CONSIDERATIONS FOR INSTITUTIONAL OVERSIGHT OF HUMAN GENE TRANSFER STUDIES

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Clinical trials involving human gene transfer pose several unique challenges to academic institutions. This presentation provides an overview of regulatory requirements faced by the IBC, IRB and EHS. Discussion topics will include best practices for conducting risk assessments, communication between the IRB and IBC as well as strategies for addressing the NIH single IRB policy and the changes to the common rule affecting federally funded multi-site studies.