Appendix 3

Biobank self-assessment form.

This form should be read alongside the Confederation of Cancer Biobank's general standard (http://ccb.ncri.org.uk/wp-content/uploads/2014/03/Biobank-quality-standard-Version-1.pdf). It is intended for use by biobanks wishing to assess their activities against the requirements of the biobank standard and is used for self-assessment prior to a peer review audit.

Domain	Comment	Self - score[10]
Quality management system **General requirements** How does the biobank ensure that its quality management system complies with the requirements of the standard? What evidence is available to demonstrate the biobank's efforts to continually improve the effectiveness of its quality management system?		
Quality Manual and Quality Policy Does the biobank have a quality manual that provides an overview of the biobank's quality management system? Does this overview include or show where to find: • the quality policy? • a description of the quality management system? • a description of the organisational structure and governance arrangements? • a description of the roles and responsibilities of laboratory management? • a description of the documentation that supports the quality management system? Are biobank personnel familiar with the quality management system, the contents of the quality manual and all procedures relevant to their work? Does the biobank take a systematic approach to the improvement of quality?		
Best practice: Does the quality policy set out the biobank's commitment to defining the quality of its products and services, and to meeting those quality parameters?		

[10] Using HTA scoring system; 1=non-compliant or not applicable, 2= some progress towards compliance, 3=compliant with regard to most important features, 4=fully compliant

Documentation requirements Are there documented policies and procedures covering all aspects of activity relating to the biobank, including but not limited to consent, collection, storage and release of tissue and data, the management of the biobank and its adherence to applicable quality and regulatory standards? Does the biobank maintain records which provide evidence that its activities are being performed in compliance with the requirements of the quality management system?		
Document control Has the biobank established and maintained a procedure to control all documents that form part of its quality management system (internally generated or from external sources) such as regulations, standards and methods as well as proformas, drawings, software, specifications, instructions and manuals? Is there a master list showing all documents currently approved for use and their location or authorised holder? Are documents approved by authorised personnel prior to issue? Are documents and the procedures they describe reviewed regularly? Do documents contain a unique identifier, activation date, review date, version number, total number of pages and name of the approver? Are documents legible, readily identifiable and available at the point of use? Does the procedure for document control ensure that the authorised holder or location of each controlled copy is known at all times? Are superceded versions of documents archived and copies removed promptly from circulation so that staff members have access to the latest version of documents only? Are archived documents marked as obsolete to prevent their accidental use?		
Best Practice: Are all biobank documents identified with the document title, author, owner, approver, date activated, version number, and, for paper-based systems, copy number? Is each page numbered and the total number of pages shown or the end of the document identified?		

Document review and revision Is there a documented procedure and schedule for document review and, if necessary, revision? Are document revisions approved by authorised personnel prior to issue? Is consideration given to the need for additional training when implementing document changes? Are staff notified whenever a new version of a document is issued?		
Best Practice: Are changes to documents approved by the original document approver or their nominated deputy? Is a description of the changes made included in the revised document? Are all biobank documents identified within a document control database or log which tracks different versions of the document with dates of activation and withdrawal and a brief description of the reason a new version was issued?		
Document retention Has the biobank management determined the appropriate retention times and method of destruction for documents removed from current use?		
Control of records Is there a documented record management system that specifies what data is to be recorded, where it is to be recorded, how long it is to be retained and how it is to be disposed of (if appropriate) in light of relevant data protection laws? Are all records legible and stored in an environment that maintains their legibility? Are all records kept secure and is confidentiality maintained? Does the biobank have procedures to protect and, if held electronically, back up records? Do these procedures prevent unauthorised access to or amendment of records? Are all paper records signed and dated by the person creating the record at the time it is made? Is an equivalent system implemented for electronic records, enabling the person creating the record to be traced and the date and time of creation of the record to be recorded? If changes to records are permitted, do any changes made ensure that the original record remains legible? Are all changes to paper records dated and signed by the person making the change at the time the change is made? Are equivalent measures taken for records stored electronically?		
Best Practice:		

Does the biobank's quality manual list all data types and specify where each data type should be recorded, together with a record retention period and, if appropriate, the disposal route? Are biobank data generated during the sample conservation process and quality assessments retained for a period of not less than 10 years from the expiration date of the products to which the data relates, or, if there is no expiration date, from the date of final product distribution? Is there an audit trail showing any changes to electronic records, who made the changes and the date and time of such changes?		
Change control Is there a systematic approach to change control? Do documented procedure(s) exist for creation, review, amendment and deletion of techniques and procedures? If new techniques or procedures are being considered, or existing ones revised, is there a documented procedure for the assessment, recording and mitigation of the potential and actual impact of changes? Is consideration given to the potential need for validation and the provision of additional training to all those affected by the changes?		
Best Practice: Does the change control system incorporate the requirement to undertake an assessment of the risks associated with change, to validate fully any new techniques and procedures before they are introduced and to monitor the potential cumulative effects of multiple minor changes?		
Management responsibility and governance Does the biobank have a documented governance policy that has been agreed by relevant stakeholders and outlines the governance of the biobank? Does this policy cover: • Who has legal responsibility for the biobank? • Who has oversight of the biobank and responsibility for its organisation and policies? • Who is responsible for its day to day operation? • How responsibility is delegated? • How the consent, collection and release of tissue is governed including reference to its access policy and arrangements for ensuring ethical approval of research? • The standards to which the biobank will adhere? • The requirement for the biobank to maintain		

Research Tissue Bank ethical approval status? • The requirement for the biobank to hold an appropriate licence to store tissue for research (where relevant)? • The requirement to protect the privacy of donors and maintain their data confidentially? • The requirement to protect any IP rights accruing to the biobank or its stakeholders?		
Best Practice: If the biobank is disease specific, are donors or others affected by the disease able to influence the operation of the biobank? If the biobank is not disease specific does it allow advocates of those on whom the biobank relies for tissue and/or those it aims ultimately to benefit to influence the operation of the biobank? Are the processes to allow donor involvement, and the input expected from the donors documented? Does the governance document grant ultimate responsibility for the biobank to one group such as a Tissue Bank Executive Committee which consists of appropriately qualified and experienced personnel? Does generic ethical approval and each donor's consent extend to the collection and release of all relevant materials and associated data according to documented criteria?		
Organisational structure Is there an organisational plan that defines the organisation and management of the biobank, its place in any host organisation and its relationship to any partner organisations? Does the organisational plan include the responsibilities, authority and interrelationships of all organisations involved? Is there a documented organisational chart detailing relationships and responsibilities/duties of all biobank personnel (whether employed directly by the biobank or by a host or partner organisation)?		
Best practice: Does the Quality Manual have a section describing the organisational structure and interrelationships of the biobank and its host, and are diagrams and tables used to provide clarity?		
Management committees Are biobank stakeholders, including researchers, donors and lay representatives, involved in the biobank's steering, management and access committees?		

