ISBER
INTERNATIONAL SOCIETY FOR BIOLOGICAL AND ENVIRONMENTAL REPOSITORIES

Connecting Repositories Globally through Best Practices
leading since 1999

ISBER Best Practices: Recommendations for Repositories

"*From Collection to Discovery*"

Webinar - February 2nd, 2018

#ISBERBestPractices #ISBERBP2018 #BiobankingBestPractices2018

Introduction to ISBER

ISBER is the only global forum that addresses harmonization of scientific, technical, legal, and ethical issues relevant to repositories of biological and environmental specimens.

Mission

ISBER is a global biobanking organization which creates opportunities for networking, education, and innovations and harmonizes approaches to evolving challenges in biological and environmental repositories.

Vision

ISBER will be the leading global biobanking forum for promoting harmonized high quality standards, education, ethical principles, and innovation in the science and management of biorepositories.

Schedule

Presenters	Topic	Duration
Daniel Simeon-Dubach	Introduction and Background Rationale for Update and Process of Updating the Best Practice Guidelines	10
Heidi Wagner	Summary of Changes	15
Cathy Seiler	Communication of Updates Adaptation of Materials to Align with the Best Practices Dissemination to Non-English Speaking Regions	10
Marianna Bledsoe	Discussion	15

Introduction and Background

Daniel Simeon-Dubach

medservice, biobank consulting & services

Walchwil, Switzerland

Chair, ISBER Standards Advisory Committee

Modern Biobanking in the 21st Century

isber
INTERNATIONAL SOCIETY FOR BIOLOGICAL AND ENVIRONMENTAL REPOSITORIES

ISO International Organization for Standardization

Time Period	2000+	2010+	2020+
Significant Challenges	ELSI, Quality, Ownership	Sustainability, Reproducibility	Professionalism, Standards
Importance and Acknowledgement of Biobanks	*	***	*****

What are Best Practices?

Techniques, procedures, or methods that are used to maintain quality as a complement to mandated or regulated standards.

Guidelines on effective practices for management of specimen collections and repositories.

- Consensus-based.
- Evidence-based when possible.

Best Practice vs. Standards

- Best practices do not constitute a mandatory standard; rather they are recommendations that can support the development of SOPs in the context of the repository's quality management system.
- Standards represent requirements that are often used to pursue accreditation, certification, or other form of conformity assessment.

Adoption of best practices will vary based on the goals and circumstances of a given initiative and may not be possible to implement in all instances.

History of ISBER Best Practices

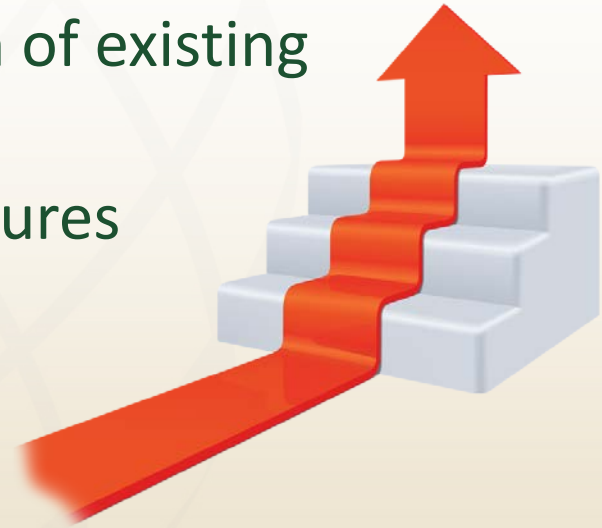
ISBER was founded in 1999 with a Key Objective to develop harmonized principles in the science and management of repositories.

- **1st edition, 2005**
  - Addressed only human specimens, U.S.-centric.
- **2nd edition, 2008**
  - Revised to include environmental repositories and international perspective.
- **3rd edition, 2012**
  - Expanded to include Cost Management and Specimen Access, Utilization, and Destruction.
- **4th edition, 2018**
  - Updated to reflect advances in biospecimen science and new technologies.

Aim of ISBER Best Practices

Harmonization of the scientific, technical, legal, and ethical issues relevant to repositories of biological and environmental specimens.

- Improve quality management of specimens.
- Provide guidance to improve policies and procedures.
- Assist in evaluation and optimization of existing practices.
- Assist in development of new procedures and performance of administrative oversight.



Content of ISBER Best Practices

- Reflect the collective knowledge and experience of experts in biobanking and repository management.
- Addresses scientific, technical, legal, and ethical issues relevant to repositories of biological and environmental specimens.



