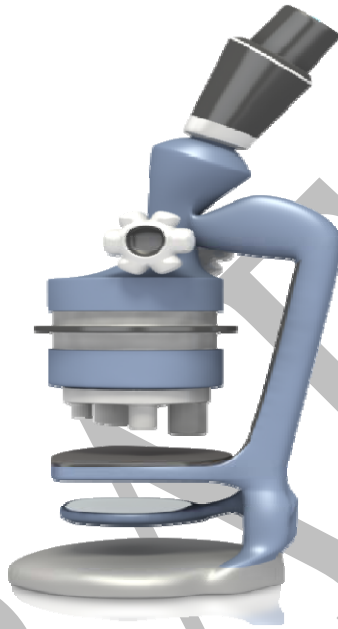


Enhancing Responsible Science
Considerations for the Development and Dissemination of Codes of Conduct
for Dual Use Research of Concern



Draft Report of the
Codes of Conduct Working Group (CCWG)

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Abbreviations and acronyms

CCWG	Code of Conduct Working Group
DURC	Dual Use Research of Concern
HHS	Department of Health and Human Services
IBC	Institutional Biosafety Committee
NIH	National Institutes of Health
NSABB	National Science Advisory Board for Biosecurity
PI	Principal Investigator
USG	United States Government

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Executive Summary

The National Science Advisory Board for Biosecurity (NSABB) was established by the U.S. Government (USG) to provide advice, guidance, and leadership regarding the oversight of dual use life sciences research – that is, research with a legitimate scientific purpose that yields information or technologies that may be misused to pose a threat to public health or other aspects of national security. According to the Board’s current charter, one key function of the NSABB is to “[A]dvice on the development, utilization and promotion of codes of conduct to interdisciplinary life scientists, and relevant professional groups.” In the performance of this function, NSABB has formed two working groups on codes of conduct in dual use research. This report provides a summation of the activities of both working groups with a focus on the second working group and on the principal outcomes of its work—a toolkit for individuals and groups interested in formulating codes of conduct for dual use research and an educational module on dual use research.

Codes of conduct for dual use research exemplify a long tradition in morality. For millennia, individuals and groups have used codes, along with oaths, as tools for several interrelated aims: to prevent or encourage certain morally significant behaviors and to form and solidify the moral identity of a group. The Oath of Hippocrates and the American Medical Association’s Code of Ethics (first formulated in 1847) are statements of moral precepts that have been, and continue to be, central to the moral and professional identity of physicians. Many scientific societies have also adopted codes in an effort to promote certain ethical principles in such activities as research and publication.

In recent years, interest in codes of conduct has intensified within and beyond the global “community” of scientists, mainly in response to concerns spawned by 9/11 and the subsequent anthrax attacks. The latter incidents revealed both the risks and the vulnerabilities associated with life sciences research of dual use potential. Given the risks, many within the scientific community have argued that scientists themselves must lead the way in developing and instituting measures to raise awareness about—and inculcate responsibility for—dual use research. Among these measures are codes of conduct. Although codes, whether of ethics or of conduct, have been utilized in differing domains, in the context of dual use research, they often raise questions of *what*, *why*, and *how*: in *what* should a code of conduct consist, *why* are codes of conduct useful in dual use research, and *how* might a code of conduct in the context be formulated, disseminated and sustained?

The first NSABB working group, established in 2005, produced a set of “considerations in developing a code of conduct,” presented as Appendix 3 to the NSABB’s June 2007 *Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information*. With these considerations, NSABB sought to spell out the potential content for any given code of conduct by identifying key individual, group, and institutional responsibilities at each phase of the research process; it thereby addressed the questions of *what* a code of conduct might consist in and *why* a code is justified as a tool in cultivating awareness and responsibility for dual use research among scientists. The working

group activities that led to the development of the considerations are described and summarized in Part I of this report.

Created in March 2010, the second working group has sought to address the question of *how* a code of conduct can be formulated, disseminated, and sustained as a living document and force in the promotion of awareness and responsibility. The activities the working group has undertaken in this effort—a survey, a literature review, and a roundtable—are described in Part II

Parts III and IV present the culmination and chief outcomes of these activities: a code of conduct toolkit and an educational module. In assembling the toolkit and the module, the working group set out from two basic assumptions about codes of conduct: *first*, developing and implementing a code of conduct is ideally a voluntary, grass roots activity, freely undertaken by scientists in any context, be it a professional society, an industrial entity, or an academic institution; and *second*, a code of conduct is optimally used for the purposes of educating and raising awareness among scientists. With these assumptions as its conceptual foundation, the toolkit goes on to provide a series of tools that are adaptable to different settings, including background on the dual use issue and tools for getting started, for formulating a code, for disseminating a code and for evaluating a code within the broader context of initiatives aimed at the creation of cultures of responsibility in dual use research.

Introduction

The scientific community, governmental authorities, and the public have raised the concern that research conducted for legitimate scientific purposes could be misused for harmful and malicious intent. This type of research is known as “dual use” research of concern (DURC). To help address concerns regarding DURC, certain scientific and professional societies have advocated the use of codes of conduct as a way to guide scientists’ work.

The United States government established the National Science Advisory Board for Biosecurity (NSABB) to provide advice on oversight of dual use life science research. According to the Board’s current charter, one key function of the NSABB is to “[A]dvice on the development, utilization and promotion of codes of conduct to interdisciplinary life scientists, and relevant professional groups.”

In its Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information (June 2007), the NSABB articulated “considerations in developing a code of conduct for dual use research in the life sciences” (Appendix 3), which includes a set of core responsibilities regarding dual use research of concern and a comprehensive delineation of responsibilities in the research process.

Building on these accomplishments and in response to the Board’s charter in 2010, the NSABB established a working group, the Codes of Conduct Workgroup (CCWG). The CCWG’s task is to promote the dissemination, awareness, and adoption of codes of conduct by academic institutions as well as by professional societies and individuals engaged in dual use research.

