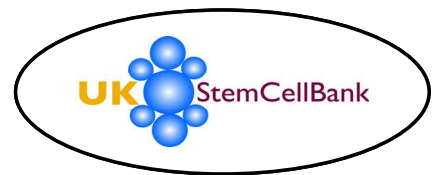


Development of the UK Stem Cell Bank

Phase II

Proposed Plan for 2006 - 2010



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List of Abbreviations

BBSRC	Biotechnology and Biological Sciences Research Council
CBI	Cell Biology and Imaging
CE	Conformité Européene (European Conformity marking)
CG	“Clinical Grade”
CPD	Continuing Professional Development
EMA	European Medicines Evaluation Agency
ES(C)	Embryonic Stem (Cell)
EU cGMP	European Union (current) Good Manufacturing Practice
FDA	Food and Drug Agency
HPA	Health Protection Agency
IDA	International Depository Authority
IP	Intellectual Property
ISCI	International Stem Cell Initiative
IVF	In Vitro Fertilisation
MC	Management Committee for the UKSCB
MHRA	Medicines and Healthcare-products Regulatory Agency
MRC	Medical Research Council
NIBSC	National Institute for Biological Standards and Control
QC	Quality Control
QA	Quality Assurance
R&D	Research and Development
RG	“Research Grade”
SC	Steering Committee for the UKSCB and the Use of Stem Cell Lines
ToR	Terms of Reference
WG	Working Groups
UKSCB	United Kingdom Stem Cell Bank

1. Executive Summary

Following on from legislative decisions to allow limited use of human embryos for research into human disease, and recommendations from a House of Lords Select Committee and the Chief Medical Officer, the MRC and BBSRC called for proposals from interested bodies to establish a UK Stem Cell Bank (UKSCB).

In 2002, after competitive tender, the National Institute for Biological Standards and Control (NIBSC) was awarded a contract to establish the UKSCB.

NIBSC's aims in establishing the Bank at the outset were:

- to provide, within a stringent quality framework, ethically sourced and well characterised stocks of human stem cell lines from adult, foetal and embryonic sources;
- to promote stem cell research both in the UK and abroad by providing ready access to such lines;
- to provide stringently tested, safe cell banks under EU cGMP (Good Manufacturing Practice) conditions for clinical trials;
- to work with the scientific and clinical communities, commercial organisations and regulatory agencies to assure the quality of human stem cell lines used research and clinical therapy and disseminate best practice;
- to operate in a transparent and independent manner in order to avoid conflicts of interest that might arise from close involvement either in product development, or research into stem cell biology.

In order to accomplish these aims, new facilities were required, in particular to deal with the stringent quality control requirements of cell lines with potential for use as human therapeutics. NIBSC presented two options in its initial bid:

Option A: Establish from the outset a purpose-built, permanent building at a cost estimate of £2.3M.

Option B: Establish the Bank in two phases:

- Phase 1: Construct a temporary, prefabricated, facility incorporating limited facilities for "Clinical Grade" cell banking with an expected 5-year lifespan;
- Phase 2: Towards the end of the initial 5 year period, begin construction of a permanent facility to maintain continuity with Phase 1.

Option B, though potentially more expensive in the long run, provided for a considerably more rapid start-up time and reduced financial risk associated with an early-stage project with significant uncertainties.

The MRC/BBSRC assessment panel preferred Option B and in December 2002, a contract was awarded to establish the Bank on this basis, accepting the need for a

permanent facility from 2008. Build costs for the temporary facility were provided, together with set up and running costs for a three year period.

In addition a set of milestones and deliverables for Phase 1 of the project (shown in the table below) were agreed with the sponsors and with the high level Steering Group overseeing the Bank's operation. These involved not only the rapid construction and accreditation of an appropriate GMP facility, the installation of a comprehensive quality system and the trained personnel to operate it – all within a short time frame, but also the ability to begin operating as a bank for "Research Grade" material within the first year.