Best practice: Is there at least one donor/lay representative member of the steering, management and access committees? Is the role of the lay person clearly defined and communicated, with training provided to the individual(s)?		
Licences and legal requirements Does the biobank operate and provide evidence that they are operating within the legal parameters of the country in which they are based, holding all necessary licences and approvals? Does the biobank comply with all relevant regulatory Codes of Practice, for example the HTA's Codes of Practice on consent and disposal of tissue?		
Best practice: Is a Human Tissue Coordinator (however named) nominated to oversee adherence to licence and regulatory requirements? Are current reference codes for all appropriate regulatory permissions (for example Human Tissue Authority (HTA) and Research Ethics Committees (RECs)) included in biobank communications and are they easily identifiable on the biobank website?		
Ethical approvals Does the biobank maintain appropriate and current ethical approvals for tissue and data storage/use for research, encompassing procedures for data and sample collection, storage, release and disposal? Does the biobank produce an annual report of its activities to satisfy the requirements of its ethical approval? Are the access policy, procedures and decision-making process outlined in the biobank's research ethics protocol? Does the audit regimen in place for the biobank include scrutiny of compliance with the ethical approvals that govern its operations?		
Access to tissue and data Does the biobank have documented access policies and procedures? Is the access policy clearly stated and referenced in all of the biobank's donor-facing and client-facing? Does the policy ensure that bona fide researchers in any sector can be granted access to samples and data? Does the biobank ensure that operational policies do not preclude involvement by any individual or group, or clearly justify why exclusive policies exist? Do researchers have to apply in writing for access to samples and associated data from the biobank? Are guidelines for researchers/applicants available? Do such		

guidelines explain clearly the application submission process, application review process, time to review and notification of outcome? Is each request accompanied by a lay summary of the research and its sample requirements? Are all applications fully reviewed by a tissue access committee for scientific merit and impact of the research in the wider context of research in the relevant field? Are guidelines for application reviewers available? Do such guidelines explain clearly the detail of the application review process, scoring system and all possible outcomes? If there is competition for scarce samples, are samples provided to the project with greatest scientific merit as judged by the access committee? Is feedback provided to all research applicants (whether successful or unsuccessful) who have submitted an application to access samples from the biobank? Are unsuccessful applicants able to appeal the decision?		
Best practice: Are researchers required to provide feedback to the biobank on progress of the study, sample quality, findings and publications? Are researchers required to return their research results to the biobank to enrich the data associated with the samples? Are researchers required to acknowledge the biobank as the source of the samples used in their research? Is information about the samples and data held, and the procedure when applying for access to them, available online without registration?		
Access review Does the biobank review, at least annually, the number and nature of samples accrued balanced against those released for research? If a collection or sub-collection is determined to be inappropriately under used, is there a mechanism for prompt investigation and decision on the value of continued accrual including a review of the biobank's access policy?		
Material and data transfer agreements Do material and data transfer agreements (MTAs) form a contract governing the rights and obligations of the biobank and the recipient of samples and associated data? Are MTAs drawn up and signed by the biobank and their clients before any samples or data are released to the client?		
Best practice: Do MTAs specify the client's responsibilities in respect of:		

• Obtaining ethical approval for the planned work? • Complying with any restrictions on the use of the samples? • Returning surplus sample and/or derived materials to the biobank (if required by the biobank)? • Maintaining the security and traceability of the samples when they are issued to them? • Complying with instructions for disposal of the samples? • Complying with obligations to the biobank in regards to intellectual property, provision of data generated to the biobank, co-authorship and/or acknowledgement of the biobank in publications? • Providing periodic reports to the biobank Does the biobank seek legal advice for stating the appropriate rights and obligations in the MTA/contract for biobanks hosted by larger institutions?		
Health and Safety Does the biobank comply with all applicable health and safety legislation and good practice? Does the biobank operate according to documented health & safety policy and procedures?		
Communication with stakeholders Are policies governing the biobank transparent? Are there effective lines of communication among stakeholders?		
Best practice: Prior to the initiation of collection, did stakeholders, including potential donors, their representatives, researchers and other potential clients, discuss communication strategies to promote transparency and trust? Has the biobank developed clear guidance as to what services are provided, the costs for the provision of those services, and the hours during which services are available? Is contact information readily available to stakeholders?		
Internal communication Are effective procedures for the dissemination of information to staff implemented and is their effectiveness reviewed periodically? Are there regular meetings for exchange of information between all members of the biobank staff and management? Are records of these meetings kept and disseminated to staff and other stakeholders?		

