	Principal Risk Description	Risk Level		Over-all Risk Level	Expected Controls	Assurances including categorisation	Gaps in controls Including evidence from items on risk register	Gaps in Assurances	Actions required/Timescale and Lead Officer/ Progress
		Impact	Likeli-hood						

The Whittington Hospital NHS Trust

Board Assurance Framework revised January 2009

1. To consistently meet regulated standards of clinical care, delivered through a framework of well governed systems and processes.

2009-10 Directorate objectives:
OP1, OP2, MD1, MD2, MD3, NU1, NU2, NU3, PC3, FA1, HR1, HR2, IN3, IN4, PP3, AD1, AD3

Care Quality Commission (formerly Healthcare Commission) core standards:
C1 patient safety, C2 child protection, C3 NICE guidance, C4 reducing infections, C5 evidence based practice, C15 food & nutrition

1.1	Risk of poor clinical outcomes Objective: MD1 NU1 AD3 AP 3.4.1	3	3	9 Amb to green	Incident and SUI reporting well established and policy up to date. Departmental audit meetings review clinical outcomes regularly. Care pathways implemented and followed in appropriate settings Up to date information available to clinical and other staff via intranet and internet Risk management awareness and training	Dr Foster data used by clinical groups regularly Regular Clinical Governance Committee Reporting to Audit Committee since June 2008 bimonthly Dashboard Report to TB since March 2008 Clinical audit programme mapped to national priorities Health commission standards being assessed Patient safety first campaign action plan approved by board March 2009. Progress report to September board. Audit of out-of-ITU cardiac arrests **Substantial Assurance**		None identified	Review and improve patient transfer arrangements with Queen Square. New SOP under development (GM with consultant) By April 2010 GIC Training, dissemination of policies, supervision mentorship **Medical and Nursing directors ongoing** **GIC**

	Principal Risk Description	Risk Level		Over-all Risk Level	Expected Controls	Assurances including categorisation	Gaps in controls Including evidence from items on risk register	Gaps in Assurances	Actions required/Timescale and Lead Officer/ Progress
		Impact	Likeli-hood						
1.2	Insufficient numbers of staff in key areas to provide adequate clinical care Objectives: OP1 HR2 AP 3.3.1	4	3	12	Local management responsible for identifying if insufficient staff to relevant director/ HMB Early plans developed to address issues	Executive Committee monitors staff numbers against activity on a weekly basis. Internal management review. SHA review regular reports e.g. on vacancies. **Substantial Assurance**	Recruitment and retention difficulties for middle grade doctors in ED, paeds, O&G and anaesthetics (London wide problem)	None identified	Recruitment drive in India for ED middle grade doctors. Appointed to 3 posts. Arrangement with Sri Lanka to support the secondment of anaesthetic middle grades. **Director of Ops** **High priority** **March 2010** GIC
1.3	Failure to plan effectively to meet the requirements of a pandemic e.g. swine flu Objectivse: OP1 AP reference to winter pressures 3.4.1 **REVIEW FOR DELETION**	4	2	8	Detailed plan developed	Plan agreed by HMB and SHA Flu resilience plan rated green by NHS London **Substantial Assurance**			Agreed plan with NHS supply chain, Director Ops and infection control. Facilities to locate storage area March 2010 **Director of Facilities** **High priority**

	Principal Risk Description	Risk Level		Over-all Risk Level	Expected Controls	Assurances including categorisation	Gaps in controls Including evidence from items on risk register	Gaps in Assurances	Actions required/Timescale and Lead Officer/ Progress
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1.4	Failure to provide adequate decontamination services Objective: AD3 AP 3.3.1	4	3	12	Operational protocols in place Monitoring of incidents Staff training programme User group meetings Use of 49-point survey to establish cleaning efficiency of ward based equipment Deep clean facility using HTM2030 compliant washer for all non-electrical ward based equipment (i.e. commodes) Medical Equipment Library to ensure that all electrical medical devices are subject to regular cleaning using approved methods	Part of Northwest London Joint Venture (NWLJV) project. Attendance at project Board and Service Review Group meetings. Contract manager oversees service, monitors service failure and implementation of remedial action Clinical governance steering group and TB review clinical incidents Decontamination Committee Infection Control Committee Annual systems and department audit Local implementation team working towards transition of services off site from 8 Feb 2010 **Substantial Assurance**		Failure of sterile field around instruments during transit. Misplacement of instruments between service provider and trust	Equipment washer use has been suspended pending stabilisation of service from off site provider. Implementation of containerisation project to be fast tracked to offset risk arising from torn wrapping of instruments in transit On site sterile services dept to be kept operational to reduce risk of cancelled operations until off-site service stabilised Regular attendance of experienced staff to Premier Park to review quarantined instruments. GIA Director of Facilities **High priority**