Milestones and Deliverables: Phase 1

Milestones and Deliverables													
Key Milestones	2002		2003				2004				2005		
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	
Grant Awarded to NIBSC			*										
Tender for GMP Facility/ Contractor Appointed			*										
Operations Manager Appointed			*										
QA Manager Appointed											*		
Staff Recruitment (Phase 1)					*								
GMP Facility Build					*								
Facility Handover/Official Opening							*						
CBI Cleanroom Modification Phase 1			*										
"Research Grade" Facilities On-line					*								
Facility cGMP Qualification							*						
Establishment of UKSCB Quality System							*						
MHRA Inspection/Accreditation							*						
ISCI Project Cell Banking/Technical co-ordination											*		
Staff Recruitment (Phase 2)						*							
IDA Application/Award of International Patent Depository Status										*			
Co-sponsor Sheffield ES Cell Banking Course			*					*				*	
Website Operational								*					
QC Testing Regime in Place/Annual Quality Review												*	
1st Accession under Patent Depository Status												*	
1st Accessions to UKSCB (WT3 & hES NCL-1))											*	*	
1st ES Cell Line Banked (WT3)											*	*	
Approval from Steering Committee/ Accessioning initiated (20+ cell lines)											*		
Timeline Delivered Milestone											*		

The achievements to date against these objectives are detailed in the accompanying documents. In summary, all the project goals have been met on time and within budget, and the UKSCB is now fully established, accredited and in a position to fulfil the overall aims of the initiative.

This proposal sets out the objectives, plans and resource requirements to support Phase 2 of the project.

Objectives for Phase 2

The Bank aims to consolidate its position as the foremost repository of both UK and international stem cell lines in order to provide ethically sourced and well characterised stocks of human stem cell lines banked within a stringent quality framework,. This will help sustain research and development in the field of stem cell biology and emerging therapeutic applications.

Additionally, the Bank will continue its international supporting role in the development of stem cell therapy, through its world-leading work programme on best practice, its training of stem cell scientists and its quality assurance and safety testing of "Clinical Grade" stem cell lines.

The overall aims for the next 5 years will be to:

- establish sufficient resource capacity to cope with the demand of increasing numbers of stem cell lines;
- establish UKSCB credentials as a high quality and reliable source of stem cell lines and other appropriate materials required for stem cell research and clinical trials;
- develop the UK Stem Cell Bank website as a valuable tool for stem cell researchers on cell lines, associated technology and best practice as well as an additional mechanism for organisations outside the UK to gain access to UK stem cell networks;
- consolidate the Bank's profile as an 'honest broker' in regulatory issues relating to stem cell products in support of national and international regulatory authorities and health-service groups and companies developing stem cell products;
- establish the Bank as the international partner of choice for training initiatives in the stem cell field and as a valuable independent partner in stem cell collaborative projects and initiatives;
- prepare and establish a programme of income generation based on provision of cell lines and services to the stem cell community with clear long-term targets for supporting the activity of the Bank through IP, services and international funding.

2. Introduction

Following on from legislative decisions to allow limited use of human embryos for research into human disease, and recommendations from a House of Lords Select Committee and the Chief Medical Officer, the MRC and BBSRC called for proposals from interested bodies to establish a UK Stem Cell Bank (UKSCB).

In 2002, after competitive tender, the National Institute for Biological Standards and Control (NIBSC) was awarded a contract to establish the UKSCB.

NIBSC's aims in establishing the Bank at the outset were:

- to provide, within a stringent quality framework, ethically sourced and well characterised stocks of human stem cell lines from adult, foetal and embryonic sources;
- to promote stem cell research both in the UK and abroad by providing ready access to such lines;
- to provide stringently tested, safe cell banks under EU cGMP (Good Manufacturing Practice) conditions for clinical trials;

- to work with the scientific and clinical communities, commercial organisations and regulatory agencies to assure the quality of human stem cell lines used research and clinical therapy and disseminate best practice;
- to operate in a transparent and independent manner in order to avoid conflicts of interest that might arise from close involvement either in product development, or research into stem cell biology.

