



ASU's Institutional Biosafety Committee (IBC)

Recombinant DNA Compliance

- What you need to know
- What you need to do

Safety and regulatory compliance is everybody's job

ASU's ability to seek and receive external funding including federal grants and many foundation gifts and industry contracts can be undermined by failure to meet regulatory requirements

ASU's Institutional Biosafety Committee (IBC) supports the oversight and approval process required for research involving recombinant DNA

What is an Institutional Biosafety Committee (IBC)?

- An institutional committee created under the *National Institutes of Health (NIH) Guidelines* to review research involving recombinant DNA
- An IBC is required if ASU is conducting or sponsoring any recombinant DNA research that is funded by NIH or other federal funding agencies (likewise required by many other private and public funding agencies or foundations)
- Failure to comply could lead to suspension, limitation or termination of funding

What is recombinant DNA and what are the *NIH Guidelines*?

- Recombinant DNA (rDNA) is defined as
 - DNA molecules constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell
 - Molecules resulting from the replication of those described above
- The *NIH Guidelines* are the federal policy that specifies practices for constructing and handling
 - Recombinant DNA molecules
 - Organisms and viruses containing rDNA molecules
- The *NIH Guidelines* can be accessed at <http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>

What are ASU's responsibilities regarding rDNA and an IBC?

- Implement policies for the safe conduct of recombinant DNA research
- Establish an Institutional Biosafety Committee meeting the required composition and expertise
- Assist and ensure compliance with the *NIH Guidelines* by investigators
- Ensure appropriate training for IBC members and staff, Principal Investigators (PIs), and laboratory staff
- Determine necessity for health surveillance of personnel
- Report any significant problems or violations to NIH's Office of Biotechnology Activities (OBA) within 30 days

What must ASU's IBC review?

- Recombinant DNA (rDNA) research for conformity with the *NIH Guidelines*
- Potential risk to environment and public health
- Adequacy of facilities, standard operating procedures (SOPs), PI and lab personnel training
- Institutional and investigator compliance

What are the Deans' and Department Heads' responsibilities?

- Ensure that their faculty are aware of their responsibilities with respect to rDNA research as well as other safety and regulatory requirements
- Provide information that directs their faculty to safety and regulatory compliance information and training required at ASU (which can be accessed via the Office of Research and Technology Transfer and Environmental Health & Safety websites)
 - e.g., <http://ehc.astate.edu/safetycomp&trng.html>

What are Principal Investigator (PI) responsibilities?

- The PI (ASU faculty leading the research) shall
 - Determine whether experiments require approval and at what containment level
 - Seek IBC approval before initiating rDNA research
 - Determine whether newly initiated research is appropriately covered under previous approvals or requires a new submission or program addendum
 - Be adequately trained in good microbiological and rDNA techniques and ensure training of all laboratory personnel
 - Adhere to IBC emergency plans for spills and personnel contamination
 - Report any significant problems or violations to IBC and OBA within 30 days

How does a PI obtain IBC approval?

- Access and submit *Program Approval* applications at
 - <http://ehc.astate.edu/safetycomp&trng.html>
 - <http://researchoffice.astate.edu/bio/registration.htm>
 - or at <http://www.irbnet.org/> if you have a user name and password (contact ORTT for these)
- The IBC currently meets every 2 months; scheduled meetings can be viewed on the ASU calendar
- Applications should be submitted at least 1 week prior to a scheduled meeting

I do not work with rDNA. What do I need to know?

