Marshall University Human Gene Transfer Protocol Policy

On April 25 2019, NIH released amended NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules given at https://osp.od.nih.gov/biotechnology/nih-guidelines/. The amendments remove the requirement to register and report on human gene therapy protocols to NIH Recombinant DNA Advisory Committee (RAC) under the NIH Guidelines. However, oversight over gene therapy trials will continue at the Food and Drug Administration (FDA) and local levels. **At Marshall University, approval by MU Institutional Review Board (IRB) and the MU Institutional Biosafety Committees (IBC) is required before any research using rDNA or sDNA in human participants can be initiated. Further, these protocols must be reviewed and approved by the IBC before they can be reviewed by the IRB**

Specific guidance on rRNA/sDNA work in human subjects can be found in section III-C of the NIH guidelines. Please contact the IBC chair if you have any questions about rDNA work in human subjects.

Consistent with removal of the requirement for RAC approval, NIH is refocusing the RAC to provide advice on safety and ethical issues associated with emerging biotechnologies which include or are not restricted to technologies surrounding advances in recombinant or synthetic nucleic acid research. Accordingly, the RAC has been renamed the Novel and Exceptional Technology and Research Advisory Committee (NExTRAC) to the change in its mission.

Additional information of the amendment can be in the April 2019 Amendment of the NIH Guidelines (Human Gene Transfer Research) FAQ document from the NIH Office of Science Policy.