3. Progress to Date

Progress to date is reviewed in the accompanying Progress Report for the UKSCB and in the 1st Annual Report to the Steering Committee.

4. Limitations of Existing Capacity

The capacity already provided by the current Bank facilities together with the shared 'cleanroom' facilities provided by NIBSC's CBI Division, will accommodate the stem cell lines already approved by the Steering Committee up to December 2004 (the shared NIBSC facilities currently provide for handling of 'Research Grade' cell lines whilst also providing a backup facility for handling "Clinical Grade" cells).

The existing facility will also permit banking of the first UK clinical grade ES cell lines that we anticipate will become available over the next 2/3 years. Numerous research groups around the UK are now involved in stem cell derivation and research. The experience gained in the derivation of early stem cell lines now means that these groups are increasingly proficient at producing embryonic stem cells. These groups are building cGMP facilities starting in 2005 and with support from the UKSCB, we anticipate that new stem cell lines prepared under cGMP conditions will be available from 2006/7.

Beyond 2008, however, the existing facility will no longer be adequate for the following reasons:

- In 2002 the contract to establish the Bank was awarded recognising that the temporary structure built to house the Bank would have limited planning permission. Planning permission for the existing facility is due to expire in 2006. Provision was included in the original permissions for NIBSC to apply for an extension to 2008, subject to progress toward the completion of a permanent facility on the NIBSC site (**Phase 2**).
- Whilst the projected throughput of stem cell lines already approved by the Steering Committee is compatible with the shared NIBSC resources, projected increases in cell banking needs of both UKSCB and NIBSC make this arrangement untenable in the longer term. There has already been a dramatic acceleration in the number of newly derived stem cell lines generated in the UK and elsewhere; numerous non-UK groups have signalled their intention to offer their cells to the Bank. Alongside this, as cell-based therapies and products, grow in clinical importance, NIBSC is

increasingly required to take a lead in development of robust quality assurance frameworks and associated materials.

In order to replace the current temporary facility and provide for the projected increase in the number of stem cell lines to be made available to the UKSCB, funding is required to provide a permanent facility to house the Bank. The proposed facility would permit the Bank to meet projected demands for "Research Grade" cell banks at the same time as providing new cGMP facilities for the banking of "Clinical Grade" cell lines, and to develop its position as a leading international centre for supporting stem cell research.

5. The Proposal

The Bank aims over the next five years to consolidate its position as the foremost repository of both UK and international stem cell lines in order to provide ethically sourced and well characterised stocks of human stem cell lines banked within a stringent quality framework. This will help sustain research and development in the field of stem cell biology and emerging therapeutic applications.

Additionally, the Bank will continue its international supporting role in the development of stem cell therapy, through its world-leading work programme on best practice, its training of stem cell scientists and its quality assurance and safety testing of "Clinical Grade" stem cell lines.

The overall objectives for the next 5 years will therefore be to:

- establish sufficient resource capacity to cope with the demand of increasing numbers of stem cell lines;
- establish UKSCB credentials as a high quality and reliable source of stem cell lines and other appropriate materials required for stem cell research and clinical trials;
- develop the UK Stem Cell Bank website as a valuable tool for stem cell researchers on cell lines, associated technology and best practice as well as an additional mechanism for organisations outside the UK to gain access to UK stem cell networks;
- consolidate the Bank's profile as an 'honest broker' in regulatory issues relating to stem cell products in support of national and international regulatory authorities and health-service groups and companies developing stem cell products;
- establish the Bank as the international partner of choice for training initiatives in the stem cell field and as a valuable independent partner in stem cell collaborative projects and initiatives;
- prepare and establish a programme of income generation based on provision of cell lines and services to the stem cell community with clear long-term targets for supporting the activity of the Bank through IP, services and international funding.

Achievement of these objectives will depend on success in several different, but closely interlinked areas.

