

NCI Best Practices for Biospecimen Resources (2011)	OECD BEST PRACTICE GUIDELINES FOR BIOLOGICAL RESOURCE CENTRES (2007)		ISO 9001:2008	
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B.6 ヒト生物資源保管施設の 情報処理・データ管理お よび在庫管理と追跡	9.1. Data	<p>35. BRCs should ensure a minimum amount of information is available for each accession in the collection (the Minimum Data Set (MDS)). Additional data may comprise a Recommended Data Set (RDS). Best practice for what should comprise each data set is listed in Appendix 2. The MDS should be recorded and made available.</p> <p>36. The data should be updated with the most recent information related to donor's sample (i.e. clinical data, results of scientific research).</p> <p>37. Exceptionally, BRCs may accept collections of scientific value that cannot meet the full MDS and should disclose which items of the MDS are missing.</p> <p>38. The data vocabulary used for the BRC catalogue should be in accordance with an identified thesaurus (e.g. Online Mendelian Inheritance in Man).</p> <p>39. A procedure for defining the MDS and RDS for a collection should be established before the collection is constituted.</p> <p>40. BRCs should be equipped with information systems that can handle physical management of samples. This implies a system that records data on all stages of handling from sampling to transfer of all or part of a collection. There should be traceability of analyses undertaken, as well as of quality controls and transformations.</p> <p>41. Identifying (associated) data may be recorded and transmitted securely, e.g. by e-mail or over the Web, only in accordance with the applicable regulations.</p> <p>42. Donor identities should be encrypted in databases. The procedure for coding biological material is paramount to the protection of the donor's privacy as well as for allowing distribution and use for research purposes.</p>		
B.6.1 機能範囲—全般	9.3. Internet publication.	<p>45. The BRC should publish a catalogue of human-derived biological material accessible in order to:</p> <ul style="list-style-type: none"> i) Optimise the utilisation of biological material. ii) Ensure transparency of BRC activities. <p>46. A catalogue should contain the list of available samples associated with a synopsis of the minimum data set (see Appendix 2) and the conditions for access.</p> <p>47. Prior to publication, sufficient means should be taken to ensure that no individual can be identified from the information provided.</p>		
	12.2. Accession	63. The biological material received should be accompanied by information required by the individual BRC.		
	14.3. Information provided with the biological material supplied	<p>85. The BRC should at least provide to the user:</p> <ul style="list-style-type: none"> i) A minimum data set according to the type of resource (See Appendix 2) ii) The repository conditions needed to maintain the biological material (temperature, medium, culture conditions etc.). iii) The transportation conditions. iv) A safety data sheet in the case of a material containing a hazardous organism or its derivative, including the containment level required for handling the biological material, disposal measures and measures to take in case of spillage. Human cells, tissues should always be treated as hazardous unless they are tested for infectious diseases or treated with an appropriate inactivation measure (e.g. fixation with formaldehyde). The safety data sheet should be mandatory for any dangerous material and should be included in the package, together with instructions for handling. <p>86. In circumstances in which information is supplied that pertains to a donor's identity, such information should be encrypted (type of code depending on procedures previously determined).</p>		
B.6.2 機能範囲—生物試料の 特定および追跡	10. Services of BRCs	<p>48. BRCs may engage in research and development activities relevant to their missions.</p> <p>49. BRCs may provide services in accordance with ethical and legal regulations.</p> <p>50. BRC should take reasonable steps to ensure that services from an outside provider are rendered in accordance with the regulations and good practices in force in the appropriate field, that are applicable in the jurisdiction relevant to the BRC as well as in the jurisdiction relevant to where the service is to be performed.</p> <p>51. Inflows and outflows of biological material should be recorded, and when it is necessary to transport samples, their transport should be documented and carried out in compliance with the applicable standards and regulations.</p>	7.5.3 Identification and traceability	<p>Where appropriate, the organization shall identify the product by suitable means throughout product realization.</p> <p>The organization shall identify the product status with respect to monitoring and measurement requirements throughout product realization.</p> <p>Where traceability is a requirement, the organization shall control the unique identification of the product and maintain records (see 4.2.4).</p>
B.6.3 双方向の運用性				
B.6.4 ヒト生物資源保管の情報 処理管理システムの開 発				
B.6.5 ヒト生物資源保管の情報 処理管理システムの選 択				
B.6.6 ヒト生物資源保管の情報 処理システムの検証お よび適用				
B.6.7 情報処理システムに関 連する規制上の問題	9.2. Security of data	<p>43. In order to guarantee security, BRCs should use a specific database for storing the personal data of the donor, never available to outsiders. Such data should be updated as additional information related to donors become available.</p> <p>44. Data should be saved reasonably regularly in order to avoid data loss.</p>		