	Principal Risk Description	Risk Level		Over-all Risk Level	Expected Controls	Assurances including categorisation	Gaps in controls Including evidence from items on risk register	Gaps in Assurances	Actions required/Timescale and Lead Officer/ Progress
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1.5	Failure to replace or maintain medical equipment to keep pace with technology and demand	3	4	12	5 year capital investment plan Annual medical equipment plan approved by the Medical Devices Group	Capital Monitoring Committee reporting to board. Managed Equipment Service and Investment Committee for Imaging Centralised medical equipment asset register identifying all medical and laboratory equipment and expected replacement dates Medical devices group reports to clinical governance committee Resuscitation Committee reports to the clinical governance committee		Resuscitation policy to be updated SUI report and action plan to be fully implemented	Roll-out of new ttolleys to be complete by end March Director of Nursing Review of staff resources Director of Ops **GIC** SUI Action plan to be monitored by the Resuscitation Committee Director of Nursing **GIA**

	Principal Risk Description	Risk Level		Over-all Risk Level	Expected Controls	Assurances including categorisation	Gaps in controls Including evidence from items on risk register	Gaps in Assurances	Actions required/Timescale and Lead Officer/ Progress
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2. To improve our operational management to achieve resource efficiencies and continuous service improvement

2009/10 Directorate objectives:
OP1, OP2, OP3, MD1, MD2, MD3,NU1, NU2, NU3, PC1, PC2, PC3, FA1, FA2, HR1, HR2, HR3, IN1, IN2, IN3, IN4, PP1, PP2, PP3, FD1, FD2, FD3, AD1, AD3, AD4

Care Quality Commission (formerly Healthcare Commission) core standards:
C1 patient safety, C5 evidence based practice, C7 corporate & clinical governance, C8 leadership & accountability
C9 records management, C15 food & nutrition, C18 equality & choice, C24 major incident plan

2.1	Failure to meet healthcare core targets as set out in NHS operating framework, and other performance and SLA targets, with the possibility of financial penalties Moved from section 1 and now incorporates 18 week target	4	3	12 Red to amb	Service plans in place Establishment and recruitment strategy	Performance monitoring –all HMB & TB meetings (internal and external) from April 2008 to present Dashboard reports from March 2008 to present Weekly performance meetings to discuss all access target performance and identify risks and mitigating actions	Problem with cancer 62 day target in Urology due to low denominator and the requirement for complex cancer surgery to be undertaken at UCLH	None identified	Action plans to address issues. Implementing organisational change to create a single access centre responsible for all appt bookings. Urology 62 day Action Plandeveloped and agreed with consultant. Daily emails to escalate areas of risk. Weekly performance meetings. **Director of Ops March 2010** **High priority** **GIC**

	Principal Risk Description	Risk Level		Over-all Risk Level	Expected Controls	Assurances including categorisation	Gaps in controls Including evidence from items on risk register	Gaps in Assurances	Actions required/Timescale and Lead Officer/ Progress
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	Objective: OP1, OP2 MD2 NU1, NU2 AD1, AD3 AP 3.4.1					Daily reports on potential breaches of 18wk target with actions identified Monthly reports to NHS London re cancer target performance. Agreed trajectory for meeting 2 week breast cancer target and associated action plan Quarterly reports to NHS London **Substantial Assurance**			GIC Director of Operations **High priority**
2.2	Failure of data security (loss or breach of confidentiality) leading to potential civil or criminal action and damage to reputation	4	3	12	Encryption across all portable media Up to date IT Security policy and mandatory training for all staff	Encryption in place for all Trust laptops. Up to date IT Security policy in place and mandatory training for all staff from Sept 2009. Now included in mandatory training for all new starter and all clinical staff. Trust is now live on PACS exchange, the London CfH solution for sharing emergency images across London and elective images across sector	Encrypted USB memory sticks are available but not rolled out because of need to implement data loss protection software on all PCs to ensure that data can only be written to the trust on encrypted memory sticks. The CfH procured solution by McAfee has been tested but has inferior audit and management reporting tools compared with the Trust's new anti-virus solution from Sophos.	None identified	**New anti-virus and data loss protection (DLP) software by Sophos is being rolled out in March 2010 wwith a view to implementing encrypted USB memory sticks in April. The risk likelihood score should then reduce to 1 when all portable media are encrypted.** **IM&T consultant** **High priority** **GIC**

