



## HEADSpAcE Access Policy

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# HEADSpAcE Access Policy

## 1. Introduction

### 1.1 History and mission of HEADSpAcE Data Centre

The International Agency for Research on Cancer, the specialized cancer research agency of the World Health Organization (“IARC/WHO”) coordinated translational studies of a large consortium focusing on head and neck cancer in South America and Europe (HEADSpAcE Study), the VOYAGER study (The role of germline and somatic DNA mutations in oral and oropharyngeal cancers), and the GWA Study of Oral Cavity, Pharynx and Larynx Cancers in European, and North and South American Populations. These efforts have resulted in a large repository containing well-annotated clinical and exposure data from thousands of cancer patients and controls.

This repository is called the HEADSpAcE Data Centre, is hosted by IARC/WHO and constitutes an outstanding research resource. The HEADSpAcE Data Centre is open to any new additional centres willing to include their data and/or samples on head and neck cancer to the HEADSpAcE Data Centre.

The HEADSpAcE Resources held within the HEADSpAcE Data Centre are made available to the international research community, with as few restrictions as possible, for investigators who seek to answer important questions on cancer within a research project that is in line with the HEADSpAcE scientific mandate (Section 1.2). Such research projects must be conducted in compliance with internationally recognised standards and applicable laws and regulations, and in a manner that is consistent with the legal and ethical frameworks of IARC/WHO and the Providing Centres, as laid out in this Policy.

### 1.2 HEADSpAcE Scientific Mandate

The HEADSpAcE Data Centre brings together HEADSpAcE Member Institutions with a long and successful record of collaboration in the study of head and neck cancer who have contributed and may continue to contribute head and neck cancer data to the HEADSpAcE Data Centre.

The HEADSpAcE Data Centre is committed to facilitating the use of these data by the wider research community for research within its scientific mandate, including:

**Global Collaboration:** fostering international collaboration in cancer research, bringing together expertise and resources from across the globe to tackle the complex challenges of cancer prevention and control.

**From Understanding Cancer Causes to Early Detection and Survival:** aiming, through rigorous research, to identify the various causes of cancer, to inform strategies and interventions for cancer prevention, early detection and to improve cancer outcomes.

**Supporting Low- and Middle-Income Countries (LMICs):** recognizing the disproportionate burden of cancer in LMICs, conducting research and building partnerships in these regions. Collaborating with local researchers to tailor prevention strategies that are both effective and culturally relevant.

### 1.3 Purpose and scope of the HEADSpAcE Access Policy

This Policy governs and sets out the terms and conditions to preserve, further develop and enable use of and access to data held within the HEADSpAcE Data Centre.

### 1.4 Who can request to use the HEADSpAcE Resources?

Submission of Data Use Request Forms (see **Chapter 5** of this Policy) are open for ‘bona fide’ scientists affiliated with a public, academic, or non-profit research institution, who want to apply for access to and use of the HEADSpAcE Resources that are held in the HEADSpAcE Data Centre for a not-for-profit research project consistent with the HEADSpAcE scientific mandate.

## 2. Definitions

In addition to the capitalised terms defined elsewhere in this Policy, the following terms shall have the meaning as defined here below, whether used in singular or plural.

<b>HEADSpAcE Data Centre:</b>	Repository of data gathered within the contributing projects and hosted by IARC/WHO.
<b>HEADSpAcE Member Institution:</b>	An institution that has contributed in the past or will contribute individual-level data or biological samples to the HEADSpAcE Data Centre. All together referred to as “ <b>HEADSpAcE Member Institutions</b> ”.
<b>HEADSpAcE Local PI:</b>	Designated scientist (principal investigator) of and affiliated with a HEADSpAcE Member Institution. Each HEADSpAcE Member Institution is represented by a HEADSpAcE Local PI.
<b>HEADSpAcE Data Use Committee:</b>	Committee consisting of five (5) elected members from HEADSpAcE Member Institutions, responsible for reviewing and clearing Proposals to access and use the HEADSpAcE Data Centre.
<b>Policy:</b>	The present HEADSpAcE Access Policy, including its appendices and other referenced HEADSpAcE forms and documents.
<b>HEADSpAcE Data:</b>	Data that are part of the HEADSpAcE Data Centre. These include the de-identified individual-level data collected from the Study Participants at baseline or during the follow-up, that were transferred to IARC/WHO by the respective HEADSpAcE Member Institutions; and the biological data or variables derived from the use of HEADSpAcE Resources, including all laboratory results such as, e.g., genome sequencing results, results of biochemical analysis, scanned histopathological images, etc., all of which may qualify as Personal Data.
<b>HEADSpAcE Biospecimens:</b>	Biospecimens that are part of the HEADSpAcE Data Centre that have been collected from Study Participants and that were transferred to IARC/WHO by the respective HEADSpAcE Member Institutions.