Best practice: Do staff and management meetings take place not less than every three months?		
External communication Does the biobank promote good communication with external stakeholders, including funders, donors and researchers, ensuring they are regularly informed about its activities, plans and developments? Do all stakeholders have the opportunity to shape the biobank's direction and contribute to its development?		
Best practice: Does the biobank provide stakeholders with information about the use of its samples and data? Does this feedback include: • The number of samples used? • The purpose of their use? • The number of projects supported? • The outcome of research (in broad terms) including any publications?		
External staff Does the biobank engage with staff of partner organisations involved in the collection, transport and processing of tissue for research to ensure mutual understanding of clinical and biobanking matters relating to clinical samples? Does this engagement include medical, nursing, allied professional and administrative staff, including trainees, and including Surgery and Pathology? Does the biobank engage with researchers to ensure mutual understanding of the possible uses and limitations to the use of available tissue for research? Does the biobank ensure that it understands researchers' needs with respect to types and formats of tissue and associated data, ensuring that it will be suitable to support research using emerging technologies?		
Best practice: Do Pathology staff contributing to R&D have this in their job plans as core activity? Is there regular pathology input into education and training for biobank staff, and *vice versa*? Does the biobank have a regular programme of activities and/or other events/publications aimed specifically at engaging hospital staff, with feedback? Is there input into the design and delivery of these activities, events and publications by hospital staff groups and donor representatives?		

Patients and donors Does the biobank promote biobanking to potential donors and their families as part of a wider donor engagement programme? Are donor views sought on biobank activities on a regular basis? Is there active and ongoing involvement of donor/lay representatives to provide input into the promotional and operational activities of the biobank? Are donor representative/lay members involved in the design and analysis of the biobank's feedback mechanisms? Does the biobank have a mechanism in place to seek donors' views on sensitive issues and feedback to donors the results of these consultations? Does the biobank have a mechanism in place to seek donor/lay input into any information produced for donors? Are the general results of research undertaken with samples from the biobank communicated to interested donors?		
Best practice: Are the general results of research undertaken with samples from the biobank published (for example on the biobank's website)? Is non-use of samples a component of discussion/ information sharing with donors associated with the biobank?		
Return of research results or incidental findings to donors Does the biobank have a clearly defined, justified policy and, where necessary, process for the management of clinically relevant research results and incidental findings? Is this policy fully and clearly described to the donor during the consent process (prior to consent being given) by an appropriate person? If the policy permits the return of research results or incidental findings, is the donor's consent to be re-contacted sought and this information logged in accordance with the section on sample traceability? Is feedback given only to donors and/or donors' families who have consented to be re-contacted for this purpose? Is feedback given by trained, qualified personnel who understand the implications of the results for the donor and/or their family? If samples have been collected without the donor being informed about communication of clinically relevant findings, or if their opinion is not recorded, has the biobank consulted a local ethics committee for advice on the best course of action should a clinically relevant finding arise?		
Best practice: Is a feedback pathway defined, resourced and tested (if the biobank's policy permits feedback of results)?		

Communication with researchers Does the biobank have a method for publicising its existence and the types and numbers of samples held within it? Is the biobank readily visible to researchers as a resource for samples, with local, regional and/or national visibility in formats appropriate for the scope of collection(s)? Is the biobank shown on the NCRI's web-based portal (See: http://biosampledirectory.ncri.org.uk/)?		
Best practice: Does the biobank have an independent presence on the web? Are the biobank's holdings searchable via web-based sample directory portal(s)?		
Stakeholder feedback Does the biobank have a documented policy describing how it will seek and respond to feedback regarding its operation, performance and quality? Is there a documented procedure for assessing client satisfaction?		
Best practice: Does the stakeholder feedback policy: • outline procedures for actively seeking feedback? • outline procedures for improving the biobank in response to feedback? • ensure that improvements are highlighted to those using the biobank? • ensure that those giving the feedback receive a response outlining what the biobank will do / has done in response to the feedback?		
Complaints, anomalies and non-conformities **Complaints** Is there a documented procedure showing how the biobank will receive, assess and respond in a timely fashion to complaints from donors, prospective donors and clients? Does the biobank record all complaints and acknowledge them as soon as possible by the most appropriate method? Are records kept of responses/solutions and are these records reviewed? Does the biobank investigate all complaints so as to identify the root cause and implement any necessary corrective actions?		

Best practice: Has the biobank developed a clear complaints procedure and made this available to all stakeholders? Are the communication methods available for complaints appropriate for all likely complainants? On receiving a complaint, does the biobank acknowledge it and communicate this by the same means as the complaint was initially made? Is the complaint procedure clearly communicated to the complainant at this stage? Is the complaint logged, together with the results of any investigation and a clearly stated outcome? Is the complainant made aware of the results of any investigation and the ultimate outcome? Is there any appeals process? Is the complaints procedure referenced in all of the biobank's donor-facing and client-facing media?		
Anomalies and non-conformities Does a documented procedure exist for recording, investigating, reporting and reviewing anomalies and non-conformities? Is any breach of protocol logged in such a way that it is flagged whenever an affected sample is requested? Do records detail each event? Are decisions made promptly as to what corrective action(s) shall be taken to prevent inappropriate use of compromised samples and to suggest corrective and preventive action to avoid recurrence?		
Best practice: Do the procedure(s) for logging adverse events and non-conformities include a risk assessment of how that event might influence the integrity of the sample and the type of analysis this might affect? Is the category of risk recorded for each sample affected so that it is flagged whenever the sample is requested? Are meetings held as required to discuss complaints, anomalies and non-conformities so as to identify trends and suggest broader corrective or preventive measures?		
Corrective and preventive actions Does the biobank operate documented procedure(s) for implementing corrective and preventive actions? Do such procedures ensure that such actions are implemented in a timely manner and include the requirement to ensure that the actions taken address the root cause of the problem or potential problem? Do the procedures include an assessment of the effectiveness of corrective and preventive actions?		

