

Appendix 1

Outline of the Quality Mark Scheme

Overview of the accreditation process.

The process is envisaged as a 3 year cycle.

Year 1 Initial application

- Biobank completes a self-assessment questionnaire and application form, and submits them together with a copy of their quality manual, to the CCB Secretariat.
- Documentation supplied is assessed within one month of receipt.
- If the application is acceptable, the applicant becomes a “Registered Biobank”.
- If the application is **not** acceptable the biobank is advised to seek support from a named CCB member biobank and re-apply at a later date.
- When the application is acceptable, arrangements are made for an inspection visit. This is carried out by one or two peers from the biobank community who will be trained and appointed by the CCB Secretariat.
- A verbal report will be given at the end of the inspection visit.
- A written report of the findings will be prepared by the inspectors and submitted to the Lead Auditor for review within one week of the inspection. The report may recommend accreditation, identify conditions that must be met before accreditation is granted, suggest that the applicant seeks support from a named CCB member biobank or recommend that accreditation be refused and the applicant advised to reapply at a later date.
- The CCB Secretariat will consider the recommendations and issue a decision to the biobank. The approved report and decision will be provided to the applicant within two weeks of the inspection.
- If conditions are identified that need to be met before accreditation is granted, the biobank will be required to respond to the findings, showing how and when the conditions will be met, within one month of receipt of the report and decision.
- Once actions to meet the required conditions are completed the biobank will notify the CCB Secretariat who will assess the actions taken and either approve accreditation or arrange an inspection visit to verify the effectiveness of those actions.
- If an inspection visit is required, a written report of the findings will be prepared by the inspector and submitted to the CCB Secretariat for review within one week of the inspection visit. This may result in confirmation that the actions taken are effective at which point accreditation will be granted by the CCB Secretariat. If it is judged that the actions have been insufficient or ineffective the CCB Secretariat may suggest that the applicant seeks support from a named CCB member biobank or recommend that accreditation be refused and the applicant advised to reapply at a later date
- It is expected that all conditions will be met by the biobank in a timely manner and normally within six months of receipt of the report by the biobank. During this process the biobank will remain a “Registered Biobank” but if conditions are not met after six months have

elapsed the biobank will be removed from the register and will need to re-apply for accreditation.

Years 2 and 3 Maintenance of accreditation

- Biobank completes a self-assessment questionnaire to confirm continued compliance with the accreditation requirements and submits it to the CCB Secretariat.
- Documentation supplied is assessed within one month of receipt.
- If the documentation is acceptable, accreditation is retained.
- If the documentation is not acceptable, the CCB Secretariat may ask supplementary questions of the biobank or may require an inspection visit. If an inspection visit is required it will be performed as shown above.

Year 4 and onwards - Maintenance of accreditation

Years 1-3 are repeated in a three year cycle.