Sheffield Teaching Hospitals NHS
NHS Foundation Trust

Research Department

STANDARD OPERATING PROCEDURE

Gene Therapy Research: Local Safety Group Approval

SOP History	*None*
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Related SOPs	
Approved by	*Research Coordinator (RP)*

Standard Operating Procedure

Gene Therapy Research: Local Safety Group Approval

In accordance with the national Gene Therapy Advisory Committee, the SACGM Compendium of guidance on the use of genetically modified microorganisms in a clinical setting, and the Genetically Modified Organisms (Contained Use) Regulations 2000 (No.2831), it is necessary for local review and approval of all gene therapy studies to be undertaken at the hosting site. This SOP will outline the procedure for local approval of all gene therapy studies at STH.

Background
In accordance with the national guidance and legislation, it is necessary for local review and approval of all gene therapy studies to be undertaken at the hosting site. At STH, the Gene Therapy Research Safety Group advises and oversees local arrangements for the conduct of research studies involving gene therapy, and undertakes any risk assessments on individual projects as appropriate.

Definition
Gene therapy is a technique for correcting defective genes responsible for disease development. Researchers may use one of several approaches for correcting faulty genes:

- A normal gene may be inserted into a non-specific location within the genome to replace a non-functional gene. This approach is most common.
- An abnormal gene could be swapped for a normal gene through homologous recombination.
- The abnormal gene could be repaired through selective reverse mutation, which returns the gene to its normal function.
- The regulation (the degree to which a gene is turned on or off) of a particular gene could be altered.

Procedure
1. The Principal Investigator (PI) registers the research study with the Research Department.
2. The PI, research team member or Sponsor delegate forwards to the assigned Research Department Coordinator, electronic copies of the following:
   - Protocol
   - Information Sheets and Consent forms
   - Gene Therapy Advisory Committee (GTAC) approval letter
   - Risk Assessments undertaken by Sponsor
   - Any other supporting documentation
3. The Research Coordinator with assistance from the Research Department lead for Gene Therapy forwards the submitted documents to the Gene Therapy Research Safety Group.
4. The Gene Therapy Research Safety Group review the documentation for local feasibility and risk assessment, seeking additional information from the PI, delegated research team member and/or Sponsor as applicable; the PI with support from the Research Coordinator will communicate any queries from the Gene Therapy Research Safety Group to the Sponsor.
5. The Gene Therapy Research Safety Group ratifies the study if all the necessary approvals are in place.
   5.1. Where there are outstanding issues, the PI collaborates with the Gene Therapy Research Safety Group to ensure any issues are resolved.
   5.2. Once all issues have been resolved the Gene Therapy Research Safety Group ratifies the study.
6. The Research Department lead for Gene Therapy forwards to the PI confirmation of Gene Therapy Research Safety Group approval.
7. The PI and Sponsor with appropriate support from the Research Department submit a notification of the intention to use the premises (STH) for activities involving genetic modification to the Health & safety Executive (HSE), as appropriate and in line with national guidance.
8. The PI continues to liaise with and forward any outstanding documentation for Research Governance approval to their assigned Research Coordinator.

Appendix- Associated Documents

	Document	Research Department Network Location	Website	Database	Created by
1.	Gene Therapy Research Safety Group Areas of Expertise	..\..\..\Gene Therapy Research\Committee membership\Proposed New Committee 2011\CRO GTRSG Areas of expertise_v1 10Aug2011.doc	No	No	LB
2.	The SACGM Compendium of guidance. Part 6: Guidance on the use of genetically modified microorganisms in a clinical setting	..\..\..\..\..\Research Governance\Gene Therapy Research\HSE Part6 Guidance on the use of genetically modified microorganisms in a clinical setting.pdf	No	No	HSE