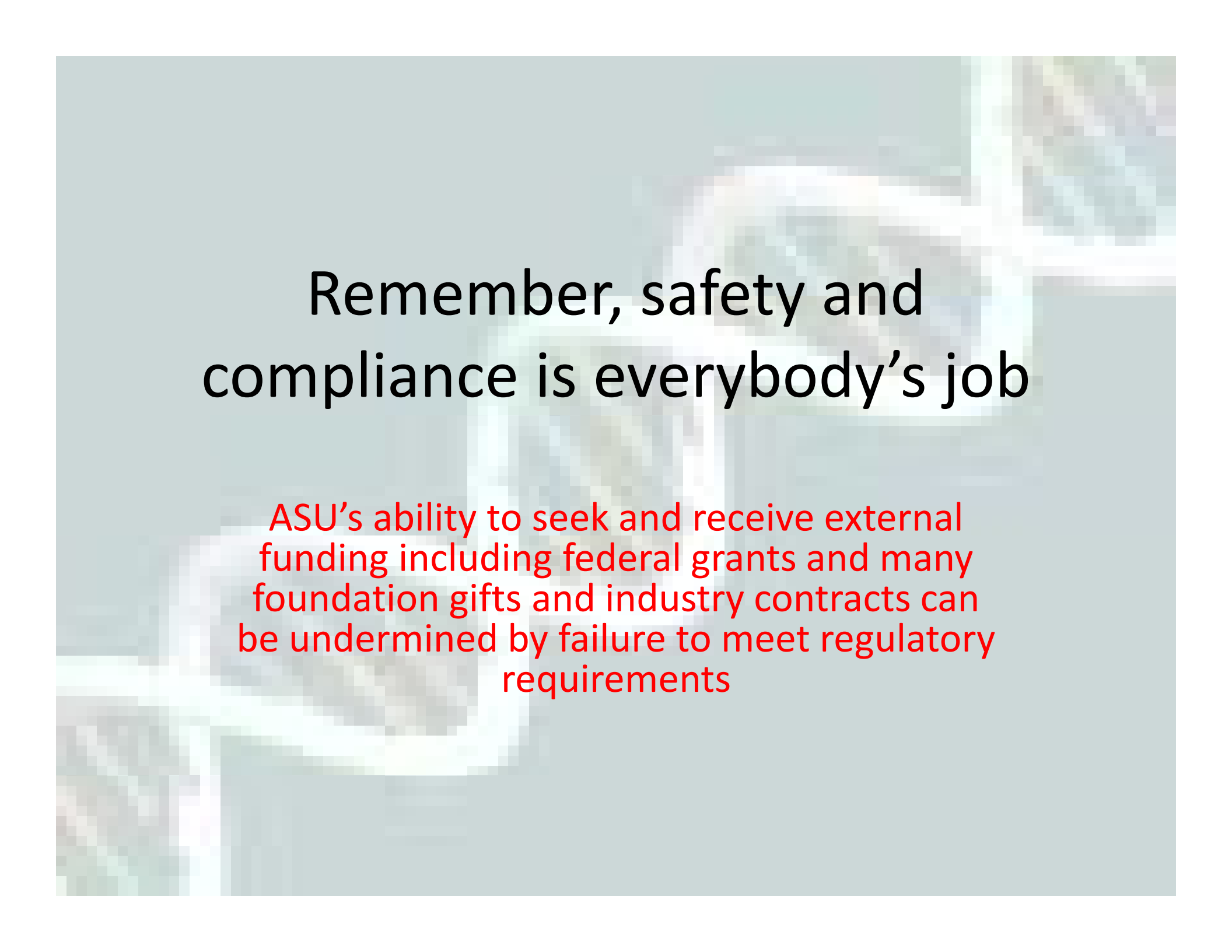
- All faculty and administrators at ASU need to be aware of federal regulations for:
 - Environmental health and safety (OSHA)
 - Research involving human subjects (oversight by IRB)
 - Research involving laboratory animals (oversight by IACUC)
 - Research involving recombinant DNA (oversight by IBC)
- Faculty that interface with colleagues and students doing research in areas of science & technology, medicine, agriculture, or science education should have an elevated awareness of rDNA compliance issues.
- Even if you have no direct involvement in research involving rDNA, you may serve on graduate advisory committees, mentor new faculty, or participate in collaborations where it is indeed your responsibility to ensure that everyone is aware and in compliance.

I do not work with rDNA. What are my responsibilities?

- If you observe or become aware of research that involves rDNA, it is your responsibility to inquire as to compliance/rDNA training and to direct researchers to appropriate channels to ensure compliance.
- Your involvement may be initiated in a quite casual manner. A colleague or student may ask you to store, grow, or transport samples, microbial cultures, or plants. If these samples contain rDNA, they may have special requirements for
 - Handling, labeling, transport, and disposal
 - Growth in IBC- (or US Department of Agriculture-) approved locations, incubators or greenhouses
 - Elevated containment due to environmental or health risks

I do not work with rDNA. What are my responsibilities? (continued)

- It is your responsibility to:
 - Ask researcher specifically if samples or organisms require IBC approval (i.e., contain recombinant DNA) or regulatory oversight
 - Confirm with researchers' supervisor or advisor that request does not involve rDNA concerns
 - If rDNA compliance is required, it is your responsibility to be trained and comply with all rDNA regulatory procedures and protocols and to ensure that all personnel involved are appropriately trained



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