



How to join HEADSpAcE: Applicant guide

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1. Introduction

HEADSpAcE is an international consortium of scientists involved in research on head and neck cancer, comprising oral cavity, oropharynx, pharynx and larynx. Although originally organized among principal investigators of epidemiological case–control studies of head and neck cancer, HEADSpAcE is now open to external investigators with ongoing studies in head and neck cancer epidemiological research. The eligibility criteria for HEADSpAcE membership are shown below.

HEADSpAcE members are epidemiologists and clinicians involved in head and neck cancer studies and scientists with expertise in molecular domains relevant to head and neck research. Members are expected to bring to the consortium their expertise, ideas and resources, including results, raw data and biological samples.

**Members are expected to have their own funding,
because funding cannot be provided
through HEADSpAcE from the EU or from IARC.**

The membership process has two stages:

1. A decision on inclusion is taken by the HEADSpAcE General Assembly.
2. Membership becomes fully effective upon inclusion in the EU Grant Agreement and acceptance by the EU.

2. Eligibility criteria

Studies are eligible for inclusion in HEADSpAcE if they have the potential to contribute to research on causes, mechanisms and prevention of head and neck cancer within the framework of collaborative projects carried out in the consortium. Studies should be methodologically sound and contribute good-quality data and biological samples. Studies considered for inclusion are *mainly* molecular and genetic epidemiological studies (typically of case–control or cohort design, including both information on exposure to risk factors *from questionnaires or similar sources* and biological samples). However, well-conducted clinical series from understudied populations, and large-scale *case-series* and epidemiological studies without biological samples will also be considered for inclusion.

To be eligible, the following are considered:

- Type and quality of information on exposure to risk factors and potential confounders;
- Type and quality of results of biological measurements;
- Type, amount and quality of biological samples available for further analyses (blood, tumour, normal H&N, other);
- Information on clinical aspects (e.g. treatment) and outcome;
- Sample size (number of cases);
- Uniqueness of study population (e.g. in terms of exposure or genetic background);
- Secured funding.

3. Applying to HEADSpAcE

Simply send an email to HEADSpAcE@iarc.fr with:

- How you heard about the HEADSpAcE consortium
- A brief description of your study using **Appendix 1 – Application Form**, available on the [HEADSpAcE website](#).

We will get back to you on the timeline for the steps described in this guide.

In particular, the Application Form will be submitted to the HEADSpAcE General Assembly for their consideration.

4. Administrative requirements

Once the application is approved by the HEADSpAcE General Assembly, applicants will need to go through the following steps to formalize their participation. Access to all the necessary documents will be given through the HEADSpAcE password-protected Members' Area.

4.1 Join and sign EU Grant Agreement

A Grant Agreement is in place between the EU and the HEADSpAcE Coordinator, IARC, which has been signed by each HEADSpAcE member.

New members will need to be included in the Grant Agreement through an Amendment. To do so they will need to provide information (see **5.1 Grant Amendment** and **Appendix 2 – Grant Amendment Form**), as well as institutional signature on the EU Participant Portal.

4.2 Sign Consortium Agreement

A Consortium Agreement is in place among HEADSpAcE members, which defines rights and obligations within the consortium, in particular confidentiality, liability, intellectual property rights and ownership, duration and termination.

New members will need to sign the Accession Form as acceptance of the agreement. A prerequisite to do so is to be included in the Grant.

The unsigned version of the Consortium Agreement and the Accession Form are available in the [HEADSpAcE Members' Area under Agreements](#).

4.3 Sign Asset Donation Agreement – optional

The Asset Donation Agreement (ADA) is a straightforward two-page document that may need to be signed for prospective recruitment in the event that IARC provides lab materials.

An ADA template can be found in the [HEADSpAcE Members' Area under Agreements](#).

4.4 Sign DMTA

One multi-party Data and Material Transfer Agreement (DMTA) is in place among HEADSpAcE members, allowing transfer of material and data to and from any and every HEADSpAcE member.

New members will need to sign the Accession Form as acceptance of the DMTA. A prerequisite to do so is to be included in the Grant and to sign the Consortium Agreement.

The unsigned version of the DMTA and the Accession Form are available in the [HEADSpAcE Members' Area under Agreements](#).

4.5 Reporting to the EU

All HEADSpAcE Members will need to contribute to scientific reporting required by the EU on a periodic basis. The next report is due in early 2022, which will be followed by the final report in early 2023. Guidance will be provided in the HEADSpAcE Members' Area.

5. Step-by-step process for the Grant Amendment

5.1 Grant Amendment

Based on the fact that each Grant Amendment requires several months, amendments for the inclusion of new members will happen 2–4 times a year.

New collaborators will need to complete **Appendix 2 – Grant Amendment Form**, available on the [HEADSpAcE website](#), to provide the necessary information.

Below is a description of the various steps to follow.