5.1. Accession of Cell Lines

Aims and Objectives

The accessioning of both research and clinical grade cell lines requires careful planning to ensure efficient transfer of new lines into the Bank. In addition the process of accessioning is the start of an ongoing and long-term relationship between the depositors and the Bank that will enable the UK Stem Cell Bank to establish and promote technical and scientific best practice. Furthermore, it will ensure that the Bank obtains appropriate feedback on the needs of the research community as well as helping to maintain the Bank as the centre of choice for depositing cell lines. For these reasons, it is intended that the UKSCB will be seen as a natural partner in stem cell related activities.

Over the period covered by this forward plan, our aims will be to:

- to build capacity for banking up to 20 stem cell lines per year (comprising both “Research Grade” and “Clinical Grade” lines);
- to add new cell line characterisation and safety testing methods to the existing range of tests, to reflect new advances in stem cell science;
- to bank the first “Clinical Grade” cell lines (to be achieved prior to completion of the new building programme);
- to bank the first somatic stem cell lines;
- to streamline the mechanisms for accessioning stem cell lines into the Bank, so that the depositing process is smoother and less complicated;
- to optimise the rate of accession of lines to ensure that the bank stocks represent the latest developments in stem cell science;
- to introduce new mechanisms for distribution, such as exchange of batches of ampoules from cell banks, whilst maintaining the requirements of the Steering Committee;
- to produce additional reference standards and research materials for the research community to facilitate the development of stem cell research and therapy.

Cell Characterisation and Safety Testing

One of the main aims of the Bank is, and will continue to be, the production of high quality, well characterised and safety-tested cell banks. The need for stringently tested seed stocks for clinical therapies is of particular importance. The Bank is actively developing its strategy for safety testing and characterisation through:

- its Working Group on adventitious agents;

- its developing relationships with commercial testing companies (e.g. Bioreliance, TDL, MRC Geneservice);
- its R&D collaborations (e.g. MRC ISCI project on ES cell characterisation);
- its development of in-house assays in collaboration with CBI and NIBSC.

Details of the work undertaken to date are provided in the accompanying progress report.

The current testing strategy comprises a set of core tests appropriate for both “Research Grade” and “Clinical Grade” cells with additional safety testing for “Clinical Grade” cell lines. Testing is carried out on the depositor’s material and each of the three Banks generated from this (Pre-master Bank, Master Bank and Distribution Bank). The extent of testing and the criteria for release are dependent on the individual cell line and the cell line history as well as the stage reached in the banking process. Additionally, cell characterisation studies (so-called stability studies) will be carried out on high passage cell material.

The testing strategy is being tested on qualified banks of feeder cells currently being provided to the Department of Health for clinical use in the NHS skin banks. The testing strategy and test methodology for these banks has been endorsed by both the MHRA and the Biological Subcommittee of the Committee on the Safety of Medicines.

Tumorigenicity studies on non-ES “Clinical Grade” cell lines were included as part of the testing strategy and costed into the original grant proposal accepted by the MRC. Such studies were also included in the Code of Practice for the Bank developed by the Steering Committee. It is accepted that undifferentiated embryonic stem cells will exert a tumorigenic effect in mice. These studies are likely therefore to be of most use in testing the differentiated cells obtained from the seed stock of undifferentiated stem cells provided by the Bank. Animal testing by the Bank on the ES cell lines is therefore restricted in this proposal to limited testing for continued pluripotency. Tumorigenicity studies will ultimately be required to support clinical use of cell lines, but in view of the potential for cell differentiation, this will need to be the responsibility of end users. Tumorigenicity studies, which would be very costly, are therefore not currently included in this proposal.

The aim of the Bank will be to:

- develop and introduce an enhanced panel of cell characterisation tests;
- develop and scope under ISO 17025 as many as possible of the tests currently required to be outsourced in order to comply with the EU directive requiring testing to be carried out by an accredited laboratory.

