



**ToR call for
single experts or expert teams**

**to participate in a ResInfra@DR support activity
in the field of**

Biobanks as research infrastructures

Terms of References

BACKGROUND and PURPOSE

The ResInfra@DR project is designed to strengthen Research Infrastructures (RI) in the Danube macro-region (DR) and runs from January 2017 to June 2019. The project is co-funded by European Union funds (ERDF, IPA).

The main activities of the ResInfra@DR project include:

- a dialogue focusing on relevant regional, national and macro regional but also EU level policy fields involving also end-users of RIs;
- special trainings for defined target groups, thus contributing to capacity building with an outreach to the entire macro-region and beyond the partnership involved;
- a collection of a dataset of competent and qualified reviewers for RI assessments;
- **two pilot activities focusing on**
 - (a) peer actions including existing RIs (pilot activity 1);
 - (b) **Ex-ante support of planned or planned to be upgraded RIs in countries of the Danube macro region (pilot activity 2 und subject of this ToR);**
- the dedicated dissemination and capitalisation actions contribute to the policy take up and utilisation of the results.

The present call concerns the second pilot activity (b) , “Ex-ante support to planned or to be upgraded RIs in the Danube macro-region”.

The core element of this support action will consist of specific **recommendations provided by an expert team** that will work together with the ResInfra@DR partnership.

Teams will consist of **two external experts which are identified with the help of this ToRs** and will be supported by further ResInfra@DR partner team members.

SPECIFIC SUPPORT REQUESTED

The Nicolae Testemitanu State University of Medicine and Pharmacy, Moldova, is interested to set up a population specimen biobank, also in connection to its genotyping facility. It looks for specific guidance for the preparation phase of this planned centre of excellence, which is strongly related to its planned research infrastructure. The university has sent a request to ResInfra@DR, the addressed questions were clarified in advance by the partners of ResInfra@DR.

Specific guidance for the upcoming processes and related to research infrastructures is requested by SUMPh and a list of specific challenges and questions have been identified to specify the support sought from experts with this call.

The core topics of interest were identified jointly with the interested organisations in this support activity of ResInfra@DR:

| Challenges addressed | Specific questions identified/focus of recommendations |
|-----------------------------|---|
| Strategy and vision | <p><u>How to develop a specific vision and strategy</u> for a biobank that fits to the current environment of users?</p> <ul style="list-style-type: none">- This includes considerations of “ownership” of the smaller biodata resources in the country existing at other organisations (i.e. to establish equal and shared ownership based on common understanding).- This might include also specific documentation requirements for activities of a biobank – a process that can be linked with establishing a specific and fitting monitoring framework.- The governance of the biobank is an additional aspect |
| Legal aspects | <p>Given the countries <u>lack of dedicated laws, specific regulations or established standards</u>, specific solutions for this situation are necessary to avoid legal complications for the use fo the research infrastructure. The specific solutions searched for include:</p> <ul style="list-style-type: none">- Legals framework options for establishing the RI- Specific legal considerations for biobank activities and general standards in the field from international experience- Governance structure models related to the biobanking |

| | |
|---------------------------------|---|
| Meeting international standards | How to <u>upgrade and develop the current resources</u> to best follow international standards and protocols? <ul style="list-style-type: none"> - Is the current infrastructure of existing collections appropriately following international standards, are the current buildings etc. sufficiently fulfilling the needs of a biobank? - What is missing to meet the international standards |
| Operation models | What would be <u>exemplary operation models for the biobank</u> that could fit for the specific situation? <ul style="list-style-type: none"> - Can international best practice like “core facilities” or similar structures and approaches be a solution or what other solutions could be proposed for the management of the resources and access? - What would be interesting - fitting - models for the country (e.g. international examples could be showcased; specific elements usually in place that can be taken on might be proposed as solutions) |
| International up- link | How to <u>connect better to international biobank initiatives</u> and research infrastructures? <ul style="list-style-type: none"> - Current cooperations with Estonia and Romania show the relevance of the existing resources and collections. - What would be core points for the better integration in broader EU research infrastructures e.g. BBMRI? |
| User access | How to establish a fitting <u>user access strategy</u> also beyond the current core users, to “open” to external users? |
| Staff capacity building actions | How to integrate staff capacity development for technical staff and active researchers including PhD students in the context of a biobank (management of content, access management, ethical standards, protocols, international link-up...)? |
| Investment observations | If possible a general picture of <u>usual ranges of investments</u> in similar situations on the initial investment range and the <u>expected operation costs</u> would be a helpful expert contribution (especially recent examples would be helpful) |

