

Keep Calm and Be Prepared

Lessons Learned from Emory's NIH OBA Site Visit

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Emory University

- * Located in Atlanta, GA
- * Founded as Oxford College (1836)
- * 14, 513 enrolled students (2013)
- * Main campus spans over 600 acres
- * 9 individual schools within the University
- * 16 major research buildings
- * Approximately 500 PIs and 1500 laboratory spaces
- * Multiple satellite campuses

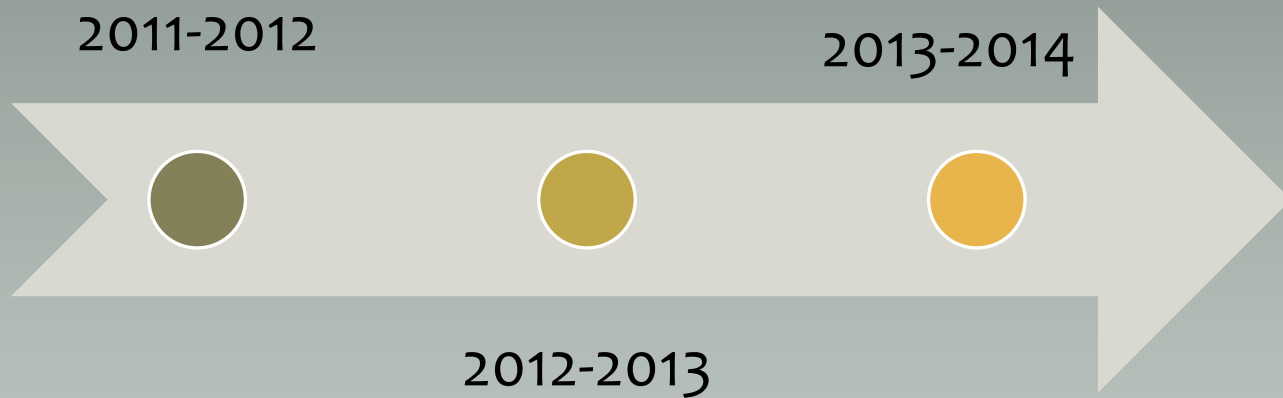


NIH-OBA Site Visit

- * Emory University had not been through a NIH-OBA site visit previously.
- * Were we ready for the site visit?
- * How did we proactively prepare for the site visit?

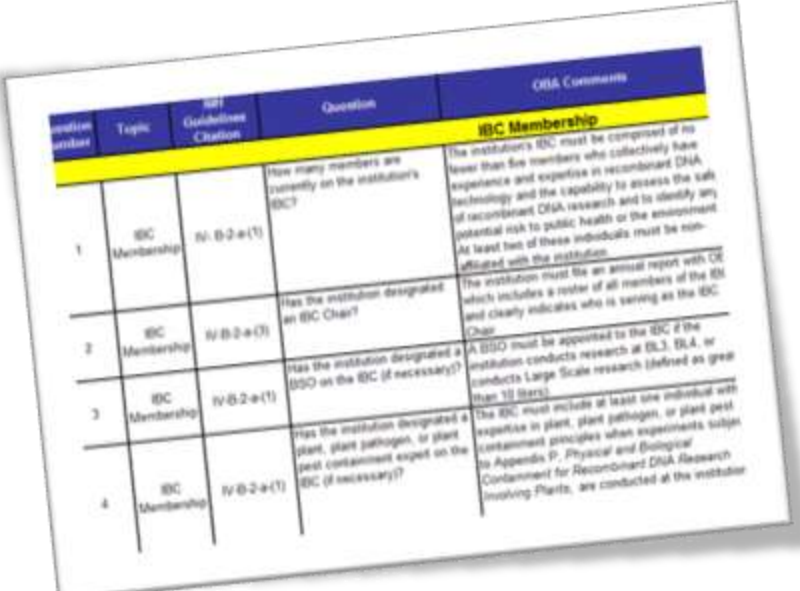


Timeline...



NIH Self-Assessment Tool...

- * We identified the inspection check list on OBA website
 - * *Tool for the Self-Assessment of the Institutional Biosafety Committee and Program of Oversight of Recombinant DNA Research*
- * We used the check list as the first step to identify the gaps in our program
- * We developed a scoring system for our biosafety program review



Question Number	Topic	NIH Guidelines Citation	Question	OBA Comments
1	IBC Membership	IV B-2-a(1)	How many members are currently on the institution's IBC?	The institution's IBC must be comprised of no fewer than five members who collectively have experience and expertise in recombinant DNA technology and the capability to assess the safe technology and the capability to assess the safe of recombinant DNA research and to identify any potential risk to public health or the environment. At least two of these individuals must be non-affiliated with the institution.
2	IBC Membership	IV B-2-a(3)	Has the institution designated an IBC Chair?	The institution must file an annual report with OI which includes a roster of all members of the IBC and clearly indicates who is serving as the IBC Chair.
3	IBC Membership	IV B-2-a(1)	Has the institution designated a BSO as the IBC (if necessary)?	A BSO must be appointed to the IBC if the institution conducts research at BL3, BL4, or conducts Large Scale research (defined as greater than 10 liters).
4	IBC Membership	IV B-2-a(1)	Has the institution designated a plant, plant pathogen, or plant pest containment expert on the IBC (if necessary)?	The IBC must include at least one individual with expertise in plant, plant pathogen, or plant pest containment principles when experiments subject to Appendix P, Physical and Biological Containment for Recombinant DNA Research Involving Plants, are conducted at the institution.

http://oba.od.nih.gov/rdna_ibc/ibc.html

Program Scoring...