Milestones and Deliverables: Accessioning of Cell Lines

Key Milestones	Milestones and Deliverables																								
	2005		2006				2007				2008				2009				2010				2011		
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	
Review Accessioning Procedures	■	■							■	■							■	■							
Develop Cell Line Information Form		■	■	■	■	■																			
Develop Cell Line Database/Master File					■	■	■	■	■																
Develop New/Existing International Links			■	■	■	■				■	■	■	■					■	■	■	■				
Review Requirements for Reference Materials	■	■					■	■						■	■					■	■				
Establish QC'd Reference Preparations			■	■	■				■	■	■	■		■	■	■	■	■							■
Establish QC'd CG Human Feeder Cells										■	■	■	■	■	■	■									
Implement Enhanced Cell Characterisation Panel				■	■	■																			
Accession 1st Clinical Grade Cell Line							■	■	■	■	■														
Accession 1st Somatic Stem Cell Line					■	■	■	■																	

5.2. Scientific and Technical Activities

Aims and Objectives

The Bank is already making significant contributions in scientific and technical areas. Currently, the Bank is acting as the technical hub for the MRC led ISCI project on ES cell characterisation and has provided a generic work package utilised by a number of international groups preparing research grant applications. The Bank has also been actively involved in a number of training initiatives such as the University of Sheffield training course in ES cell derivation and banking (2003 – 2005). Members of staff are already active on a number of University courses involved in cryopreservation and cell and tissue banking.

It is absolutely critical that the Bank maintains a high scientific and technical profile. The Bank needs to further develop this area to ensure its credibility is maintained at the highest levels, providing a 'gold-standard' for international activity in the delivery of cells for research and stem cell therapy.

It is proposed that the Bank will develop its existing collaborative links in order to pursue its research programme in the areas of cell banking, cell characterisation and preservation. It is intended that this will lead to research grant applications for competitive funding.

The Bank will also establish a role in organising high quality interactive workshops in line with the established role of NIBSC as an independent forum for discussion of issues relating to quality, safety and standardisation of biological medicines.

The Bank will:

- expand its programme of scientific and technical development to include the provision of QC testing services;
- establish collaborations with depositors and other research groups on improvements in the characterisation, culture and preservation of stem cell lines;
- introduce and evaluate new techniques for the characterisation, quality control and safety testing of stem cell lines;

- develop an in-house programme of focussed R&D concentrating on key issues in stem cell banking and the quality of stem cell lines including:
 - cell characterisation;
 - cell culture methods;
 - cryopreservation;
 - detection of adventitious agents;
 - validation;
- target an appropriate level of scientific liaison activity at stem cell researchers working on somatic stem cells whilst maintaining the strong interactions required for the ES cell derivation community;
- expand its programme external training;
- contribute to scientific development by engaging actively with the developing UK stem cell networks through a programme of visits to specific centres, development of its web site and NIBSC-hosted workshops on important issues;
- promote developments in best practice for banking of stem cell lines.

Milestones and Deliverables: Scientific and Technical Activity

Key Milestones	Milestones and Deliverables																								
	2005		2006				2007				2008				2009				2010				2011		
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	
Establish QC Testing Services																									
Establish Research Collaborations into:																									
• ESC Characterisation (currently ongoing)																									
• Serum-free ES Cell Culture*																									
• Effective Cryopreservation of ES Cells																									
• Detection of Adventitious Agents																									
• Validation																									
Establish Best Practice Guidelines																									
Participate in UK ES Cell Training Course																									
Develop Links to Somatic Stem Cell Groups																									

5.3. UK Stem Cell Bank Facilities

Aims and Objectives

The aim of the build programme is to provide a permanent facility incorporating facilities for banking of both “Research Grade” and “Clinical Grade” stem cell lines to appropriate quality standards. The integration of “Research” and “Clinical” grade banking within a single facility (they are currently physically separated) will simplify operation of the facility, reduce overheads and allow integration of the quality system for GMP and CE-marking (ISO 13485, EU IVD Directive), thus providing for future developments in the use of stem cell lines as diagnostic tools whilst maintaining a GMP back-up facility for contingency planning.

