# ISARIC Sample and Data Sharing Policy
# Version 4
# 21 July 2014

## Introduction:

The principles and policy outlined in this document are recommendations to be considered for improving access and promoting opportunities for sharing samples and data among ISARIC members.

By adoption of these principles and policy recommendations, each member expresses interest in subscribing and a commitment to working together towards the attainment of such principles for sharing samples and data in good practice and in alignment with their own institutional policies, local and national regulations, the requirements of funders and sponsors and international ethical principles (Declaration of Helsinki, 2008).

Working together towards better access and sharing mechanisms for samples and data among ISARIC members brings to each member the need to assess, and if possible to achieve the appropriate balance between the cost (scientific, economic, legal, political) of increasing access and the benefits that result from such access to the scientific community and to the public at large.

Increasing access and sharing of samples and data among collaborators and the research community within ISARIC has implications for intellectual property rights and the protection of privacy of individuals (human subjects) contributing to clinical research. Consequently, each ISARIC member should consider the applicable legal framework from their own context along with the principles and policy recommendations outlined in this document before an explicit commitment is made within each research initiative and protocol.

## Objective:

**The ultimate objective of these principles and policy recommendations is to maximise the access and sharing of samples and data among members of the ISARIC research community and external collaborators working in severe emerging infections.**

## Scope and Definitions:

**This policy applies to research samples and data generated by:**

**ISARIC Partnership Studies**: research collaborations or studies endorsed by the ISARIC Executive Committee as meeting the appropriate criteria for a Partnership Study.

**Samples:** are considered to be biological laboratory samples [body fluids, blood, pathogen isolates] and/or genetic data that have been taken from human subjects [patients] or pathogens with the primary intention of clinical treatment or research. Storage and use of samples should have the appropriate ethical approval and subject consent where appropriate.

**Research data:** is defined as clinical factual records, images, genetic data, and digital computer generated data that are used by investigators and accepted by the scientific community as necessary

to validate research findings, and that have the ethical approval and subject consent where appropriate to be used in present and future clinical research.

**Exclusion:** These policy recommendations are not intended to apply to samples and research data gathered by clinical research generated and fully funded by the private sector with commercial purposes; or any other research activity outside the remit of the ISARIC research community's main interests.

**This policy may serve as a framework for any research coordinated, facilitated, or initiated by ISARIC members at the discretion of the investigators.**

## Rationale:

ISARIC is a consortium of networks and individuals that have come together to ensure that clinical researchers have the open access protocols and data-sharing processes needed to facilitate a rapid response to emerging diseases that may evolve into epidemics or pandemics.

It is important that policy recommendations consider the wider context of scientific research, the stakeholder's position and the policy initiatives that have impact upon initiatives for data sharing among the research community.

ISARIC's ultimate principle for increasing practice of sharing samples and data is that sovereignty of physical samples and clinical data remains with the contributing investigator in compliance with applicable quality standards of the investigator's institution, sponsor, funder and legal frameworks involved.

In addition, in order to establish agreements and systems for sharing samples and data, it is important to consider the following two distinctive sets of guidance:

The Principles of Accountability when Sharing Research Data are focussed on the need for public accountability which emerged from initiatives to foster the sharing of data among the research community when scientific research is funded by any level of government body, department, or agency that use public funds. These principles have been based on the *OECD Principles and Guidelines for Access to Research Data from Public Funding,* and were approved by the OECD's Committee for Scientific and Technological Policy and endorsed by the OECD council in December 2006. (OECD 2007)[i]

The Principles of Clinical Research when Sharing Research Data have been based on the guiding principles for clinical data sharing outlined by the Committee on Strategies for Responsible Sharing of Clinical Trial Data published in the *Discussion Framework for Clinical Trial Data Sharing* by the Institute of Medicine, National Academy of Science (2013)[ii]

## Guiding Principles for sharing sample and data:

**Principles of Ownership:**

- **Sovereignty of physical samples and clinical data remain with the contributing investigator(s)**.

**Principles of Accountability when sharing research data:**

- **Legal conformity with legitimate stakeholders in the research field**
- **Protection of intellectual property rights and licensing terms**
- **Professionalism of conduct for best practice**
- **Compliance with explicit quality standards**[iii]

**Principles of Clinical Research when sharing research samples and data:**

- **Respect of participant/patients by actively protecting their confidentiality and ensuring appropriate ethical review**
- **Maximising benefits while minimising harm for individuals and society**
- **Increasing public respect for, and interest in clinical research and its findings**
- **Ensuring fairness for individuals and society**[iv]

## Agreements:

If required by investigators' institutional requirements, an agreement should be signed between involved parties for sharing samples and data in compliance with local and international laws (if applicable). This agreement should outline the nature of their relationship, level of collaboration, degree of access, responsibilities, confidentiality and secure management of material and data. This may involve one or both of the following:

**Material Transfer Agreement**. This will be between investigators from different institutions, will take into account the principles and policy recommendations outlined in this document and will follow local institutional procedures and regulations. The agreement will be signed by the appropriate authorities as required.