<b>HEADSpAcE Resources:</b>	HEADSpAcE Data and HEADSpAcE Biospecimens held in the HEADSpAcE Data Centre.
<b>Agreement:</b>	An agreement established between IARC and the Approved Investigator’s institution, to lay out the terms and conditions of use of HEADSpAcE Resources.
<b>Personal Data:</b>	Any information relating to an identified or identifiable natural person (for the purpose of this Policy, ‘natural person’ refers to Study Participant).
<b>Study Participants:</b>	Individuals whose data are held within the HEADSpAcE Data Centre.
<b>Research Applicant:</b>	A ‘bona fide’ scientist affiliated with a public, academic, or non-profit research institution, who wants to apply for access to/use of the HEADSpAcE Data Centre for a not-for-profit research project consistent with the HEADSpAcE scientific mandate.
<b>Approved Investigator:</b>	A Research Applicant whose Proposal has resulted in a Cleared Research Project and who has been granted access to/use of the HEADSpAcE Data for the purpose of conducting the Cleared Research Project. For the purpose of this Policy, all obligations applying to the Approved Investigator, in particular in relation to the use of HEADSpAcE Resources, shall also apply to scientists who are affiliated to the same institute as the Approved Investigator, are involved in the Cleared Research Project and who shall be under the direct supervision and responsibility of the Approved Investigator (“ <b>Approved Users</b> ”).
<b>Cleared Research Project:</b>	A research project proposed by the Research Applicant for which clearance of the HEADSpAcE Data Use Committee, as well as approval of the IARC Ethics Committee, and the relevant local ethic(s) committee(s), as may be required by the respective Providing Centre(s), has been obtained.
<b>Research Results:</b>	All scientific results obtained from the use of HEADSpAcE Resources held within the HEADSpAcE Data Centre within a Cleared Research Project.

### 3. Governance of the HEADSpAcE Data Centre

#### 3.1 HEADSpAcE Data Use Committee

The HEADSpAcE Data Use Committee consists of five elected scientists that are affiliated to HEADSpAcE Member Institutions and is responsible for evaluating and clearing HEADSpAcE Data Use Request Forms (“**Proposal(s)**”) and any other tasks as described in this Policy.

The first HEADSpAcE Data Use Committee was established and elected 6 June 2023 by the HEADSpAcE Member Institutions. Every two years there will be a new election among the HEADSpAcE Member Institutions to appoint five new members for a term of two years.

The HEADSpAcE Data Use Committee will meet when required, but at least four times a year to quarterly review the submitted Proposals.

Elections shall take place at a biyearly planned meeting organized by IARC/WHO as the coordinator and host of the HEADSpAcE Data Centre, to which all HEADSpAcE Local PIs of all HEADSpAcE Member Institutions are invited. Before elections, each HEADSpAcE Member Institution shall be granted the opportunity to nominate a candidate affiliated with a HEADSpAcE Member Institution (either a HEADSpAcE Local PI or a researcher in the team of such a PI). Nominations will be collected and compiled by IARC/WHO. To ensure transparency and impartiality, the voting process shall be conducted anonymously. Only HEADSpAcE Local PIs can vote during the elections. Each HEADSpAcE Local PI can cast up to three votes. The five nominated candidates with the highest number of votes are declared elected as members of the HEADSpAcE Data Use Committee. The results of the election are announced publicly at the conclusion of the Elections Meeting and on the HEADSpAcE website. There will be additional rounds of voting between nominated candidates that have the same amount of votes, if electing all of those candidates would mean that a higher number of candidates is elected than the expected five.

