/weblist.htm) and was last updated on March 6, 2002. NIH/IC Web page creators periodically review material on the Web page to determine whether it is accurate and up to date. Information, particularly time-sensitive information, should be posted as soon as possible. Web page creators are expected to promptly update or remove out-of-date information.

Unless noted otherwise, it is safe to assume that information posted on public Web sites within the "NIH.GOV" domain is considered to be "in the public domain." As such, others are free to establish links to NIH online resources. In establishing such links, NIH requests that others avoid creating the impression that NIH is endorsing or promoting any particular product or service. In the same vein, any outside link to an external resource from an NIH Web site needs to be examined on a case-by-case basis. In general, the Web developer of each site determines when links to outside entities are justified.

NIH Web managers are urged to exercise caution when linking to non-NIH, external websites. Professional judgment should be used to weigh the benefits against the possible risks of linking to other resources. In particular, links to sites providing medical and scientific information needs to be on par with the standards used at NIH to ensure the credibility of the information offered there. Steps should be taken to ensure that such links do not give the impression of endorsing the organizations we link to. NIH/IC Web pages containing links to external Web pages not located on NIH servers should include a link to a statement that releases NIH from responsibility for the material included in the external Web page. Again, it is important to avoid giving a user the impression that NIH is endorsing information or a commercial product described in an external site. Disclaimers on copyright, endorsement (general and external links), liability, and medical information are also used, as appropriate, for individual IC Web sites.

The IC designates a main office or contact person for information and approvals related to Web pages and the operation of Web servers. NIH personnel, contractors, and other authorized users of NIH networks must notify this office or contact person prior to setting up a Web server. Information about appropriate security measures regarding Web Servers is available at: irm.cit.nih.gov/nihsecurity/NIHWebServPol.doc. The IC or the OD Information Office can provide detailed information on required approvals including both NIH and IC-specific policies relating to publication of documents. NIH/IC documents derived from IC-approved printed publications should not need additional approvals (see Section V.2).

The NIH Center for Information Technology (CIT) is charged with providing, coordinating, and managing information technology for NIH, and with advancing computational science. In

terms of computer security, CIT has three distinct objectives: Confidentiality -- ensuring that there is no deliberate or accidental improper disclosure of sensitive automated information; integrity -- protecting against deliberate or accidental corruption of automated information; and availability -- protecting against deliberate or accidental actions that cause automated information resources to be unavailable to users when needed. Information is accorded protection against disclosure, alteration, loss, or destruction based on the degree of sensitivity.

CIT staff use appropriate safeguards to protect data from improper disclosure by backing up critical data periodically, and, if a security incident occurs, by following proper incident response procedures. In 1994, CIT adopted a security incident response policy and procedures statement that establishes the responsibilities of CIT staff in responding to and reporting computer security problems. Supervisors are responsible for ensuring that employees, both Government and contractor, observe all security requirements, and that employees receive appropriate security training.

CIT has instituted a structured management control review process that applies throughout the system life cycle. Risk analyses are conducted to strike a balance between an acceptable level of risk and the costs and inconvenience associated with safeguards. A system recertification/accreditation must be conducted at least once every 3 years. Additional information about NIH computer security measures can be found in The Computer Security Handbook of CIT (www.cit.nih.gov/security/handbook.html).

VI. Agency Administrative Complaint Procedures

NIH has developed administrative procedures to allow affected persons to seek and obtain correction of disseminated information that does not comply with OMB, HHS, and NIH guidelines (See NIH Manual Chapter 1185, forthcoming). Additional guidance on appropriate responses can be obtained from OCPL/OD/NIH, particularly if the complaint involves a policy statement or official position. NIH will establish a website to advise information consumers of the agency's information quality guidelines, the process to submit a request for correction, information needed by the requestor, and a description of the complaint adjudication process.

The resolution process addresses the valid needs of the complainant without disrupting NIH processes. Complainants should be aware that they bear the "burden of proof" with respect to the necessity for correction, as well as with respect to the type of correction they seek. In making a determination of whether or not to correct information, NIH may reject claims made in bad faith or without justification, and is required to undertake only the degree of correction that is appropriate for the nature and timeliness of the information involved.

