

The Policies of the Microbial Resource Research Infrastructure MIRRI – a European Research Infrastructure Consortium

(MIRRI-ERIC Policies)

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Executive Summary

Microbial domain biological resource centres (mBRC) provide live cultures, their associated data and expertise to foster and support the development of basic and applied science. Based on a long tradition, individual not-for-profit mBRCs were established to add value to known and yet unknown microbial biodiversity and to exploit unknown sources and knowledge to discover and disclose for the bioeconomy and bioscience. For several decades, collaboration among some mBRCs resulted in the achievement of several common goals of mutual interest. The pan-European Microbial Resource Research Infrastructure (MIRRI, www.mirri.org) has been established to go beyond these first hesitant collaborating attempts. By placing MIRRI on the ESFRI roadmap in 2010 the community of major European public mBRCs was trusted to expand the collaboration to contribute to the long-term needs of the European research communities. The progress made in the first half of the Preparatory Phase has been confirmed by the ESFRI assessment and MIRRI remains on the ESFRI roadmap until 2020. MIRRI goals have been expressed in the MIRRI mission statement early on in the Preparatory Phase (2012-2015) which states that service to Bioscience and the Bio-industry users will include facilitated access to a broad range of high quality bio-resources and data in a legal compliant way. At the end of the Preparatory Phase MIRRI expresses convincing ideas to generate solutions to societal challenges by stimulating interaction between academia and bio-industry. Directed by the MIRRI mission and user needs the current independent, often institutional policies and managed processes will be adapted by partner mBRCs to harmonize holdings, services, the training offer, accessions policy and share expertise. Better managed resources provided with legal compliance coupled with improved interaction with stakeholders will lead to further discovery in all areas of the Life Sciences. A vision of knowledge transfer has been outlined to offer access to human expertise, to increase knowledge and promote professional development, and to provide a platform for long-term sustainability of microbial biodiversity. The knowledge transfer will be realized through a virtual Collaborative Working Environment inspiring excellence and to drive collaboration across borders and disciplines. Within concerted efforts, the consortium partners coherently and jointly work together with the objective to alleviate the current fragmentation of bio-resource holdings and information, and eliminate duplication and redundancy at the national and pan-European level. In doing so, MIRRI's outreach will encompass i) national interests in supporting the protection of the investment, empowering bio-economy growth and increasing the competitiveness of the country; ii) service to the European user by creating synergies with other research infrastructures, bringing together research, education and industry to promote global responsibility towards biodiversity and to construct an innovative Europe; iii) liaison with regional research infrastructures globally to allow facilitated and compliant access to foreign resources. The following pages include the policies of the Microbial Resource Research Infrastructure MIRRI, a prerequisite for public mBRCs to join MIRRI as partners in the envisaged legal entity MIRRI-ERIC as indicated in the Partner Charter.

For more information on MIRRI please visit our website www.mirri.org.

MIRRI Policy on Accession

One element of the MIRRI mission is to acquire, curate and provide live microorganisms that are interesting or valuable to the scientific, educational and business communities to foster and support the development of basic and applied science. Based on a long tradition, individual European not-for-profit microbial domain Biological Resource Centres (mBRCs) were established to allow facilitated and legal access to resources worldwide, to add value to known and yet unknown microbial biodiversity and to exploit unknown sources and knowledge to discover and disclose for the bio-economy and bioscience.

The present content, scope and range of biodiversity within individual European mBRCs is due to the history of individual research projects and the history of national mandates of funding bodies. More than 450.000 microbial resources are presently housed in the MIRRI partner collections with annual uptakes between a few dozen to up to 1.200 strains, consisting of obligatory deposits of type and reference strains and non-mandatory accessions of research material deposited by scientists. As the acquisition of novel material is not harmonized among European partner collections a stringent accession policy is required to guide mBRC managers and curators to coordinate a most complete offer that will satisfy the demands of users whilst balancing the needs of the individual mBRCs and their stakeholders.