### **3.2 HEADSpAcE Member Institutions and HEADSpAcE Local PIs**

Each HEADSpAcE Member Institution is represented by a designated HEADSpAcE Local PI, who acts as the scientific liaison between their respective HEADSpAcE Member Institution and IARC/WHO as the coordinating centre, host, and custodian of HEADSpAcE Data Centre. The incoming contributions of resources from the HEADSpAcE Member Institution to the HEADSpAcE Data Centre, including how their resources within the HEADSpAcE Data Centre can be used and accessed by IARC/WHO and possible third parties, are governed by a separate agreement that has been established between each HEADSpAcE Member Institution and IARC/WHO (such as a Material & Data Transfer Agreement (“MDTA”). Additional legal instruments governing transfer of data and biospecimens will be established if required by new HEADSpAcE Member Institutions.

The HEADSpAcE Member Institutions retain ownership of the HEADSpAcE Resources they contributed to the HEADSpAcE Data Centre and decisions on use of their respective HEADSpAcE Resources remains at their discretion. Following clearance from the HEADSpAcE Data Use Committee, the HEADSpAcE Member Institutions from which HEADSpAcE Resources are requested to be used within a Proposal can choose to participate in the proposed research project through approval by their designated HEADSpAcE Local PI, as authorized in their respective agreement (MDTA) with IARC/WHO.

A list of the HEADSpAcE Member Institutions and their designated HEADSpAcE Local PI can be found on the HEADSpAcE website.

### **3.3 IARC Ethics Committee**

All research projects using the HEADSpAcE Resources require approval of the IARC Ethics Committee (“IEC”). The IEC is composed mainly of external independent members with diverse expertise and backgrounds. The current IEC composition and mandate as well as information on submission procedures, reference guidelines and useful resources are available on the IEC website: <https://ethics.iarc.fr>.

### 3.4 IARC/WHO: Coordinating Centre, host, and custodian of HEADSpAcE Data Centre

The International Agency for Research on Cancer is the cancer research agency of the World Health Organization, a Specialized Agency of the United Nations, headquartered in Lyon, France. IARC/WHO has served as coordinating centre and the host and custodian of the HEADSpAcE Data Centre since its establishment.

As an intergovernmental institution of the UN System, IARC/WHO operates within a particular legal and regulatory framework, under the general principles of public international law and the applicable international treaties and conventions. To ensure the independent exercise of its functions and fulfilment of its public health mandate, it enjoys privileges and immunities under international law, and is subject to IARC/WHO's rules, regulations, and policies, as adopted by its governing bodies.

Accordingly, IARC/WHO has the obligation to ensure the highest ethical and professional standards are adhered to in any of its research activities, including any research project using the HEADSpAcE Data Centre. This includes, without being limited to, matters related to research with human biological material, and data protection and privacy related matters. For such matters, in addition to its governing bodies and the IARC/WHO regulatory framework, IARC/WHO seeks guidance from the IEC (see 3.3) and the IARC Data Protection Officer ("IARC DPO") as appropriate (see 4.3).

### 3.5 IARC Biobank

The HEADSpAcE Biospecimens hosted by IARC/WHO will be stored in the IARC Biobank ("IBB"). The IBB is a centralized biological resource storage facility for samples collected from studies conducted worldwide by IARC/WHO in collaboration with international partners (<https://ibb.iarc.fr/>). It also provides support for pre-analytical sample processing and shipment.

## 4. General Principles governing use of the HEADSpAcE Data Centre

### 4.1 Conditions for use and access of HEADSpAcE Resources

It is the Research Applicants' responsibility to ensure that they have read and understood the Policy and that they, as well as their institution and other potential Approved Users under their direct supervision and responsibility who may need access to HEADSpAcE Resources, as applicable, will be able to fully comply with the Policy. To this effect, Research Applicants should liaise with their institution's administration at the earliest stage to avoid potential complications or issues arising down the line.

**Chapter 6** of this Policy on 'Access Limitations' set outs other conditions for the use of and access to HEADSpAcE Resources.

### 4.2 Ethical principles

As a general principle, any research project requiring the use of or access to the HEADSpAcE Data Centre must comply with internationally recognized ethical standards and must be ethically and scientifically reviewed and approved by an appropriate independent board or committee.

By approving the use of their HEADSpAcE Resources within a proposed research project, the HEADSpAcE Local PI confirms that the proposed analysis complies with their respective ethical approvals, unless it is indicated an additional ethical clearance is required. Restrictions on the use of their contributed HEADSpAcE Resources may be imposed based on specific regulatory requirements applicable to a HEADSpAcE Member Institution.