The NIBSC 10 Year Development Plan agreed with the local planning agency allows for the building of a number of permanent buildings on specified areas of the site. None of the specified areas for development are contiguous with the existing NIBSC building and any new facility will need to operate as a separate structure. An area to

the north-west of the site has been allocated for the new UK Stem Cell Bank. This has the advantage of providing a dedicated facility with its own car park and enhanced security (being sited in the middle of the site). The building options have been considered in light of the possibility that NIBSC itself may need to expand its on-site facilities.

Lessons learned from the current prototype facility have been incorporated into the outline design for the new Bank. The basic design (three GMP-grade cleanrooms accessed via a clean corridor with appropriate change facilities) has been retained with an increase in the size of the laboratories to permit clinical grade feeder cells to be grown in the same laboratory during banking of the stem cell line. A fourth laboratory for the banking of "Research Grade" lines has also been included as has a QC/R&D laboratory. This integrates "Research Grade" and "Clinical Grade" cell banking and QC in a single unit, leaving the upgraded CBI laboratories available as a GMP-Back-up facility as was intended in the initial phase of the development of the Bank. This will ensure that the Bank retains its flexibility to meet the changing and as yet undefined future needs of the stem cell community.

The remaining areas of the build will house general storage, offices and restrooms. A dedicated secure area with its own dedicated liquid nitrogen supply (4000 litre capacity) to house and feed the liquid nitrogen storage refrigerators that contain the stem cell lines is also included in the plan. This will ensure secure storage at two independent locations on-site as well as the planned off-site storage.

The new UK Stem Cell Bank will:

- provide long-term facilities for banking of high quality, safety-tested well characterised "Research" and "Clinical Grade cell lines;
- integrate Research and Clinical grade cell banking to optimise use of laboratory facilities and provide both GMP and CE-marked stem cell lines;
- ensure flexible facilities to accommodate future developments in stem cell biology;
- provide qualified off-site storage for both clinical and research grade cells;
- be validated in line with current and developing EU and other international guidelines.

Milestones and Deliverables: Cell Bank Facilities

Key Milestones	Milestones and Deliverables																							
	2005		2006				2007				2008				2009				2010				2011	
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2
Off-site Storage Established (Research)																								
Off-site Storage Established (Clinical)																								
Planning Process																								
Building Design Qualification																								
Validation Master Plan																								
Tender Process																								
Building Phase																								
Building Handover																								
Facility Qualification																								
Equipment/Process Qualification																								
Banking Transferred to New Facility																								
New Facility Operational																								
Demolition of Existing Temporary Facility																								
(Temporary) Reduced "Clinical Grade" Capacity																								
(Temporary) Reduced "Research Grade" Capacity																								

5.4. Quality Assurance

Aims and Objectives

The UKSCB has implemented an unprecedented quality system compliant to EU cGMP and is the only MHRA accredited facility currently banking cell lines. The Bank works closely with the scientific community and carries out regular reviews with respect to cell line quality control and safety testing to ensure that the most appropriate and up to date test methods and protocols are used. In addition the Bank is providing advice and support on Quality Assurance to regulatory agencies in the UK and abroad as well as to research groups and clinical units deriving human stem cell lines.

A comprehensive and ongoing validation process is required to maintain accreditation and ensure that the quality system remains compliant with the relevant national and international guidelines and directives. To ensure that this is achieved, regular reviews and internal audits will be carried out.