1. Responsibility of the Complainant

To seek a correction of information disseminated by the NIH or its components, an individual should submit or mail the request to the disseminating office (contact information for individual ICs will be made available through the NIH Information Quality website), or submit the request by electronic mail (email) to InfoQuality@od.nih.gov or mail the complaint to:

Associate Director for Communications
Office of the Director
National Institutes of Health
Building 1, Room 344

9000 Rockville Pike
Bethesda, MD 20892

The request should state that an information quality request for correction is being submitted, and should provide the following information:

- A detailed description of the specific material that is proposed for correction, including where the material is located, i.e., the publication title, date, and publication number, if any, or the website and web page address (URL), or the presentation, presenter, date and mode of delivery;
- The specific reasons for believing that the information does not comply with OMB, HHS, or NIH guidelines and is in error, and supporting documentation, if any;
- Suggested recommendations for what corrective action(s) should be taken;
- A description of how the person requesting the correction is affected by the information error; and
- Complete contact information for the requestor, including name, mailing address, telephone number, e-mail address, and organizational affiliation, if any.

2. Determination of Appropriate Response

Requests for correction should be handled primarily by the originating IC Director or designee (e.g., Scientific Director, Laboratory or Branch Chief). IC Directors are responsible for establishing and maintaining procedures to ensure that requests are properly addressed, that an objective and qualified review of the merits of the request is undertaken, and that an appropriate response is provided in a timely manner. The procedures may include forming a review committee or equivalent, and shall allow for response by the originating and contributing authors, as well as input from the IC Communications Director.

A complaint about information originating from a division or office within the Office of the Director (OD), NIH, should be addressed by the director of the division or office, with input from the Office of Communications and Public Liaison (OCPL), OD, NIH.

If more than one IC was involved in releasing the information, the IC of the lead NIH author should take primary responsibility for coordinating a response.

3. Appropriate Responses

Based on a review of the information provided, the responding office should determine whether a correction or clarification is warranted and if so, what action to take. Agencies may choose not to change claimed defects that are frivolous or unlikely to have substantial future impact. If NIH determines that action is warranted, NIH may respond in any of the following ways:

- Provide a clarification by personal contact via letter or telephone;
- Issue a written retraction or clarification, which can be accomplished through a press release, mass mailing, or some other reasonable method that corrects a widely disseminated error or addresses a frequently raised complaint;

Suspend further dissemination of the information in question;

- Refer complainant to the underlying data if the data are available in a public archive;
- Arrange for an independent reanalysis of the data by NIH or a mutually acceptable third party if the data are not publicly available, and the complaint involves "influential scientific or statistical information." Complainants must agree to pay the costs of reanalysis or the process terminates.
- Work with the grantee institution to respond to the complaint, when it involves research from a grantee. Complaints must be about information derived from a project that is supported in whole or in part with Federal funds under a new or competing continuation grant awarded after April 17, 2000, and that is cited officially by a Federal agency in support of an action that has the force of law, such as a new regulation or administrative order. (If not available elsewhere, these types of data can be obtained from a FOIA Coordinator for the granting IC, see www.nih.gov/icd/od/foia/coord.htm. Additional information about NIH FOIA procedures, including requests, appeals, and fees, is available at www.nih.gov/icd/od/foia/. For NIH guidance on OMB Circular A-110 see grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm).

The response to the complainant will be by letter or email, and should explain the findings of the NIH review of the merits of the complaint, and the actions to be taken, if any. The response should consider the nature and timeliness of the information involved and such factors as the significance of the correction on the use of the information and the magnitude of the correction. The response should also describe how the complainant may request reconsideration. NIH will respond to all requests for corrections within 60 calendar days of receipt. If the request requires more than 60 calendar days to resolve, the responsible official will inform the complainant that more time is required and indicate the reason for the delay and an estimated decision date.

Whether or not corrective action is warranted, the response to the complainant should describe the preparation, clearance, review, and approval process prior to the information being disseminated, including any specifics about the peer review process to support the rigor and objectivity of the review, e.g., the breadth and depth of experts, community input, and message testing. The response should also reiterate any disclaimers that accompanied the information when it was first released.

Additional guidance on appropriate responses can be sought from OCPL, OD, NIH, particularly if the complaint involves a policy statement or official position.

4. Reporting Requirements

The IC (or OD office) receiving a request for information correction is required to enter the complaint into the NIH tracking database for this purpose. The IC is

encouraged to contact OCPL, OD, NIH to discuss the nature of the complaint, and to provide a preliminary assessment of whether the complaint is legitimate. Among the criteria to be used:

- The information is considered official NIH information, i.e., approved through the NIH clearance process and intended to represent the views of NIH.
- The information is substantive (i.e., reports, studies, summaries) rather than pertaining to basic agency operations.
- The information was disseminated on or after October 1, 2002
- The information is not exempt according to Section C (Applicability) of this chapter.
- The complainant is someone who may benefit or be harmed by the disseminated information. This includes persons who are seeking to address information about themselves as well as persons who use information.