Overall, the SUMPh looks for recommendations that proposes important steps or activities that contribute to its development. The expert opinion and suggested activities addressing the SUMPh are considered as important for the further acquisition of funding in a short and mid-term perspective. SUMPh is aware that the recommendations which will be received are expert opinions and recommendations but do not follow a specified evaluation criteria. As the biobank is in development, the recommendations can also reflect the feasibility. Expert contributions and findings should follow a critical friend approach and do not follow a specified set of criteria as the action is not considered as evaluation. This approach shall allow to provide field specific and whenever possible context related knowledge.

This ToR call tries to identify experts or expert teams

This call can be answered either by single experts or expert teams consisting of two experts.

- Teams of experts should hand in jointly their documents, it is necessary that teams demonstrate the complementarity of their expert knowledge.
- In case of single experts the ResInfra@DR will try to match the expertise of the expert with other applicants to cover if possible most of the questions addressed.

More technical details on the application find later in the document on the following pages!

Experts are invited to contribute by:

- interacting with the SUMPh during virtual meeting(s) to clarify open questions concerning the expectations and questions; setting up a schedule for the 1-1.5 days visit;
- participating as experts in the 1-1.5 days visit and all its specific sessions, a reflection meeting on site (travel No1)¹;
- drafting the core parts of the recommendations including field specific examples to showcase good practice (the length of this document is not specified);
- present the recommendations findings on site (travel No2)² or during online meetings;
- support the identification of general experiences made during the exercise to advise similar actions in future and draft some core points that should be take on in future (learning results from the action).

SUMPh as the final beneficiary of the organised support action will

- inform the experts before their visit on site about the current situation, the planned visit schedule by use of documents, provision of information during virtual meetings, skype calls etc.;
- identify the relevant persons and stakeholders in Moldova which can provide further input in the specific field;
- prepare the necessary schedule for (3-5) meetings with stakeholders for a 1 or 1.5 day visit of experts and will agree with stakeholders on their participation in the necessary meetings;
- host and organise the necessary meetings with concerned stakeholders in the country;
- organise a meeting venue for the expert team to prepare recommendations and reflect on first findings of the days of the visits;
- welcome for a follow up visit (if necessary) the experts and team members of ResInfra@DR in order to discuss the developed recommendations and most important, to facilitate the internal process by informing the relevant stakeholders;
- participate at the planned ResInfra@DR learning event planned to be held in May 2019 in Slovakia.

¹ Costs for Travel No1 including the 1-1.5 days on site visit are included in the expert fee and need to be arranged after joint agreement with the included team members.

² Travel No2 or further travels will be arranged directly by the financing partner and will be covered by an additional contract only covering the travel and accommodation costs but no daily fee/allowance can be covered.

Role of the ResInfra@DR team member/s

The contracting ResInfra@DR partner is the core addressee for clarifications in the team, but the responsibility for its functioning is shared with the further ResInfra@DR team members. The project ResInfra@DR team members (partners of ResInfra@DR) involved support the action by:

- identification of the above listed topics in a dialogue with SUMPh (preparation of this ToR call); publishing the ToRs and sending the ToRs document to relevant experts to invite and ask for their participation;
- collecting replies to this ToR call and selecting together with SUMPh the best fitting experts;
- contracting of external experts and processing the necessary payments;
- organising the confidentiality agreements,
- organising virtual meetings to prepare the visit of experts to Moldova, interacting with SUMPh to facilitate the structure of the 1-1.5 days working visit;
- presence during the 1-1.5 days meetings to ensure best focus of the action (one/two ResInfra@DR team members can participate);
- contributing to the recommendations drafting process, its writing and presentation when necessary and in case it can add up to the expert recommendations, organising agreed virtual meetings etc;
- supporting the presentation in Moldova, if possible together with expert(s)
- reconsidering findings to identify what could be relevant for repeating similar peer learning processes beyond Moldova. Such are considered “learning results” from the pilot action which can be shared at a specific ResInfra@DR learning event (organised in May 2019 in Slovakia)

Confidentiality:

Involved team members (external experts, ResInfra@DR team members) will sign a confidentiality agreement with the SUMPh. While the content of the prepared documents is to be kept generally confidential, agreed parts should be made available by SUMPh for cost documentation of experts work, for sharing of the experiences made during the pilot exercise within ResInfra@DR. SUMPh also provides the necessary background documents to enable the work of experts and the involved teams.