5.1.1 Future members need to provide the following:

5.1.1.1 Participant Identification Code (PIC) number (EU identifier)

To find out if your organization already has a PIC number, please visit the [EU PIC search page](#). Make sure to enter the name of your institution in your local language, and to search for the legal name of your main institution, not of your group or department. Examples are provided below:

✘	Instituto de Oncología Angel H Roffo	= <i>legally dependant to the University of Buenos Aires (UBA), and considered a department within UBA</i>
✘	University of Buenos Aires	= <i>name in English, not the official legal name in the local language</i>
✔	Universidad de Buenos Aires	= <i>name of legal entity in the local language</i>

Once you find your PIC number, check that the status is “validated” and that a signing official of your institute (Legal Entity Appointed Representative [LEAR]) is appointed on the EU Participant Portal. This is usually done by your Grants department.

If you cannot find your institute PIC number, if the status is not validated, or if a LEAR is not appointed, please contact HEADSpAcE@iarc.fr for further guidance.

5.1.1.2 Budget

No funds can be provided to members to contribute to HEADSpAcE, and new members will need to give the EU an estimate of the amount that they will be able to spend on HEADSpAcE, as well as an estimate of time-effort measured in person-months.

Example of person-month: one person working half-time for one year = 6 person-months.

5.1.1.3 Description of future member (EU Grant Annex 1 Part B, 4.1 & 4.2)

In addition to **Appendix 2 – Grant Amendment Form**, new collaborators will need to complete **Appendix 3 – Team Description Form**, available on the [HEADSpAcE website](#). Examples can be found in Appendix 4 – Team Description Examples.

5.1.2 IARC to launch Grant Amendment

Once all the necessary information is received from applicants, IARC as a Coordinator will launch a Grant Amendment on the EU Participant Portal on behalf of the HEADSpAcE consortium.

5.1.3 Future members need to sign the Grant Amendment on the EU Participant Portal

From the EU Participant Portal, an official representative needs to sign the following two documents online, to confirm institutional approval of participation in HEADSpAcE:

- Declaration of Honour (DoH)

The DoH template can be found [here](#). How to sign the DoH is explained [here](#).

- Accession Form

How to sign documents on the EU Participant Portal in general is explained [here](#).

Make sure to assign Roles as required by the EU. In particular, the roles of LEAR, PLSIGN and PFSIGN must be allocated to someone. This can be done when accessing the EU Participant Portal under “My Organisation” and “My Projects”, respectively.

IARC will be able to submit the Grant Amendment only after this step is completed.

5.1.4 IARC to submit Grant Amendment on behalf of the HEADSpAcE consortium

Only after applicants have signed the necessary documents on the EU Participant Portal can IARC as a Coordinator submit the Grant Amendment. The EU must accept or reject the amendment request within 45 days.

First, it checks whether the request is valid and may request additional information/documents, which must not change the amendment itself. The Commission then has 45 days to assess the request.

Acceptance: If the Commission accepts the request, its authorized representative e-signs the amendment. The Coordinator and beneficiaries are formally notified. The countersigned amendment appears in the project’s document library, in the Funding & Tenders Portal’s ‘My Area’ section. No further action is required.

Rejection: If the request is invalid, incomplete or wrong, or if the granting authority disagrees with it, the Commission’s authorized representative formally rejects it.

6. Scientific process

Once the application is approved by the HEADSpAcE General Assembly, the scientific inclusion can be initiated while the administrative process is being completed. Access to all the necessary documents will be given through the HEADSpAcE password-protected Members’ Area. New members will need to:

6.1 Access HEADSpAcE documentation

The latest versions of the study documents are available in the HEADSpAcE password-protected Members’ Area. The password will be shared with potential new members.

The HEADSpAcE Members’ Area includes:

- HEADSpAcE Lifestyle and Delay questionnaire (PDF template) – these are tailored to centres. They may be provided in the local language. Centres will need to provide the national average disposable income in their country. Disposable income is the amount of money from all sources available for spending and saving after direct taxes (such as income tax) have been accounted for. Information on the education system will also be requested.
- A RedCap data entry guide as well as several video tutorials
- The HEADSpAcE study protocol, currently available in English and Spanish
- The list of materials to be used for prospective sample collection
- Standard Operating Procedures (SOPs) for:
 - Plasma collection, processing and storage
 - Assembly of tissue microarrays (TMAs)
 - Immunohistochemistry procedure on FFPE tissue
 - DNA extraction from FFPE
 - HPV genotyping from FFPE tissue
 - Quality of FFPE slides

- Slide sharing
- Ethics guidelines

The HEADSpAcE Members' Area is regularly updated with new content.

6.2 Obtain local ethics approval/IRB

Check with your institute or local Institutional Review Board (IRB) how to obtain the necessary approvals. All documents needed, such as HEADSpAcE consent form template, protocol, etc., are available in the HEADSpAcE password-protected Members' Area. The password will be shared with potential new members.

Once local IRB approval is obtained, please send a copy to IARC, with a translation in English if needed, to begin the study at your centre.

6.3 Purchase lab materials as needed

6.3.1 For prospective recruitment

New HEADSpAcE partners will need to purchase the necessary lab materials. A list is provided in the HEADSpAcE Members' Area under Patient Recruitment. IARC will provide materials for the first 100 subjects. IARC will also provide labels for sample collection with centre/HEADSpAcE IDs on a case-by-case basis; see 6.4.