Content of ISBER Best Practices (cont.)

- Effective practices are presented throughout the document.
- Term “Best Practice” is used:
  - for a level of operation that is above the basic recommended practice.
  - to more specifically designate the most effective practice.
- Includes standardized terminology and definitions for use by the global biobanking community.

How to use ISBER Best Practices

- No detailed procedures but consists of principles by which policies and procedures should be developed.
- Achieving full compliance regarded as pinnacle of success, but few organizations will reach this level of quality.

- Repositories should decide how best to incorporate these recommendations as each Best Practice may not be applicable for each type of repository.

Repositories should refer directly to their own national/federal, regional, and local regulations and requirements, as appropriate.

Rationale for Update

- New developments in biospecimen science.
- Technological innovations.
- To remain current on ethical, legal, and social issues relevant to repositories.

"Best" Practices evolve as new technologies and practices are discovered.

The Updating Process

Phase 1

- Project Plan Established
- Editorial Board Selected
- Solicitation for Contributors

Phase 2

- Editorial Board Meetings (overall content discussions, format changes, additional sections defined, Section Leaders assigned)

The Updating Process (cont.)

Phase 3

- Contributions
- Input from Best Practices International Review Board

Phase 4

- Working Group (WG) and Special Interest Group (SIG) Review
- Standards Advisory Committee Review

Phase 5

- Board Review and Approval
- Publication/Release (January 31st 2018 on the ISBER website)

Summary of Changes

Heidi Wagner

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Supervisor, Pathologists' Assistants
Translational Molecular Pathology
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ISBER Education and Training Committee member

The fourth edition builds on the foundation established in the previous versions.

Includes new areas of interest to the biobanking community, expands and updates existing topics, and presents an international perspective that reflects the growing diversity of the ISBER membership.

New Topics

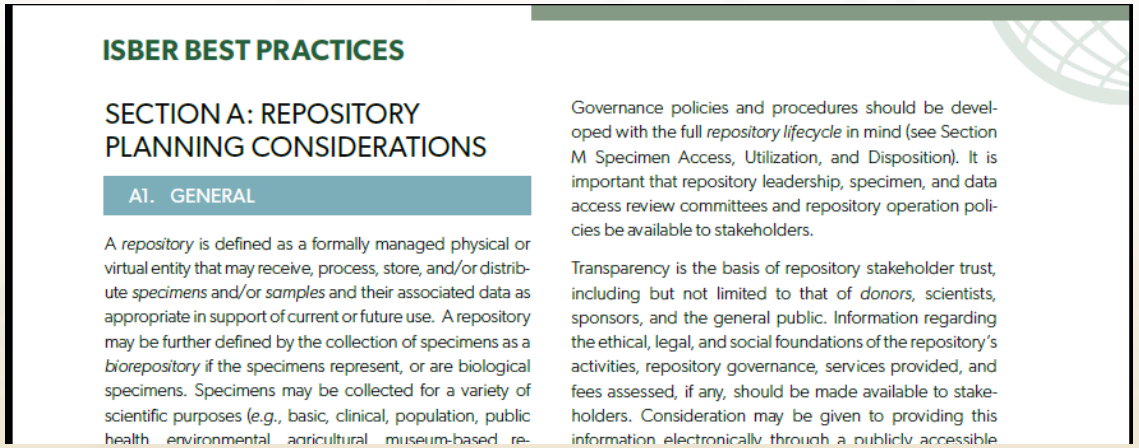
- ***Repository Planning Considerations*** now includes Repository Governance and Development of a Governance Plan.
- **Access and Benefit Sharing** of materials derived from non-human sources.
- Biological Hygiene Plan added to ***Safety.***
- **Quality Assurance** considerations (Key Performance Indicators, Non-conformities, Corrective and Preventive Actions) added to ***Quality Management*** section.

New Topics (cont.)

- Guidance on identification of appropriate specimen storage container labels/identifiers.
- Cold Chain and Cold Chain Validation added to ***Packaging and Shipping.***
- Automated Storage Systems and Automated Liquid Handling Robotics added to ***Storage and Processing Equipment.***
- Cloud Computing and descriptions of Data Exchange Standards added to ***Repository Information Management Systems.***

Areas of Expansion

- Expansion of **Establishing Repository Models** to include Federated Collections and Biodiversity and Environmental Biobanks.
- Development of a repository business plan discussed in greater depth.