To fulfill the requirements of this task, the Working Group undertook several objective-driven initiatives:

- 1) In order to provide an assessment of “the state of the issue,” that is, the extent to which professional societies and institutions have adopted—or are considering the adoption of—codes of conduct, the CCWG with support from NIH/OBA staff, surveyed scientific associations and academic institutions.
- 2) In order to identify barriers to the formulation and dissemination of codes, along with strategies for the effective accomplishment of these ends, the CCWG with support from NIH/OBA staff reviewed the scholarly literature. In addition, and with the same objective in mind, the working group convened a roundtable in which representatives of professional societies, academic institutions, and industry discussed the problems with and potential for codes of conduct in dual use research.

The Purpose of this Report

This report describes the activities of the NSABB's two working groups on codes of conduct and the principal outcomes of the efforts of the second working group, i.e., a code of conduct toolkit and an educational module for use by institutions and scientific associations with an interest in formulating and disseminating codes of conduct.

Early on its deliberations, the second NSABB working group reached agreement on two basic assumptions that then informed the remainder of its work, especially the content and objectives of the toolkit and the educational module: *first*, developing and implementing a code of conduct is ideally a voluntary, grass roots activity, freely undertaken by scientists in any context, be it a professional society, an industrial entity, or an academic institution; and *second*, a code of conduct is optimally used for the purposes of educating and raising awareness among scientists.

In the course of its deliberations, research, and consultations, the Working Group reached a number of conclusions and findings about codes of conduct—conclusions and findings that have been incorporated into the toolkit presented in Part III. These conclusions and findings are:

1. Codes of conduct can be effective in raising awareness about dual use research.
2. The very process of formulating and developing a code of conduct is rich in opportunities for educating and raising awareness about dual use research.
3. As such, that process should be designed to engage as many stakeholders as possible.
4. Disseminating a code of conduct is not simply a process of distributing the code to affected parties; it is also a process of ensuring that the code will be a “living” document and, as such, a vital force in shaping the day to day moral behavior of scientists in a given context. To achieve this aim, the following points should be considered:
 - To make a code effective, strong institutional commitment is needed. This entails that sufficient resources would need to be allocated for developing and disseminating the code.
 - A successful code also depends on a strong commitment by individuals who undertake the responsibility for “championing” the code and for disseminating it throughout the institution. Institutions should identify such individuals.
 - Allocation of time for discussing the code is required. Multiple existing venues can be used, for example, student orientation sessions, faculty meetings, lab meetings, RCR courses, conferences and workshops, etc.
5. The advantage of utilizing codes in an educational setting is that in these settings a code could be used as a guide for addressing real life case studies.

6. To maintain their effectiveness and relevance over time, codes should be revised and updated on an ongoing basis.

These findings and conclusions have relevance in any organization, i.e., academic institutions, scientific associations, and industry. In any one setting or context, however, they should be “applied” with care and sensitivity, especially to the particular needs and features of that context. An obvious example is this: academic institutions and scientific associations are different in many respects and strategies for developing and disseminating a code of conduct should be designed accordingly.

Part I:

The Activities and Accomplishments of the First NSABB Working Group on Codes of Conduct

The first NSABB Working Group (WG) on Codes of Conduct invested significant effort in evaluating the status of codes of conduct in general, their utility, and how best to formulate them. Its activities and the outcomes of those activities have provided the foundation for the subsequent efforts of the second working group.

The charge and objectives of the first working group were two-fold. First, the Board’s initial charter specifically stated that NSABB will “provide recommendations on the development of a code of conduct for scientists and laboratory workers that can be adopted by professional organizations and institutions engaged in the performance of life science research.” Second, the working group will develop standards and principles that can be incorporated into a formal educational and training program to cultivate awareness and appreciation for codes of conduct in the life sciences disciplines.

To fulfill the charge, the working group pursued three key activities: (1) it conducted a survey of codes of conduct; (2) it formed and consulted with focus groups of ethicists, scientists, and others, especially with the aim of identifying elements of a code; and (3) it formulated a set of considerations in the development of codes of conduct.

A. The survey:

Before formulating its recommendation on the utility of codes of conduct, the WG embarked on an extensive survey on existing codes with the aim of clarifying the kinds of codes of conduct then in use, their components, their differing uses, and the types of organizations that have adopted them. The survey gathered the necessary background knowledge to inform the WG’s development of a template code of conduct.

Seventy codes were selected for analysis and inclusion, on the basis of content, type of organization, and applicability to the scope of bio-security in the life sciences. Preference was given to codes with well defined elements, and to organizations with large or national memberships. The intent was to include a sufficient number of domestic and international codes of comparable scope originating from a variety of disciplines and professions.

Notable Elements: During the analysis, certain elements were identified in the codes that are considered noteworthy in terms of preparing a code of conduct for dual use research in the life sciences. These elements included:

- **National Security:** Three codes addressed national security concerns.
- **Resources:** Several of the codes included requirements for the proper use of funding or institutional resources, such as equipment, supplies, laboratory, or office facilities.
- **Training:** Although, only one of the codes specified that a mentor must be identified for all trainees and provided specific expectations for that mentor's role, many of the codes addressed the education of future generations, with some specifically requiring ethical training.
- **Dual Use:** Two codes specifically contained text that alluded to dual use dilemmas within particular fields of study.
- **Communication:** Many of the codes surveyed contained statements requiring members to be truthful when communicating with the public about the organization or the field of study, and even more contained statements regarding a responsibility to inform and educate the public on matters fundamental to the field or organization.
- **Review Practices:** Many of the codes described a process for convening an ethical review body to review and arbitrate violations of the code, and several acknowledged that the code is a "living document" that is subject to revision and "adaptable and relevant to new situations as they occur".

