U.S. Government Public Consultation on
Oversight of Dual Use Life Sciences Research

Natcher Conference Center (Bldg 45)
National Institutes of Health (NIH) Campus
Bethesda, Maryland

July 15, 2008
8:30 am – 5:00 pm

Agenda
(Please note that times are approximate and subject to change)

8:30 am **Welcome and Opening Remarks**

8:40 am **Introduction to the NSABB's Oversight Framework**

8:55 am **Informing the Policy Development Process: Why A Public Consultation Meeting?**

9:10 am **Panel I – "Criterion for Identifying Dual Use Research of Concern"**

Background: The NSABB proposed a criterion for identifying "dual use research of concern," or that research with the highest potential for yielding knowledge, products, or technology that could be misapplied to threaten public health or other aspects of national security. The criterion is:

> ***Research that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety, agriculture, plants, animals, the environment, or materiel.***

The criterion is followed by guidance that provides examples of research that deserve careful consideration with regard to the applicability of the criterion. The guidance and its examples are not meant to be definitive in identifying dual use research of concern, but rather to serve as a tool for focusing attention and evaluation. The U.S. Government is seeking input on the utility of the criterion and the guidance and on how they could be implemented.

Discussion questions:

- Is the criterion sufficiently specific and understandable so that it can be applied consistently? If not, how could it be improved?
- Is the criterion too broad? Will the criterion capture research that is not appropriately considered dual use of concern? If so, what are some examples of

research that would be inappropriate captured?

- Is the criterion too narrow? Might it fail to include research that should be considered dual use of concern? How might it be modified to be more appropriately encompassing?
- Is the guidance that follows the criterion for identifying dual use research of concern helpful and sufficient? Is it clear and understandable? Should additional categories of research that may yield dual use findings of concern be included in the guidance?
- What share of research at your institution or company would likely be captured with the proposed criterion for dual use research of concern?

Panel discussion

Public Comment

11:00 am **Break**

11:20 am **Panel II – "Responsibilities and Process for the Identification and Oversight of Dual Use Research of Concern"**

Background: Everyone involved in life sciences research has a responsibility for identifying and responding appropriately to dual use research of concern. The NSABB has put forth recommendations regarding the general framework within which these responsibilities for oversight would be carried out. The U.S. government must determine how to translate those recommendations into policies and requirements that would apply to investigators, other laboratory staff, senior research administrators, institutional review committees, and other parties. Toward that end, the government is seeking input on the following matters:

Discussion questions:

<u>Investigator responsibilities</u>

Should the principal investigator bear primary responsibility for making the initial determination as to whether his or her research might be considered dual use of concern?

If so, how should that determination be made?

- Should the determination routinely include input from others? If so, who else should participate in the initial evaluation?
- To whom should the investigator report this determination?

If not, who should make this determination?

<u>Institutional review responsibilities</u>

What are the characteristics of a dual use research review committee? What expertise will be needed?

How should institutional review responsibilities be fulfilled?

Should institutions be required to establish their own review committees?

- Can existing institutional review committees fulfill these characteristics (e.g., the Institutional Biosafety Committee) as is or with some modification?
- If the IBC, what additional expertise would be needed to facilitate the review of dual use research of concern?
- Would most institutions likely have the necessary in-house expertise for this review?
- Would it be helpful to have the option of utilizing a commercial review entity or the review entity at another institution?

Should regional committees or a national committee be established

- As optional review mechanisms?
- In lieu of a requirement to establish committees at the institutional level?
- In an advisory capacity (e.g., the NIH RAC) to give recommendations on specific protocols, leaving final approval authority with the institutions?
- How resource-intensive would this proposed oversight system be to implement at your institution?

Panel discussion

Public Comment

12:30 pm **Lunch**

1:30 pm **Panel II - Continued**

2:15 pm **Break**

2:35 pm **Panel III – "Guidance and Educational Resources Needed to Assist the Research Community in its Fulfillment of Oversight Responsibilities for Dual Use Research"**

Background: Since the outset of its deliberations, the NSABB has noted the importance of awareness in dealing effectively with dual use research and the need for more outreach and education on this issue – particularly to the investigator community, where various studies document a low level of awareness. In its report, the NSABB makes a number of observations and recommendations for promoting awareness, as well as receiving stakeholder input on evolving policies. The NSABB also views several elements of the oversight framework – the code of conduct, communications guidance, and the guidance on identifying dual use research – as key educational tools. The U.S. Government is

seeking input on the following matters:

Discussion questions:

Has the NSABB identified the major educational and outreach priorities in its report (pages 29-31)? If not, what other priorities should there be?

- How might the following elements of the Oversight Framework be used as educational tools:
  - Criterion and associated guidance
  - Guidance on responsible communication of dual use research of concern
  - Code of conduct
- What other kinds of educational resources, tools, and strategies would be helpful or particularly effective in educating various audiences, such as investigators, research administration, biosafety staff, and others?

Panel discussion

Public Comment

4:45 pm **Wrap-up and Concluding Remarks**

5:00 pm **Adjournment**