Audit and review of biobank activities **Internal and external audit** Does the biobank operate a documented procedure for submitting all aspects of its operations to horizontal and vertical, internal and external audits, in accordance with a predetermined schedule, to demonstrate that its operations continue to comply with the requirements of its management system and this standard? Does the audit system cover all aspects of the biobank's management system? Are all auditors trained and competent in auditing? Are internal auditors clearly defined in the organogram, showing how they will be assigned tasks so that they are not auditing their own practice? If the audit findings cast doubt on any aspect of the biobank's operations, does the biobank take timely corrective actions? Are audit records maintained, showing the area audited, audit findings and any corrective actions arising from them? Does the biobank assess and record the effectiveness of any corrective actions implemented?		
Management review Does the biobank's top management review the quality management system at least annually? Does this review include a comprehensive review of the quality management system and its continued suitability and effectiveness? Are any necessary changes or improvements introduced using the biobank's change control procedure? Are the findings from management reviews and the actions that arise from them recorded? Are actions discharged within an appropriate and agreed timescale?		
Biobank sustainability Does the biobank have a documented strategy to safeguard its continued financial viability for the expected lifetime of the sample storage and handling activities? Does the biobank maintain a legacy plan for its own holdings, in case the future of the biobank is threatened? Are plans reviewed periodically and amended as needed?		
Best practice: Has the biobank developed a breakdown of the costs associated with the collection, storage and distribution of samples such that the annual headline costs for (a) maintaining and (b) adding		

to the biobank are known? Can the biobank distinguish within its budgets, (1) the costs required to continue collecting and distributing and (2) those required for continued maintenance and distribution of the current collection? If the biobank is funded predominately from one source, has a risk assessment and contingency plan been developed against the loss of that funder? Has the biobank developed a protocol for the transfer of samples to another biobank should it fail to continue to be financially viable or need to transfer its holdings for any other reason? Has this protocol been developed in coordination with an appropriate ethics committee and with lay input?		
Risk assessment and contingency planning. Has the biobank performed a documented assessment of the risks to its business, operations and products, covering: • Risks to the management and operation of the biobank and the samples and data it holds? • Minimisation and mitigation of those risks? • Contingency plans, including an emergency procedure, a business continuity plan and a disaster recovery plan? • Roles and responsibilities of key staff in implementing the contingency plans? • Risk assessment and detailed plans for biobank legacy in short, medium and long term, addressing personnel, premises and technology? Are the risk assessment and contingency plans reviewed regularly and amended as needed? Does the biobank have documented procedures for assessing the impact of unplanned events on its operations and the samples and data it holds?		
Best practice: Does the biobank, or the organisation of which it is a part, maintain detailed plans and standard operating procedures for implementation in case of an emergency? Are staff aware of these plans and procedures? Is each potential risk documented, showing how high or low the risk is, the consequence(s) of that risk occurring, the actions taken to mitigate the risk and the remedy/actions to be taken should that risk occur? Do plans include instructions for contacting key personnel out-of-hours?		

Staff **Roles and responsibilities** Is each role within the biobank described in a job description and person specification? Are the qualifications and competencies required for each role defined, and communicated? Are there clear reporting lines and accountability, documented levels of authority and responsibility associated with each role, a system of staff appraisal, and training and development of staff? Are staff members performing specific roles within the biobank qualified on the basis of appropriate training, experience and/or demonstrated skills, as appropriate? Does the biobank shall have a director (however named) with overall responsibility for management of the biobank? Is the director qualified by training and experience to direct and manage the scope of activities conducted by the biobank? Has a person responsible for quality assurance management been identified? If this individual has other roles, are they independent of biobank services they are responsible for quality assuring?		
Training, competence and staff development Does the biobank maintain a documented training procedure that includes: • A new-starter induction procedure • Training staff in skills specific to their job according to documented protocols • Assessment of staff competence against documented criteria • Recording of staff training and competence, with sign-off • Assessment of the need for and, if necessary, implementation of staff training and competency assessment before the introduction of new technologies or practices • A documented procedure for staff appraisal, with annual review of training needs, including a procedure for managers and their staff to review continuing professional development needs and personal development plans.		

• Experienced individuals designated to be responsible for delivering training and appraisal. • Clear line-management of biobank personnel. • Mechanism in place to promote staff development and progression. In the case of a biobank storing samples as part of a clinical trial, are staff recruited with certified GCP-L training or is such training provided before staff members begin work with any trial material? Are all staff who will work in the laboratory or storage facility where the trial samples are processed or stored trained in the GCP-L requirements specific for that trial? Is GCP-L training repeated at least once every 2 years in order to keep abreast of latest legislation relating to clinical trials? Is the GCP-L training and induction certified and recorded in the individual's training record?		
Best practice: Is a bespoke training programme created for every member of staff at the time they are appointed and does this training programme serve as a structure for the employee's training throughout their deployment in the biobank? Are biobank staff members with a clinical and/or scientific role encouraged to undertake continuing professional development (CPD)? Is staff training managed in a structured way? Is training delivered by appropriately experienced, authorised individuals? Is there a corporate system of staff appraisal linked to personal development plans and continuing professional development? Is the appraisal system delivered by suitably trained staff? Do appraisal meetings take place annually, with follow-up meetings six months later and regular reviews? Is job progression possible and encouraged? Are opportunities provided to mentor junior members of staff so they can take on new roles as and when additional (often senior) positions become available? Does the biobank, regardless of involvement with clinical trials, provide basic GCP-L training? Are all samples treated as if they could be used to influence trial outcome measures (i.e. with full audit trails)? Are all GCP-L training courses used accredited and are online courses used only as a temporary measure?		

Is face to face training carried out as soon as possible even if an online course is completed?		
Professional behaviour Are biobank staff members who have access to donor identities and/or donor identifiable data bound by a professional code of practice that includes standards of ethical behaviour? Do staff meet the requirements of their host institution(s) in respect of holding honorary contracts, or equivalent, governing their access to patient-identifiable data?		
Best practice: Do Person specifications for roles that involve access to donor identities and/or donor identifiable data include a requirement that the post-holder is registered with a Council for Healthcare Regulatory Excellence - monitored regulator (such as the General Medical Council or Health & Care Professions Council) or, for staff who are not eligible for registration with a statutory regulator, with the Voluntary Registration Council or an equivalent non-statutory regulatory body?		
Indirectly managed staff Are the requirements of this standard applied to staff of other organisations, such as a host organisation or affiliated organisation, if they carry out work on behalf of the biobank? Does the biobank ensure that indirectly managed staff members are clear about their biobank roles as distinct from other NHS or service/research roles they may have? Are indirectly managed staff supervised by appropriate person(s) within the biobank for the part of their work they carry out on behalf of the biobank?		
Facilities **Suitability of premises** Are the accommodation and environment within which the biobank operates adequate and suitable for its operations? Do areas used for storage of human tissue or data, for use in research, provide an environment that is safe for biobank staff and preserves the integrity of the tissue and data? Is the biobank kept clean and tidy with visible evidence of good housekeeping?		
Best practice: Is there a documented assessment of the facilities' "fitness for purpose"? Do the facilities allow for the completion and storage of accompanying paperwork and electronic data? Is the suitability of the facilities reviewed regularly?		