Basic Considerations in Code Development: Based on the survey results, it appears that although the mere existence of a code of conduct may lay the foundation for ethical standards within an organization, it does not guarantee compliance. The content of the code, the degree to which leadership is committed to the code, and the degree to which it becomes embedded in the organization's standard operations are all critical to the effectiveness of the code in reducing unethical behavior. It is also important to recognize that codes are not intended to be static documents and should be developed with sufficient flexibility to encourage review and revision by the sponsoring group as responsibilities, expectations, and biotechnologies evolve.

The survey helped the WG crystallize some findings with regard to developing and disseminating codes of conduct, including:

- Code language should be simple, concise and readily understood by all persons affected.
- The code should state expected behaviors and avoid a legalistic tone, unless legal restrictions apply. Codes do not supersede existing regulations or ordinances, but they may elevate the ethical norms beyond the minimum expectations outlined by law.
- The code should be sufficiently general and global in scope.

- In recognition that a single issue may have multiple perspectives and consequences, the code should be written, reviewed, and edited by a multidisciplinary team, including members of the public, to ensure consistency with other communications and policies that may be in effect and to facilitate acceptance by the affected constituents.
- Although it is difficult to fully anticipate all the consequences of an activity, all relevant risk areas with appropriate plans for abatement should be considered prior to initiation.
- Codes should be revised and updated to reflect changes in professional values and advances in technology.
- When considering the development of a code, an evaluation component and objective criteria should be included.

Content Considerations: The survey also helped in identifying appropriate content for codes of conduct. Although the specific content of a code varies according to the purpose, intended audience, and sponsoring organization, almost every code should include some standard components:

- An introductory section that sets a tone and emphasizes the importance of ethics and compliance.
- Guiding principles that articulate the profession's underlying core values and guiding principles to the highest degree possible.
- Models for decision making to assist an individual in making the right choice about a possible course of action. Such constructs can contain straightforward examples or a decision framework to guide the individual in making a decision.
- Provisions for dissemination of the code to appropriate audiences and recommendations for the proper education and training of these individuals.
- Procedures for reporting suspected misconduct and advice on mechanisms for the protection from retribution of those who report violations.
- Implementation mechanisms to establish individual and organizational accountability and enforcement procedures to censure unethical behavior.
- A listing of any additional ethics and compliance resources with applicable supplementary policies and procedures.
- A list of available educational and training resources.

The survey and its lessons remain a valuable resource that can be consulted when deciding to pursue a code of conduct for dual use research. These lessons were incorporated into the Second Working Group's efforts.

B. Focus Groups:

The second task the first WG undertook was to solicit input from focus groups for the purpose of developing of a draft code. Participants in these focus groups included practicing scientists, administrators, leaders of scientific and professional organizations, local oversight personnel, and ethicists. General attitudes towards codes and dual use research concerns were sampled.

Most participants had experience with codes and found that they had a positive impact personally. One issue of particular relevance to the current context is the mixed views about the level of detail that is helpful in a code of conduct. In general, codes that are detailed might provide concrete guidance but would fail to apply when new circumstances arise. More general codes have the advantage of leaving room for interpretation as they direct attention to the major concerns. However, such codes do not give specific guidance which is often needed.

Opinions of participants also varied regarding the ability of codes to influence behavior. There was a general agreement that those who intend to do wrong will not be deterred by a code. For others, one of the main contributions of a code is that it can be helpful in clarifying or reinforcing behavioral principles, particularly for those inexperienced in research or in contexts where the standards may not be obvious. Moreover, participants expressed the view that “A code can make good people better”.

Many participants agreed that a code would be an effective tool to raise awareness about “Dual use” research concerns in the life sciences. Three specific benefits were mentioned: a code can catalyze discussion in the community about dual use, it can serve as an educational tool for individuals, and it can enhance sensitivity to the possible misuse of research results.

Focus Groups were also asked about what a code should include, they suggested that in general, a code of conduct should:

- Include principles unified by a clear underlying philosophy regarding the dual use research concern;
- Add value and not redundancy to the body of existing codes in the life sciences;
- Have a clear scope, including specific target audiences;
- Be concise and compelling;
- Articulate realistic expectations;
- Have a peer-oriented voice, speaking to scientists as professionals;
- Be positive in tone and convey the value of the scientific endeavor.

Based on the results of the survey and the focus groups, the WG formulated a set of considerations in developing a code of conduct.

C. Considerations in Developing a Code of Conduct

A pivotal challenge in formulating a code of conduct for dual use research is determining the specific content of the document. To help interested individuals and groups meet this challenge, the first NSABB working group sought to catalog and delineate all of the responsibilities inherent in every phase of the process of scientific research. The results of this effort were presented as Appendix 3 to the NSABB’s June 2007 report, entitled *Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information*.

In addition to describing the utility and potential applications of a code of conduct, the Considerations articulate a set of core responsibilities related to dual use research, along with an additional responsibilities specific to the various phases of the research process and research related activities. The core set of responsibilities and delineation of specific responsibilities offer interested individuals and groups several potential uses: they may be adopted verbatim, modified, or used as the basis for a code of conduct in dual use research.

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Core Responsibilities of Life Scientists in Regard to Dual Use Research of Concern

Life sciences research is a critically important endeavor that has benefited society by advancing our understanding of living systems. Critical to the future of scientific progress and freedom is the preservation of public trust and support, which scientists have earned through their attention to responsible research practice. Despite a scientist's conscientious approach to research conduct, the knowledge, products, or technologies derived from some life sciences research may be misused by others to pose a threat to public health, agriculture, plants, animals, the environment, or materiel. Research with this potential is known as "dual use research of concern."

Individuals involved in any stage of life sciences research have an ethical obligation to avoid or minimize the risks and harm that could result from malevolent use of research outcomes. Toward that end, scientists should:

- Assess their own research efforts for dual use potential and report as appropriate;
- Seek to stay informed of literature, guidance, and requirements related to dual use research;
- Train others to identify dual use research of concern, manage it appropriately, and communicate it responsibly;
- Serve as role models of responsible behavior, especially when involved in research that meets the criteria for dual use research of concern; and
- Be alert to potential misuse of research.