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C 倫理上、法律上および政策上の実務要領	4.1. Compliance with law and ethics regulations 10. BRCs must comply with appropriate national and international laws, international rules and regulations and should follow the Ethical Committee's recommendations concerning use of human-derived biological materials and ethics. 11. In particular, human BRCs should respect laws and regulations in the areas of: i) National certification of Biological Resource Centres, where such systems may be in place under the responsibility of national governments. ii) Professional secrecy. iii) Health and Safety (including Good Management Practice) or good manufacturing practice. iv) Ownership of Intellectual Property Rights (IPR), when applicable. v) Ethical matters, including, as appropriate, informed consent and respect for human dignity. vi) Management of data bases and security of associated data. vii) Employee safety. viii) Environmental safety. ix) Transport legislation, including import and export. x) Classification of biological material on the basis of hazard (to take into account the actual or potential infectious status of human-derived biological material). In particular, BRCs should comply with (Best Practice Guidelines on Biosecurity for BRCs). 12. When engaged in activities related to the collection and use of human-derived material, BRCs should ensure: xi) The preservation of the donor's dignity. xii) The respect for the autonomy of the donor, particularly through informed consent, up to and including the possibility to withdraw his/her informed consent when samples and derived data have been stored in an identifiable manner. xiii) The right of each individual to decide whether or not to be informed of the results of research if human-derived biological material is not anonymous. xiv) The protection of the confidentiality of data stored or processed for research purposes. xv) That the only samples included in a BRC are those for which enough material for potential future diagnostics and clinical purposes for the donor and/or his/her family, is available. Biological material collected without informed consent can, however, be distributed by BROs so long as such actions have the approval of an ethical committee in accordance with national regulations.	
C.1 管理者責任 (responsible custodianship) の原則	4.3. Responsibilities of management 14. The BRC manager (see General Best Practice Guidelines for BRCs) should be qualified to make sound decisions, particularly on ethical, scientific and managerial issues. He/she should have the responsibility particularly to confirm: i) The establishment of proper procedures for the sound operation of the BRC. ii) The respect of ethical rules. iii) The implementation and surveillance of quality control. iv) The application of the decisions of the Review Board regarding control, access to and use of biological material. v) The publication of general information on the activities of the BRC and research results obtained by using the biological material. 15. Many biological materials are initially collected for clinical purposes; their transfer into a BRC environment for research purposes and distribution need specific management (e.g. quality control, traceability, management of consent).	5 Management responsibility 5.1 Management commitment Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements, b) establishing the quality policy, c) ensuring that quality objectives are established, d) conducting management reviews, and e) ensuring the availability of resources 5.5.2 Management representative Top management shall appoint a member of the organization's management who, irrespective of other responsibilities, shall have responsibility and authority that includes a) ensuring that processes needed for the quality management system are established, implemented and maintained, b) reporting to top management on the performance of the quality management system and any need for improvement, and c) ensuring the promotion of awareness of customer requirements throughout the organization.
C.1.1 ガバナンス	4.3. Responsibilities of management 14. The BRC manager (see General Best Practice Guidelines for BRCs) should be qualified to make sound decisions, particularly on ethical, scientific and managerial issues. He/she should have the responsibility particularly to confirm: i) The establishment of proper procedures for the sound operation of the BRC. ii) The respect of ethical rules. iii) The implementation and surveillance of quality control. iv) The application of the decisions of the Review Board regarding control, access to and use of biological material. v) The publication of general information on the activities of the BRC and research results obtained by using the biological material. 15. Many biological materials are initially collected for clinical purposes; their transfer into a BRC environment for research purposes and distribution need specific management (e.g. quality control, traceability, management of consent).	5.4 Planning 5.4.1 Quality objectives Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy. 5.4.2 Planning of the quality management system Top management shall ensure that a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

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			5.5	Responsibility, authority and communication
C.1.2 レガシープラン/危機管理計画	8.	Documentation management 28. All documents should be readable and stored in a place where they can easily be located by authorised staff. They should be conserved in an environment which will avoid deterioration, fire damage, loss and/or tampering. 29. BRCs should use a data management system that includes a computerised inventory tracking system with appropriate security/data-access control safeguards. 30. All BRC procedures should be subject to documentary management throughout their lifetime. 31. All movements into or out of the collection of biological material should be documented. 32. Often, human BRCs require that stored biological material be linkable to the personal genealogical and clinical data of the donor. It is imperative that security and confidentiality are respected to address privacy issues. Any documentation on biomedical data should be kept in secure cabinets accessible only to authorised personnel. 33. The documentation managed by databases should be saved, secured and duplicated in a different site. 34. BRCs should develop a disaster plan which includes appropriate privacy protection for personal information and equipment.		