All research projects using the HEADSpAcE Data Centre require approval of the IEC.

The Approved Investigator and their institution remain responsible for ensuring that they comply with applicable laws, rules, regulations, research governance and ethical guidelines, or other regulatory requirements that may apply to the Cleared Research Project and use of the HEADSpAcE Data Centre.

### 4.3 Data protection and privacy principles

HEADSpAcE Resources that are part of the HEADSpAcE Data Centre held at IARC/WHO are de-identified, the individual identifiers being kept solely by the respective HEADSpAcE Member Institution.

IARC/WHO, as the custodian and coordinating centre of the HEADSpAcE Data Centre, in collaboration and close consultation with relevant bodies such as the HEADSpAcE Data Use Committee, the IEC and the IARC DPO shall ensure the compliance of the storage, use, processing and/or transfer of HEADSpAcE Resources, with internationally recognized data protection standards, including but not limited to the IARC Data Protection Policy.

Approved Investigators are expected to adhere to the highest standards of data protection, confidentiality, and privacy principles. Under no circumstances may Approved Investigators attempt to identify Study Participants from the HEADSpAcE Resources.

IARC/WHO acknowledges that Approved Investigators and their respective institutions may be subject to national/regional data protection legislations.

For the avoidance of doubt, by virtue of their privileges and immunities under national and international law, IARC/WHO is not subject to any national/regional/federal data protection legislation. Notwithstanding the foregoing, ensuring the appropriate protection of Personal Data is of the utmost importance to IARC/WHO. To this effect, IARC/WHO shall process Personal Data in accordance with its data protection framework, which is in line with internationally recognized data protection standards. IARC's data protection framework includes, without being limited to, the Personal Data Protection and Privacy Principles for UN System Organizations, UN-HCLM 2018 (the "[UN Principles](#)"), and the [IARC Data Protection Policy](#).

## 5. HEADSpAcE Data Use Process

### 5.1 Submission of Data Use Request Form

Research Applicants who are interested in using the HEADSpAcE Resources held in the HEADSpAcE Data Centre for their research project are invited to fill in and submit the required HEADSpAcE Data Use Request Form ("**Proposal**") to the HEADSpAcE Data Use Committee.

Before submitting a Proposal, Research Applicants should review the variables which are available within the HEADSpAcE Data Centre including endpoints and coding via the [HEADSpAcE website](#).

The HEADSpAcE Data Use Request Form is available and can be submitted [here](#) via REDCap, and includes information on the proposed research project such as:

- Project title and short summary of the background basis of the proposed research project, for example: what founding research is the project based on;
- The overall aim of the proposed research project such as, research question and overall aim and hypotheses; what the project hopes to achieve using the HEADSpAcE Resources;
- a list of variables from the HEADSpAcE Data Centre which are envisaged to be used;
- the date of the proposal;
- a project timeline, including an end date of the project;
- the primary PI contact, information on the Research Applicants institute and team;
- funding sources and declaration of conflict of interest;
- a publication plan.

IARC/WHO will be automatically notified via email ([headspace@iarc.who.int](mailto:headspace@iarc.who.int)) when a Research Applicant submits a Proposal to be considered by the HEADSpAcE Data Use Committee.

## 5.2 Proposal evaluation and clearance

Submitted Proposals are evaluated and if eligible cleared by the HEADSpAcE Data Use Committee.

Proposals to use the HEADSpAcE Resources are evaluated on a quarterly basis by the HEADSpAcE Data Use Committee. Dates of the HEADSpAcE Data Use Committee meetings are shared on the HEADSpAcE website. Research Applicants will be notified of the decision of the HEADSpAcE Data Use Committee within approximately twenty (20) days of the date on which the subsequent HEADSpAcE Data Use Committee meeting was held.

The HEADSpAcE Data Use Committee consists of five elected scientists that are affiliated to HEADSpAcE Member Institutions and is responsible for evaluating and clearing HEADSpAcE Data Use Request Forms (see 3.1).

Proposals will be assessed by the HEADSpAcE Data Use Committee to:

- ensure that the Proposal falls within the HEADSpAcE scientific mandate, has scientific relevance, taking into account the feasibility of the proposed analysis, and the potential overlap with other ongoing analyses using the HEADSpAcE Data Centre;
- review and prioritise research proposals and assess the scientific integrity of submitted Proposals to ensure the highest ethical and professional standards are adhered to in any of the proposed research activities;
- take into account the Limitations of Use as set out in **Section 6** of this Policy.