Responsibilities in the Research Process

Research is a complex, iterative process, and the potential for dual use may be recognized at many junctures and through different activities. Consequently, while it is valuable to be mindful of the core responsibilities articulated above, those involved in the life sciences research may also benefit from a more specific review of their responsibilities in regard to dual use research of concern.

Proposing Research

When designing and proposing research, the ethical responsibilities of life scientists include:

1. Considering whether the knowledge, products, or technology resulting from the research could be deliberately misused to endanger public health, agriculture, plants, animals, the environment, or materiel.
2. Striving to design research that promotes beneficial scientific advances, while avoiding or minimizing elements of study design that raise concerns about dual use.
3. Weighing carefully the benefits of study elements presenting dual use concerns that cannot be completely eliminated against the harm that could occur through their deliberate misuse.
4. Considering ways to modify the research design to manage and mitigate potential misuse when it is clear that the benefits of the research with dual use potential outweigh the potential harm.

Managing Research

The ethical responsibilities of individuals, who manage research programs, whether within the public or private sector, include the following:

1. Promoting awareness of dual use research of concern and the ethical responsibilities it entails.
2. Developing and maintaining systems, policies, and training to ensure that dual use research of concern is identified and managed appropriately.
3. Implementing Federal, state, and other appropriate guidelines specific to dual use research of concern.

Reviewing Research

The ethical responsibilities of those responsible for establishing and managing the review process (e.g., funding agencies) include the following:

1. Ensuring that when research proposals are reviewed, appropriate systems are in place to identify the possibility of dual use of concern and to address related issues. Examples of common means of reviewing research proposals include Institutional Animal Care and Use Committees [IACUCs], Institutional Biosafety Committees [IBCs], Institutional Review Boards [IRBs], and peer review groups.
2. Ensuring that both researchers and reviewers are knowledgeable of, and adhere to, all ethical, institutional, and legal requirements that apply to the review of possible dual use research of concern.
3. Reconsidering institutional review systems periodically to ensure that they reflect current criteria defining dual use research of concern and are consistent with applicable Federal and state guidelines.

The ethical responsibilities of individuals serving on peer review groups or otherwise engaged in research review include the following:

1. Becoming well educated about dual use research of concern and related ethical, legal, and institutional requirements, as well as applicable Federal and state guidelines.
2. Being mindful during the review process of whether the research could meet the criteria for dual use of concern.
3. Using methods in keeping with the reviewer's charge and context to make appropriate people aware that the research being reviewed meets the criteria for dual use research of concern.

Conducting Research

The ethical responsibilities of life scientists engaged in research include the following:

1. Observing safe practices¹ and ethical behaviors in the laboratory and ensuring that subordinate personnel do so as well.
2. Using appropriate security measures and continually reassessing their adequacy as concerns about potential misuse evolve.
3. Observing applicable guidelines for the responsible conduct of dual use research of concern.
4. Being attentive to the dual use potential of the knowledge, products, or technology resulting from research activities as they emerge.

¹ Safe laboratory practices are embodied in such documents as the *DHHS Biosafety in Microbiological and Biomedical Laboratories*, the *NIH Guidelines for Research Involving Recombinant DNA Molecules*, and applicable occupational and safety regulations and standards.

5. Alerting responsible institutional officials when dual use research of concern is identified and when decisions must be made to manage associated risks.

Collaborating on Research

Research endeavors frequently involve the participation and cooperation of multiple laboratories and disciplines, which can be subject to different management, codes of conduct, cultural values, or operating procedures. Besides the ethical responsibilities associated with conducting research, scientists involved in such collaborations have the additional obligations of:

1. Engaging in open dialogue regarding whether knowledge, products, or technology resulting from the research could be considered dual use research of concern; when such research is pursued, ensuring that all parties are aware of their ethical responsibilities.
2. Agreeing on specifically assigned responsibilities to ensure ethical oversight of all aspects of research with dual research potential, including its outcomes.
3. Considering and respecting expressions of concern regarding the possible dual use of knowledge, products, or technology resulting from the research and ensuring these concerns are raised with those charged with responsibility for research oversight.
4. Considering appropriate measures to reduce or eliminate risks to public health, agriculture, plants, animals, the environment, or materiel resulting from the research project.
5. Maintaining a current awareness of national and international standards and policies regarding dual use research of concern.

Communicating the Results of Dual Use Research of Concern

Regardless of the stage of the research process and the form of the communication, those involved in communications regarding knowledge, products, or technology that can be considered dual use research of concern have the following ethical responsibilities:

1. Being aware of ethical and legal considerations relevant to communications regarding knowledge, products, or technology that can be considered dual use research of concern.
2. Analyzing potential risks to public health, agriculture, plants, animals, the environment, or materiel that could result from research-related communications, balancing them against the potential benefits.
3. Considering options for communication that may reduce or eliminate risks when communicating information with dual use potential is clearly warranted by its benefits.

Examples of mitigating strategies may include a delay in releasing the information, the addition of appropriate contextual information, or communicating the information to a more limited audience.

Scientific Education and Mentorship

Practicing scientists who serve as role models to developing scientists (e.g., their trainees, students, and staff) have the following ethical responsibilities:

1. Raising developing scientists' awareness of what constitutes dual use research of concern and why it matters.
2. Informing developing scientists of their ethical, legal, and institutional responsibilities when engaged in dual use research of concern, as well as applicable Federal and state guidelines.
3. Encouraging open and respectful discussion of issues related to dual use research of concern, including whether or not a particular project could be considered dual use research of concern.

