

*Gene Therapy at
Hammersmith Hospitals
NHS Trust*

Northern Biological Safety
Officers Meeting, Leeds
15 May 2006

Once upon a time.....Jo's Story

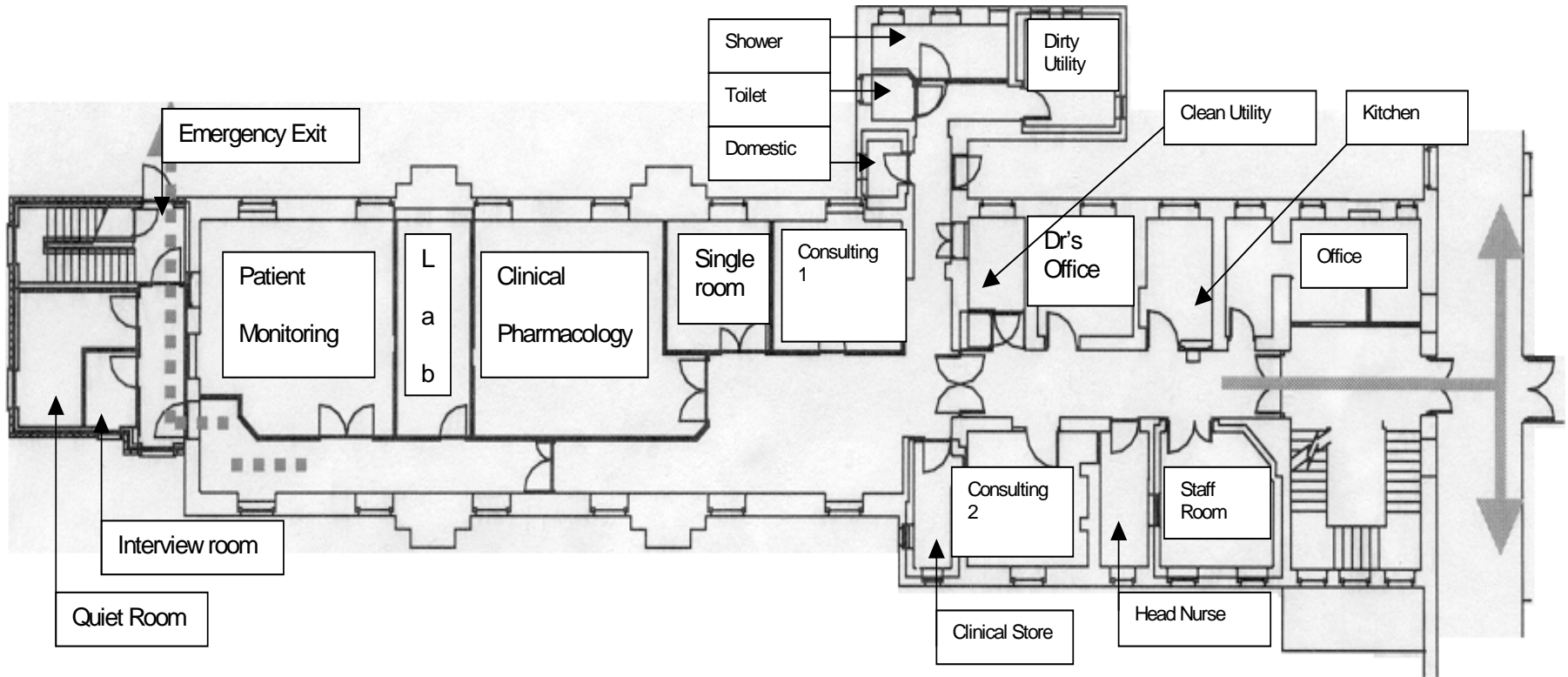
Sir John McMichael Centre

- Gestation 5+ years
- DOB - 9/10/00
- Height - two floors
- Weight - equivalent of an inpatient ward and outpatient area combined

