



Approval process for BBMRI-ERIC

Procedures, guidelines and standards

V2.0

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2 OBJECTIVE

On the basis of a broad pan-European network of experts in the field of biobanking and biomolecular resources research, BBMRI-ERIC supports user driven need in the development of BBMRI-ERIC specific procedures, guidelines and standards.

This document describes the approval process for BBMRI-ERIC procedures, guidelines and standards, the application criteria the assessment and vote process

Adopted by Assembly of Members 27 October 2015.

3 TERMS AND DEFINITION

Terms	Definition
BBMRI-ERIC procedure	A BBMRI-ERIC procedure is relevant for the research and scientific advancement of the Member states, Observer countries and stakeholders.
BBMRI-ERIC guideline	A BBMRI-ERIC guideline is a set of procedures based on identified user needs and developed by an expert group of the BBMRI family for intended use.
CEN - European Committee for Standardisation	<p>CEN is one of three European Standardization Organizations (together with CENELEC and ETSI) that have been officially recognized by the European Union and by the European Free Trade Association (EFTA) as being responsible for developing and defining voluntary standards at the European level. CEN supports standardization activities in relation to a wide range of fields and sectors including: air and space, chemicals, construction, consumer products, defence and security, energy, the environment, food and feed, health and safety, healthcare, ICT, machinery, materials, pressure equipment, services, smart living, transport and packaging.</p> <p>www.cen.eu</p>
ISO – International Organisation for Standardisation	<p>ISO is an independent, non-governmental membership organization and the world’s largest developer of voluntary International standards, made up of 162 member countries.</p> <p>A standard is a document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose; established by consensus and approved by a recognized body.</p> <p>www.iso.org</p>
BBMRI-ERIC standard	BBMRI-ERIC standards fill the gap between existing European and International standards and the need for specific standards for practical use in biobanking and biomolecular resources research.
DG	Director General of BBMRI-ERIC

BBMRI-ERIC-HQ	BBMRI-ERIC Headquarter (DG and Central Executive Management Office), Neue Stiftingtalstrasse 2/B/6, 8010 Graz
MC	Management Committee (Statutes of BBMRI-ERIC, Official Journal of the EU 30 November 2013, L320/63-80, Article 14)
AoM	Assembly of Members (Statutes of BBMRI-ERIC, Official Journal of the EU 30 November 2013, L320/63-80, Article 10)

4 DESCRIPTION OF APPROVAL PROCEDURE FOR BBMRI-ERIC PROCEDURES, GUIDELINES AND STANDARDS

BBMRI-ERIC procedures, guidelines and standards are systematically developed statements and recommendations, which assist the scientific community of biobanking and biomolecular resources research and stakeholders to make informed decisions about research undertakings. In general procedures, guidelines and standards differ from regulations, directives and decisions, in that they are not legal binding. However, power procedures, guidelines and standards disseminated by BBMRI-ERIC do have a political weight, without obligatory power, for Member States, Observer countries and for unique stakeholders with the strong recommendation to be implemented in the scientific and organisational tasks, to foster efficacy and excellence of the European biomedical research.

4.1 BBMRI-ERIC procedures

General

The BBMRI-ERIC procedure is an instrument of indirect action focusing the preparation of guidelines and standards following the vision of harmonisation within the BBMRI-ERIC family.

In general, once a procedure relevant for the research and scientific advancement of the Member states, Observer countries and particular stakeholders for BBMRI-ERIC is investigated and considered favourable, this procedure will be approved, implemented and disseminated in the BBMRI-ERIC family by Director General.

Assembly of Members, Management Committee or BBMRI-ERIC-HQ can submit a procedure to BBMRI-ERIC.

The written submitting documents meet following criteria

1. Definition of purpose and scope of the submitted procedure
2. Description of methods used for the development of the specific procedure
3. Procedure format (Edited and proof read)
 - a. Executive summary
 - b. Main procedure
 - c. Appendices (References)

Assessment

Director General ensures that BBMRI-ERIC procedures are of high quality and are developed through a transparent and systematically developed process.

Vote

The approval or rejection of the submitted procedures is the task of Director General.

In terms of conflict of interest, Director General will pass on this obligation to the Management Committee.

4.2 BBMRI-ERIC guidelines

General

BBMRI-ERIC guidelines meet the need for biobanking and biomolecular resources research and follow a best practice research perspective.

A BBMRI-ERIC guideline is a set of procedures based on identified user needs and developed by an expert group of the BBMRI family for intended use.

Assembly of Members, Management Committee or BBMRI-ERIC-HQ can submit a guideline to BBMRI-ERIC.