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Part II:

The Activities and Accomplishments of the Second NSABB Working Group on Codes of Conduct

A. Working Group Charge

In its current charter, the NSABB charge included the provision to, “Advise on the development, utilization and promotion of codes of conduct to life scientists and relevant professional groups. “ This basic charge was expanded by the Codes of Conduct Working Group to include specific tasks that are intended to promote the dissemination, awareness, and adoption of codes of conduct in specific venues such as in academic institutions or professional societies, and among individuals engaged in dual use research.

Specifically, the Working Group’s tasks are to:

- 1) Advise on ways to promote the adoption of Codes by academic institutions and scientific societies; and
- 2) Provide guidance on how to maintain Codes as “living” documents that continue to reflect changes in the field of dual use research (DUR).

To achieve these tasks, the Working Group reviewed previous NSABB work addressing codes of conduct (see Part I), and conducted a survey of existing codes among professional societies and institutions and a literature review. Based on the findings of the previous Working Group, and the 2010 survey and literature review, a Roundtable was held in October 2010. The Roundtable’s goal was to gather input from relevant Working Group members, researchers in the life sciences, and representatives of the Office of Research Integrity’s Responsible Conduct of Research (RCR) programs regarding best practices for promoting and adopting codes of conduct by academic institutions and scientific societies.

B. Survey of Professional Societies

To prepare for the October 2010 Roundtable, NSABB staff conducted an online survey in 2010 to identify organizations with DUR-related codes. The survey was intended to update the 2006 list of existing society and institutional codes of conduct, ascertain how many relate specifically to DUR, and to help identify questions for exploration at the Roundtable of the barriers or challenges the societies or institutions experienced in the process of adopting codes of conduct. The survey was conducted as an environmental assessment of scientific societies and professional organizations and, initially, did not involve direct contact with any of the organizations surveyed. However, several of the organizations with codes of conduct were subsequently invited to participate in the Roundtable to provide additional information about their code and the process of its development.

Organizations were surveyed based on the 2006 survey and also included societies identified through the activities of the first working group. However, there are limitations to the amount of information the survey provides as it did not involve follow up questions or other direct contact with societies or associations, was conducted online, and it did not include academic institutional codes of conduct, where much of the dual use research is conducted. In addition, the survey did not reveal how scientific societies promote, disseminate or use their codes, whether there are sanctions for members, or whether society members even know about these codes or use them.

The survey included fifty (50) associations and found that twenty (**20**) societies had either a general code of conduct or statements related to ethics, and fourteen (14) had either a specific code devoted to dual use research, statements on social responsibility or bio-security, or statements indicating their intention to develop a code (see Table --). Those with specific codes relating to dual use research include the American Society of Microbiology (ASM), the American Phytopathological Society (APS), and the American Medical Association (AMA). ASM, for example, adopted a Code of Ethics in 1988 that was revised in 2000 and that contains sections that specifically “seek to discourage ASM members from activities that involve misuse of microbiology”. Following the terrorist incidents of 2001, ASM made further revisions to its code and, by 2005, had adopted specific policies and procedures establishing “that it is the responsibility of microbiologists to conduct research that is beneficial to humankind and that openness of research activities provides the transparency necessary to help prevent activities that could result in the misuse of microorganisms as biological weapons.”

Those with a statement of social responsibility include the Society of Toxicology and the **Biotechnology Industry Organization (BIO)**. The BIO’s statement is of particular note, as it represents the international biotechnology industry’s response to the issue of dual use research, and the commitment of an important partner with academia and professional societies in promoting awareness of DUR. Although not designated as a code of conduct, their statement notes the organization’s commitment to “the socially responsible use of biotechnology to save or improve lives, improve the quality and abundance of food, and protect our environment.” The BIO board of directors adopted this Statement of Ethical Principles, established a standing committee on bioethics in 2006, and continues to refine “a comprehensive vision of ways to ensure biotechnology is used for the betterment of humankind and not abused.”

In addition to the 14 associations with codes or statements, three (3) societies (the Institute of Medicine (IOM), the American Association for the Advancement of Science (AAAS), and the Federation of American Scientists (FAS)) have organized conferences, created resources, or initiated projects on dual use research. The FAS, for example, has developed educational tools on its website (www.fas.org/biosecurity/education/dualuse/) that include case studies in dual use for biological research. These case studies are provided in three languages and “help define the issues associated with “dual-use” research and security in the research lab” and “include interviews with researchers whose legitimate scientific work could potentially be used for

questionable or harmful endeavors, as well as a historical perspective on their research, bioterrorism, and research regulations”. The AAAS has also actively engaged its members on the topic of DUR; this includes organizing symposia, such as the 2010 forum on Minimizing the Risks of Synthetic DNA, developing an online database of existing resources and programs for educating practicing scientists about dual use life sciences research, and the dissemination of professional and graduate-level programs on DUR and biosecurity through its Center for Science, Technology and Security Policy for scientists working in the biological sciences (<http://cstsp.aaas.org/dualuse.html>). In addition, the AAAS participated in 2007 in a collaborative effort with the National Research Council to survey attitudes and actions on DUR in the life sciences (National Academies Press, 2009 (ISBN-13: 978-0-309-13140-7)). The survey yielded some of the first empirical data on US life scientists’ views about the potential misuse of legitimate scientific research and also explored actions scientists might support to reduce the risk of misuse of research.

The findings of the 2010 survey demonstrate a heightened interest among many scientific societies and associations about DUR and a broader commitment to address members’ responsibilities for dual use potential throughout the research process. As compared to the results from the 2006 survey, which identified only 5 societies with codes on DUR, by 2010 there had been a notable increase in the development of codes and resources focused on DUR related issues. In addition, since 2006 there has been an increase in the number of conferences, workshops and symposia focused on this topic. These fora have served as effective venues for disseminating the message about DUR among life scientists and bioengineers, and provided opportunities to reach out to related disciplines, such as non-life scientists and do-it-yourself biologists, whose activities also have a dual use potential.

