Human Gene Transfer – General Process

Office of Sponsored Programs (OSP)

- Submit IBC application (Via e-protocol)
- Submit IRB application
- Submit PA-005 to OSP (if applicable)

Principal Investigator

- IBC Processes Application
- IBC Review and Approval Process
- IBC Approved?

Institutional Biosafety Committee (IBC)

- IRB Processes Application (pending IBC approval)
- IRB Review and Approval Process
- IRB Approved?

Institutional Review Board (IRB)

- Office of Research Review and Approval Process
- Office of Research Approved?

Office of Research (OR)

- OR notifies PI, OSP, IBC, and IRB (ORRP) of HGT approval

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

- HGT Opens to Accrual

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- HGT Approved?

- HGT Approved?

- OSP finalizes Sponsored Research Agreement

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- OSP negotiates Sponsored Research Agreement

- OSP negotiates Sponsored Research Agreement

- OSP Processes PA-005

- OSP Processes PA-005

- 4/23/2012