The Bank will continue to:

- adapt to and comply with new regulatory frameworks by working with the new authority under the Human Tissues Act (2004) and the MHRA;
- ensure that it is fully prepared for successful re-inspection and accreditation in 2006;
- ensure that the new Facility gains MHRA accreditation in 2009;
- validate the new safety tests and cell characterisation methods developed by the Bank;
- provide a cGMP advisory service for stem cell therapies which works with national and international regulatory authorities (e.g. MHRA ,FDA, EMEA);
- establish robust and effective procedures for “Look-back” and “Traceability” for “Clinical Grade” cells destined for transplantation;
- establish an effective viral safety testing regime for “Clinical Grade” cells acting on the advice of the Bank’s Working Group on Adventitious Agents.

Milestones and Deliverables: Quality Assurance

Milestones and Deliverables																									
Key Milestones	2005		2006				2007				2008				2009				2010				2011		
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	
Provide Advice/Support on QA to IVF Centres																									
Establish QA Specification for CG ESC Lines																									
Formalise Look-Back & Traceability Processes																									
Review New Techniques for QC Safety Testing																									
Qualification & Validation of the New Facility																									
Review & Re-validation of Processes/Equipment																									
Validation of Analytical Techniques																									
Accreditation Inspection under EU Directive																									
Internal Audit Review																									
Annual Quality Review																									

5.5. Staffing

Aims and Objectives

The Bank has assembled a team of highly competent staff with complementary skills. Over the past 18 months, the team has developed the necessary expertise required to meet cGMP requirements for cell banking in a fast moving and novel area. This expertise base must be preserved to ensure that the Bank maintains momentum and continues to fulfil its mission. Current contracts for staff begin to expire in early 2006 and it is thus essential that a decision on future funding for the Bank is made in sufficient time to secure their continued service and commitment.

Proposals for new recruitment remain consistent with those predicted in the original five year plan submitted with the first bid for the Bank from NIBSC, taking into account the likely increased levels of activity.

The aims will be:

- to secure existing staff through delivery of new contracts and a programme of continuing professional development;
- to recruit additional technical staff to accommodate the projected increase in banking activity;
- to maintain effective succession planning;
- to establish a programme of continuous professional training and development to attract and retain high calibre staff.
- to review training needs for all UKSCB staff on a regular basis.

Milestones and Deliverables: Staffing

Milestones and Deliverables																									
Key Milestones	2005		2006				2007				2008				2009				2010				2011		
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	
Existing Staff Secured/Contracts Renewed																									
Recruitment of Further Technical Staff																									
1st phase Training New Staff complete																									
Training & Update Programme - Technical																									
Training & Update Programme - Quality																									
Review Training Programmes																									
Carryout 'Gap Analysis'																									
Develop CPD Programme																									
Implement CPD Programme																									
Establish Succession Planning																									

5.6. Financial Operation

Aims and Objectives

Through Phase 1, the Bank has continued to meet all its financial targets and the project is well on track to stay within its three year budgetary envelope.

There continues to be uncertainty, however, about the issue of cost recovery, an important element of forward financial planning. Though accurate cost data for stem cell banking is difficult to generate at this early stage in the project, it has already been recognised that full-cost recovery will not be viable, even when the bank is fully operational, and that the aims of the Bank can only be met if it continues to provide services at a reasonable cost to users with financial support from its sponsors.

For the next five years, the Bank will:

- monitor spending and continue to carry out regular financial reviews through the UKSCB Operations Group and MC to keep spending in line with grant funding;
- report the outcome of the financial reviews regularly to the SC and Bank’s sponsors;
- submit proposals for full economic cost recovery from commercial users to the Bank’s sponsors and UKSCB Steering Committee;
- review and develop charging schedules for supply of “Research Grade” and “Clinical Grade stem cell lines.

The Bank will also:

- develop charging schedules for provision of technical and other services;
- scope possible income generation proposals through and an advisory group of NIBSC/HPA management and the funding bodies (MRC/BBSRC) and prepare a business plan with NIBSC (HPA) business development section;
- develop a limited, free testing service for potential depositors to streamline and protect cell line accessioning.