Where a Proposal is declined, a follow-up discussion can take place with the Research Applicant to discuss the concerns of the HEADSpAcE Data Use Committee and to discuss what would be required to develop a stronger proposal that might be successful if re-submitted.

If two Proposals are containing similar research questions or trying to do the same thing, priority will be given to the one that was submitted first, and the second Research Applicant can be referred to the first so that they can liaise with each other and potentially work together and submit a joint Proposal should they wish to do so.

## 5.3 Approval of use of HEADSpAcE Resources by HEADSpAcE Member Institutions

Following clearance from the HEADSpAcE Data Use Committee, IARC/WHO will send the Proposal of a Cleared Research Project to the designated HEADSpAcE Local PI of each HEADSpAcE Member Institution from whom use of their HEADSpAcE Resources is requested within the Cleared Research Project, for their consideration and approval to participate on behalf of the HEADSpAcE Member Institution, as authorized in their respective agreement with IARC/WHO. Once participation is confirmed, IRB approval must be sought as outlined in Section 4.2.

Each HEADSpAcE Member Institution is requested to provide their approval or refusal of the usage of their HEADSpAcE Resources within the Cleared Research Project within thirty (30) days after receiving the initial request.

IARC/WHO shall be authorized to provide access to HEADSpAcE Resources to a Research Applicant only if the designated HEADSpAcE Local PI on behalf of their HEADSpAcE Member Institution has explicitly approved the usage of their HEADSpAcE Resources within the Cleared Research Project.



A HEADSpAcE Member Institution can at any time still approve their participation in and the usage of their HEADSpAcE Resources within a Cleared Research Project by notifying IARC/WHO accordingly via [headspace@iarc.who.int](mailto:headspace@iarc.who.int).

Cleared Research Projects may only use the HEADSpAcE Resources for the objectives and analyses outlined in their approved Proposal. If these objectives and analyses change during your approval period or if you wish to explore a different aspect of your research, you will need to submit a separate Data Use Request Form regarding this new aspect of your research.

All Cleared Research Projects will be shared publicly on the HEADSpAcE website to be transparent on which projects are using which HEADSpAcE Resources.

#### 5.4 Providing access to the HEADSpAcE Data Centre for a Cleared Research Project

Following the approval by the respective HEADSpAcE Member Institutions of the use of their HEADSpAcE Resources, an Agreement will be signed between IARC/WHO and the institution of the Approved Investigator who will use HEADSpAcE Resources within the Cleared Research Project. The Agreement sets out the terms and conditions governing the use of the HEADSpAcE Resources. The terms and conditions stipulated in the Agreement are in principle non-negotiable.

Once the Agreement is established, IARC/WHO will prepare and provide (either by transfer or remotely) the HEADSpAcE Resources that were requested and approved to be used within the Cleared Research Project to the Approved Investigator.

HEADSpAcE Data is accessed via the IARC Scientific IT Platform and a reasonable cost may be charged to the institution of the Approved Investigator as well.

The cost of the transfer of any HEADSpAcE Biospecimens if requested, including retrieval, processing, packaging and shipment will be charged by IARC/WHO to the institution of the Approved Investigator at the latest rate posted on the IARC/Biobank website (<https://ibb.iarc.fr/access-policy>).

##### *Remote access to HEADSpAcE Data*

IARC/WHO has established a high performance and highly secured platform (the “**IARC Scientific IT Platform**”) to serve as centralized repository for all HEADSpAcE Data. The IARC Scientific IT Platform is governed under clearly defined procedures to ensure adequate controls and the highest level of protection and security of the data hosted therein, in accordance with the WHO regulatory framework and IARC/WHO policies.

By providing remote access to de-identified data via the IARC Scientific IT Platform, IARC/WHO aims to address data protection and privacy concerns, and to avoid physical transfer of HEADSpAcE Data. Accordingly, where the Research Applicant requests access to HEADSpAcE Data for the purpose of the proposed research project, access will be granted remotely via the IARC Scientific IT Platform. The HEADSpAcE Data cannot and may not be downloaded from the IARC Scientific IT Platform.