If the IC determines that corrective action is warranted, the IC shall forward the following information to OCPL, OD, NIH without delay:

- A copy of the complaint.
- A list of the relevant contacts within the NIH IC or OD office, including the names of those most knowledgeable about the information in question.
- A draft letter response with any supporting documentation.

OCPL responsibilities include:

- Assisting with the review of the complaint for legitimacy. If the complaint is later determined not to be legitimate, the IC must provide a clear explanation of the rationale for that determination to the complainant.
- Reviewing the proposed IC response for appropriateness, and assisting in finalizing the response.
- Maintaining a tracking database of complaints, including information on their disposition and any resolution or corrective action taken.
- Submitting an annual report on behalf of NIH to the Department of Health and Human Services (HHS) with the number and types of complaints, and the action taken, in time for the HHS to report to OMB by January 1 (beginning in 2004).
- Posting on the OCPL Web site any further clarifications, guidelines, and Frequently Asked Questions (FAQs) about handling NIH information complaints.
- Making examples of typical complaints and appropriate responses available to ICs.

5. Appeals

If NIH denies a request for correction, the complainant may send within 30 days of receipt of the agency's decision a written request for reconsideration. The request should state the reasons for the appeal and may be sent as hard copy or electronically to InfoQuality@od.nih.gov. Requestors should reference the NIH tracking number provided in the NIH response to the original request. If sent by hard copy, requestors should also clearly mark the appeal and the outside envelope,

"Information Quality Appeal," and send the appeal to the following address:

Associate Director for Communications
Office of the Director
National Institutes of Health
Building 1, Room 344
9000 Rockville Pike
Bethesda, MD 20892

Any office that originally disseminated the information and/or responded to the original complaint should not have responsibility for the resolution of the appeal. If the information in dispute was originally disseminated by the OCPL/NIH, then an appeal should be addressed to the NIH Director at the address listed above, or sent electronically to InfoQuality@od.nih.gov.

NIH will respond to all requests for appeals within 60 calendar days of receipt. If the request requires more than 60 calendar days to resolve, the agency will inform the complainant that more time is required and indicate the reason for the delay and an estimated decision date.

VII. Influential Scientific, Financial, and Statistical Information

The OMB Information Quality Guidelines require that "influential" scientific, financial, or statistical information in official Government documents must be based on studies that can be substantially reproduced if the original or supporting data were to be independently reanalyzed using the same methods. "Influential" when used in the phrase "influential scientific, financial, or statistical information" means that the NIH can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions, or will have important consequences for specific health practices, technologies, substances, products, or firms." NIH is committed to applying rigorous scientific standards to ensure the accuracy, reliability, and reproducibility of research results.

The reproducibility standard applies to analytic results and not necessarily to the original and supporting data used to produce the analytic results. To facilitate the replication of scientific and other influential information by qualified third parties, NIH continues to encourage the sharing of original data and methods where practicable. After publication, the research data, any unique reagents, and any supporting data that form the basis of any research communication should be made available promptly and completely to any person who seeks further information.

Since the influence and implications of NIH-disseminated information cannot always be fully anticipated, all NIH scientific reports are expected to state clearly how analytic results are generated -- the specific data used, various assumptions, specific analytic methods, statistical procedures, sources of error -- making the analysis sufficiently transparent so as to be capable of being reproduced. NIH advocates the archiving of data where feasible to facilitate the reproducibility of influential information. Exceptions may be necessary to maintain the confidentiality of clinical data or if unique materials were developed or obtained under agreements that preclude their dissemination. Investigators should retain research data long enough to allow replication of study results -- in general, 5 to 7 years. In situations where public access to underlying data is not practicable, NIH shall apply especially rigorous robustness checks to analytic results and document what checks were undertaken.

Examples of the types of information disseminated by NIH that have the potential of being considered influential and that fall within the scope of the OMB Guidelines include:

- NIH Consensus Statements
- NIH Research Reports
- NIH Recommendations about Health Practice or Medical Treatment
- NIH Funding for Research Areas of Interest

For scientific and technical documents, the scientific community recognizes peer review as the primary means of quality control. NIH routinely seeks input from qualified peer reviewers of influential materials for propriety, accuracy, completeness, and quality (including objectivity, utility, and integrity) prior to dissemination. Although concerted efforts are made to ensure that influential information be subjected to rigorous peer review and reproducibility specifications, standard operating procedures may be temporarily disrupted under urgent situations, such as when an imminent threat to public health or homeland security is identified.