ISBER BEST PRACTICES

SECTION A: REPOSITORY PLANNING CONSIDERATIONS

A1. GENERAL

A *repository* is defined as a formally managed physical or virtual entity that may receive, process, store, and/or distribute *specimens* and/or *samples* and their associated data as appropriate in support of current or future use. A repository may be further defined by the collection of specimens as a *biorepository* if the specimens represent, or are biological specimens. Specimens may be collected for a variety of scientific purposes (*e.g.*, basic, clinical, population, public health, environmental, agricultural, museum-based, re-

Governance policies and procedures should be developed with the full *repository lifecycle* in mind (see Section M Specimen Access, Utilization, and Disposition). It is important that repository leadership, specimen, and data access review committees and repository operation policies be available to stakeholders.

Transparency is the basis of repository stakeholder trust, including but not limited to that of *donors*, scientists, sponsors, and the general public. Information regarding the ethical, legal, and social foundations of the repository's activities, repository governance, services provided, and fees assessed, if any, should be made available to stakeholders. Consideration may be given to providing this information electronically through a publicly accessible

Areas of Expansion (cont.)

Significant updates in areas addressing **Quality Management.**

ISBER BEST PRACTICES

SECTION E: METHOD VALIDATION AND QUALITY CONTROL CONSIDERATIONS

E1. VALIDATION OF SAMPLE PROCESSING METHODS

Repositories should use validated *processing* methods for their specimens. The *repository* can use scientific literature, feedback from the end users, and/or laboratory *quality control* results to evaluate and validate a processing method. The repository should list the circumstances requiring new validation measures to be taken (*e.g.*, instrument changes, specimen type changes). Each processing method should be validated for one or more specific intended end uses.

If no relevant scientific literature is available, the repository may have biospecimen research performed to assess the potential impact of the most important pre-analytical variables, following recommendations on biospecimen research. Features of biospecimen quality, including structure of proteins, function of enzymes, level of metabolites, gene expression levels, DNA methylation status, cell viability, and microorganism viability, can be affected by the specific procedures followed during *sample* collection, transport, isolation, and storage.

Implementation of a system to track pre-analytical variables will facilitate tracking and communication of the critical sample processing steps[3,4] in lieu of more sophisticated methods found in relational *databases* and laboratory information systems (LIS/LMS) that allow for aggregation of pre-analytical data (*i.e.*, time to processing, time to storage).

Best Practices: A pre-approved documented method evaluation plan should describe the methods used in the verification/validation, what is in/out of scope of the verification/validation, and the proposed criteria which will be used to determine the outcome of the evaluation. A summary *document* should be created after the validation exercise to accurately represent the results of the method validation.

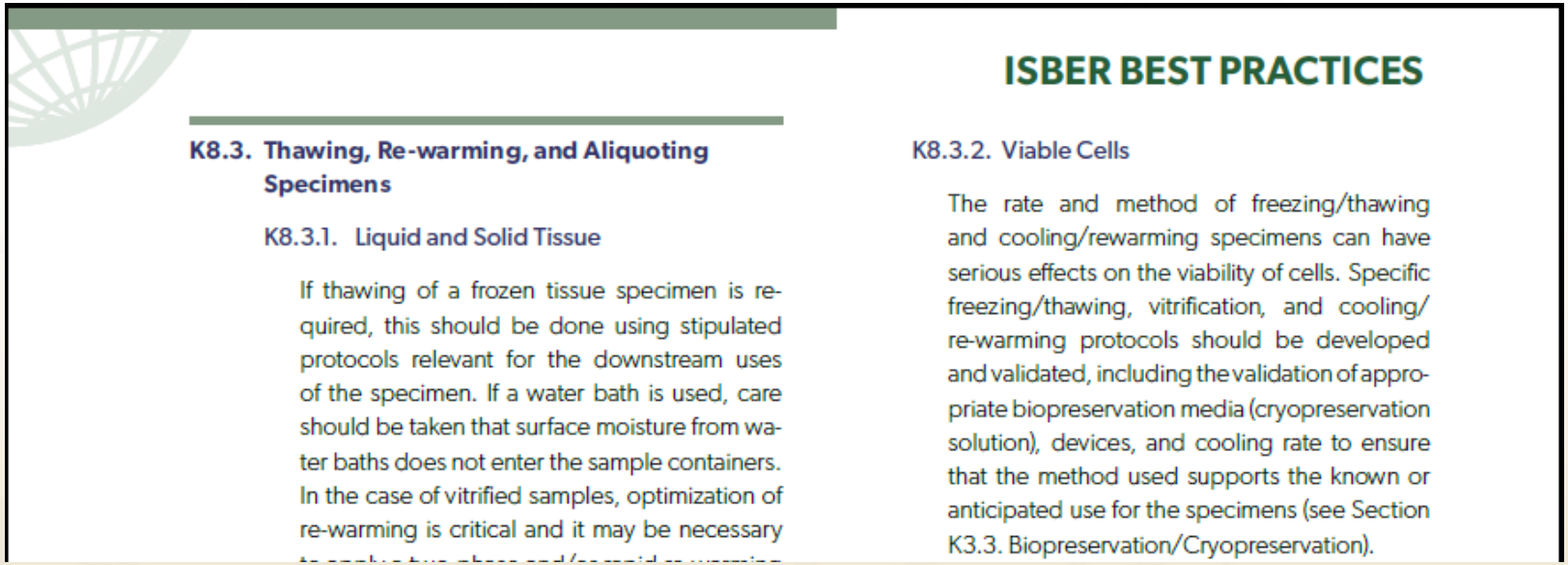
Best Practice: External Quality Assurance programs should be followed, where available, at least once a year.

