

*Frequently Asked Questions about the NIH OBA
Institutional Biosafety Committee (IBC) Site Visit Program*

General

1. What is the purpose of the IBC site visit program?

The IBC site visit program is one of several OBA initiatives aimed at enhancing compliance with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*. The aim of the site visits is to enhance institutional awareness of the requirements of the *NIH Guidelines* and also to inform OBA about the challenges faced by institutions in the oversight of recombinant DNA research.

The site visits will involve the evaluation and analysis of institutional systems of oversight of recombinant DNA research to identify practices that optimize fulfillment of requirements under the *NIH Guidelines*. In addition to correcting any deficiencies identified at particular institutions, the information gathered during the site visits is used by OBA to tailor and target outreach programs to serve the educational needs of individuals involved in the conduct and oversight of research subject to the *NIH Guidelines*.

2. Will all institutions with IBCs registered with OBA be visited?

OBA visits a diverse set of institutions as part of the site visit program. The total number of visits that will be conducted as part of the program is yet to be determined.

3. How are the institutions selected?

The aim of the site visit program is to obtain information from a representative sample of institutions subject to the *NIH Guidelines*. Toward this end, visits will be conducted at academic and commercial institutions, hospitals and clinics, research institutes, and government facilities. The institutions visited will also reflect a range of research programs, varying in size as well as scope.

4. How frequently will institutions be visited?

OBA expects that, initially, a single formal site visit will provide the necessary information. Some information will be collected before and after the site visit.

5. Who will be conducting the site visit?

The site visit team is typically consists of NIH OBA outreach staff members. Contractor staff may assist with site visit logistics and may also be part of the site visit team.

6. Whom can I contact at NIH OBA for more information about the site visit program or requirements under the *NIH Guidelines*?

Questions about the site visit program may be directed to Dr. Kathryn Harris (Senior Outreach and Education Specialist) at harriskath@od.nih.gov or by calling (301) 496-9838. Questions about the *NIH Guidelines* can be sent to oba@od.nih.gov.

Information regarding the requirements of the *NIH Guidelines* can also be found on the OBA web site: <http://oba.od.nih.gov>

Before a visit

7. Is advance notice given when an institution is selected for a visit?

When an institution is selected for a site visit, a letter will be sent to the IBC contact person identified in the IBC registration that the institution has submitted to OBA. The site visit team will then work directly with the institutions designated contact to schedule a date for the visit.

8. What do institutions need to do to prepare for the site visit?

Prior to the site visit, the institution will be asked to provide documentation related to the institution's oversight program for research subject to the *NIH Guidelines* such as:

- A current IBC roster identifying the chair, contact, BSO, animal, plant, and human gene transfer experts as appropriate.
- Copies of the IBC members' biographical sketches.
- Copies of the minutes for all IBC meetings held in the past two years. The minutes provided should be the same version that would be made available to the public if so requested.
- Copies of emergency plans for handling accidental spills and personnel contamination.
- Copies of any forms or registration documentation used to register research subject to the *NIH Guidelines* with the IBC.
- A list of all protocols subject to the *NIH Guidelines* that are currently registered with the IBC indicating which section of the *NIH Guidelines* each registration falls under and the Biosafety Level for which they have been approved. The following additional documentation should also be provided if available:
 - Any documentation describing the IBC standard operating policies and procedures (e.g., IBC charter, memoranda of understanding between the IBC and other institutional oversight committees, institutional policy for providing IBC meeting minutes to the public, etc.)
 - *NIH Guidelines*-related training program materials (e.g., power point slides, biosafety manuals, web-based training, etc.).
 - All reports of laboratory accidents involving research subject to the *NIH Guidelines* or violations of the *NIH Guidelines* occurring in the last 5 years.
 - Copies of laboratory inspection checklists and a sample of an inspection report.

During a visit

9. Will NIH OBA be looking at the research facilities?

Inspection of the institution's research facilities will not be a routine part of the visits.

10. Will NIH OBA want to attend an IBC meeting?

If the schedule and timing of the site visit permits, the site visit team may attend an IBC meeting. The institution is not required to schedule an IBC meeting in conjunction with the site visit.

11. Who will NIH OBA want to talk to at the institution?

Interviews will be conducted with the IBC contact or Biological Safety Officer (as appropriate), IBC chairperson, a senior research administrator, and several investigators conducting research subject to the *NIH Guidelines*, who will be selected by the site visit team in consultation with the IBC contact. The team may also ask to meet with other institutional personnel as appropriate.

12. Will we receive feedback on our IBC program during the visit?

The site visit team will conduct a debriefing with institutional personnel at the end of the visit to discuss major observations and immediately discernible compliance issues.

After a visit

13. Will NIH OBA conduct any follow up visits?

It is anticipated that the site visit team will gather all the necessary information at the time of the visit.

14. Will the institution receive a report about the visit?

OBA will communicate findings from the visit to the institution in writing.

15. What will happen if a problem is discovered?

If OBA identifies practices that are not in keeping with the *NIH Guidelines*, it will work with the institution to rectify any problems.