The HEADSpAcE Lifestyle and Delay questionnaire will be accessible online through REDCap, and the initial HEADSpAcE partners access it using a tablet. New members will need to have one, because IARC will not provide this.

6.3.2 For retrospective studies

New partners that will store samples on site until needed will not need to purchase lab materials, although they will have to assign HEADSpAcE IDs for the Sample Tracking System (STS).

6.4 Obtain labels with centre and HEADSpAcE IDs from IARC – optional

Labels will be provided on a case-by-case basis. In principle, IARC may provide labels to new members who ship samples to IARC for storage or aliquoting, as needed, for prospective recruitment.

Retrospective studies that will keep their samples on site will not need labels, although HEADSpAcE IDs will need to be assigned to samples for the STS.

6.5 Recruit patients/Provide materials and data

Recruitment protocols must be followed for prospective recruitment. SOPs for samples are available on the HEADSpAcE website and must be followed closely. If you would like to add components to the study beyond the HEADSpAcE objectives, feel free to do so. The consortium will only use data/samples as per the consortium objectives.

Transfer of samples and data can start only after the DMTA and prerequisites are signed.

6.5.1 Data collection using RedCap (prospective or existing/retrospective studies)

- For prospective recruitment

All members are required to use RedCap for data collection of the HEADSpAcE Lifestyle and Delay questionnaire. Therefore, new members will need to contact IARC to receive a RedCap account giving access to the HEADSpAcE data collection forms.

- For retrospective recruitment/existing studies

If retrospective studies have data compiled in a format that is easy to merge with HEADSpAcE data, then IARC and HEADSpAcE members will use their dataset. However, the data required to join HEADSpAcE are likely different than the data collected for the retrospective studies. In this case, IARC will make a copy of the existing HEADSpAcE RedCap forms available to new HEADSpAcE members, and they will need to fill out the RedCap forms with the information that they are able to obtain. IARC will not design specific RedCap forms for retrospective studies. It is expected that there will be missing values if new members did not collect information that is requested in the HEADSpAcE RedCap forms.

6.5.2 Sample Tracking System (STS)

The Sample Tracking System (STS) gives information on samples made available by participating partners for HEADSpAcE WorkPackages and potentially additional projects. As long as prospective recruitment continues the STS will be updated regularly.

Retrospective studies will be asked to provide sample information to be included in the STS.

6.5.3 Transfer of samples

The administrative process must be completed before starting this step, i.e. inclusion in Grant Agreement, signature of Consortium Agreement and of Data and Material Transfer Agreement.

Samples will be stored on site by each new member until needed for HEADSpAcE analyses, whether for prospective or retrospective studies. If space is an issue, samples may be stored in the IARC Biobank, depending on availability of space. For details on sample shipment, please refer to Appendix 9 of the HEADSpAcE protocol, available in the HEADSpAcE Members' Area.

6.5.4 Use of samples

Depending on sample collection timelines, samples may be included in existing HEADSpAcE WorkPackages. If WorkPackage sample limits have been reached, samples will remain stored on site by each new member until needed for projects. Using the information in the STS, all HEADSpAcE partners may propose new analyses to the consortium.

- **Prospective recruitment**

Using RedCap information from sample log sheets, sample information will be added to the STS for HEADSpAcE partners to view.

- **Retrospective/existing studies**

The STS will be updated every 6 months or every year, at which point the centres will have to take inventory and inform IARC about samples that are available for use. The STS gives HEADSpAcE partners an idea of sample availability at a given time, but when the list is sent to the biorepository, a requested sample may be depleted, in which case the biorepository will inform the requestor that the sample is not available and to select another one.

7. Your contacts

7.1 General queries

Contact Laurene Bouvard, HEADSpAcE@iarc.fr, for general enquiries and administrative requirements.

7.2 Recruitment

Contact Shama Virani, viranis@iarc.fr, leader of WorkPackage 1, for scientific queries, in particular about recruitment or the Sample Tracking System (STS).

Please specify “How to join HEADSpAcE” in your email subject line.

8. Abbreviations

ADA	Asset Donation Agreement
CA	Consortium Agreement
DMTA	Data and Material Transfer Agreement
DoH	Declaration of Honour
EU	European Union
FFPE	Formalin-fixed, paraffin-embedded
GA	Grant Agreement
ID	Identifier
IRB	Institutional Review Board (ethics)
LEAR	Legal Entity Appointed Representative (EU role)
PIC	Participant Identification Code
PFSIGN	Project Financial Signatory (EU role)
PLSIGN	Project Legal Signatory (EU role)
SOP	Standard Operating Procedure
STS	Sample Tracking System
WP	WorkPackage

9. Appendix 1 – Application Form

See the [HEADSpAcE website](#).

10. Appendix 2 – Grant Amendment Form

See the [HEADSpAcE website](#).

11. Appendix 3 – Team Description Form

See the [HEADSpAcE website](#).

12. Appendix 4 – Team Description Examples

See the [HEADSpAcE website](#).