C.1.3 保管に関する方針	12.1.	Receipt and handling of biological material 56. BRCs should implement safe, documented procedures for the receipt and storage of humanderived biological material that are appropriate to the hazard posed by such material. All incoming parcels that contain unknown or hazardous biological material should be opened in a suitable containment laboratory or appropriate microbiological safety cabinet with local facilities for the safe handling and disposal of biological material. Safety procedures should be laid down and documented. 57. Conditions of deposit should be determined and agreed upon, if pertinent, in a material transfer agreement (MTA). Where deposits are outside the remit of a BRC, suitable BRCs should be recommended. 58. The depositor should provide proof that prior informed consent to collect and deposit the primary human-derived biological material in a BRC has been obtained or reasonable efforts have been taken to obtain such consent (with proof of ethical review). 59. On deposit of human-derived biological material, BRCs should record ownership and terms and conditions for further distribution. 60. A unique identification number should be allocated to the biological material, which should never be reassigned to other material even if the original biological material is later discarded. 61. In any situation in which a BRC has in its possession information that could identify a donor, such information should be dissociated from the biological material concerned and any other associated data. 62. Specific care should be taken to ensure that data in the possession of a BRC is not misused in such a way as to cause harm to individuals or groups of individuals.	5.3	Quality policy Top management shall ensure that the quality policy a) is appropriate to the purpose of the organization, b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system, c) provides a framework for establishing and reviewing quality objectives, d) is communicated and understood within the organization, and e) is reviewed for continuing suitability.
C.1.4 利益相反			5.2	Customer focus Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).
C.1.5 機密保持およびセキュリティ	4.1.	Compliance with law and ethics regulations 10. BRCs must comply with appropriate national and international laws, international rules and regulations and should follow the Ethical Committees recommendations concerning use of human-derived biological materials and ethics. 11. In particular, human BRCs should respect laws and regulations in the areas of: i) National certification of Biological Resource Centres, where such systems may be in place under the responsibility of national governments. ii) Professional secrecy. iii) Health and Safety (including Good ManagementPractice) or good manufacturing practice. iv) Ownership of Intellectual Property Rights (IPR), when applicable. v) Ethical matters, including, as appropriate, informed consent and respect for human dignity. vi) Management of data bases and security of associated data. vii) Employee safety. viii) Environmental safety. ix) Transport legislation, including import and export. x) Classification of biological material on the basis of hazard (to take into account the actual or potential infectious status of human-derived biological material). In particular, BRCs should comply with (Best Practice Guidelines on Biosecurity for BRCs). 12. When engaged in activities related to the collection and use of human-derived material, BRCs should ensure: xi) The preservation of the donor's dignity. xii) The respect for the autonomy of the donor, particularly through informed consent, up to and including the possibility to withdraw his/her informed consent when samples and derived data have been stored in an identifiable manner. xiii) The right of each individual to decide whether or not to be informed of the results of research if human-derived biological material is not anonymous. xiv) The protection of the confidentiality of data stored or processed for research purposes. xv) That the only samples included in a BRC are those for which enough material for potential future diagnostics and clinical purposes for the donor and/or his/her family, is available. Biological material collected without informed consent can, however, be distributed by BRCs so long as such actions have the approval of an ethical committee in accordance with national regulations.		

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C.1.6 バブリック・コミュニケーション			5.5.2 Management representative	Top management shall appoint a member of the organization's management who, irrespective of other responsibilities, shall have responsibility and authority that includes a) ensuring that processes needed for the quality management system are established, implemented and maintained, b) reporting to top management on the performance of the quality management system and any need for improvement, and c) ensuring the promotion of awareness of customer requirements throughout the organization.
C.2 インフォームド・コンセント	4.1. Compliance with law and ethics regulations	10. BRCs must comply with appropriate national and international laws, international rules and regulations and should follow the Ethical Committees recommendations concerning use of human-derived biological materials and ethics. 11. In particular, human BRCs should respect laws and regulations in the areas of: i) National certification of Biological Resource Centres, where such systems may be in place under the responsibility of national governments. ii) Professional secrecy. iii) Health and Safety (including Good ManagementPractice) or good manufacturing practice. iv) Ownership of Intellectual Property Rights (IPR), when applicable. v) Ethical matters, including, as appropriate, informed consent and respect for human dignity. vi) Management of data bases and security of associated data. vii) Employee safety. viii) Environmental safety. ix) Transport legislation, including import and export. x) Classification of biological material on the basis of hazard (to take into account the actual or potential infectious status of human-derived biological material). In particular, BRCs should comply with (Best Practice Guidelines on Biosecurity for BRCs). 12. When engaged in activities related to the collection and use of human-derived material, BRCs should ensure: xi) The preservation of the donor's dignity. xii) The respect for the autonomy of the donor, particularly through informed consent, up to and including the possibility to withdraw his/her informed consent when samples and derived data have been stored in an identifiable manner. xiii) The right of each individual to decide whether or not to be informed of the results of research if human-derived biological material is not anonymous. xiv) The protection of the confidentiality of data stored or processed for research purposes. xv) That the only samples included in a BRC are those for which enough material for potential future diagnostics and clinical purposes for the donor and/or his/her family, is available. Biological material collected without informed consent can, however, be distributed by BRCs so long as such actions have the approval of an ethical committee in accordance with national regulations.		