- * We used an internal scoring system to calculate an overall program score
- * Each line item received a score:
 - * 1 = fully compliant
 - * 2 = in process (partially compliant)
 - * 3 = nothing in place
- * Each line item received a justification for each score provided



Results from Gap Analyses...

2011

- Training on NIH rDNA Guidelines for PIs/researchers

2012

- Autoclave Validation Program; training for animal handlers

2013

- rDNA Classification for all protocols

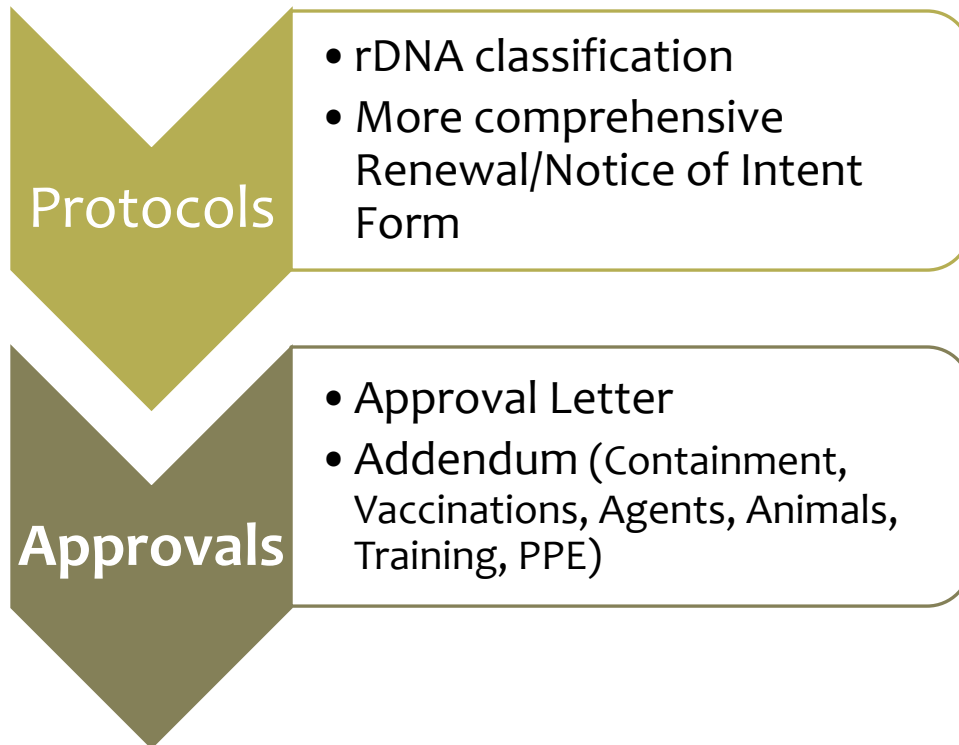
Our Response...

- * Identify gaps in the program
- * Use a systematic approach
 - * Management Systems
- * Focus on those gaps
- * Benefits of gap analysis:
 - * More resources needed?
 - * Upper management buy-in?
 - * Additional FTE?
 - * Other?



The Next Step: Implementation...

Example: Biosafety Protocols



NIH OBA to Visit Emory...

- Emory received a notice from NIH OBA announcing their visit in March 2014
- Emory provided the requested documentation- E.G.
 - List of all rDNA protocols
 - IBC Charter
 - Committee Meeting Minutes
 - Incident Reports

NOTICE

**NIH OBA will visit
Emory University on
Tuesday March 18, 2014**

Preparing for the site visit...

- * Requested Documentation:
 - * Overall Prep Time = ~1 hour
- * How were we able to do this so quickly??
 - * NIH OBA Self-Assessment Tool
 - * Program Management
 - * Management Systems



PI Interview

- * **Before the Site Visit**

- * NIH OBA sent a list of PIs to interview from the protocol list
- * BSO meeting with those PIs
 - * ZERO knowledge of talking points
 - * My advice to PIs: Be honest with your opinion -working relationship with BSO and our services

- * **During the Site Visit**

- * NIH OBA meeting with selected PIs



NIH OBA Site Visit Results...

- * Final Outcome: Beautiful!
 - * Only minor recommendations
- * Future Plans:
 - * Do not stop!
 - * Continue to review documents, SOPs, etc.
 - * Make changes where needed
 - * Biosafety Stewardship
 - * New DURC Policy



Lessons Learned from Emory's NIH OBA Site Visit...

- * Systematic Management of Programs
 - * BABY STEPS!
 - * Identify gaps and address them systematically
 - * Always be prepared
- * Keys to a successful Biosafety Program:
 - * Proactive approach
 - * Systematically address gaps
 - * Continue to evaluate programs



Thank you

- * Meagan Fitzpatrick
- * Michele Edenfield
- * Patty Olinger

QUESTIONS?



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