Physical transfer of HEADSpAcE Data will only be considered on an exceptional basis. In such case the Research Applicant must justify in the Proposal the need for physical transfer of the requested HEADSpAcE Data, and clearly demonstrate that the research goal cannot be achieved by accessing/analyzing the HEADSpAcE Data remotely via the IARC Scientific IT Platform. The HEADSpAcE Data Use Committee can take this part of the Proposal into account when evaluating the Proposal and if cleared the HEADSpAcE Member Institutions must be explicitly approving the physical transfer via their HEADSpAcE Local PI.

#### 5.5 During the Cleared Research Project

During the Cleared Research Project, if a new variable is generated from HEADSpAcE Resources, it must be returned to the HEADSpAcE Data Center for integration into the HEADSpAcE Data. Any output resulting from data algorithms of digital images from the HEADSpAcE Data Centre needs to be returned and integrated into the HEADSpAcE Data Centre.

A formal progress report must be submitted to the HEADSpAcE Data Use Committee twelve (12) months after the Cleared Research Project's start date. The HEADSpAcE Data Use Committee also reserves the right to request updates for progress of specific Cleared Research Projects, also upon request of participating Providing Centres.

Based on the progress reports the HEADSpAcE Data Use Committee can monitor the use of the HEADSpAcE Resources and Cleared Research Project's progress. In cases where Cleared Research Projects are not progressing sufficiently, and other investigators have requested to pursue the same topic, the HEADSpAcE Data Use Committee reserves the right to retract their clearance of the Cleared Research Project after which the access to the HEADSpAcE Resources shall be terminated. The institute of the Approved Investigator of such project shall receive a written statement in which it will be indicated that the clearance has been retracted, that the access will be terminated and any transferred HEADSpAcE Resources must be deleted and or returned as instructed by IARC/WHO.

#### **5.6 End of use of HEADSpAcE Resources & completion of Cleared Research Project**

Access to the HEADSpAcE Data Centre is provided to an Approved Investigator for the time that there is a need to access the HEADSpAcE Data Centre for a Cleared Research Project during the term of the Agreement. The Agreement may be extended if required. Access to the HEADSpAcE Data Centre is, at the latest, ended after (a) publication of the final manuscript from the Cleared Research Project or (b) at the end date of the Cleared Research Project, whichever is earlier.

Upon completion of a Cleared Research Project, the Approved Investigator and its institute must:

- Provide IARC/WHO as the Coordinating Institute with a copy of any derived data that have been generated within the Cleared Research Project through use of the HEADSpAcE Resources (e.g., results of biochemical analyses or genotyping) ("Research Results"), in raw data or other relevant format as agreed upon with the Coordinating Centre;
- If requested, provide IARC/WHO and the HEADSpAcE Data Use Committee with a report on compliance with applicable data protection regulations, in particular where the research is deemed to give rise to additional risks to the rights and freedom of Study Participants (e.g., due to an increased risk of re-identification or the use of genomic data).

## **6. Limitations of Use**

Use of the HEADSpAcE Resources held within the HEADSpAcE Data Centre is restricted to 'bona fide' researchers, who are affiliated with academic, non-profit, or governmental research institutions, and who have no links to the tobacco or arms industries and whose Proposal has resulted in a Cleared Research Project ("**Approved Investigator**").

The Coordinating Centre cannot grant access to the HEADSpAcE Data Centre to commercial entities and/or for commercial purposes, including development of patents.

Access to the HEADSpAcE Data Centre may be denied for various reasons. The following list, while not exhaustive, provides examples:

- The Proposal falls outside the HEADSpAcE Scientific Mandate (see **1.2**).

- The Proposal overlaps with ongoing or planned projects/analyses leading to unnecessary duplication of work and waste of resources;
- The scientific quality of the Proposal is considered inadequate;
- The HEADSpAcE Resources held in the HEADSpAcE Data Centre are not suitable to answer the research question mentioned in the Proposal;
- There are ethical or legal issues with the Proposal, including, for example, when the proposed use of the HEADSpAcE Resources is not compatible with the original informed consent of the Study Participants, or if the proposal is non-compliant with the applicable data protection regulations;
- The Proposal is not compatible with the goals of public health;
- The institution of the Approved Investigator and IARC/WHO are not able to agree on the terms and conditions of the Agreement under which access to HEADSpAcE Resources would be provided;
- The Agreement under which access to HEADSpAcE Resources was provided has expired;
- The proposed research project is considered not to be in compliance with the general guiding principles of this Policy such as: committed to respecting and protecting the rights, privacy, and consent of their Study Participants at all times.