	Principal Risk Description	Risk Level		Over-all Risk Level	Expected Controls	Assurances including categorisation	Gaps in controls Including evidence from items on risk register	Gaps in Assurances	Actions required/Timescale and Lead Officer/ Progress
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3. To deliver excellence in customer care, by being caring and responsive in every patient contact.

2009/10 Directorate objectives:
OP1, OP2, NU2, NU3, PC1, PC2,PC3, FA1,FA2 ,FA3, HR1, IN1, IN3, IN4, AD1, AD3
Care Quality Commission (formerly Healthcare Commission) core standards:
C13 dignity & respect, C14 complaints management, C15 food & nutrition, C16 patient information, C17 patient feedback, C18 equality & choice

3.1	Failure to implement the Whittington service promise Objectives: OP2 NU2 PC1, PC3 FA1, FA2, FA3 AD1, AD3 AP not referenced	4	3	12	HMB & TB reports on progress of implementation	HCC and local patient surveys New feedback from hand held electronic short surveys Dashboard Report Reduction in complaints **Limited assurance**	.	Fuller evidence-based reporting to TB	Implementrelevant elements of customer focussed marketing strategy by April 2010. GIC GIA Director of Primary Care **High priority**
3.2	Service quality compromised through reactive cost reduction	4	3	12	Dashboard reports to Trust Board, Hospital Management Board and Divisional Boards on performance against the key performance indicators in the clinical quality, patient experience , access and targets and workforce domains. Reports from Clinical governance committee to Audit committee	SMR HCC and local patient surveys Staff survey results Complaints reports HAI rates Risk register review of risk action plan Board assurance framework review of risk Target performance **Substantial assurance**	None identified	None identified	Early budget-setting under general manager supervision reporting to Business Planning Group All directors Dir of Planning and Performance March 2010

	Principal Risk Description	Risk Level		Over-all Risk Level	Expected Controls	Assurances including categorisation	Gaps in controls Including evidence from items on risk register	Gaps in Assurances	Actions required/Timescale and Lead Officer/ Progress
		Impact	Likeli-hood						

4. Provide a safe and sustainable environment for the delivery of healthcare, by modernising and improving the clinical estate.

2009/10 Directorate objectives:
OP2, OP3, MD1, MD2, MD3, NU1, PC3, FA1, HR1, PP4
Care Quality Commission (formerly Healthcare Commission) core standards:
C13 dignity & respect, C20 environment, C21 cleanliness

4.1	Insufficient investment in the physical environment and IT infrastructure and failure to redevelop effectively the hospital site to accommodate future business requirements Objective: PP1, PP4 AD1, AD2, AD3,AD4 AP 3.3.1	4	4	16	Estates strategy 5-year capital programme based on business and estate needs Compliance with legal requirement re H&S and DDA	ERIC (Estates Return Information Consortium) returns Business Planning Group, Capital Monitoring Committee Reporting to Trust Board via Executive Committee and Audit Committee **Substantial assurance**		Uncertainty over NCL strategy Insufficient evidence of affordability and competing demands for space envelope	Interim maternity scheme to be completed over a three year period to 2013 Director of Facilities High priority GIA Future requirements dependent on outcome of NCL reconfiguration plans Lead. CEO GIA
4.2	Failure by WFL and their facilities management service provider to deliver a safe and effective service to the GNB and new acute wing, giving rise to Trust exposure to PFI legal and statutory non-compliances that	4	3	12	Weekly operational meetings with JASL Monthly performance monitoring meetings with WFL Effective application of payment mechanism Robust performance	Liaison committee meetings formally reported to EC Independent survey commissioned August 2008 Legal opinion on options			Follow up to the DDCA audit required for 2010 Lead Director of Facilitiies High priority

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	cannot be addressed though the payment mechanism Objective: not referenced AP 3.3.1				management data from WFL/JASL Dedicated performance monitoring officer Planet FM operational database PPM condition B action plan from JASL Trust/WFL H&S Committee	**Substantial assurance**			

5. To position the Whittington as an integral part of the local community's health resource and the hospital of choice for local people.