With respect to health, safety, and environmental information, NIH does not have a mandate to conduct formal risk assessments, which are the purview of the appropriate Federal, State, and local health regulatory and research agencies (see Section V.2.iv). NIH makes every effort to ensure that the presentation and dissemination of information about environmental health is comprehensive, informative, and understandable, and that scientific conclusions are based on: (1) The best available science and supporting studies, particularly peer-reviewed studies, conducted in accordance with sound and objective scientific practices; and (2) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data).

VIII. Special Considerations for Agency Dissemination

Sometimes NIH provides "late breaking news" of urgent import to the public on research findings prior to publication in scientific journals and prior to peer review by journals. Under such special circumstances, NIH may temporarily waive adherence to information quality guidelines. However, when it does so, there is an internal review process that routinely draws upon external expertise and relevant monitoring or advisory boards to ensure that information disseminated to the public summarizes the facts as NIH currently knows them, and that appropriate disclaimers are attached.

IX. References

HHS Standards of Conduct Regulations (45 CFR 73.735-705). Updated October 1, 2000.

Guidelines for the Conduct of Research in the Intramural Research Programs at the National Institutes of Health, 3rd edition, January 1997 (for a discussion of publication practices and authorship issues.) www.nih.gov/news/irnews/guidelines.htm

The HHS Printing Handbook, September 1998.

NIH Grants Policy Statement, March 1, 2001. grants.nih.gov/grants/policy/nihgps_2001

NIH Instruction and Information Memorandum OER 90-8. NIH Staff (Co-)Authorship of Publications Resulting from NIH Extramural Awards (1184). December 7, 1990.

NIH Manual Chapter 1130 Delegation of Authority, Program: General No. 3, Publish Articles and Results of Scientific Research and No. 4, Availability of Records for Examination or Copying (June 12, 1985) www1.od.nih.gov/oma/manualchapters

NIH Manual Chapter 1183 -- NIH Publications and Audiovisuals: Preparation, Review, Approval,

and Distribution, February 27, 2002. www1.od.nih.gov/oma/manualchapters/management/1183

NIH Manual Chapter 1184 -- Scientific and Professional Information Presented By NIH Employees: Review, Approval, and Distribution, February 27, 2002. www1.od.nih.gov/oma/manualchapters/management/1184

NIH Manual Chapter 1185 -- Complaints about NIH Information Quality, forthcoming.

NIH Manual Chapter 6308 -- Acquisition of Printing Requirements at the NIH, February 2, 2002. www1.od.nih.gov/oma/manualchapters/contracts/6308

Office of Management and Budget Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies. Final Guidelines. February 22, 2002 www.whitehouse.gov/omb/fedreg/reproducible2.pdf

OMB, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies. September 28, 2001. http://www.whitehouse.gov/omb/fedreg/final_information_quality_guidelines.html

OMB, Circular No. A-130, Revised (Transmittal Memorandum No. 4). Management of Federal Information Resources. November 30, 2000.

World Wide Web NIH Guidance. April 15, 1998. irm.cit.nih.gov/policy/guideli2.html

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1. In general, grantees own the data generated by or resulting from a grant-supported project. Special terms and conditions of the award may specify alternative rights, e.g., under a cooperative agreement or if there are shared rights to data. Except as otherwise provided in the terms and conditions of the award, the grantee is free to copyright without NIH approval when publications, data, or other copyrightable works are developed under, or in the course of, work under an NIH grant. For this purpose, "data" means recorded information, regardless of the form or media on which it may be recorded, and includes writings, films, sound recordings, pictorial reproductions, drawings, designs, or other graphic representations, procedural manuals, forms, diagrams, work flow charts, equipment descriptions, data files, data processing or computer programs (software), statistical records, and other research data. Grantees are required to place an acknowledgment of NIH grant support and a disclaimer, as appropriate, on any publication written or published with such support and, if feasible, on any publication reporting the results of, or describing, a grant-supported activity. An acknowledgment shall be to the effect that: "This publication was made possible by Grant Number _____ from _____" or "The project described was supported by Grant Number _____ from _____" and "Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the (name of awarding office or NIH)." For more details, see the NIH Grants Policy Statement.

2. CRISP is a searchable database of federally funded biomedical research projects

conducted at universities, hospitals, and other research institutions. The database, maintained by the Office of Extramural Research at NIH, includes projects funded by NIH, Substance Abuse and Mental Health Services (SAMHSA), Health Resources and Services Administration (HRSA), Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), Agency for Healthcare Research and Quality (AHRQ), and Office of Assistant Secretary of Health (OASH). Users, including the public, can use the CRISP interface to search for scientific concepts, emerging trends and techniques, or identify specific projects and/or investigators.