Analysis of the survey results led to the development of topics and questions for the Roundtable. In addition, since the survey had focused on professional societies and associations and some understanding of the state of codes among those groups had been obtained, the Roundtable invitees included academic representatives and those who teach Responsible Conduct of Research (RCR). By including individuals responsible for training academic personnel in RCR, the Working Group charge to promote development of codes of conduct among societies as well as in academia would be fulfilled, as would the charge to develop standards and principles for incorporation in formal education and training programs.

C. Literature Review

Aims and Methodology: A review was conducted in PubMed of peer-reviewed articles, professional society and governmental websites, and scientific news articles to identify relevant information on the history and implementation of codes of conduct. This included a review of articles describing the specific development of a code of conduct for dual use research, the legal, cultural and behavioral aspects affecting implementation of a code for dual use research in the United States, and case studies of how codes were implemented in other countries and the lessons learned from those experiences. The information obtained through the review was intended to help identify relevant topics for further exploration at the Roundtable and to

inform Working Group members of historical and recent activities related to code of conduct development. Forty (40) articles were chosen and reviewed to ascertain relevant themes and topics pertinent to current NSABB efforts to promote the adoption of codes of conduct for dual use research (see Appendix A – Bibliography of Selected Articles).

Themes and Topics: Major themes that emerged from the review included the historical context and justification for why codes were first developed, the types and utility of various codes and their intended purposes, the relation of codes to the conduct of science and to the regulatory and cultural context in different countries, the identification of gaps in existing codes and best practices, and, most importantly in terms of the NSABB aims, how to implement codes in various venues. Examples and details of these themes include:

- **Historical background:** many of the articles situated codes of conduct in the context of the development of the scientific process and as a manifestation of science as a self-regulating culture with implicit notions of professional behavior. Atlas (2009) proposes that “from the inception of modern science, the community of scientists acknowledged that it needed to act responsibly to protect the public against potentially dangerous scientific information”, and cites Sir Francis Bacon (1626) as one historical example of the philosophical basis for a code of conduct,

“And this we do also: we have consultations, which of the inventions and experiences which we have discovered shall be published, and which not; and take all an oath of secrecy for the concealing of those which we think fit to keep secret; though some of those we do reveal sometime to the State, and some not”.

These articles note other precedents and historical codes of ethics and conduct, such as the Nuremberg Code, and the emergence of formalized bioethical considerations of scientific activities, particularly in the U.S., as other essential contextual elements leading to current efforts to develop codes of conduct.

- **Justification for development of a code for dual use research:** the historical context leading to a heightened interest in code development is explored in several articles, all of which mention the impetus of recent events such as 9/11 and anthrax-laced letters, or cite examples of dual use research, such as adapting pathogens to be drug-resistant.

“While emerging technologies have the potential for many benefits, they also tend to be dual-use, capable of both good and pernicious applications....[and] the progress of scientific research may reach a point where the results could have devastating consequences (so called “existential” or “catastrophic” risks). Such catastrophic risks have only become apparent in recent decades, and create a new and compelling case for restricting some types of scientific research”. (Marchant and Pope, 2009)

These articles justify code development as one mechanism to increase awareness of the potential for bioterrorist threats, and as a non-traditional tool to regulate problematic scientific research. One article situates the development of codes within “the context of the basic conflict between the freedom of science and the duty to avoid causing harm” and as an ethical problem wherein the “freedom of science conflicts with other values” (Ehni, 2008). Many of these articles provide a timeline of the recent activities that underlie code development, including the formation of the Biological and Toxic Weapon Convention (BTWC), the Biological Weapons Anti-Terrorism Act of 1989, the National Research Council 2004 report on Biotechnology Research in an Age of Terrorism, establishment of NSABB, the Interacademy Panel on International Issues (IAP), and other governmental responses to threats of terrorism, biological weapons and the potential for dual use research.

- **Types of Codes/Utility of Codes:** several articles delineate codes by type. Three basic types of codes are proposed by Brian Rappert (2004, 2003) as serving specific purposes and functions. This includes aspirational codes that propose principles, educational codes that provide guidelines, and enforceable codes that are embedded within wider systems of professional and legal regulations. Rappert (2007) distinguishes between and among advocacy codes that provide general life science principles, adopted codes with “elements specific to matters of biosecurity and biological weapons”, and advisory codes which is language that is developed by international scientific societies for inclusion into other existing codes.

Types of Codes	Purpose
Aspirational codes	Philosophical – set out ideals that practitioners should uphold
Educational codes	Awareness raising – provide guidelines suggesting how to act appropriately
Enforceable codes	Regulating - seek to codify what counts as acceptable behavior and delineate illegal or sanctionable behavior
Advocacy codes	Principles for the life sciences
Adopted codes	Principles specifically related to biosecurity and biological weapons
Advisory codes	Language for inclusion into existing codes

Several other authors reference Rappert’s categories and explore the relation between the intended goal of a code and the specific functions they are supposed to fill, and provide useful information for how to design and implement an effective code.

“If the primary goal is to educate new as well as current members of a discipline about what is expected in a societal role or professional capacity, then an ethics code should have practical use. In other words, it

should be capable of providing researchers or professionals with guidance on the correct course of action in particular cases. If a professional code is intended to be enforceable, it should include procedures for handling allegations of misconduct or unethical behavior.” (Bullock and Panicker, 2003).

The articles also explore the general utility of codes and the advantages of the different approaches to “presenting ethical principles in different formats....the less detailed codes of conduct can articulate the profession’s most important ethical precepts, while the more-detailed codes can provide the context and detail needed to apply ethical standards to real life circumstances” (Iverson et al. 2003). Ultimately, the utility of a specific code may be whether it addresses “questions about who needs to do what and how to reduce security concerns” (Rappert, 2007).