The MIRRI accession decision matrix focuses on:

- increasing taxonomic, metabolic, geographic, and ecological strain diversity;
- reducing redundancy at lower ranks (i.e. avoiding the acquisition of genera, species and strains which are already well covered in other collections);
- resources that have been published and deposited outside public (academic and industrial) collections;
- resources which are in an actual focus of innovative science and research & development;
- the provision of specialized collections, including consortia, for applications in bio-industry.

MIRRI decision making policy

According to the MIRRI Partner Charter mBRC partners agree to a targeted accession of biological material to broaden the range of strains that are of high interest for bio-industry and bio-science; this being financially supported by the respective mBRC host country. The mBRC Directors Forum (Article 10 of the MIRRI Statutes), consisting of all directors of the signatory Partner-mBRCs of the MIRRI-ERIC, shall discuss and conclude on an annual update of the common accession policy and make adjustments when deemed necessary (e.g. new member mBRCs, or new taxa and properties described). These updates shall be included in the annual Work Program to allow the Executive Director of the Central Coordinating Unit to coordinate its implementation through national nodes.

It will be a task of the Central Coordinating Unit to develop a strategy to make the deposition of microbial resources included in scientific publications into mBRCs mandatory by liaising with publishers of scientific journals.

It will be the task of National Nodes to evaluate national academic research collections for the presence of valuable material worth depositing in public collections.

It will be the task of the Central Coordinating Unit, the National Nodes and of individual mBRCs to seek national and international funding opportunities to expand the infrastructure to broaden the range of accessions and to link data to resources.

Accession Priorities

As the number of microbial strains cited and used in public research by academia and industry exceeds the maximal number of annual acquisition in public collections a pre-selection of available resources must be defined.

For Prokaryotes and fungi including yeasts:

- Metabolic uniqueness, based on the presence of a new pathway, modification of an existing pathway, metabolic differences compared to the type strain or novel products including any strains with demonstrated useful properties i.e. production of specific molecules, biopesticide, biofertilizer, degradation of specific compounds, etc. to facilitate biotech exploitation;
- Strains associated with significant or new plant and animal diseases in order to ensure reliable reference material is available for diagnostic services and activities;
- Strains from unexplored or extreme environments (e.g. naturally extreme environments, foodstuffs, polluted environments).
- Strains with potential for bioremediation or as soil health improvers
- Strains from population studies, to further estimate biodiversity in various niche, environments, substrates etc.;
- Any strain associated to a complete (or partial) nuclear genome sequence (as a reference and/or as part of future population studies). This includes the genomic uniqueness criteria of the prokaryote list;
- Several strains of those species for which only the type strain has been described (to allow delineation of species and to find strains with opposite mating types for genetic experimentation and strain improvement); it is useful to deposit strains from the same locality as they may show differences in virulence and other biological properties. Similarly, sub-species, special forms and different races may often exhibit different and unique properties;
- Strains associated with significant or new plant and animal diseases in order to ensure reliable reference material is available for diagnostic services and activities;

Additional for Prokaryotes:

- Phylogenetic uniqueness, based on a cut-off point of $\leq 98\%$ of 16S rRNA gene sequence from its nearest phylogenetic neighbour;
- Genomic uniqueness, such as significant differences ($\geq 20\%$) in genome size, genome architecture or new regulatory mechanisms;
- Resources and parts thereof with fully sequenced genomes (microorganisms, phages, plasmids);

Additional for fungi including yeasts:

- (Ex-) type strains of novel taxa – currently there is not a mandatory process for storing living cultures of the dead dried reference material for fungal types;
- Phylogenetic uniqueness, based on significant differences in the various phylogenetic markers defined for yeasts and fungi (e.g. ITS, D1/D2, SSU, LSU, EF1-alpha, tubulin, etc.);

Selection criteria for the accessioning of microbial resources not listed above but falling into the MIRRI portfolio of resources shall be defined by members of the mBRC Directors Forum.