The BBMRI-ERIC management process for assessing BBMRI-ERIC guidelines includes two feasible request procedures:

1. **A user request for guideline development** is proposed to BBMRI-ERIC
BBMRI-ERIC will support the development of the guidelines. The final proposal for the guideline will be submitted, assessed and voted as described hereinafter.
2. **A existing guideline (not yet published) is proposed** to BBMRI-ERIC for approval
BBMRI-ERIC will assess the already proposal of the guideline as described hereinafter

The written submitting documents meet following criteria

1. Definition of purpose and scope of the submitted guideline
2. Description of methods used for the development of the specific guideline
 - a. Scientific based evidence of need, identified by systematic review, external review, or expert recommendation
3. Guideline format (Edited and proof read)
 - a. Executive summary
 - b. Main Guideline
 - c. Appendices (References)

Assessment

The assessment of the submitted guideline proposed for BBMRI-ERIC approval verifies if the guideline meets an unmet need and uses internationally accepted best practices, including the scientific based evidence of need.

Director General ensures that BBMRI-ERIC guidelines are of high quality and are developed through a transparent and systematically developed process and DG will, if applicable, invite an ad hoc expert review committee, with technical capabilities to evaluate the guideline proposal.

The review of the final submitting documents [1-3] ensures that the guideline developing process follows the requested criteria and contains a clear and valuable guideline.

Director General will bring forward a recommendation for consensus-based approval of the guideline to the Management Committee.

Vote

The approval or rejection of the submitted recommendation is the task of DG and the Management Committee.

The applicants may take corrective action on the submitting documents, if requested by DG and the MC in favour to reach a unanimous positive vote, or the submitted guideline will be rejected.

DG will take action for publication and dissemination of the guideline within the BBMRI-ERIC family and appropriate stakeholders.

4.3 BBMRI-ERIC standards

General

A standard is a document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose, established by consensus and approved by a recognized body (www.iso.org). Standards are designed for voluntary use and do not impose any regulations.

BBMRI-ERIC strongly recommends implementing applicable existing European and International Standards. These Standards are developed consensus based within European Member State (CEN European Committee for Standardisation) or consensus based within International Member States worldwide (ISO International Organisation for Standardisation).

BBMRI-ERIC will offer the advantage, due to a broad network of Experts in the field of biobanking and biomolecular resources research, to serve as Consortium for supporting user-need driven development of specific BBMRI-ERIC standards.

A specific BBMRI-ERIC standard must fill the gap between existing standards on one hand and the need for a specific standard for practical use of biobanking and biomolecular resources research on the other hand. The aim is not duplicating existing standards, rather supplementing them.

Hence the BBMRI-ERIC standard management process is a research driven community-based process, improving research needs, that requires standard based solutions.

BBMRI-ERIC Standards meet following principles:

- User-driven standard development
- Openness & transparency
- Consistency
- Consensus and voting principles
- Stakeholder participation
- European applicability
- Interface for international applicability

BBMRI-ERIC standards are developed by and within technical experts of BBMRI through a multi-stakeholder process. The technical committees are made up of experts from academia but will include if applicable, consumer associations, the relevant industry, NGOs and government. These technical

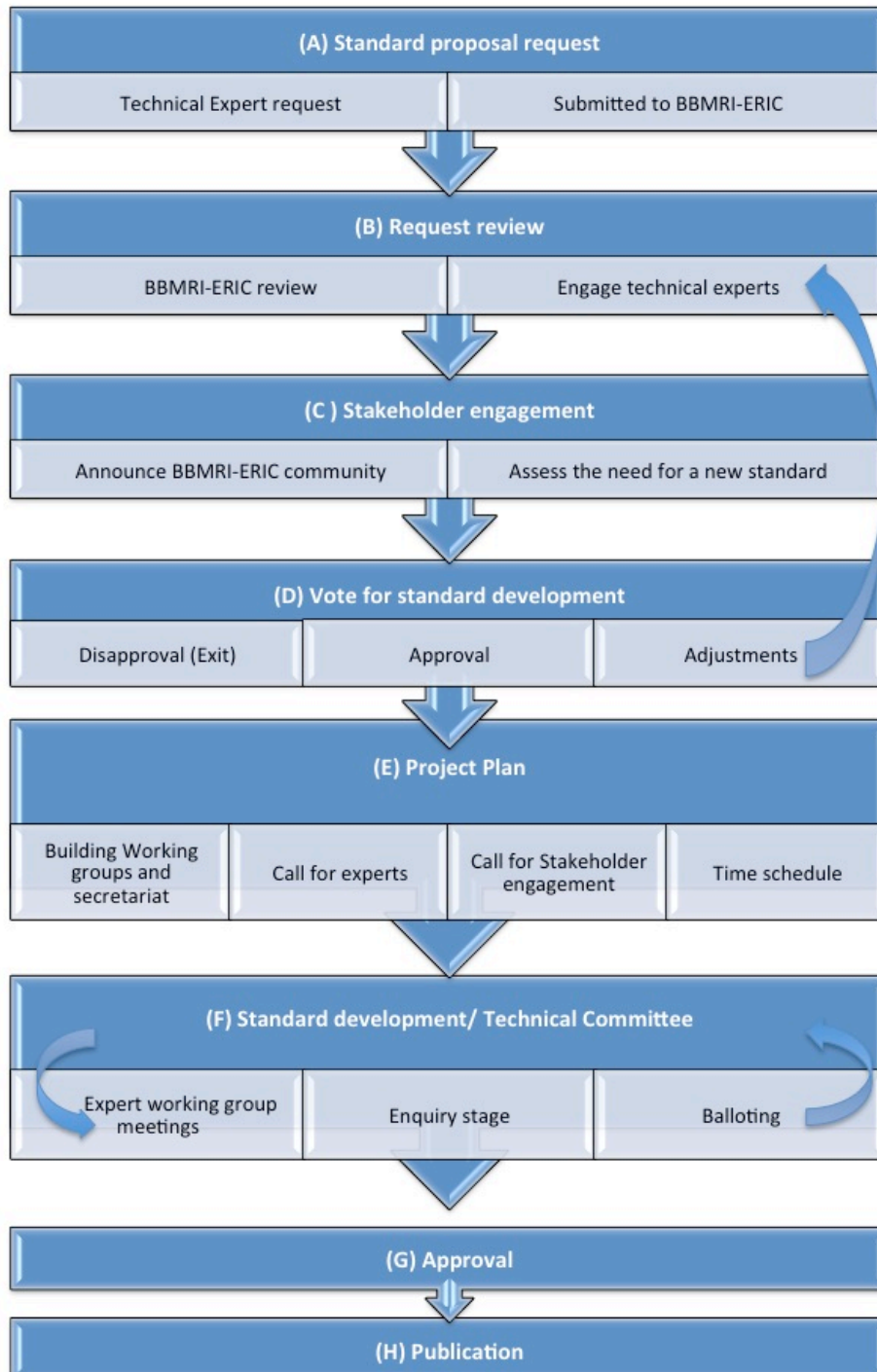
experts negotiate all aspects of the standard, including its scope, key definitions and content.

