



# OBA Educational Site Visit: Overview & Lessons Learned

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## Introduction

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- Pilot institution
- Assess institutional oversight of rDNA research (NIH Guidelines)
- Test and refine site visit criteria
- To ensure that UM benefits, prepare report summarizing observations
- Friendly tone throughout

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## Assessment to include

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- Review of UM's program for rDNA research oversight
- Review of UM's documentation related to rDNA research
- Interviews with selected personnel
  - Conduct
  - Oversight

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## Focus of Assessment

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- Current IBC practices
- Interactions between IBCs, PIs and other oversight committees.

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## Not included

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- Lab inspections
- Attendance at IBC meeting

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## Review of Documentation (required)

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- IBC roster
- IBC members' biographical sketches
- Meeting minutes of past 2 years
- Emergency plans
- rDNA registration forms
- List of rDNA protocols currently registered with IBC

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## Review of documentation (if available)

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- IBC SOPs (charter)
- rDNA related training program materials
- Reports of lab accidents involving rDNA
- Reports of violations of the NIH Guidelines
- Lab inspection checklists

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## Audit Team

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- OBA staff (3)
- Constella (contractor) staff (2)

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## Time Line

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- On-site for 1.5 days
- Coordination-intensive
- Requested documentation within 2 weeks
- Extension available

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## Interviews

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- IBC manager
- IBC chair
- BSO
- Senior university administrator

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## Interviews

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- 3-4 PIs selected by OBA
  - Basic research
  - Transgenic animals
  - High containment-animal
  - High containment-basic



## Agenda

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- Introductory meeting
- Interviews: IBC manager, IBC Chair, Sr. Research Administrator
- Interviews: 4 PIs
- Time allotted to review missing documents, if needed
- Exit debriefing



## Formal report

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- 3 months later
- Positive characteristics and practices of UM oversight program
- Considerations for possible change or improvement

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## Our Response

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- More lab audits
- Training on NIH Guidelines and PI's responsibilities during audits
- Will develop an online training for annual update

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## Lessons Learned

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- Time commitment
- Meet with PIs before interview
  - Review their responsibilities (Section IV)
  - Review role of IBC
- Ask for what you need
- Occasional lack of communication between contractor and OBC staff