

IBC Authority and Oversight:

As required by the NIH Guidelines, the University of Rochester Institutional Biosafety Committee (UR IBC) oversees and regulates all research with biohazardous agents and recombinant DNA molecules at the University of Rochester. Recombinant DNA molecules are defined below.

The University of Rochester has also determined that, in addition to performing these required oversight functions, the IBC will also exercise oversight of technologies that directly manipulate gene expression in cells using small informational molecules (small polymers based on DNA, RNA or mimetics thereof).

Definitions:

Recombinant DNA: The NIH guidelines define recombinant DNA molecules as either: (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) molecules that result from the replication of those described in (i) above.

Synthetic DNA segments which are likely to yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or a pharmacologically active agent) are considered as equivalent to their natural DNA counterpart. If the synthetic DNA segment is not expressed *in vivo* as a biologically active polynucleotide or polypeptide product, it is exempt from the *NIH Guidelines*.

http://www4.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261549

Informationally-based technologies that directly manipulate gene expression in cells: Technologies intended to produce disruption or modification of gene transcription, RNA processing or gene product formation, and that rely upon the introduction into cells of informational molecules to achieve this (small polymers based on DNA, RNA or mimetics of DNA or RNA) will fall within the purview of the UR IBC. Non-limiting examples of these technologies include RNAi, dsRNA, antisense oligonucleotide (PNAs, LNAs, etc). The IBC will provide guidance to investigators and through its review address safety concerns pursuant to use of these technologies, including (but not limited to) safety of laboratory workers, and other members of University community. The IBC will also advise the Research Subject Review Board on an as-needed basis on scientific issues that may be related to the safety of human subjects who participate in clinical studies that use such modalities.