Access to facilities Is there a documented procedure to restrict access to critical systems, equipment and facilities to authorised personnel only? Are visitors to areas containing critical systems, equipment and facilities accompanied by authorised personnel at all times? Does the biobank implement appropriate safeguards to prevent unauthorised access to or removal of samples or access to electronic data or paper records? Can the biobank demonstrate that samples and data are held securely in such a way as to prevent unauthorised access both during and outside normal working hours?		
Best practice: Are banked samples and records containing confidential information housed within restricted areas? Are restricted areas open only to biobank staff, with access limited, for example, by the use of electronic pass cards or by lock and key? Where it is not possible to house confidential data or banked samples in an area that is only accessible by biobank staff members, is such material held under two separate locking systems (e.g. a permanently locked cupboard or locked freezer located inside a room or laboratory that is itself locked when no authorised personnel are present)?		
Equipment **Selection and qualification** Has the biobank implemented a systematic procedure for identifying critical equipment and ensuring that documentary and/or practical evidence is in place to verify that equipment adequately meets the needs of the biobank and, where appropriate, equipment is maintained and validated?		
Best practice: Is equipment validated before it is first used?		
Calibration, maintenance and servicing Has the biobank documented its procedures and schedules for the regular cleaning, maintenance, servicing, quality assurance, validation, calibration and monitoring of equipment? Are records maintained of all cleaning, maintenance, servicing, quality assurance, validation, calibration and monitoring of equipment? Has the biobank undertaken an assessment of the control measures necessary to reduce the likelihood of failures in critical equipment? Are there documented procedures for dealing with equipment faults and breakdowns? Do these procedures include an assessment of the impact of the fault or breakdown on the samples held by the biobank?		

Is defective equipment removed from use until it has been repaired or replaced and, if necessary, re-validated? Are records maintained of all equipment faults and breakdowns and how they are resolved?		
Best practice: Is there a capital asset register or equipment database which is used to record the cleaning, maintenance, servicing, fault, repair and monitoring events for all critical equipment?		
Temperature controlled equipment Are all refrigerators and freezers located in air conditioned room(s) with controlled room temperature? Are all refrigerators, freezers and liquid nitrogen (LN_2) storage units with automatic filling systems connected to the "essential" power supply circuit and/or back-up generator? Is the effectiveness of all monitoring and back-up systems, such as the operation of alarms and back-up generators, tested to a defined schedule and are records maintained of the outcome of this testing? Are all monitoring and alarm systems connected to an uninterruptible power supply (UPS) so that data are maintained should the usual power supply fail? Are there documented procedures for safe handling of LN_2, including procedures for monitoring and recording LN_2 levels and manual filling of units? Are oxygen depletion alarms installed and maintained in every area where LN_2 units are housed? Is the effective operation of oxygen depletion alarms tested to a defined schedule and records maintained of the outcome of this testing? Is LN_2-specific health and safety training provided to all staff working with or in proximity to LN_2? Does the biobank have access to spare refrigerator, freezer and LN_2 storage capacity so that samples can be moved in an emergency?		

Best practice: Do all mechanical freezers have dual compressors? Are back-up refrigerators, freezers and LN_2 units fully validated and maintained as operational, and labelled appropriately? Do back-up systems for mechanical refrigerators and freezers include the use of dry ice to maintain temperature temporarily? Does the biobank have a contract or service level agreement for off-site storage with an approved supplier in case of disaster, for example by local collaborations to provide mutual hosting and back-up facilities?		
Room temperature storage Are all samples stored at room temperature held at constant temperature within defined and monitored parameters?		
Best practice: Is there regular monitoring of these parameters with long term records of any variations exceeding defined parameters?		
Temperature monitoring Does the biobank operate a systematic temperature monitoring procedure, including: • the definition of "alert" and "action" upper and, if appropriate, lower temperature limits • a defined schedule of temperature monitoring • recording of temperatures (including the ability to demonstrate the temperature recorded on a given date, at a given time) • an indication of the maximum time equipment doors can be open • a requirement to monitor temperatures closely following any alarm • regular alarm checks • the circumstances under which samples shall be relocated to alternative storage units? Has the biobank implemented a local and remote alarm system that notifies appropriate individuals when temperatures go outside required limits and operates at all times of the day and night?		

Best practice: Is there continuous automated temperature monitoring? Are remote alarms linked to the mobile phone of designated staff? Can fridge and freezer status be monitored via web?		
Procurement **Purchasing** Does the biobank or the organisation within which the biobank is hosted implement a documented procedure for purchasing equipment, goods and services? Has the biobank implemented a systematic procedure for identifying critical facilities, equipment, goods and services? Is a list of approved suppliers of critical items maintained? Does the biobank ensure that all equipment, goods and services are suitable for their intended purpose before they are used? Whenever equipment, goods or services can influence the quality of the final product does the biobank implement systems to ensure that these items are assessed and approved or rejected prior to their use, and are records of these assessments maintained and used as part of a regular review of suppliers? Are the systems implemented proportional to the degree of risk to the quality of the biobank's products?		
Best practice: Does the biobank have a procedure which ensures that the impact of any equipment, product or service on the quality of the tissue or data is assessed and documented? Are records maintained of the validation of the suitability of the containers used?		
Subcontracting Does the biobank assess the suitability of a subcontractor to provide services to the biobank before any work is subcontracted, and maintain records of these assessments? Are service level agreements established between the biobank or its host organisation and any organisation that provides services to the biobank? Are service level agreement reviewed at intervals and modifications made, with mutual consent, if needed? Does the biobanks contract out any of its laboratory services? If so, does it retain records of the name and address of the contracted facility, the name and contact information for key personnel at the location where the services are being provided, documentation of the inclusive dates of the contract period and copies of the contract as well as any accompanying documentation?		