2009/10 Directorate objectives:
MD2, PC1, PC2, PC3, FA3, IN3, IN4, AD2, AD3

Care Quality Commission (formerly Healthcare Commission) core standards:
C6 working with other organisations, C22 reducing inequality, C23 health promotion

5.1	Adverse changes in strategic decisions of commissioners of services Objectives: PC1, PC2, PC3 PP1 AD2 AP 3.3.1	5	3	15	Business planning and LDP process Signed SLAs with commissioners SHA strategic planning SLA – Trust/PCT - monitoring meetings Primary Care Interface Group meetings	Regular CEO/PCT meetings bimonthly CEO regular liaison monthly TB review position regularly SLA for 2009-10 signed end March 2009 SLA for 2010-11 to be signed by 22 March 2010.	None identified	Uncertainty about Healthcare for London and NCL strategy Investment by PCT in independent sector contracts (ISC) Lack of clarity of governance arrangements for the PCT joint commissioning agency	PCT will roll up decision on urgent care provision following closed consultation with the strategic review and development of the emergent polysystem model – Consultation Autumn 2010 Discussions ongoing through the SLA monitoring process on the use of ISC by the

	Principal Risk Description	Risk Level		Over-all Risk Level	Expected Controls	Assurances including categorisation	Gaps in controls Including evidence from items on risk register	Gaps in Assurances	Actions required/Timescale and Lead Officer/ Progress
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						Substantial Assurance		PCT polysystem shift plans	PCTs Discussions with Haringey PCT about Whittington providing activity in alternative settings to mitigate risk of activity shifts GIA Director of Planning and Performance/Director of Ops
5.2	Reputation damage from the communications challenge during the period of strategic uncertainty leads to loss of public confidence affecting choice & demand Objective: PC1 AD1,AD2, AD3 AP not referenced	5	4	20 Amb to red	Communications strategy Whittington Promise Damage limitation strategy Reputation awareness and assessment	Regular local patient surveys and HCC surveys Regularly report to HMB & TB Systematic consideration of reputational aspects of all risks at EC Mitigations through actions and communications Role of Council of Governors as ambassadors and sources of feedback Membership engagement **Substantial Assurance**	Draft communications strategy needs to be agreed Whittington Promise not yet fully embedded	Lack of clarity about the future configuration of services in NCL Insufficient information from stakeholder surveys Comprehensive dashboard indicators not yet complete	Finalise communications strategy for April board 3 – year Customer Focused marketing and patient experience strategies being implemented. Target September 2011 Further development of dashboard indicators Director of Primary Care Director of Planning and Performance Medium priority Continuous w-i-p GIC GIA

	Principal Risk Description	Risk Level		Over-all Risk Level	Expected Controls	Assurances including categorisation	Gaps in controls Including evidence from items on risk register	Gaps in Assurances	Actions required/Timescale and Lead Officer/ Progress
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6. To employ competent, motivated staff who place the interests of patients first

2009/10 Directorate objectives:
OP3, MD1,MD3, NU1, NU2, NU3, PC1,PC2,PC3, FA1,FA2 HR1, HR2, HR3, IN1, PP2, PP3, FD2, FD3, AD1, AD2, AD3
Care Quality Commission (formerly Healthcare Commission) core standards:
C8 leadership & accountability, C10 employment, C11 education & development, C13 dignity & respect

6.1	Inability to recruit adequately skilled staff and develop staff competencies sufficient to deliver services and meet quality objectives Objective: HR1 AD1 AP 3.3.1	4	3	12	Monitoring recruitment and retention rates by the HMB & TB in dashboard IWL Steering Group to review regularly Implementation of Oracle Learning Module (training record system)	Achievement of Investors' in people accreditation Achievement of Improving working lives practice plus validation Improved scoring in staff attitude survey Establishment of education and development strategy group Implementation of HR audit recommendations **Substantial assurance**	Incomplete take-up of mandatory training		**Ensure all relevant staff receive non-clinical mandatory training by September 2010** GIC **Director of HR** **Director of Facilities** **High priority**