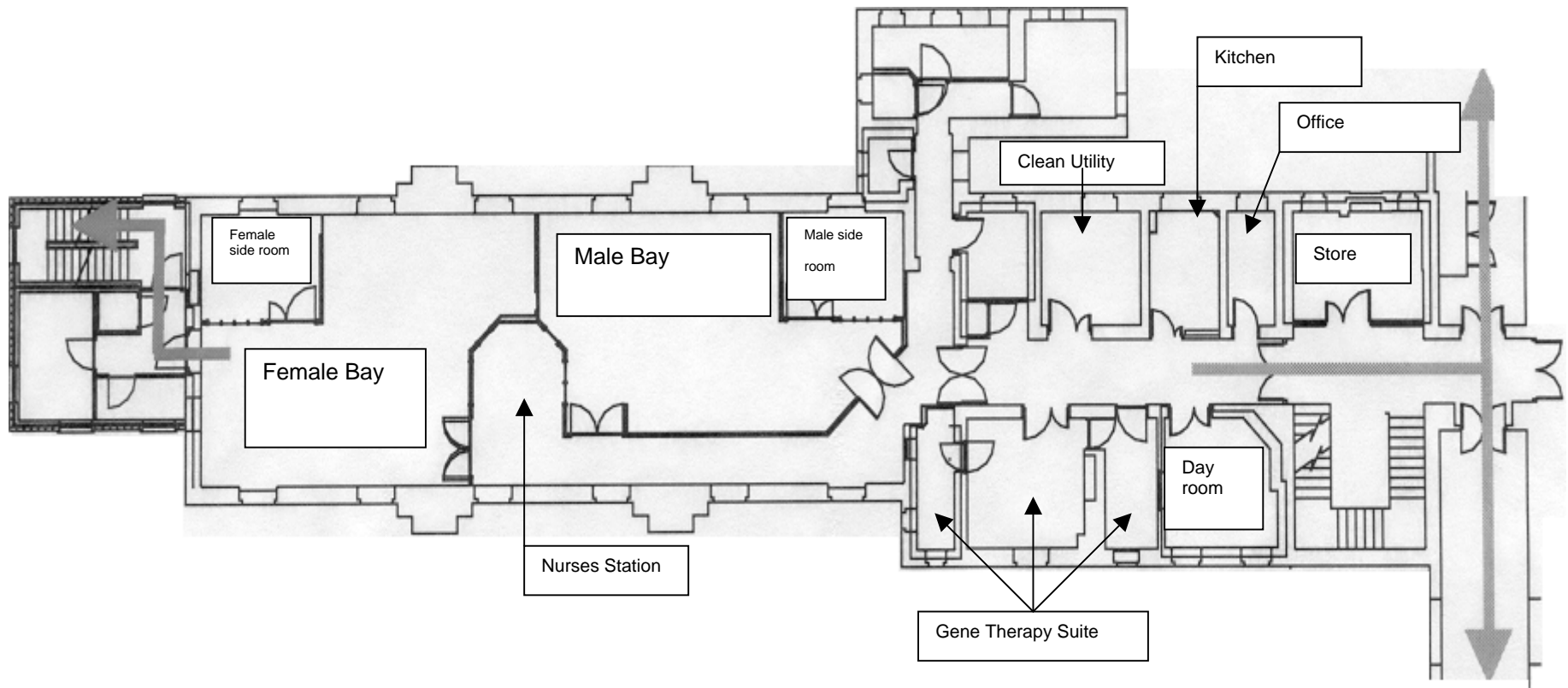
Jo's Story part 2.....

- New addition to the family announced Spring 2000
- Gene Therapy Suite required
- Due date early 2001
- Plans adapted - from rooms originally intended as a one-bedded patient room with en-suite facility.....

Ground Floor - C2



First Floor - C4



Sharon's Story

- Heard 'by chance' from two sources (Imperial College and Trust)
- Registered premises / set up GMSC
- Consider Trustwide approach
- Assess 1st activity
- Design training
- Produce forms / procedures / guidance
- One system for Class 1 and 2

Areas involved

- Pharmacy
- Primary ward
- Diagnostic labs
- Research labs
(HHT/ IC / MRC)
- Labs off site - inc
overseas
- 'Secondary ward'
e.g. ITU / CCU
- Theatres
- A/E
- Mortuary / PM room

The GMSC

- Hammersmith Hospitals NHS Trust Gene Therapy and Genetic Modification Safety Committee (HHT GT/GMSC)
- Sub committee of the Trust's Health, Safety, Fire and Security Committee (HSFSC)
- Set up to consider gene therapy and GM proposals
- Chaired by Consultant in Infectious Diseases
- Terms of Reference – reviewed annually
- Risk register (one high risk – ‘adverse publicity’)

HHT GT/GMSC

- Safety Office
- R&D Office
- Partner Organisations
- Unions (JUP)
- Partner Organisations Safety Office (GM Officer)
- Dept of Infectious Diseases
- Facilities
- Environmental Manager
- Research Heads
- SJMMC
- Pharmacy
- Infection Control
- Occupational Health
- Ethics Committee

Biological Safety Officer

- One for each project
- Not in the traditional role – support via Safety Office (USC)
- First volunteer...?
- Support from Senior Management (via Clinical and Non-clinical routes)

Communication issues

- Academic and clinical staff
- Defined roles / responsibilities
- Defined reporting routes
- PI must talk to all involved
- Contingency plans / emergency contacts
- Cross representation on committees
- Accident reporting

Projects

- 11 approved so far
- 4 active (three now 'closed') – Schering, Trovax, Oncovex and MetXia
- 2 about to start - approved in March
- 1 not directly Trust (drug administered elsewhere - scans carried out on HHT premises) – need to be aware in event of emergency admissions

GT/GM Risk Register

- Adverse publicity
- Exposure to GMOs
- Unforeseen clinical outcomes
- Release of GMOs
- Waste management
- Unrecognised risks of the biological agent used
- Unauthorised work
- Malicious acts

Standards

1. Board level commitment to gene therapy development in the Trust
2. GMSC to endorse all GM activities, guidance, policy, monitoring etc
3. Properly constituted investigative team
4. Written policies, procedures, guidance
5. Regular report to HSFSC, Risk Management Committee and Trust Board

Standards continued...

6. GMSC and BSO have access to relevant, up to date legislation and guidance
7. Staff trained to an appropriate level
8. Monitoring and review by management
9. Audit – internal and external
10. Use of GMMs should comply with good research governance within the Trust and Partner Organisations

Contacts / Further Info

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- K.B. Bamford, S. Wood, R.J. Shaw '*Standards for gene therapy clinical trials based on pro-active risk assessment in a London NHS Teaching Hospital Trust*' Q J Med 2005; **98** 75-86

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First floor – C4



Gene therapy Suite



Suction containment



Waste



Labelling



Procedures