Are the scope of work, roles, responsibilities and timelines for all contracted services clearly articulated and recorded? Is a risk assessment produced and a record held that specifically addresses the nature of the samples under test? Is consideration given to the amount of sample that will remain in the biobank and whether it would be possible, if necessary, to repeat the test using the same contractor, another contractor or in-house?		
Best practice: Is a consideration of other contractors and in house analysis made each time sub contracting is undertaken? Is there an onus to prove that risks to samples are less if the specific subcontractor is used than would be the case with alternatives and that the gain to the value of the samples will outweigh any risk to the samples? Has the subcontractor been audited by or on behalf of the biobank before any contract was placed?		
Consent and withdrawal Does the biobank seek generic consent for the prospective collection, storage and research use of donated samples and data or document clearly the reasons why generic consent is inappropriate? Does the biobank implement processes to ensure that consent is obtained in line with legal requirements, with appropriate information and due process? Does the biobank maintain records of donors' consent, including identification of the person(s) seeking consent? Does the biobank ensure that, where legally required, a record of informed consent is in place prior to accepting a sample collected after 01 September 2006 into the biobank? Where samples held within a diagnostic archive are made available for research, does the diagnostic archive hold any appropriate licences to store tissue for research purposes? In the UK (except Scotland) are samples from the living (and data about them) that are held in the diagnostic archive and surplus to diagnostic requirements, for which specific consent has not been sought: • anonymised before transfer out of the diagnostic archive, and • transferred only for use in research that has appropriate ethical approval? Is there a clear, justifiable and documented policy for seeking renewal of consent should it be required? If this policy permits donors to be re-contacted, is the policy made clear to donors at the time consent is sought and specific		

consent to re-contact the donor shall be sought? Does the biobank maintain a procedure for dealing with unsolicited requests to donate tissue and data? Does the biobank's consent process make it clear to donors that they have the right to withdraw their samples and data from the biobank at any time? Are the limitations on withdrawal, in terms of samples and data that have already been used in research, made clear to donors?		
Best practice: Is specific informed consent sought for every sample, where practical and appropriate? Does a copy of the informed consent record accompany the sample to the biobank? Does the biobank endeavour to integrate generic consent for research biobanking into procedural consent processes in the biobank's partner hospital(s)? Are biobank staff members involved in training all staff (biobank, NHS or other) who seek consent for biobanking? If there are reasons why the biobank cannot accept unsolicited donations, is the potential donor provided with details of other biobanks that may do so? Does the biobank make information about withdrawal available in a number of formats and visible to donors at a number of points in time? Are donor/lay persons involved in development of consent and withdrawal information and procedures? Is withdrawal possible by a number of different routes to make it easy for the donor to withdraw? Are requests for withdrawal acknowledged promptly and handled as a matter of urgency? Are donors notified when their samples and data have been removed from the biobank?		
Types of samples Has the biobank documented its policy with respect to collection of samples? If research and/or diagnostic samples are included in the biobank, is there appropriate governance of tissue transfers between the relevant researcher and/or NHS Trust(s) and the biobank? Are samples transferred into the biobank accompanied by detailed information on how the samples were collected, processed and stored prior to transfer?		

Best practice: Are there practical and strategic relationships between biobank and NHS pathology staff for mutually beneficial continuous improvement in tissue and data handling for diagnostic and research purposes? Is there strategic planning for sustainability and maintaining donor confidence in the face of increasing private sector involvement in providing NHS diagnostic services? Does the biobank have access to procedures used in research and/or NHS pathology departments from which they receive samples, and is it notified when changes are made to these procedures?		
Selection of samples for banking Do the biobank's procedures ensure that collection of samples for research does not interfere with donor diagnosis, treatment or monitoring, or otherwise compromise donor welfare? Are tissue samples assessed by a pathologist or other suitably qualified member of staff to determine their adequacy for both clinical and research requirements and to approve the selection of surplus material to be used in research?		
Legacy samples Does the biobank have a legacy plan for the adoption or rejection of investigator-led and orphan collections of tissue and data? Does the biobank provide guidance to external holders of such collections? When bringing samples in from other external collections, does the biobank consider how the samples were obtained (including the consent for their use in research)? Do the records accompanying such adopted samples allow a recipient to be confident that all samples have been collected legally and ethically for the use intended? Are these details logged in accordance with the standard on 'Sample Traceability'? Does the recipient biobank hold copies of the protocols/SOPs used by the external collector and any deviations from them?		
Best practice: Is a risk assessment made on the likelihood that the intended protocol was followed as described? If there is any reason to suspect that the protocols were not followed, are the samples marked accordingly? Where no protocols are available, does the biobank make an assessment as to the usefulness of banking the samples? Where there is a lack of information, are worst case assumptions made about the extent of consent if evidence is not available to the contrary? Is consent sought, whenever practical, for storage and research		

use of samples collected prior to 2006 (existing holdings)? Does the biobank undertake appropriate QC on representative samples from a collection that is being adopted? Is the nature and the results of this QC flagged for all samples from that collection (not just the ones tested)? Where consent forms and donor information sheets are not available for samples, are samples irreversibly anonymised before banking? Does this include a case by case analysis extracting all relevant data for each donor that may have been logged by the original recipient, evaluating its potential relevance and ensuring only data that cannot be tracked back to the donor is stored by the biobank? Where consent forms are available, are copies of each completed consent form held by the receiving biobank along with donor information sheets, any ethics application and copies of any ethics committee approval letters? Are such collections always considered and clearly identified as a sub-collection?		
Traceability Is there is complete traceability of tissue and data, from donor to researcher and/or destruction, such that: • Each sample and aliquot has a unique identifier. • Samples are labelled appropriately so that identification of the samples and traceability to donors/parent samples is maintained. • Each sample is associated with a consent procedure that records the detail of permissions or restrictions associated with the use of that sample. • Each sample is associated with a collection SOP and, where relevant, processing and storage SOPs. • Each sample is associated with any significant event (such as a freezer thaw) that might impact on the characteristics of that sample. • It is possible to identify the location of any sample at all times, including those that have been distributed to researchers or destroyed. Does this include aliquots and derivatives of samples such as sections of tissue and extracts of nucleic acids? • The biobank is able to track shipments from dispatch to receipt, whether or not a courier is used Does the biobank maintain a chain of custody for the samples it holds, maintaining records of: • the name and role of any person who receives or		