- **Relation of codes to conduct of science:** Codes of conduct for scientific research are proposed as an analogue to the Hippocratic Oath for physicians, and “send important signals to scientists about professionalism in the practice of a discipline; codes make explicit many tacit assumptions about scientific practice; and codes convey a rejection of improper research behavior” (AAMC Committee on Research Integrity, 1997). Articles propose implementing codes as Standard Operating Procedures in laboratories, discuss the culture of mentorship in science, and the influence of this type of relationship on the adoption of new guidelines. Several articles provide arguments that address some of the perceived barriers to developing or implementing codes, such as their lack of enforcement. For example, Frankel and Bird (2003), propose that when developed by scientific societies, a code becomes a part of the

“hidden curriculum, i.e., what individuals learn implicitly from observing the actions of others” and “reflects the recognition that professional societies are the ideal setting in which peers can clarify their professional standards and values, make explicit their expectations regarding colleague’s behavior, and influence each other to conform”.

The articles delineate the structural components of scientific institutions within which codes operate. These structural components include the inter-related responsibilities for dual use research among individuals (researchers, lab technicians, and administrative staff) and academic units, and the larger framework provided by Federal, State and local regulations, certification and licensing requirements of funding entities, professional society standards, and international conventions. The development of codes is envisioned by these authors as one means of establishing “a discipline’s norms and traditions” and for “codifying the community’s conventions and standards”. In addition,

“the research community [could] demonstrate, through its various professional and scientific associations, a clear and tangible concern about the integrity of federally-funded research programs. Codes.....are

an important embodiment of this concern and, apart from leading to more responsible behavior, they may offer convincing evidence of the research community's intent to use federal resources responsibly.” (AAMC Committee on Research Integrity, 1997)

- **Relation of codes to legal/regulatory frameworks:** several of the articles explored how even non-enforceable codes have become 'codified' in law, and often represent the only written guidance on a particular topic.

“A court's inclusion of a professional standard or guideline in its analysis may result in the professional norm's becoming the legally accepted standard of care”; particularly in cases where “clinical practice guidelines help courts discern whether professional conduct was reasonable and consistent with accepted practices”. In such cases, “ethics codes [may] guide their assessment of the moral underpinnings of professional choices and behaviour” (Campbell and Glass, 2001).

Other articles examined codes in an international context under the premise that “research in the life sciences is a global endeavor” (Atlas, 2009). These articles identified barriers to harmonizing or standardizing codes internationally and the specific cultural differences, or differences in the historical context for concerns that will require a “dialogue across cultural, religious and philosophical perspectives that [can] shape ethical decisions and professional behaviour” (Komersaroff, 2009).

- **Best practices:** a sub-set of articles expounded on what has worked and what has not worked in the development and implementation of codes. Although, this literature is not focused exclusively on codes for dual use research, it includes case studies from The Netherlands and Australia that may be applicable to the challenges faced by the NSABB in its development of a toolkit. In Australia, for example, a proposed medical practice code

“aims to define 'clear, nationally consistent standards of practice' that can be applied to regulate standards of practice...and used in the assessment of complaints and allegations of unprofessional conduct. The Code is not a mere statement of principles, a discussion document, or a hortatory guide for practitioners seeking to respond to the complexities of daily practice; it is a comprehensive statement of how doctors must behave”. (Komesaroff and Kerridge, 2009).

Although, the Australian code's immediate relevance is for medical practice, the principles it embodies are applicable to code development for dual use research in terms of codifying norms of professional behavior. The case study from Netherlands focused on the utility of codes which the authors propose is not self-evident in influencing scientific practice. For these authors, the utility of a code “largely depends on the implementation phase following their establishment – a phase which often receives little attention” (Schuurbiens et al.

2009). This article is based on interviews among researchers about a newly established code of conduct.

“although researchers perceive the principles within the code to be almost self-evident, the application of these principles in practice may lead to morally complex situations” and the researchers “did not see how the principles were meant to guide conduct in practice. They considered the code too general to apply” (Schuurbiens et al. 2009).

Examples of the limitations of codes might prove useful guidance to the NSABB, or provide clues to what should and should not be included as necessary elements of a flexible, adaptive, and effective ‘living’ code. For, if codes are too prescriptive they may have the unintended consequence of lowering awareness rather than providing a framework for researchers to learn how to recognize the potential for dual uses in their research.

“Codes of conduct can foster and reinforce the strength and effectiveness of professional communities and moral norms and processes. However, they can also provide a vehicle for oversimplifying the moral world, stripping ethics of its context and supporting an excessively rigid, restrictive and narrow moral regime. They can either expand the ability of individuals to make their own decisions and maximize their opportunities for ethical action, or they can claim authority beyond their capacity and encourage the belief that good practice simply involves following a formula or applying rules.” (Komesaroff and Kerridge, 2009).

Moreover, this attention to the potential limitations of codes is of particular importance in the development of a code for dual use research, as many of the potentially negative uses of biological materials and technologies are difficult if not impossible to foresee. A ‘living’ code would be most effective if it provided ways to evaluate and respond to the potential for dual use, rather than establish a set of fixed rules for known select agents or identifiable misuses of technology. Other articles provide suggestions for the promotion of codes by scientific societies or by (senior) scientific leaders in academia as proven best practices for implementation.

- **Gaps in existing policies and codes:** a particularly useful theme that emerged in the review was identification of gaps in existing codes. Examples of such gaps include not having a process in place for protecting whistleblowers, the need for guidance on the implementation of codes in settings with limited resources, the undue emphasis on individual rather than organizational (shared and inter-related) responsibilities, and the need to resolve contradictory, overlapping or confusing sets of guidelines. Sutton notes in her commentary on the document “Responsible Conduct by Life scientists in an Age of Terrorism” that

“In the U.S. regulatory framework for ensuring biosafety and biosecurity, the focus on life scientists has left a number of gaps in the framework...In fact, the goals of biosafety and biosecurity may not be sufficiently met because researchers are the target of the regulation almost exclusively.”

