

RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES in Human Subjects

Duke Institutional Biosafety Committee

Revised January 2021

Summary. All Duke Research using recombinant or synthetic nucleic acid molecules in human subjects must comply with the NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES (NIH GUIDELINES) available at <https://osp.od.nih.gov/biotechnology/nih-guidelines/>). This research requires approval by the Duke Institutional Review Board (IRB) and the Duke Institutional Biosafety Committee (IBC) [NIH Guidelines Section III-C and III-C-1].

In the context of the *NIH Guidelines*, recombinant and synthetic nucleic acids are defined as:

- (i) molecules that a) are constructed by joining nucleic acid molecules and b) that 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.

Please note that **every** human trial recombinant and/or synthetic nucleic acids requires its own review by **both** the Duke IRB and IBC even if the same rDNA material is used in multiple trials.

Materials required for all rDNA research in humans

- (1) Duke rDNA/viral vector (or study agent made or modified using these materials) registration (**available on the Duke iRIS eIRB platform**). Please answer all questions on this form. Be sure to clearly identify the exact plasmid, vector, or cells to be used in humans.
 - a. If a biological (viral) vector is used in the research, the PI must provide an Investigational Product Handling Plan (IPHP) that serves as Duke-specific standard operating procedures (SOP) outlining the safe handling of the material to be administered to humans. The IPHP should include a summary of the risks associated with the material, including procedures, personal protective equipment, risks to clinicians preparing and administering the study agent, risks to others such as household members not enrolled as subjects, and risks to the environment. Include a list of the locations where the material will be handled to include, as appropriate, the receipt, packaging, storage, aliquot preparation, transport, administration, and disposal. Contact OESO-Biological Safety Division (biosafety@dm.duke.edu or 919-684-8822) for an IPHP template, if needed.