3. Excluded from this discussion are non-work-related and private writing, speaking, and publishing by an NIH employee, unless the employee's NIH responsibilities are likely to be regarded as influencing the content.

4. NIH Manual Chapter 6308 (Acquisition of Printing Requirements at the NIH) sets forth guidelines on how requirements for printing are to be handled by ICs at the NIH, in compliance with Federal printing rules and procedures. Manual Issuance 6308 covers direct acquisition for printing, as well as printing that is a peripheral deliverable in a contract for a larger purpose (e.g., an R&D contract for a study, the results of which are to be published).

5. To merit approval for (co-)authorships on publications from extramural awards (including grants, contracts, and other award mechanisms), NIH staff must have played a substantial role beyond normal program officer duties, including the following:

   - Originating the specific ideas that led to the research activity and manuscript,
   - Performing significant portions of the activity, and
   - Participating actively in preparing manuscripts.

   The conditions allowing NIH staff to be (co-)authors of publications under NIH extramural awards ordinarily arise only from contracts and cooperative agreements, where, by definition, there is substantial programmatic, i.e., scientific-technical, staff involvement. Deviations from these provisions must be approved by IC directors, and only when justified under special circumstances. The Office of Extramural Research, OD, can provide further information and advice on this subject.

6. The National Toxicology Program (NTP) was established in 1978 by the Department of Health and Human Services (HHS) to coordinate toxicological testing programs within the Department, strengthen the science base in toxicology; develop and validate improved testing methods; and provide information about potentially toxic chemicals to health regulatory and research agencies, the scientific and medical communities, and the public. NTP's mission is to evaluate agents of public health concern by developing and applying tools of modern toxicology and molecular biology. The NTP is an interagency program consisting of relevant toxicology activities of the National Institutes of Health's National Institute of Environmental Health Sciences (NIH/NIEHS), the Centers for Disease Control and Prevention's National Institute for Occupational Safety and Health (CDC/NIOSH), and the Food

and Drug Administration's National Center for Toxicological Research (FDA/NCTR). The NIH's National Cancer Institute (NIH/NCI) was a charter agency; however, the NCI Carcinogenesis Bioassay Program was transferred to the NIEHS in 1981. The NCI remains active in the Program through membership on the NTP Executive Committee.

Last revised: November 12, 2003

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 05-1097 **Caption:** Salt Institute et al. v. Michael O. Leavitt, Health & Human Services

CERTIFICATE OF COMPLIANCE WITH RULE 32(a)

Certificate of Compliance With Type-Volume Limitation,
Typeface Requirements, and Type Style Requirements

1. This brief complies with the type-volume limitation of Fed.R.App.P. 32(a)(7)(B) because:

[principal brief may not exceed 14,000 words or 1,300 lines; reply or amicus brief may not exceed 7,000 words or 650 lines; line count can be used only with monospaced type]

☑ this brief contains 10,863 [*state the number of*] words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii), *or*

☐ this brief uses a monospaced typeface and contains _____ [*state the number of*] lines of text, excluding the parts of the brief exempted by Fed.R.App.P. 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Fed.R.App.P. 32(a)(5) and the type style requirements of Fed.R.App.P. 32(a)(6) because:

[14-point font must be used with proportional typeface, such as Times New Roman or CG Times; 12-point font must be used with monospaced typeface, such as Courier or Courier New]

☑ this brief has been prepared in a proportionally spaced typeface using Word 2000 _____ [*state name and version of word processing program*] in Times New Roman-14 pt [*state font size and name of the type style*]; *or*

☐ this brief has been prepared in a monospaced typeface using _____ _____ [*state name and version of word processing program*] with_____ _____[*state number of characters per inch and name of type style*].

(s) _____

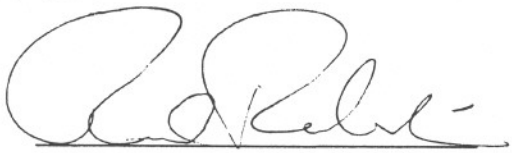
Attorney for Appellants

Dated: April 15, 2005

CERTIFICATE OF SERVICE

I hereby certify that on April 15, 2005, a copy of the foregoing Appellants' Brief was served on the following parties by first-class mail, postage prepaid and electronic mail:

Alisa B. Klein
Mark B. Stern
U.S. Department of Justice
Civil Division, Appellate Staff
950 Pennsylvania Avenue NW
Washington, D.C. 20530-0001



Reed D. Rubinstein