	Principal Risk Description	Risk Level		Over-all Risk Level	Expected Controls	Assurances including categorisation	Gaps in controls Including evidence from items on risk register	Gaps in Assurances	Actions required/Timescale and Lead Officer/ Progress
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7. To be financially robust and achieve a surplus every year

2009/10 Directorate objectives:
OP1, OP2, OP3, MD3, NU1, PC1, PC2, PC3, HR1, HR3, IN2, PP1, PP2, PP4, PP5, FD1, FD2, FD3
ALE (Auditors and Local Evaluation) Assessment:

7.1	Failure to maximise income due to inaccurate data collection and delayed PCT payment, especially in relation to Payment by results Objectives: IN2 AD4 AP 3.1.1, 3.3.1	~~4~~	3	12	Finance Plan in place Regular reviews of position by every HMB and TB SLAs in place with PCTs Project team and action plan in place to increase capture of activity	Internal Audits Peer review HMB monitors financial position monthly TB monitors financial position monthly External Audit and review of PbR coding quality Late data entry report to project team **Substantial Assurance**	Data quality for Service Line Reporting Completeness of data for unbundled activity and out-patients under HRG4	None identified	Continuous programme of identification of gaps in data capture and data quality Director of Planning and Performance **High priority** GIC
7.2	Base costs increase by a greater amount than identified in the annual plan such that services cannot be provided within tariff Objective: PP3 FD2, FD3 AD4 AP 3.1.1	4	3	12	Tight control through Executive Team, HMB Business Planning Group	TB monitor overall position every meeting PCTs performance management review monthly **Substantial Assurance**	Inability to control costs influenced by national policies, eg, inflation implementation of NICE guidelines, consultant contracts MPET funding Service level costing being implemented	None identified	Ensure financial implications of national policies are assessed, ongoing, Included in 5 year annual plan Dir of Finance March 2010 Continue roll-out of service level costing, reporting and management **Dir of Planning & Performance** **GIA** **High priority**

For directorate objectives see separate table
AP = Annual Plan 2009-10

GIC = gap in control
GIA = gap in assurance

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7.3	2009-10 Cost improvement and increased productivity programme is not achieved leading to budget overspend Objectives: OP1, OP2, OP3 MD3 ND1 HR1, HR3 IN2 AD3, AD4 PC1, PC2,PC3 FD1,FD2,FD3 CE2 AP 3.1.1	3	5	15	CIP schemes in place to achieve breakeven Good quality and timely financial information Compliance with SFIs and procurement procedures including the booking of bank and agency staff Monthly meetings with budget holders KPI included in appraisal process	Exec Committee HMB & TB monitor at every meeting Weekly meetings by Directors with CEO to examine in detail performance against each scheme Efficient services collaborative established to support the work in the Directorates to ensure delivery and risk assessment Dedicated finance manager to monitor actual release of savings from budgets EC and TB monitoring through dashboard and finance report Quarterly report to NHS London Internal audit reports **Insufficient Assurance**	Inadequate sanctions for overspending in appraisal process (Audit Committee)	Accountability within directorates for financial performance, particularly in relation to clinical staff (Audit Committee)	Action plans underway to reduce spend in top 25 overspending areas Vacancies reviewed to determine whether the posts can be removed Action plans to be implemented to reduce spend in the top 25 overspending areas March 2010 GIC Director of Finance Director of Planning and Performance High priority Director of Finance Director of Planning and Performance High Priority **GIC**

	Principal Risk Description	Risk Level		Over-all Risk Level	Expected Controls	Assurances including categorisation	Gaps in controls Including evidence from items on risk register	Gaps in Assurances	Actions required/Timescale and Lead Officer/ Progress
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7.4	SIFT allocation materially reduced from 2010/11 Objectives: AD4 AP 3.3.1	4	3	12	Participate in SHA modelling exercise and validate data.	Report to TB	Outcome is mainly outside the control of the Trust.	None identified	Impact will be in 2010/11 with decision known during 2009/10. A transitional arrangement is expected which would cap gains and losses. Impact to be reflected when known and options for restoring viability may need to be identified. RM March 2010 GIC
7.5	Economic recession resulting in lower growth in allocations combined with higher morbidity and demand Objective: PP1 FD3 AD2,AD4 AP 3.3.1	4	4	16	Contingency planning Partnership working with PCTs	Report to TB Quarterly report to NHS London	Outcome outside the control of the trust	None	Economic horizon scanning Risk reflected in Annual Plan Implementation of primary care marketing strategy Ongoing