Assembly of Members, Management Committee or BBMRI-ERIC-HQ can submit a BBMRI-ERIC standard to BBMRI-ERIC

The BBMRI-ERIC management process for assessing BBMRI-ERIC standards includes two feasible request procedures:

1. **A technical expert request for a new standard development** is proposed to BBMRI-ERIC
BBMRI-ERIC will support the development of user-driven need of a specific standard.
The request for a specific standard development will be submitted, assessed, voted and developed as described hereinafter.
2. **A standard (not published yet) is proposed** to BBMRI-ERIC for assessment and approval
BBMRI-ERIC will assess the user need of the proposed standard

Flowchart of BBMRI-ERIC standard proposal and development process



The written submitting documents meet following criteria

1. Definition of purpose and scope of the submitted request for standard development or if applicable request for standard approval
2. Description of methods used for the development of the specific standard
 - a. Scientific based evidence of need, identified by systematic review, external review, or expert recommendation
3. Standard format (Edited and proof read), if applicable
 - d. Scope
 - e. Normative References
 - f. Terms and definitions
 - g. General Consideration
 - h. Main Standard
 - i. Annexe (References)

Assessment (Flowchart A-C)

The assessment of the submitted standard proposed for BBMRI-ERIC approval verifies, if the BBMRI-ERIC standard meets an unmet need, uses internationally accepted best practices, including the appropriate use of evidence.

Director General ensure that BBMRI-ERIC standards are of high quality and are developed through a transparent, evidence-based decision-making process and will if applicable, invite an ad hoc expert review committee, with technical capabilities to evaluate the standard proposal (flowchart A to C)

The review of the final submitting documents [1-3] ensures that the standard developing process followed the requested criteria and contains a clear and request and/or standard proposal.

Director General will bring forward a recommendation for the vote of standard development (flowchart D) to the Management Committee and the Assembly of Members.

Director General will bring forward a recommendation for the approval (flowchart G) to AoM in the case of a non-published standard, in order to fulfil the user-need of the BBMRI-ERIC family; once approved this becomes a BBMRI-ERIC standard.

Vote (Flowchart D)

The approval, disapproval or adjustment of the proposed standard development is the task of the Assembly of Members.

The applicants may take corrective action (adjustments) on the submitting documents, if requested by

the AoM in favour to reach a unanimous positive vote, or this submitted standard proposal is rejected by AoM.

Approval of the standard development proposal is the kick off for the main standard development process outlined in the flowchart E to H

Project-plan for standard development (Flowchart E)

The main task of BBMRI-ERIC is to build a secretariat and working groups, call for experts and stakeholder engagement and to set up a comprehensive work and time schedule.

Standard development / Technical committee (Flowchart F)

The standard development is performed in Working group meetings and follows a stepwise approach of enquiries and balloting actions. On a consensus basis the standard is developed within the working groups and is prepared for a final general approval. The secretariat of BBMRI-ERIC (Director General and a appointed member) is leading the standard developing process in close interaction with a technical expert who chairs the process. He will periodically update the MC and the AoM with the technical progress.

Approval (Flowchart G)

The final standard is revised and approved by Director General in close interaction with the Technical committee.

Director General will present the BBMRI-ERIC Standard to the AoM and will take action for publication and dissemination of the standard.

Publication (Flowchart H)

BBMRI-ERIC will publish and maintain on its website a list of approved BBMRI-ERIC processes, BBMRI-ERIC guidelines and BBMRI-ERIC standards.