E2. METHOD EVALUATION CONSIDERATIONS FOR SPECIFIC TYPES OF SPECIMENS

Many of the QC processes are generic across all types of repositories and they concern the four "pillars" of *collection* quality:

Areas of Expansion (cont.)

Additional details added to ***Specimen Collection, Processing, Receiving, and Retrieval*** section.



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K8.3. Thawing, Re-warming, and Aliquoting Specimens

K8.3.1. Liquid and Solid Tissue

If thawing of a frozen tissue specimen is required, this should be done using stipulated protocols relevant for the downstream uses of the specimen. If a water bath is used, care should be taken that surface moisture from water baths does not enter the sample containers. In the case of vitrified samples, optimization of re-warming is critical and it may be necessary

K8.3.2. Viable Cells

The rate and method of freezing/thawing and cooling/rewarming specimens can have serious effects on the viability of cells. Specific freezing/thawing, vitrification, and cooling/re-warming protocols should be developed and validated, including the validation of appropriate biopreservation media (cryopreservation solution), devices, and cooling rate to ensure that the method used supports the known or anticipated use for the specimens (see Section K3.3. Biopreservation/Cryopreservation).

Additional Revisions

- Section Title Changes

  (*example:* Publishing and Provision of Data to Repositories retitled to ***Acknowledging Repositories and Reporting Utilization***)

- Section Relocations

  (*example:* Records Management incorporated into **Quality Management**)

- Section Updates

  (*example:* Informatics updates in ***Repository Information Management Systems***)

Example of a “Best Practice”

B5.2. Generators

The most common type of backup power is a motor generator. Generators have automatic controls that cause them to produce electricity when commercial power is interrupted and are typically fueled by diesel, natural gas, or propane. The actual backup system employed should be determined based upon a risk management assessment of the facility, region, and resources.

Best Practice: A generator should have a fuel supply to run continuously for a minimum of 48 hours and preferably a minimum of 72 hours, with an ability to re-fill fuel storage supplies.

Internet Resources

ISBER BEST PRACTICES

APPENDIX A: INTERNET RESOURCES

These internet references are made available for information only. ISBER does not warrant any of the information contained therein.

SUBJECT	WEBSITE	ORGANIZATION/SOURCE	TOPICS
Access and Benefit Sharing (Genetic Resources)	http://abs.scnat.ch	Swiss National Academy of Sciences	The joint regulation of access to genetic resources and the sharing of benefits arising from their use by the researchers or companies from user countries and the representatives of the states, in which the genetic resources have been accessed
Access and Benefit Sharing (Genetic Resources)	https://www.cbd.int/	Convention on Biological Diversity	Bonn Guidelines and the Nagoya Protocol that address sharing the benefits from the utilization of genetic resources in a fair and equitable way
Access and Benefit Sharing (Plant Genetics)	http://www.fao.org/plant-treaty/en/	Food and Agriculture Organization of the United Nations	International Treaty on Plant Genetic Resources for Food and Agriculture addresses conservation and sustainable use of plant genetic resources
Access and Benefit Sharing (Biodiversity)	https://absch.cbd.int/	The Access and Benefit-sharing Clearing-house (ABSCH)	A platform for exchanging information on access benefit sharing and a key tool for facilitating the implementation of the Nagoya Protocol

Standardization of Terminology and Definitions

- Document utilizes terminology that is generally understood among all repositories, limiting the use of sector-specific terms.
- Glossary provides clarification where terms are used ambiguously in the biobanking community.