	Principal Risk Description	Risk Level		Over-all Risk Level	Expected Controls	Assurances including categorisation	Gaps in controls Including evidence from items on risk register	Gaps in Assurances	Actions required/Timescale and Lead Officer/ Progress
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8. Collaborating with other agencies to shape the delivery of healthcare in the locality

2009/10 Directorate objectives:
OP2, NU1, PC1,PC2,PC3, FA3,IN1, IN3, IN4, PP1,
Care Quality Commission (formerly Healthcare Commission) core standards:
C6 working with other organisations, C22 reducing inequality, C23 health promotion

8.1	Failure to agree a sustainable solution for the provider landscape – and breakdown in collaboration across organisational boundaries	4	4	16	Clinically and financially sustainable organisations within a reconfigured NCL health economy meeting the needs of the population and implementing the HfL strategy	Trust actively involved in the E&Y review on behalf of the Acute commissioning agency of the services configuration for NCL. Trust working with RFH to review the acute healthcare needs for the total catchment population to determine how HfL could be implemented and deliver cost reductions in the challenged economic climate. Trust approaching the Autonomous Provider Organisations to undertake a review of the potential for increased collaboration across the primary secondary care interface which meets local needs and achieves clinical quality and efficiency and cost reduction **Limited assurance**		CEO and Chairman actively involved in strategic working groups at NHS London and meeting with peers within NCL to inform Acute Commissioning Agency planning	Future dependent on outcome of NCL reconfiguration plans Jan 2010 Discussions taking place on a bilateral level with RFH and tripartite level with RFH and UCLH. Includes options for vertical integration of community and primary care health services. GIA Lead: CEO **High priority**

	Principal Risk Description	Risk Level		Over-all Risk Level	Expected Controls	Assurances including categorisation	Gaps in controls Including evidence from items on risk register	Gaps in Assurances	Actions required/Timescale and Lead Officer/ Progress
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9. Reducing hospitalisation (admissions, attendances and length of stay)

2009/10 Directorate objectives: OP1, OP2, OP3, MD1,MD2, NU1, PC3, FA1, IN4,PP1, PP2, AD3, AD4
Care Quality Commission (formerly Healthcare Commission) core standards:
C4 reducing infections, C6 working with other organisations, C5 evidence based practice

9.1	Failure to reduce rates of healthcare acquired infection Objective: NU1 AP 3.3.1, 3.4.1	4	2	8	Compliance with the Hygiene Code (Health Act 2006) Bed management policy	Report to HMB , TB Monitoring by SHA Healthcare Commission Standards 'Saving Lives' benchmarking audits in place Report by DoH team Nov 2007, August 2008 Reports to Infection Control Committee and Trust Board SUI Report **Substantial Assurance**	Insufficient isolation facilities Non-Achievement of 100% screening rates for all admissions and 100% suppression therapy for MRSA positive patients		Plans for isolation facilities shelved but a clear policy on cohorting Facilities in place Implement actions from SUI report – monitored by CGC Target achievement of screening and suppression therapy by March 2010 Lead: Director of Nursing and Clinical Development High Priority Working with Insitutute for Innovation. New ICP to be implemented. Sept 09 Director of Ops High prioriity

	Principal Risk Description	Risk Level		Over-all Risk Level	Expected Controls	Assurances including categorisation	Gaps in controls Including evidence from items on risk register	Gaps in Assurances	Actions required/Timescale and Lead Officer/ Progress
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10.To develop and deliver a modern programme of teaching and research activities, by strengthening academic links with educational partners

2009/10 Directorate objectives:
MD1, MD2, NU3, HR2, PP1, FD1, AD1, AD2
Care Quality Commission (formerly Healthcare Commission) core standards:
C11 Education & development, C12 research governance

10.1	Potential change of policy by UCL medical school. **FOR REVIEW**	3	3	9	SLAs with medical school/ universities SLA with Postgraduate Deanery/ SHA Risk Management and Governance Committee scrutiny	TB reviews regularly HMB reviews regularly SHA reviews regularly **Substantial Assurance**			