Time frame

The following timeframe applies to the action and expert involvement

- Information of possible experts about their interest to participate (opening of the ToR call and date of announcement) 14 March 2019
- Deadline for applications: 27 March 2019
- Selection procedure concluded and date of contracting completed at the beginning of April 2019
- Visits (Travel 1) should be organized in April/May 2019
- The action should end in May 2019

Selection of experts

Applications from teams of experts (two complementary experts) are highly welcome, in case of applications of single applicants two experts will be paired to form a team.

Expressions of Interest/Applications received will be screened by the ResInfra@DR partnership, the following selection criteria applies:

- Demonstrated experience in the specific field (20 points)
- Knowledge on research infrastructure processes (20 points)
- Reply to the questions and core points (10 points)
- Description of risks of the exercise (5 points)
- Cost plan (not exceeding 3000€ per expert including travel1) (5 points)

Expert teams will be assessed separately from single applications to ensure fairness in the process.

Funding of the action and contracting of the partners

The cost coverage for a single expert can not exceed 3,000€ what includes the costs for one trip to Moldova (Travel 1 to be covered from the amount). Coverage means that travel costs and accommodation costs are included.

In case of expert teams, both experts shall participate in the onsite 1-1.5 days trip (Travel 1), the expert fee per expert can not exceed 3,000€ (in total not exceeding 6,000€ for the team).

In case of teams of experts, each will receive a separate contract.

The contracts with experts will be concluded with the Czech partner in ResInfra@DR (contact details below).

Application procedure and necessary documents:

The qualifications of the experts who will contribute to the above tasks shall be demonstrated through:

- a **cover letter/e-mail** with short description of the motivation and provision of contact details, also informing about the team members in case a team of experts applies jointly (not exceeding half a page). Note that expert teams need to provide this document only once;
- a **CV**, highlighting relevant experience and reference projects or activities (not limited to scientific tasks). Teams need to provide for both experts the CVs;
- taking on the list of questions raised, a **max. 2 A4 page “considerations to questions”** document should inform about core points/issues which are considered as important for the addressed issues. This can also contain references to other developments, operation models, relevant standards etc. which are of interest for the specific case of SUMPh. Note that expert teams need to provide this document only once.
- on a single A4 page document (a) an assessment of the risks of the exercise; (b) a cost plan including the consultancy days provided. Note that expert teams need to provide this document only once.
- in case the applicant will not be available for more than 4 weeks in the upcoming 4-month period, he/she should **provide information** with the application (start and end date of the period when the expert will not be available). Note that expert teams need to provide this document only once.

The documents for the response to this ToR call (not exceeding 10 MByte) must be sent by e-mail to: resinfra.pilot@zsi.at

Contacts for further information

In the case of questions, interested entities can contact the ResInfra@DR partners for further information.

Austria:

ZSI-Zentrum für Soziale Innovation GmbH (Centre for Social Innovation)

Linke Wienzeile 246, A-1150 Vienna, Austria

Person in charge of the project: DI Martin Felix Gajdusek, Phone: +43-1-4950442-67

e-mail: gajdusek@zsi.at (resinfra.pilot@zsi.at)

University of Natural Resources and Life Sciences, Vienna, Institute of Water Management, Hydrology and Hydraulic engineering (at the Department for Water-Atmosphere-Environment)

Muthgasse 107, A-1190 Vienna, Austria

Person in charge of the project: Doris Gangl

e-mail: doris.gangl@boku.ac.at

Czech Republic:

Institute of Philosophy, Czech Academy of Sciences, (The Centre for Science, Technology, and Society Studies), Filosofický ústav AVČR Kabinet pro studium vědy, techniky a společnosti Jilská 1 110 00 Praha 1, Czech Republic

Person in charge of the project: Jan Balon

e-mail: Balon@flu.cas.cz

General information on the Pilot action

The expected **OUTPUTS of the action** and including all contributing parties

- (1) The **first core result and output** of the pilot action is a **recommendation document** which will include expert opinions and recommendations including recent examples of how the challenges can be met; or elements of roadmaps to show the development options and what could be achieved over time in a stepwise approach; thematic (scientific) expert opinions that take on the challenges in the specific field.