Reasons for not accepting a strain (and not limited to):

1. It is a duplicate of a strain already held in other MIRRI collections (except type and reference strains);
2. Resources isolated after October 2014 where mandatory documentation as required by the Nagoya Protocol and national ABS measures (e.g. PIC, MAT) but not provided;
3. It is one of several isolates from the same location and the organism is not otherwise deemed interesting enough to have multiple strains;
4. A pure culture is contaminated with other microorganisms;
5. Strains with biosecurity or biosafety implications, or strains outside licensing remit of the mBRC.

Terms and Conditions of Microbial Resource Accession and Discarding

'Accessions are subject to the terms and conditions of the accepting mBRCs, and may include restrictions related to biosafety and biosecurity of national or institutional relevance

Potential depositors must acknowledge and agree that accepting or not accepting a microbial resource for accession into MIRRI partner mBRC shall be within the sole and exclusive discretion of the respective partner mBRC. Strains will only be accepted if the depositors have undertaken due diligence with respect to the Nagoya protocol of the CBD with evidence provided for prior informed consent and mutually agreed terms where needed.

Furthermore, the discarding of a microbial resource currently being stored/maintained by the MIRRI partner mBRCs is also within the sole and exclusive discretion of the partner mBRC though the respective authority in the country of origin will be consulted beforehand.

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MIRRI Policy on Biological Diversity and the Nagoya Protocol

The aim of the policy statement is to outline the principles the MIRRI-mBRCs are expected to adhere to with regard to utilization of the genetic resources and traditional knowledge associated with these genetic resources over which countries of origin have sovereign rights. It will also assist the mBRCs to implement institutional Access and Benefit Sharing (ABS) management policies governing daily practices for accession, research and transfer of material by all staff. MIRRI aims for a light general policy, leaving the detail of the mechanisms of compliance to the discretion of individual MIRRI-mBRCs.

The policy statement applies to all mBRC holdings and other biological materials, in public and non-public collections including, but not limited to, living cultures, dried herbarium specimens, dead wet samples, DNA samples and other derivatives of biological material, as well as traditional knowledge and scientific data that are associated with these resources.

MIRRI Policy Statement on ABS

1. The MIRRI-mBRCs remain committed to support by all means possible the main objectives of the CBD, which are the conservation of biological biodiversity, the sustainable use of its components and the fair and equitable sharing of benefits resulting from the utilization of genetic resources and traditional knowledge associated with genetic resources.

More specifically, the MIRRI-mBRCs are committed to:

2. contribute to the conservation of biological diversity through the preservation and study of *ex situ* microbial materials and genetic resources thereof, or the encouragement and promotion of such study by others, in accordance with Art. 9 of the CBD;
3. deliver, in compliance with the CBD, the Nagoya Protocol and all applicable legislation and regulatory requirements, well-identified, authentic and high-quality materials that are preserved in the public collections of the mBRCs to third parties for research and development, education and biotechnology, and data associated with these resources, to the benefit of public health, food security, and social and economic development. In doing so, the mBRCs also contribute to the Nagoya Protocol's wider objective of supporting the conservation and sustainable use of biological diversity;
4. present clarity on permitted use to recipients of *ex situ* microbial genetic resources, considering that these resources are the essential raw materials that drive the bio-economy, and while fully recognizing the sovereign rights of the countries of origin over their genetic resources, to refrain from posing unnecessary restrictions upon the use of these resources in research with commercial intent, while reminding users of applicable benefit sharing obligations through transfer agreements;
5. cooperate with relevant associations of users and other interested parties in the EU and globally to develop procedures, tools or mechanisms that can facilitate the implementation of the Nagoya Protocol, stimulate the use of *ex situ* microbial genetic resources, and lead to an increase in transparency and legal certainty or a reduction in costs for both provider mBRCs and the users of the microbial genetic resources;
6. design a practical and transparent legal framework that includes transfer agreements with model clauses, and best practice under which all MIRRI-mBRCs can operate as far as is permitted under applicable national law;

