This notice sets forth final changes to the NIH Guidelines regarding those two proposals. The scope of the NIH Guidelines is being modified to cover certain classes of basic and clinical research with synthetic nucleic acids while exempting others. As discussed herein, the majority of research with synthetic nucleic acids that are not designed to replicate does not raise significant biosafety concerns that warrant oversight under the NIH Guidelines. Because of the modification of the scope of the NIH Guidelines, the title of the NIH Guidelines will be revised from NIH Guidelines for Research Involving Recombinant DNA Molecules to NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids Molecules.

These changes also clarify the criteria for determining whether an experiment to introduce drug resistance into a microorganism raises sufficient public health issues to warrant the experiment being reviewed by the RAC and approved by the NIH Director under Section III–A–1–a of the NIH Guidelines. Comments submitted were discussed at the ‘‘NIH Public Consultation on Proposed Changes to the NIH Guidelines for Synthetic Nucleic Acids’’ on June 23, 2009 (http://oba.od.nih.gov/rdna_rac/rac_pub_con.html).