This document should give guidance to SUMPh how it could develop further its research infrastructure activities.

The following stepwise approach is followed:

- A **recommendations draft document** is developed in a first step by the whole team, this is based on the following information:
 - on information received from the SUMPh what could be previous activity reports or assessments; information received in person during the preparatory exchange round in online meetings or by sending documents etc.
 - specific information received during the 1-1.5 days visits which include also meetings with stakeholders on site (university management, researchers or other scientific users, specific collections, funders etc.);
 - a reflection round of the whole team on site during the visits.
- The recommendation draft document is prepared by the team and will be presented afterwards to SUMPh in a virtual meeting to allow a revision and correction of yet unclear parts.
- After a revision round by the team at this stage a **confidential full set of recommendations** will be available for the SUMPh.
- In a next step the SUMPh will agree with the expert team on a **publishable and non-confidential version of the recommendations**.
- A **presentation of the results** during a visit (travel2) will be organised on site in Moldova, confidential parts of the recommendations (parts which should be kept internal) need to be agreed in advance. ResInfra@DR partners will be present and in case of necessity also expert/s can participate. (The financing partner needs to cover directly travel and accommodation costs as they are not covered in the expert contracts subject of the present ToR call).
- A **concluding report based on the publishable and non-confidential version of the recommendations** will be prepared which is a formal deliverable of the Resinfra@DR project and represents the documentation of the whole Pilot action conducted in Moldova.

- (2) The **second element of the action** consists of a reflection that finally should help to identify what can be learned from the process for similar actions in future and also beyond the specific field covered in the pilot action. A certain focus on the Danube Macro-region should be maintained. Note that expert contribution is only partly necessary but highly welcome.

This reflection might include exemplary the following elements:

- (1) Critical **success factors** for similar support actions based on peers putting the “critical friends approach” in the centre of support;*
- (2) **Shortcomings** of the approach (subjective approach, limited resources and timeframe, uptake of results etc.*
- (3) What would make the **approach better**;*
- (4) What **other approaches** can be suggested to reflect the limits of the action;*
- (5) What could be suggestions for developing such actions further in the **Danube macro-region**;*
- (6) **Other** issues which are of importance.*

The following stepwise approach is followed:

- During the action the transferability of the approach should be reflected also when drafting the recommendations or during the visit, here also experts can contribute accordingly;
- The already concluded process will be reflected in a **dedicated virtual meeting** or in bilateral communication i.e. by using the above list or adding more points, the presence of experts is encouraged;
- The involved ResInfra@DR partners should draft a 2-3 pages input which is collected from other parallel running peer actions in other countries, the experts can provide further feedback, as well SUMPh should use the own viewpoint to contribute;
- ResInfra@DR collects the input from all parallel running actions to prepare a **draft deliverable on learning results from this pilot activity** taking up the findings from the actions.
- A **mutual learning event** will take place in Slovakia in May 2019 (travel 3) and all parallel running actions will be presented by the Resinfra@DR partners involved and also SUMPh should participate to show its viewpoint. Up on interest of experts they will be invited.
- Especially involved actors i.e. the SUMPh and the team involved in research infrastructure planning will be invited from the organisers (cost coverage planned). Note that at the moment of this ToR call the concept of this meeting is not available.).

- (3) Note that this action is **not a formal review or evaluation, nor a comprehensive ex-ante assessment** but it can help with triggering and steering the next steps needed in an organisation to progress with the preparations for the set up of a research infrastructure.
- (4) **Confidentiality:** an **agreement on disclosure of information** will be signed to ensure confidentiality throughout the process. Confidentiality declarations on the disclosure of information will be signed with all included experts. Only explicitly agreed parts (formally approved by participating organisations) will be shared.