handles the samples, • the dates and times the samples were in each individual's custody • the dates and times of key events such as collection from the donor, placing into temporary storage, dispatch to and/or receipt from pathology/ biobank/ researcher?		
Best practice: Are records of validation of the suitability of all labels maintained, including evaluation of their adherence/ readability in adverse conditions? Are barcodes and automated management systems used?		
Collection of samples Does the biobank collect samples under conditions and using containers appropriate for each sample type? Has the biobank documented its collection protocols and does it keep records of any deviations from the protocols? Are collection protocols subject to regular review? Does the biobank maintain records of factors related to collection when they are of relevance to the quality of the sample?		
Best practice: Whenever evidence is available, does the biobank use protocols based on authoritative best practice or published research findings?		
Transport of samples Has the biobank documented procedures for the transport of samples? Do these procedures cover transport from theatre or clinic to laboratory or biobank and from biobank to researcher? Do these procedures require prompt, direct transport of samples so that the times during which samples are in transit are kept to a minimum? Has the biobank evaluated risks to the stability of samples and documented the need for control of temperature, humidity and light during transport? Is temperature, humidity and/or light controlled if this evaluation has shown that such control is needed? Are records of temperature, humidity and/or light during transport maintained if they have been shown to affect the stability of the human biological material? Are staff undertaking picking, checking, packing, transporting and/or receiving samples trained according to a documented		

procedure? Is specialist training provided for international shipments? Does the biobank's chain of custody record show who picked, checked, packed, transported and received samples? Does the biobank comply with all regulatory requirements relevant to the transport of human biological material, for example those relating to containers, packaging, labelling and shipping? Are all shipments accompanied by appropriate documentation showing the origin, contents and destination of the shipment? Does this documentation include sender and recipient contact details? Does the biobank confirm or require confirmation that the samples received match those detailed on the dispatch note or shipping manifest? If the biobank uses external couriers, does the biobank assess the ability of any such courier to meet its transport requirements? Does such evaluation cover: • Contingency plan in place by courier in case of problems - especially with frozen tissue. • Ability of courier to renew liquid nitrogen, dry ice or ice packs if there are unexpected delays in transport. • Compliance with national and international shipping regulations • Certification to ISO 9001		
Best practice: Is time in transit recorded? Are samples checked against a dispatch note or shipping manifest by a second person prior to dispatch? Are temperature data loggers used? Do shipments of cold or frozen material have sufficient and appropriate refrigerant to maintain temperature throughout the shipping cycle with allowance for at least a 24-hour delay in arrival time? Does the notification of receipt take place by e-mail, fax or telephone as soon as the shipment has been checked? Are any problems notified at this time and noted in the senders' records?		
Processing of samples Are there clear lines of communication between the biobank and any pathology department, mortuary or other subcontractor processing samples on its behalf? Is the pathology department, mortuary or other subcontractor required to notify the biobank of any changes to its sample		

processing procedures? Is the number and size of all samples and aliquots recorded? If the number and size to be collected is stated in a documented procedure, are exceptions to the documented requirement recorded?		
Best practice: Is all tissue dissected under the supervision of, or by documented agreement with, a Consultant Histopathologist or equivalent? Are staff carrying out dissecting, freezing, fixing, embedding or otherwise processing tissue for banking trained, as a minimum, to a level equivalent to a Biomedical Scientist?		
Warm ischaemia Is warm ischaemic time (the time between arterial clamping and tissue removal from the donor) recorded whenever this information is required for a specific research project?		
Best practice: Does the biobank maintain records of warm ischaemic time for all tissue samples that it holds?		
Cold ischaemia Does the biobank have procedures in place to minimise the cold ischaemic time of samples? Does the biobank set targets for and maintain records of the time(s) of each of the steps between removal of tissue from the donor and subsequent events such as receipt in pathology, placing on ice, snap freezing, placing in fixative, centrifugation or other processing steps?		
Best practice: Does the biobank reduce the sample temperature, for example by placing on ice, as soon as possible after removal from the donor and prior to further processing?		
Frozen samples Are procedures for freezing samples documented? Are records kept of the procedure used and any deviations from them?		
Fixed samples Is the procedure used for sample fixation documented? Is the fixative used and the time that the sample spends in fixative recorded?		

Storage of samples Does the biobank implement a systematic procedure for the preservation of samples? Do documented procedure(s) exist for all aspects of the storage and protection process? Are duplicate aliquots of samples stored in a separate location? Does the biobank record the storage location of all samples and aliquots in a database and with back-up? Do records of sample and aliquot position in refrigerators or freezers show the exact location in the storage box to ensure their timely retrieval and minimise warming? Are records maintained of date and time of removal from storage and, if appropriate, return to storage of samples and aliquots?		
Best practice: Are storage areas and processes designed to minimise contact with chemical or biological contamination, and to ensure maintenance of sample integrity is maximised to permit repeat or equivalent examination? Are such controls extended to areas of packaging and transport? Is a LIMS system used?		
Selection and release of samples to a researcher or other client Is the researcher/client involved in the identification and selection of samples according to a documented procedure? Are there clearly defined pathways and timelines, mutually agreed by the biobank and researcher/client? Does the biobank assess the known needs of the researcher against the known quality of the samples held and ensure that samples are allocated to the researcher only when the researcher's stated quality requirements are met? Is a list of suitable samples generated and signed by the researcher/ client and a biobank representative? Are these agreed samples specified in the Material Transfer Agreement? Are relevant sample handling data, including notification if the sample has been previously released from and returned to the biobank, and any QC test results made available to the researcher? Does the researcher/client submit interim progress reports during their use of biobank supplied materials? Is a mutually agreed process in place to report the sample status at intervals, including numbers, location and usage of tissue supplied, or allocated for supply, by the biobank?		