As other authors have done, Sutton notes the range of stakeholders and institutional entities that are involved in dual use research, and the layers of local, national and international laws and policies that regulate scientific research of select agents. Her strong warnings against putting a “disproportionate burden on the individual researcher” reflects her understanding of the complexity of the scientific enterprise; as does her injunctions to “rethink the regulatory framework for the nation’s biodefense research” and de-emphasize timely filing of reports and filling out forms as the primary means of complying with a code.

Additional important omissions in existing codes were related to the lack of enforceability, the need to maintain the relevance of codes within rapidly changing biotechnologies and ever novel potentials for misuse, and the need to identify metrics for evaluating codes, as “little is known about their effectiveness in practice” (Rappert, 2004). This literature strongly suggests the need for further research to evaluate best practices in designing and implementing codes; and particular areas that should be addressed when developing or disseminating codes of conduct.

- **Implementation of Codes:** several articles examined the issues involved in institutional enhancement of the culture of research ethics and provide strategies for initiating institutional change. Topics explored in these articles included the barriers to the full uptake of codes of conduct; how the introduction of a new code may disrupt traditional norms by providing an alternative counter-norm; and the process of effective self-regulation. Ferguson et al. (2007) note the shift in terminology in discussions about research behaviors from detecting and punishing undesirable behaviors to “promoting desirable behaviors”. These authors propose that cultural change in the academic setting is an obtainable goal,

“if we assume that the usual and/or collective beliefs and behavior of the majority of the individuals in an institution reflect institutional culture, then an institution’s ethical culture for research is reflected in what is perceived to be appropriate ethical behavior and the manner in which the majority of its members deal with ethical issues” (Ferguson et al., 2007).

Anderson’s (2000) analysis of data from two national surveys of 4,000 faculty and doctoral students in scientific disciplines showed the “significant effects of departmental climate on normative orientations”. For Anderson, an institution’s norms “are generally viewed as critically important to the group and are communicated as such to newcomers through the socialization process. Norms are not specific rules or regulations but fundamental principles that support appropriate behavior and relationships within the group, which views

violations of the norms as serious offenses.” All of these articles suggest the efficacy of promulgating codes of conduct through academic and society leadership, i.e., senior scientists and professional society leaders acting in a mentoring capacity to disseminate new norms and guidelines for behavior.

Analysis: The literature review provided an understanding of the contextual influences on the development of codes of conduct, the inter-relations of stakeholders in the process and their overlapping areas of responsibility, notable gaps in existing codes, and the challenges of identifying time, resources, and the expertise needed to develop and implement codes at the local level. The themes identified through the literature review were used to inform organization of the Roundtable and helped to identify specific challenges that, although discussed in the literature, may yet require creative thinking and coordinated efforts to resolve. Two such matters that emerged in the literature review must be emphasized:

1. The need to gather more information and data on what makes a code effective, and what makes it evolve and remain a vital source of moral inspiration.
2. How to identify best practices for implementing codes, integrating them into the culture, and keeping them relevant.

It was anticipated that participants at the Roundtable might offer specific recommendations for how to make codes effective, provide suggestions for how to integrate codes into academic culture, and help in the identification of best practices based on their experiences.

D. The Roundtable

The NSABB Code of Conduct Roundtable was organized to involve relevant individuals within academic institutions and professional societies who have the respective authority and reach to disseminate codes. The Roundtable also included the participation of instructors in the Responsible Conduct of Research who represent the front line of outreach and education for many institutions.

The aims of the Roundtable were to provide advice on ways to engage these individuals on the issue of Codes, identify barriers to awareness and adoption of codes of conduct in these settings and ways to overcome these barriers, and identify strategies for realizing the potential of codes in shaping behaviors and practices.

The Roundtable explored considerations for developing codes of conduct that had been advanced as part of an NSABB recommended oversight framework for dual use research in 2007. One key consideration was to identify the essential “raw material” that any comprehensive code should include. Other considerations included the formulation of realistic strategies for promoting codes of conduct in the settings of professional societies, academic institutions, and industry and the identification of relevant individuals who might best promote adoption of a code of conduct by an institution or professional association.

The Roundtable presentations and discussions explored the general utility of codes for changing behavior, the need for national guidelines on how to develop and implement codes, the key role academic leadership and scientific mentors play in promoting codes as the new norms of life science research, and the advantages and disadvantages of top-down vs. bottom-up development of codes. Discussions also touched upon the resources needed at the local level to develop, implement, and regularly update codes, whether academia or scientific society meetings are the most appropriate venues for disseminating codes, and the challenges of identifying what disciplines to include, and at what stage in the career or educational path to focus on when promoting codes of conduct.

Although, the presentations and discussions at the Roundtable covered a wide range of topics and opinions, a consensus on several key points emerged. First, codes should be aspirational and educational in purpose, rather than enforceable or compliance oriented. Second, codes should be dynamic rather than static—the focus of regular discussion and reflection within a particular setting and, indeed, an evolving element of the culture of the setting itself. Third, efforts should be made to ensure that codes are not perceived as restrictions on academic freedom but rather as expressions of the responsibility critical to the conduct of ethical, socially aware research. Finally, to succeed in any one setting, a code of conduct will need leaders and champions to ensure its advance and its status as a living, evolving document.

To ensure that codes become an integral part of the culture of research in a given setting, the participants and working group coalesced around a central recommendation—that NSABB undertake the development of a codes of conduct tool kit adaptable to different settings. Suggestions for such a tool kit included sample components for a code of conduct, a summary of best practices for formulating, finalizing, and disseminating codes of conduct, and a selection of the often fascinating literature on codes of conduct in general and in dual use research in particular. Subsequent to the Roundtable, and after review of the many suggestions and recommendations made by participants, the NSABB staff has developed this toolkit, and it is included in Section IV.