



Is your Institutional Biosafety Committee Prepared to Review Clinical Trials Involving Human Gene Transfer?

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Human Gene Transfer (HGT) is the deliberate transfer into human research participants of either:

1. Recombinant nucleic acid molecules, or DNA or RNA derived from recombinant nucleic acid molecules, or
2. Synthetic nucleic acid molecules, or DNA or RNA derived from synthetic nucleic acid molecules, that meet any one of the following criteria:
 - a. Contain more than 100 nucleotides; or
 - b. Possess biological properties that enable integration into the genome (e.g., *cis* elements involved in integration); or
 - c. Have the potential to replicate in a cell; or
 - d. Can be translated or transcribed.

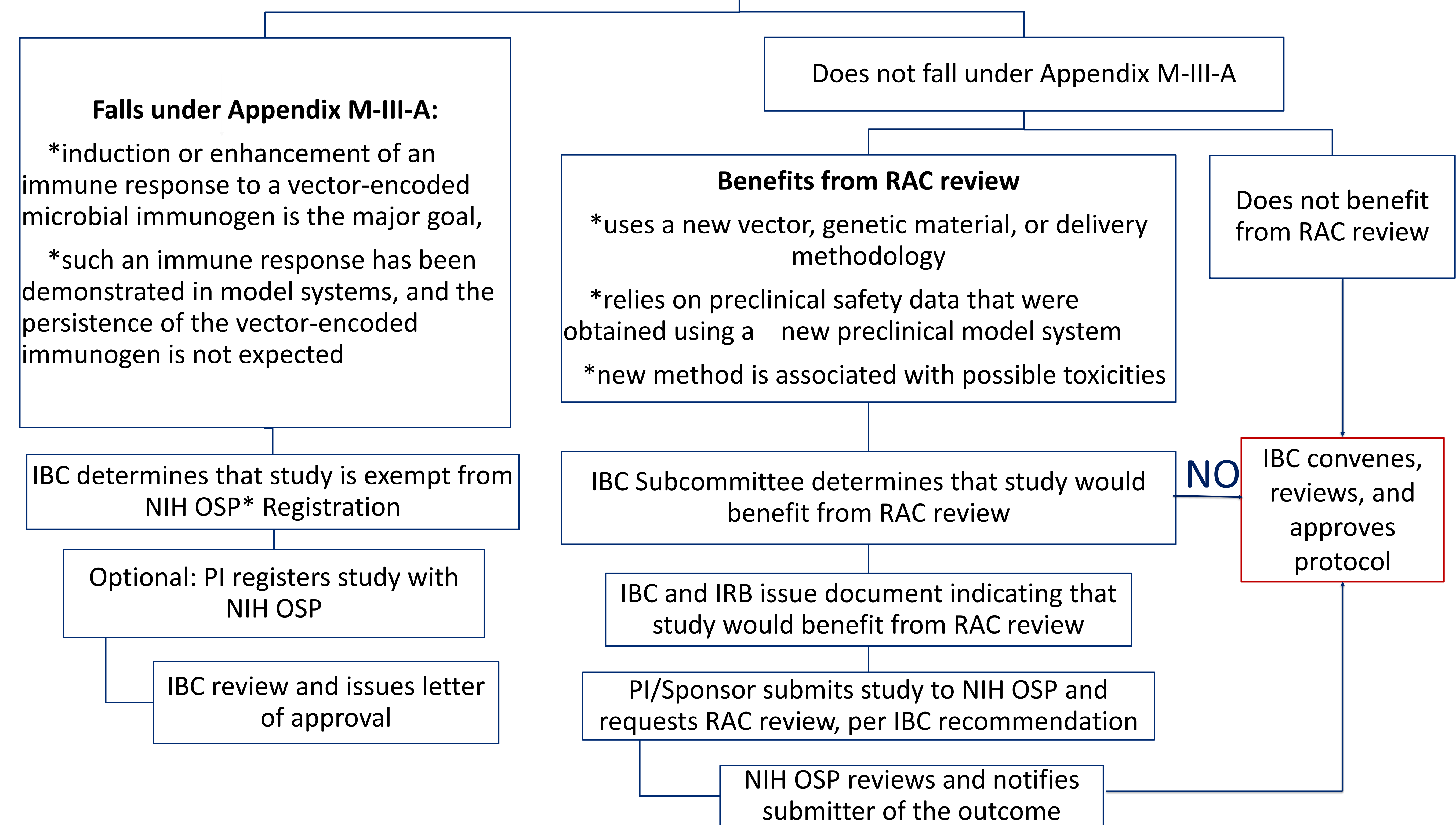
	Case 1	Case 2	Case 3	Case 4
Product	Oligonucleotide < 100 bp	Known Viral Vector	RG2 Bacterial Vector	Known Viral Vector
Initial Site	Yes	Yes	Yes	No
IBC/IRB Chairs	Yes	Yes	Yes	No
IBC or RHSC Review	RHSC	IBC	IBC	IBC
Benefits from RAC review	No	No	No	No

IBC= Institutional Biosafety Committee
 RHSC= Research Health and Safety Committee
 IRB= Institutional Review Board
 RAC= Recombinant DNA Advisory Committee

EHSO completes Summary form

ALL Human Gene Transfer Studies are submitted through the electronic platform to be reviewed by the BSO
 Emory University IBC reviews all studies involving recombinant or synthetic nucleic acids in human subjects.

IBC and IRB Chairs complete review forms



OSP= Office of Science Policy



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 Research Administration