Milestones and Deliverables: Financial Operation

Key Milestones	Milestones and Deliverables																							
	2005		2006				2007				2008				2009				2010				2011	
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2				
Financial Input to MC and Annual Report																								
Establish Accurate Cell Line Costings (RG lines)																								
Establish Cell Line Costings (CG lines)																								
Establish Cell Line Charging Structure																								
Prepare Income Generation Proposals																								
Prepare Phase 3 Business Plan																								
Establish Income Generation Services																								
Develop Income Generating Services																								

5.7. Management and Reporting

Aims and Objectives

As part of its remit, the Bank is required to work in an open and transparent manner. It is accountable to its sponsors: the Steering Committee and the stem cell community through the Clinical and User Liaison Committees that report to it. The

Bank also reports to a local Management Committee that assists in developing the Bank's strategic activity and oversees its routine operation.

The Bank will continue to:

- report regularly to the Steering Committee, Management Committee, the Bank's sponsors and other interested parties including other Research Councils and charitable organisations;
- compile an Annual report for presentation to the Steering Committee and publication on the Bank's website;
- review the composition of Management Committee to ensure effective oversight;
- secure the appropriate level of microbiological and clinical expertise for the Bank;
- complete the working group programmes from 2003-2005 and establish further programmes for Research Grade cell lines;
- establish WG programmes for clinical grade lines;
- develop further the risk management strategy and through regular review and update of the NIBSC risk database implement appropriate action plans in collaboration with NIBSC Quality Department.

Milestones and Deliverables: Management and Reporting

Key Milestones	Milestones and Deliverables																								
	2005		2006				2007				2008				2009				2010				2011		
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	
Review and approve MC ToR																									
Reporting to SC/MC and Bank's sponsors																									
Deliver Annual Report																									
Review UKSCB Advisor's ToR & Re-appoint																									
Establish WGs ToR																									
Review WG work Programmes																									
Establish Work Programmes "RG/CG" Lines																									
Complete Current WG Work Programmes																									
Review Risks/Implement Appropriate Action																									

5.8. Communications

Aims and Objectives

A primary aim of the Bank has been to promote interaction with the various groups with interests in stem cell research. Thus, the development of an effective communication strategy has played a vital role in the development of the Bank. These interactions in the form of scientific liaison with the research community have been especially valuable in shaping the activities of the Bank. In addition communication with lay groups, charities, the press and the media in general have been important in sustaining positive interest in the Bank as well as supporting the profile of stem cell research in general.

The Bank has set up a number of working groups: on adventitious agents, consent and look-back and communications. These groups provide advice not only to the Bank, but through the Bank to the stem cell community at large.

An effective communications strategy will continue to be important. The Bank will maintain and develop its characteristic active programme of interactions with UK regional networks and collaborations with depositors and other stem cell researchers.

The aims of the Bank will be:

- to maintain and develop further its scientific liaison activity by establishing strategic links with the regional stem cell research networks and commercial stem cell groups;
- to provide an essential link via the Working Groups on emerging diseases and the impact such diseases have on safety testing, look-back and consent;
- to provide regular information on technical issues in stem cell banking and quality assurance in the form of publications and related material;
- to develop a system for monitoring of IP and adverse patents with NIBSC/Health Protection Agency and make this available to UK stem cell research groups;
- to develop the UKSCB Website as a primary source of information on the Bank and other UK stem cell related activities through links to the regional stem cell networks and linked organisations;
- to include on the website cell line information on quality assurance tests, cell line characterisation, and other cell line related information via a cell line database;
- to participate in a series of media and public events in collaboration with the Medical Research Council to emphasise the Bank's role in stem cell research and regenerative medicine;

Milestones and Deliverables: Communications

Key Milestones	Milestones and Deliverables																								
	2005		2006				2007				2008				2009				2010				2011		
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	
Establish Communications WG ToR																									
Review WG Work Programmes																									
Establish new Work Programmes																									
Complete Current WG Work Programmes																									
Undertake Review of UKSCB Website																									
Implement Changes to UKSCB Website																									
Establish IP Monitoring System																									