As a general principle, the HEADSpAcE Data Use Committee reserves the right to refuse clearance of a Proposal for which an explanation will be provided. The HEADSpAcE Member Institutions have the ultimate authority over the use of their respective HEADSpAcE Resources held in the HEADSpAcE Data Centre and may each refuse the use of their HEADSpAcE Resources within a Cleared Research Project, no explanation on their refusal will be required.

## 7. Publications, authorship, use of Research Results and Intellectual Property

### 7.1 Publication guidelines of research results using HEADSpAcE Data Centre

As a general and prevailing principle, the Approved Investigator and its institute are expected to disseminate the Research Results to the public through appropriate means, most importantly through peer-reviewed scientific publications. To this end, the Research Results should be submitted for **peer-reviewed publication** in timely manner as agreed upon with the HEADSpAcE Data Use Committee and HEADSpAcE Member Institutions.

Research Results may be published subject to the terms and conditions set out in the HEADSpAcE Governing Framework and more specifically the HEADSpAcE Publication Guidelines.

To ensure that publication of Research Results conforms to the cleared use of HEADSpAcE Resources, all manuscripts of papers, reports, and abstracts, except student theses, should be submitted to the HEADSpAcE Data Use Committee before they are submitted for publication to a journal by sending the manuscripts as an attachment by email to [headspace@iarc.who.int](mailto:headspace@iarc.who.int).

### 7.2 Acknowledgement and reference to HEADSpAcE in publications

Any project conducted by Approved Investigators using HEADSpAcE Resources is by definition conducted in collaboration with the HEADSpAcE Data Centre. Accordingly, any publication arising

from the use of HEADSpAcE Resources should include at least 1 co-author from the HEADSpAcE Coordinating Centre (IARC/WHO) and at least one co-author from the Providing Institute from which the HEADSpAcE Resources were originally collected. 5. IARC/WHO and some HEADSpAcE Member Institutions have additional procedures for approval of manuscripts prior to submission which must be followed. Approved Investigators should anticipate that additional time (minimum 1 month) will be required for completion of these processes between initial circulation to co-authors and submission to a peer-reviewed journal. Approved Investigators should anticipate that additional time (minimum 1 month) will be required for completion of these processes between initial circulation to co-authors and submission to a peer-reviewed journal.

Approved Investigators are encouraged to submit to the journal of Open Access Europe (<https://open-research-europe.ec.europa.eu/>) which offers a fast publication and open peer review for research stemming from Horizon 2020, Horizon Europe and Euratom funding across all subject areas.

### **7.3 Use of Research Results and Intellectual Property**

As indicated in clause 3.2, the HEADSpAcE Member Institutions retain ownership of the HEADSpAcE Resources they contributed to the HEADSpAcE Data Centre and decisions on use of their respective HEADSpAcE Resources remain at their discretion.

Research Results, including derived data, shall be jointly owned by the institute of the Approved Investigator generating the Research Results within their Cleared Research Project, the respective originating HEADSpAcE Member Institutions that participated in the Cleared Research Project and IARC/WHO. The Research Results arising from a Cleared Research Project may be used by either of those parties for future not for profit research and academic purposes. Any other use or exploitation of such Research Results shall require prior consultation between those parties and shall be subject to a separate agreement to be negotiated in good faith with IARC/WHO.

Notwithstanding the foregoing and as general principles, the following is recognized and acknowledged by all parties, the importance of working together in a collaborative, rather than proprietary, spirit; and sharing Research Results and other research outputs from a Cleared Research Project in a manner that benefits patients, supports cancer research efforts, advances public health, and enhances the public good. Accordingly, involved institutes shall first and foremost endeavour to disseminate the Research Results and research outputs arising from a Cleared Research Project to the public, including through peer-reviewed scientific publications, in a collaborative and open access manner.

Any Research Results arising from the use of the HEADSpAcE Resources shall be used for the on-going enrichment of the HEADSpAcE Data Centre. In line therewith, the Approved Investigator and its institute agree to provide to IARC/WHO, upon the latter's request, a copy of any Research Results arising from the use of the HEADSpAcE Resources within a Cleared Research Project.