Example - use of “specimen” and “sample” vary significantly when used in a clinical versus biodiversity and/or environmental setting.

Communication and Dissemination Strategies

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Chair, ISBER Communications Committee

Fourth Edition of ISBER Best Practices

"From Collection to Discovery"

#ISBERBestPractices
#ISBERBP2018
#BiobankingBestPractices2018

Published January 31, 2018:

www.isber.org/bestpractices

Ideas and Suggestions are welcome
bestpractices@isber.org

Upcoming Articles in BIO

- February 15th 2018: *"Special Section on Standards, Tools, and Best Practices for Modern Biobanking"*
  - Editorial - Daniel Simeon-Dubach, Zisis Kozlakidis
  - Summary of Best Practices, History, Process, and Changes - Lori Campbell *et al*.
  - Update on Self-Assessment Tool - Fay Betsou
  - Standard PREanalytical (SPREC) Code version 3.0 - Fay Betsou *et al*.
  - ISBER Best Practice-Based Education – Sheila O'Donoghue *et al*.
  - CAP Biorepository Accreditation Program - Shannon McCall *et al*.
  - Update on ISO/TC276/WG2 Biobanking Standards - Koh Furuta et al.
- ISBER Corner: The intent and use of the Best Practices - Zisis Kozlakidis
- http://online.liebertpub.com/loi/bio

Citing the Best Practices

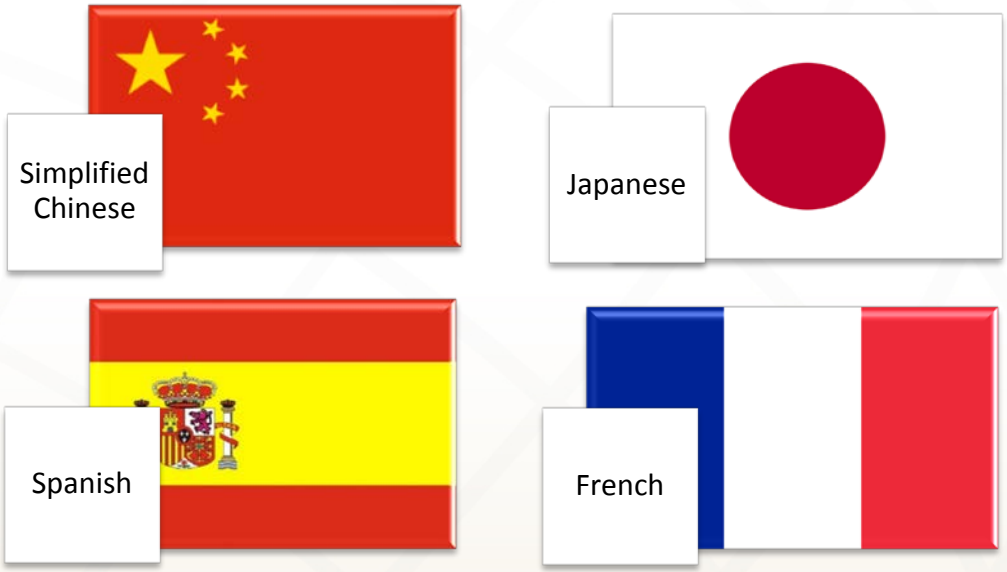
Authors wishing to cite the Best Practices in their publications should reference them as below:

Campbell, *et al*. ISBER Best Practices: Recommendations for Repositories, Fourth Edition; Biopreserv Biobank 2018; DOI: 10.1089/bio-2018-0001

Adaptation of ISBER Materials to Align with the Best Practices

- The Education and Training Committee will coordinate the delivery of 10 webinars by ISBER experts on important topics covered in the updated Best Practices guidelines.
- The ISBER-CTRNet online education will be updated to reflect the new changes (http://www.isber.org/IntrotoBiobanking).
- ISBER Self-Assessment Tool (SAT) will be revised to include new topics and updates to existing topics (http://www.isber.org/SAT).

Translations



- Please go to the best practices webpage (isber.org/bestpractices) to sign up to receive notifications as to when translations will be available.
- Announcements on social media.
- More translations to follow.

Special Thanks to…

All Individual Contributors to the 4th Edition!

Best Practices Editorial Board

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UPCOMING ISBER MEETINGS

SEIZING **BIG** OPPORTUNITIES IN **BIOBANKING** THROUGH DATA, COLLABORATION AND INNOVATION

Biospecimen Research Symposium

QUALITY MATTERS

EVENT DETAILS COMING SOON!

Questions…

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