



**Effective March 5, 2013, the NIH Guidelines have been amended** to include and address biosafety considerations for research with synthetic nucleic acids. The scope of the new [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules](#) includes the practices for constructing and handling:

- (i) recombinant nucleic acid molecules,*
- (ii) synthetic nucleic acid molecules, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, and*
- (iii) cells, organisms, and viruses containing such molecules.*

The NIH defines recombinant and synthetic nucleic acid molecules as:

- (i) molecules that a) are constructed by joining nucleic acid molecules and b) can replicate in a living cell (i.e. recombinant nucleic acids);*
- (ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules (i.e. synthetic nucleic acids); or*
- (iii) molecules that result from the replication of those described in (i) or (ii) above.*

In addition, the section of the Guidelines that covers deliberate human gene transfer experiments (III-C-1) has been amended to specify:

- *Recombinant nucleic acid molecules, or DNA or RNA derived from recombinant nucleic acid molecules, or*
- *Synthetic nucleic acid molecules, or DNA or RNA derived from synthetic nucleic acid molecules, that meet any one of the following criteria:*
  - ♦ *Contains more than 100 nucleotides; or*
  - ♦ *Possesses biological properties that enable integration into the genome (e.g., cis elements involved in integration); or*
  - ♦ *Have the potential to replicate in a cell; or*
  - ♦ *Can be translated or transcribed.*

**Because the University receives funding from NIH grants, ALL research conducted at the University must comply with the NIH Guidelines for Research Involving Recombinant DNA Molecules and University policies and all research involving any biohazards, including recombinant and synthetic nucleic acids, must be registered with the Institutional Biosafety Committee ([http://ehs.uky.edu/docs/pdf/bio\\_ibc\\_registration\\_0001.pdf](http://ehs.uky.edu/docs/pdf/bio_ibc_registration_0001.pdf))**

For more information please see:

Federal Register: [http://oba.od.nih.gov/oba/rac/fractions/77\\_FR\\_54584.pdf](http://oba.od.nih.gov/oba/rac/fractions/77_FR_54584.pdf)

New NIH Guidelines with Summary of Changes: [http://oba.od.nih.gov/oba/rac/Guidelines/NIH\\_Guidelines\\_new.pdf](http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines_new.pdf)

## TOPAZ tips



### Biosafety Protocols -

**For registration with the  
Institutional Biosafety Committee (IBC)**

[http://ehs.uky.edu/docs/pdf/bio\\_ibc\\_registration\\_0001.pdf](http://ehs.uky.edu/docs/pdf/bio_ibc_registration_0001.pdf)

To expedite amendments which add personnel, please remember to include all training dates for those added. If Blood Borne Pathogens are involved in the registered work, also attach a signed ECP Personnel Statement to the Exposure Control Plan section of the registration form for the new addition(s).

- ♦ Online training modules can be found at: <http://ehs.uky.edu/classes/>
- ♦ To access training records for personnel, visit:  
[http://ehs.uky.edu/classes/participant\\_list\\_0001.php](http://ehs.uky.edu/classes/participant_list_0001.php)
- ♦ ECP Personnel Statement form:  
[http://ehs.uky.edu/docs/pdf/bio\\_ecp\\_personnel\\_statement.pdf](http://ehs.uky.edu/docs/pdf/bio_ecp_personnel_statement.pdf)

## Biosafety Reminders:

Avoid stockpiling waste and/or leaving large amounts of unprocessed biohazardous waste unattended in either an unlocked laboratory or the autoclave room. Good housekeeping practices can prevent clutter which could pose a hazardous situation to personnel. Autoclave waste should be processed in a timely manner and always kept or transported in an uncompromised, autoclavable bag which is set within a leak proof container.



What not to do: accumulated unprocessed biohazardous waste



University of Kentucky

## Department of Biological Safety

As part of the Division of Environmental Health & Safety, the Department of Biological Safety is responsible for programs concerning the safe use of recombinant DNA, infectious agents, and potentially infectious materials such as human sourced materials in the research and teaching laboratories at the University of Kentucky. This includes training, auditing, and consulting with researchers, laboratory personnel and teaching staff concerning compliance with the federal and state laws and regulations in these areas.

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Visit us on the web!

<http://ehs.uky.edu/ehs/biosafety/>