**Data Sharing Agreement.** In some instances to facilitate the sharing of data between collaborators, an agreement will be in place as required by the collaborators' institutional requirements. These agreements should take into account the principles and policy recommendations outlined in this document and follow the appropriate procedures and regulations. The agreement will be signed by the appropriate authorities as required.

## Data Sharing System:

An essential part of sharing research data is the development of Data Management Systems and Data Sharing Systems to maximise the likelihood that data are prospectively and systematically collected and shared rapidly in a format that can be easily aggregated, tabulated and analysed across many different settings globally and among ISARC members and collaborators. This format offers the greatest potential and most cost effective way for data collection, analysis, management and distribution.

To this end, ISARIC, through its coordination centre will support central and local Data Management Systems to serve as a platform where investigators (users) around the world can contribute data and

benefit from access to the data of others upon pre-agreed conditions, ethical approvals, subject to consent and compliance with institutional and applicable legal requirements.

The pre-condition for building these platforms is that ISARIC members and collaborators agree upon strategies that allow data to be collected using a harmonised core set of research data, such as:

- Entry criteria
- Clinical Endpoints
- Data and samples to be collected
- Schedules for data and sample collection
- Methods for analysis and laboratory analyses to be conducted
- Investigational product characteristics, dose and safety management (for interventional trials)

The strategies for data collection and analysis should be included in all ISARIC Partnership Study protocols or outlined in a research collaboration agreement, material transfer agreement and/or data sharing agreement with a third party involved in such studies. Strategies are also recommended for other research and collaborations by ISARIC members.

## Decisions and oversight of research sample and data access:

To ensure integrity in the process of sharing samples and data among the ISARIC community and in the event of a third party request to access data, the lead investigator(s) will review and assess if a request meets the criteria laid out in this document and meets other legal requirements relevant to where the study was conducted.

## Policy Recommendations:

1. Sovereignty of physical samples and clinical data will remain with the contributing investigator(s).
2. Investigator(s) will have immediate access to data generated from their samples.
3. ISARIC member activity results will be made public unless they are being considered for Intellectual Property (IP) protection.
4. Authorship of ISARIC publications will reflect the genuine contributions of ISARIC investigators, in accordance with the **Publication Policy** and comply with the criteria for authorship as outline by the International Committee of Medical Journal Editors.
5. ISARIC will, wherever possible, provide feedback results of activities to participating communities, stakeholders and to the wider public.
6. All results with intellectual property value that are released into the public domain via publication and the website, should have the intellectual property rights protected to safeguard further development and if appropriate enhance technology transfer to developing and emerging countries.
7. In the event of royalties flowing from intellectual property licenses, mechanisms should be sought to ensure that the flow of royalties is balanced including protecting the appropriate rights of participating communities.

8. Wherever possible patents or other intellectual property that is derived from ISARIC endorsed activities should be licensed to academic or non-profit organisations, unless otherwise specified at the time of endorsement.
9. Transport of Samples should follow established hospital, national and international regulations and health and safety guidelines.
10. These policy recommendations do not override any existing regulations the Investigator has as a faculty member of their parent institution.

[i] Countries that adopted the recommendations are: OECD Countries are: Australia, Austria, Belgium, Canada, The Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Korea, Luxembourg, Mexico, the Netherlands, New Zealand,. Norway, Poland, Portugal, the Slovak Republic, Spain, Sweden, Switzerland, Turkey, the United Kingdom, and the United States. Other countries that adopted the declaration are: China, Israel, Russia and South Africa.

[ii] Committee on Strategies for Responsible Sharing of Clinical Trial Data
Bernard Lo (Chair), President, The Greenwall Foundation, New York City, New York
Timothy Coetzee, Chief Advocacy, Services, and Research Officer, National Multiple Sclerosis Society
Dave Demets, Professor and Chair, Department of Biostatistics and Medical Informatics, University of Wisconsin, Madison
Jeffrey Drazen, Editor-in-Chief, New England Journal of Medicine
Steve Goodman, Professor, Medicine & Health Research & Policy, Stanford University School of Medicine
Patricia King, Carmack Waterhouse Professor of Law, Medicine, Ethics, and Public Policy, Georgetown University Law Center
Trudie Lang, Principal Investigator, Global Health Network, Nuffield Department of Medicine, University of Oxford
Deven McGraw, Director, Health Privacy Project, Center for Democracy & Technology
Elizabeth Nabel, President, Brigham and Women's Hospital
Arti Rai, Elvin R. Latty Professor of Law, Duke University School of Law
Ida Sim, Professor of Medicine and Co-Director of Biomedical Informatics of the Clinical and Translational Science Institute, University of California at San Francisco
Sharon Terry, President and CEO, Genetic Alliance
Joanne Waldstreicher, Chief Medical Officer, Johnson & Johnson

[iii] This set of three principles are based on the OECD Principles and Guidelines for Access to Research Data from Public Funding

[iv] This set of four principles are taken from the key principles for sharing data outline by the "Discussion Framework for Clinical Trials Sharing Data", IOM, National Academy of Science 2014