C.2.1 インフォームド・コンセントに関連する連邦規制およびガイドライン				
C.2.2 インフォームド・コンセントに関連する NCIの全般的勧告				
C.2.3 インフォームド・コンセントの重要要素および補足資料に関連する NCIの勧告				
C.2.4 研究への参加の中止に関連する問題				
C.2.5 小児の生物試料の使用に関連する考慮事項				
C.3 プライバシーおよび機密性の保護	8. Documentation management	28. All documents should be readable and stored in a place where they can easily be located by authorised staff. They should be conserved in an environment which will avoid deterioration, fire damage, loss and/or tampering. 29. BRCs should use a data management system that includes a computerised inventory tracking system with appropriate security/data-access control safeguards. 30. All BRC procedures should be subject to documentary management throughout their lifetime. 31. All movements into or out of the collection of biological material should be documented. 32. Often, human BRCs require that stored biological material be linkable to the personal genealogical and clinical data of the donor. It is imperative that security and confidentiality are respected to address privacy issues. Any documentation on biomedical data should be kept in secure cabinets accessible only to authorised personnel. 33. The documentation managed by databases should be saved, secured and duplicated in a different site. 34. BRCs should develop a disaster plan which includes appropriate privacy protection for personal information and equipment.		
C.3.1 プライバシーに関連する連邦規制				
C.3.2 プライバシーおよび機密性に関連するNCIの勧告				
C.4 生物試料および情報の利用			7.2 Customer-related processes	
C.4.1 利用の決定に関連する一般原則			7.2.1 Determination of requirements related to the product	The organization shall determine a) requirements specified by the customer, including the requirements for delivery and post-delivery activities, b) requirements not stated by the customer but necessary for specified or intended use, where known, c) statutory and regulatory requirements applicable to the product, and d) any additional requirements considered necessary by the organization.

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C.4.2 研究の計画				
C.4.3 利用の方針				
C.4.4 持続可能性のモデル	4.2. Long-term sustainability.	13. BRCs serve an invaluable function by acquiring, maintaining, and providing human-derived biological materials. BRCs should have procedures in place that comply with their host country's regulations and ethical provisions regarding human-derived biological materials, to ensure that their key holdings (biological material and data) remain available to those that need access to them.	7.2.2 Review of requirements related to the product	The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that a) product requirements are defined, b) contract or order requirements differing from those previously expressed are resolved, and c) the organization has the ability to meet the defined requirements. Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4). Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance. Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.
C.4.5 生物試料の使用可能性				
C.5 知的財産および資源の共有			7.2.3 Customer communications	The organization shall determine and implement effective arrangements for communicating with customers in relation to a) product information, b) enquiries, contracts or order handling, including amendments, and c) customer feedback, including customer complaints.
C.5.1 試料移転合意書 (Material Transfer Agreements: MTA)				
C.5.2 発明者要件 (inventorship)				
C.5.3 知的財産権				
C.5.4 ライセンス付与				
C.5.5 情報および資源の共有				
C.6 利益相反				
C.6.1 研究者の金銭的な利益相反				
C.6.2 機関の金銭的な利益相反				
C.6.3 金銭的でない利益相反				
Term用語解説	3. Definitions.	9. These complement the definitions given in General Best Practice Guidelines for BRCs. Human-derived biological material: For the purpose of these best practice guidelines, these are biological materials that are tissues, cells, cell lines and other human-derived components (as defined in General Best Practice Guidelines for all BRCs), and associated data (see definition), used for scientific research. Such biological material may be derived from individuals, families or population groups. Collections: Assemblage, for research purposes, of biological material selected on the basis of clinical or biological characteristics Associated data: Relevant information, using internationally recognised standards if possible, by which biological material can be identified and classified. Donor: The individual from whom the biological material was derived. Review board: Group of independent experts specialising in fields of, for example, science, medicine, ethics, data protection and protection of privacy etc. Ethical Committee: A group nominated for the BRC or by the BRC or its host organisation able to draw upon appropriate fields of expertise, for example, related to issues of informed consent or intellectual property rights, relevant to ethical review. Custodian: The person or legal entity initiating a collection. User: Person authorised to use the biological material and/or associated data delivered by a BRC for scientific purposes. Service: Work performed for a client (e.g. preparation, packaging, transport, duplication, storage, quality control, analysis), whether or not for a fee	3 Terms and definitions	For the purposes of this document, the terms and definitions given in ISO 9000 apply. Throughout the text of this International Standard, wherever the term "product" occurs, it can also mean "service".