7. respect, where appropriate, the confidential nature of user information, documentation and administration associated with the transfer of microbial genetic resources;
8. put institutional policies or other measures in place which assure that the mBRC staff act with due diligence and in full compliance with applicable national and international ABS law and regulatory requirements, in all collection management activities, when collecting new biological materials during field work, or conducting research;
9. inform stakeholders in general about their rights and obligations concerning ABS, where appropriate;
10. share benefits arising from the utilization of the genetic resources by the mBRCs themselves, with the country of origin and other rightful stakeholders, in accordance with the provisions of the Nagoya Protocol and applicable legislation or regulatory requirements, where appropriate, and including, but not limited to,
 - (a) adding value by generating new information on the characteristics of the genetic resources preserved in the mBRC's collections, and where appropriate make this information publicly available through scientific and popular publications and by adding information to open access data repositories;
 - (b) providing support to initiatives for the establishment of new *ex situ* collections in developing countries through collaborative research programs, training and other means of sharing expertise.

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MIRRI Policy on Biorisk Assessment and Biosecurity Measures

Effective Biosecurity risk management is more than reliable and appropriate risk assessment. It also involves assigning responsibilities to members of staff and communication to (internal) staff and third parties (users). In this context awareness raising is the most fundamental basis for implementation of biosecurity and requires educational programs in the future in order to communicate broadly what biosecurity is and why biosecurity measures are demanded. MIRRI's policy will capture this and also addresses the issue in its training and education offer.

The key elements of the MIRRI policy on biorisk management in mBRCs

1. Follow the relevant national law
 - a. adhere to the Code of Conduct on Biosecurity for BRCs¹
 - b. other comparable recognized standards
 - c. OECD Best Practice Guidelines on Biosecurity for BRCs;
2. Follow the development of biosecurity implementation strategies and adjust practice accordingly;
3. Work in collaboration with MIRRI- and external partners towards developing and implementing protocols for adequate biosecurity risk assessment of holdings and normative compliance in MIRRI-mBRCs;
4. Offer available specific expertise to the MIRRI biosecurity expert cluster
5. Work with national authorities to increase competence and advocate the establishment of national biosecurity offices and their international cooperation;
6. Work in collaboration with MIRRI- and external partners to strengthen the ethical basis for biosecurity in the scientific community;
7. Adopt existing or develop new educational tools to raise awareness among mBRC staff.

<http://dx.doi.org/10.5281/zenodo.47248>

¹ Christine Rohde, David Smith, Dunja Martin, Dagmar Fritze, and Joost Stalpers (2013). Code of Conduct on Biosecurity for Biological Resource Centres: procedural implementation. *International Journal of Systematic and Evolutionary Microbiology* 63, 2374-2382. http://ijs.sgmjournals.org/content/63/Pt_7/2374.long

MIRRI Policy on Data Management

To overcome the current situation, the MIRRI Information System (MIRRI-ERIC IS), as part of the Collaborative Working Environment (MIRRI-ERIC CWE), will be established deploying an integrated, high-quality, automatically validated, manually annotated, semantic-rich, non-redundant micro-biological resource database which provides all relevant information and associated contextual data (metadata) about a particular biological resource. MIRRI-IS will be designed as the central entry point for users, curators and developers that need access to the integrated knowledge of mBRCs and selected third party databases while assuring that the specific competences of partner mBRCs remain transparent. The aim is to establish a trademark for high quality data and expertise, which enhances the reputation of participating mBRCs. The MIRRI policy on data management is a commitment to a FAIR (Findable, Accessible, Interoperable and Reusable) provision of data and information.

Requirements for mBRCs to comply with the MIRRI policy on data management:

To allow MIRRI-IS to be operational, MIRRI partners need to comply with:

