

FAQs about the NIH Office of Biotechnology Activities Site Visit Program

General

■ **What is the purpose of the site visit program?**

The site visit program is one of several OBA initiatives aimed at enhancing compliance with the *NIH Guidelines for Research Involving Recombinant DNA 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 will be used by OBA to tailor and target outreach programs to serve the educational needs of individuals involved in the conduct and oversight of recombinant DNA research.

■ **Will all institutions registered with OBA be visited?**

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

■ **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.

■ **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.

■ **Who will be conducting the site visit?**

OBA has contracted with the Constella Group to assist with the site visits. The site visit team will typically include OBA and Constella staff.

▪ **Whom can I contact at NIH OBA for more information about the site visit program or requirements under the *NIH Guidelines for Research Involving Recombinant DNA Molecules*?**

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://www4.od.nih.gov/oba>

Before a visit

▪ **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 Constella Group site visit staff will then work directly with the IBC contact to schedule a date for the visit.

▪ **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 recombinant DNA oversight program 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 recombinant DNA research with the IBC.
- A list of all recombinant DNA 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.)
- Recombinant DNA-related training program materials (e.g., power point slides, biosafety manuals, web-based training, etc.).
- All reports of laboratory accidents involving recombinant DNA 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

- **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.

- **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.

- **Who will NIH OBA want to talk to at the institution?**

Interviews will be conducted with the IBC contact, Biological Safety Officer (as appropriate), IBC chairperson, a senior research administrator, and several principle investigators, 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.

- **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

- **Will NIH OBA be doing follow up visits?**

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

- **Will the institution receive a report about the visit?**

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

- **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.