Is there a notification process to inform the biobank promptly at study closure, or in the event of extension of tissue-based research such as that associated with clinical trials? Is the record of final study closure signed by the researcher/client and a biobank representative? Does the biobank have a documented policy and procedure(s) for return of unused samples from the researcher? If this policy permits return of samples, are returned samples held in quarantine until their quality has been assessed according to documented procedures? Does the biobank's audit procedure evaluate compliance with these procedures and establish that tissue has been returned when appropriate?		
Best practice: Requests received, samples identified, samples issued and project interim and final reports should be reported at management committee meetings.		
Quality control of samples Does the biobank have a documented programme and procedures for the quality assessment of all samples that it holds? Does the biobank undertake regular audits of sample quality? Has the biobank implemented a systematic procedure for identifying and documenting the critical quality attributes of released samples? Are the critical quality attributes of samples communicated to the researcher using the samples? Are internal quality control records and external quality assurance records reviewed and used to identify changes that will maximise the preservation of sample quality?		
Best practice: Does the biobank work closely with researchers to identify the key sample quality criteria for the intended research? Is morphological assessment performed on every solid tissue sample prior to dispatch. Does the biobank assess and record the % diseased/ normal/necrotic tissue in each of the samples that it holds before providing it to a researcher? Does the biobank perform quality assessment (quantity and quality) of DNA and RNA samples?		

Proficiency testing Does the biobank participate in relevant external quality assurance/proficiency testing such as those provided by UK NEQAS or equivalent? Does the biobank document its participation in any external quality assurance/proficiency testing schemes, including the procedures for review and communication of results arising from such participation? Does this procedure include the requirement to investigate all anomalous results and undertake corrective and preventive actions when necessary? If another laboratory performs relevant procedures on behalf of the biobank, do these requirements apply fully to that laboratory?		
Tissue and data disposal Does the biobank have a documented disposal policy which sets when and how tissue and data will be disposed of? Is tissue disposal carried out in accordance with HTA requirements and in light of donors' wishes?		
Governance of donor and sample data **Confidentiality** Is there a documented procedure for maintaining donor confidentiality which includes a robust system of sample anonymisation or pseudonymisation and data protection? Are appropriate security measures taken whenever data is transferred between systems or individuals?		
Best practice: Is any linkage between donor identities and donor pseudonyms in linked anonymisation systems maintained in a secure database held on a server behind the NHS, host institution or other firewall? Are paper records held in a secure, locked cabinet and is access limited to named individuals?		
Data Does the biobank ensure that the design and operation of its database(s) comply with Caldicott principles and recommendations? Does the biobank have Health Research Authority (section 251) approval, if appropriate, to cover its data handling activities? Does the biobank have access to a copy of any diagnostic pathology report for all of the solid and cytology tissue samples that it holds? If the pathology report allows the donor to be identified, does the donor consent process ensure that the donor is aware of this requirement and gives permission for the biobank to hold this identifiable data? Does the biobank hold all of the data required by the CCB's Data		

Standard? Are those parameters that are unknown or unavailable marked as such?		
Best practice: Does the biobank collect all of the data specified in the "required" and "best practice" sections of the CCB's Data Standard, allowing for greater information to be made available to the researcher?		
Data protection Does the biobank implement a documented procedure for assessing documents for compliance with the UK Data Protection Acts before they are issued? Are all biobank documents relating to data protection reviewed for compliance with the UK Data Protection Acts by a suitably qualified person?		
Best practice: Are all legally binding documents referred to a corporate legal compliance team for review before issue?		
Data security Does the biobank implement a documented procedure for controlling access to biobank data so that data is restricted to approved personnel? Does the biobank manage data in such a way that it is secure from loss or corruption at all times, including during transfer into or out of the biobank? Does the data management system specify a robust process for backing-up live electronic data? Is data encrypted before it is written to any portable electronic device such as a disc or memory stick?		
Best practice: Does the data management system incorporate daily backing up of the live data array in such a way as to allow the entire data array to be recreated elsewhere in the event of a catastrophic failure resulting in loss or corruption of the live data array? Are fail-safe systems implemented? Are off-site or otherwise remote secure servers and data storage used for back-up? Are adequate electronic security measures implemented to mitigate risk of hackers gaining access to servers (e.g. encryption of data)? Are paper documents stored in fire-proof cabinets and/or rooms equipped with sprinkler systems or an inert gas system?		

Data quality Does the biobank document and regularly review its procedure(s) for assuring the quality of the data it holds?		
Best practice: For electronic data: • Is an industry standard database package used (i.e SQL Server, Oracle or Access)? • Are default codes used only where appropriate, and not as a substitute for real data? • If it is necessary to bypass a data item, is the missing data flagged for immediate follow up? • Are systems programmed to only accept valid entries? • Are regular spot checks, audits and comparisons between systems used to identify missing data? • Is every opportunity taken to check data at source? • Are all tables updated regularly? • Are all data recorded and processed in accordance with set deadlines? • Are errors identified and corrected as close to point of entry as possible?		
Return of research data to the biobank Does the biobank have a justified policy for the return of research data to the biobank and is this policy clearly communicated to any researcher? Does the biobank require that it is given citation details for any publications arising from use of samples or data it has provided? If the research is funded from public money, does the policy indicate the need for research data to be returned for future public benefit? If the policy includes a requirement to return research results to the biobank, does it include details of circumstances in which this might be waived? If the return of research results is required, is this requirement included, with a defined timescale for return of post-study results, in any MTA?		
Best practice: Does the biobank require all data to be returned for future use and enforce compliance? Does the biobank issue reminders annually to recipients, requesting an update on their use of the tissue and/or data, any publications derived and a copy of any derived data?		

Does the biobank hold these data in confidence for an agreed period prior to making them available for use in further research?		

END