1. Machine-readable mBRCs catalogues.
2. In case information is not digitally available yet, proper digitalization of key information needs to be undertaken.
3. Provision of accurate data.
4. The MIRRI Minimum Data Set (MIRRI MDS) of descriptors include 1) Strain Number, 2) Other Strain Number, 3) Present Name, 4) Organism Type, 5) Restrictions, 6) Status, 7) History of Deposit, 8) Growth conditions, 9) Form of supply, 10) Geographic Origin and 11) additional accession number(s) to link the data to the International Nucleotide Sequence Database Collaboration (INSDC), in case this is available. Besides these fundamental fields, specific “data packages” and additional subfields will be added over time to enrich the MDS. This will be extended towards a recommended data set (RDS) and finally full data set (FDS).
5. The content of the fields is expected to follow the guidelines, data model, controlled vocabularies and ontologies specified by the MIRRI consortium.
6. The final set of fields, including their expected content, will be consolidated in the Minimum Information about Biological Resources (MIaBRe) standard and checklist.
7. Curation level and quality of data needs to be assured by unified Standard Operating Procedures in mBRCs.
8. Provision of the data in a structured electronically available format.
9. For each biological resource, data need to be made available in machine-readable format and in regular time intervals. Over time, each mBRC in MIRRI should provide their data by Web Services in an XML based exchange language, e.g. based on the Microbiological Common Language (MCL) and its extensions.

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MIRRI Policy on Intellectual Property Rights

Public investments in research are closely dependent from their contribution to innovation and growth. MIRRI fosters the link of research with industry and thus their essential contribution to innovation. The concept of MIRRI with its rich services infrastructure and the implementation of the Collaborative Work Environment (MIRRI CWE) with its clusters and programs supports two measures of this important “alliance”: the first is the direct link of science to companies and second an Intellectual Property Rights (IPR) Policy allowing the commercialization of collaboration results through individually chosen mechanisms in which MIRRI itself has no stake. MIRRI as a public Research Infrastructure (RI) provides an ideal platform to facilitate key research effecting public as well as private R&D and innovation and thus is an instrument supporting public research policy as well as government's role in encouraging innovation.

The key elements of the MIRRI policy on IPR

The aim of the MIRRI-ERIC IPR policy is, that intellectual property rights shall not become an obstacle to the use of data and knowledge from the MIRRI RI for innovation and research & development. Securing non-restricted access, supporting freedom of use, identifying proprietary and copyrighted materials and withdrawal from property rights claims resulting from collaboration between partners are the pillars of the MIRRI-ERIC IPR policy:

1. MIRRI recognizes and respects the key role of Intellectual Property (IP) assets in driving innovation as well as the importance of fostering a culture of invention through the collaborating between public sector bases science and research with industry.
2. MIRRI is aware of the dynamic nature of communication and information technology and that the value of existing IP comes from the ability of its owner to control its use. MIRRI will respect this and applicable laws in the creation of the Collaborative Work Environment (MIRRI-ERIC CWE) and the MIRRI-ERIC Information System (MIRRI-ERIC IS) at the transfer procedures for data and knowledge.
3. MIRRI users will receive according to the Terms & Conditions a non-restricted access for their scientific, commercial, educational and research-related use of the knowledge, information and data made available by the MIRRI-RI and not explicitly marked as “confidential”.
4. MIRRI-ERIC as well as its partners and users acknowledge copyrighted material and intellectual property rights for the purpose of providing and carrying out services, collaborations and matchmaking.
5. The carrying out of the work program of MIRRI could generate intellectual property. MIRRI-ERIC may claim intellectual property rights within applicable national and international jurisdictions over tools, data, products or any other results developed or generated by MIRRI-ERIC while carrying out the work program. This will ensure making the results openly accessible and preventing others from imposing restrictions on MIRRI.
6. In the context of collaborations within the MIRRI RI, joint intellectual property between MIRRI-RI partners and users might be generated. The general MIRRI policy is that partners have optimal freedom to generate value out of intellectual property. The exploitation of the intellectual property as a result of collaborative work in MIRRI should thus be as flexible as possible and should be negotiated between the partners on a case-by-case basis. In case of joint inventions between industry and academia the academic partners should benefit in the form

of royalties or other benefit-sharing models that properly reflect and reward the contribution of public resources, expertise and work.

7. MIRRI encourages partners and users to define agreements covering the management of intellectual property issues, taking into consideration the specificities of the collaboration and/or project and the relevant participants. These agreements should govern aspects like but not limited to handling and ownership of information, data and/or material, use and dissemination of results, access rights and confidentiality matters.

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