Human Gene Transfer General Process



Office of Research Compliance 1960 Kenny Road, Columbus, OH 43210-1016

OFFICE OF SPONSORED PROGRAMS (OSP)

Processes the PA-005

Negotiates and finalizes the sponsored research agreement

Once the Office of Research approves the human gene transfer, the sponsored research agreement is executed.

PRINCIPAL INVESTIGATOR SUBMITS:

IBC application via e-Protocol

IRB application

PA-005 to OSP (if applicable)

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

Processes the PI's application

Committee meets for the review and approval process

Notifies the PI of the decision

INSTITUTIONAL REVIEW BOARD (IRB)

Processes the Pl's application <u>pending</u> the IBC approval

Committee meets for the review and approval process

Notifies the PI of the decision

OFFICE OF RESEARCH (OR)

Reviews the Pl's application pending the IBC and IRB approval

Notifies the PI of the decision

If approved, also notifies OSP and both committees in the Office of Responsible Research Practices

PRINCIPAL INVESTIGATOR

Human gene transfer opens to accrual

PI (or designee) submits to IBC and NIH Office of Biotechnology Activities all mandated reports