FRANCE 2030

CALL FOR PROPOSALS

UNIVERSITY HOSPITAL INSTITUTES
IHU 3

2022 Edition

Call for proposals closing date
07/11/2022 at 11h00 (11 am CEST)

Call for proposals publication address
https://anr.fr/IHU3-2022

Comment: English translation is made for information purposes only, and only the French version shall prevail in case of any difference of interpretation.

KEY WORDS

Biomedical research, basic research, clinical research, translational research, public health research, high-level higher education, improvements in healthcare and prevention, precision medicine, transformation of the practices of health professionals, research training and research-led teaching, health products, health technologies, public-private partnerships, technology transfer, value creation.

SUMMARY

French government decided to allocate €1 billion through the France 2030 plan to strengthen our capacity for world-leading biomedical research. Within this action and its €300M, this call for proposals aims to create a maximum of six new University Hospital Institutes (IHU), future centres of excellence in research, healthcare, prevention, teaching and technology transfer in the area of health.

The role of the IHUs is to develop, in their thematic area, world-class skills and research capabilities, including a clinical research infrastructure and a translational research infrastructure that are open to projects emanating from public or private partners of French or international origin. The clinical research and translational research infrastructures allow the creation of value from discoveries made in the public sector and the implementation of partnership research programmes.

These centres of excellence must reinforce the international scientific competitiveness of French research, its attractiveness for the industry players in pharmaceuticals, biotechnologies and health technologies, and its potential for value creation and transfer of research results to the bedside and to the population.

The University Hospital Institutes bring together a critical mass of researchers, teacher-researchers and health personnel within an integrated structure that combines a university, a healthcare facility, and one or more research organisations.

The appropriateness of the economic model and the governance; local coherence and integration, involvement of key partners including those geographically distant, alignment with strategies and priorities of universities and hospitals, capacity to be a national driving force in the thematic area, capacity to transform the practices of health professionals and teaching methods; the involvement of private research; the quality of organisation for value creation; its potential benefits (economic and social). These factors shall all be taken into consideration in the assessment of the proposals, in addition to the originality, excellence and scientific ambition of the project.

IMPORTANT DATES

CALL FOR PROPOSALS CLOSING DATE

It is imperative that the submission file documents (see § 5 « Submission conditions ») including the documents signed by the legal representative of each of the partners, be submitted in electronic format before:

MONDAY 07/11/2022 AT 11H00 (11 A.M.) (PARIS TIME)

to the website:
https://france2030.agencerecherche.fr/ihu

CONTACTS

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You must read carefully the "Regulations governing the conditions of awarding grants for the IHU3 Call for proposals"[1] before submitting a proposal.

[1] *Comment: only a French version of this document is available.*

CONTENTS

1. CONTEXT AND OBJECTIVES OF THE CALL FOR PROPOSALS

1.1. CONTEXT

The launching of the University Hospital Institutes (IHU) initiative in 2010 resulted in the emergence of 6 centres of excellence across France. The call for proposals IHU2 in 2017 resulted in the selection of one more IHU. Their strength lies in that they bring together, on a single site, researchers and clinicians from leading university, hospital and research teams, focusing on a single clinical thematic area (such as infectious diseases, rare diseases, diseases of the central nervous system, etc.).

The twelve years that have lapsed since the first call for proposals have highlighted not only the complexities inherent to setting up such projects, but also the success of the wager that the creation of the IHUs represented. Indeed, an international jury that evaluated the first 6 IHUs in 2019 noted the relevance of the IHU program due to their impact in terms of translational research and innovation.

The proposal is to supplement the IHU programme by launching a third call for proposals that will allow new projects to be selected under a selection system that has drawn the lessons from the implementation of the first seven IHUs. The "University Hospital Institutes - IHU 3" call for proposals will allow the creation of up to six centres of excellence in research, healthcare, prevention, training and technology transfer in the area of health thanks to an allocation of 300 million euros.

The identification of new IHUs with international visibility supported by this programme will enable France to have additional centres of excellence, at the level of the leading international institutions in terms of research, teaching and healthcare. This process will necessarily have to integrate a technology transfer objective, building on existing structures and implying close relations with the industrial players, and include a partnership with the private sector and possibly with the regional authorities concerned.

1.2. OBJECTIVES OF THE CALL FOR PROPOSALS

The University Hospital Institutes (IHU) programme aims to develop the basic, translational and clinical research components of biomedical research, and foster its transposition to all levels of the health system by setting up of a small number of IHUs. Covering a limited geographic area and a specific thematic area, each IHU must constitute an attractive environment of excellence for talented researchers and clinicians, as well as for industrial partners. The key objectives include allowing the experimentation of new care and prevention modalities, ensuring the training of outstanding professionals in the areas of healthcare and research and development, and making cultures evolve by encouraging partnerships, especially between the public and private sectors.

The creation of the IHUs should thus speed up progress in health research in France by reinforcing a dynamic current of value creation, transfer and partnership research in the health and life sciences sectors, and better interlink research, teaching and healthcare to address the major health challenges.

The setting up of an IHU must play a strategic role and have a major developmental impact on a local and national scale, more specifically in clinical research, translational research and

the discovery research which fuels them. It must be part of a common site policy in research, care, prevention, training and value creation.

The work carried out in the IHUs must aim, among other things, at creating a socio-economic impact, particularly by improving the practices of health professionals or by reducing health costs, and at developing and stimulating the industrial sectors of health over the long term.

2. SCOPE OF THE OF CALL FOR PROPOSALS

2.1. SCOPE

The IHU projects must:

- target global excellence in research, teaching, healthcare, prevention in a specified thematic area;
- put a bidirectional bench-to-bedside and bedside-to-bench dynamism at the core of each project:
    - have a significant active list of patients in the proposed thematic area and a patient management system that is consistent with the scientific project;
    - seamlessly involve clinicians and researchers in all the activities of the IHU by encouraging their joint participation in the translational or clinical research activities;
- check the integrated nature of the basic, clinical and translational research work within a limited geographical area and around a central hub of resources and skills at the core of the IHU, guaranteeing functional continuity;
- integrate an objective of value creation and technology transfer;
- be capable of attracting a significant number of projects emanating from private partners.

2.2. PARTNERS

The projects presented shall:

- involve at once a university, a healthcare facility, and one or more research organisations being Founding members of the IHU;
- display scientific and medical coherence[2] ;
- be limited to one main site, but playing the role of network leader by associating partner sites constituting an integrated whole;
- mobilise a critical mass of talents: researchers, engineers and teacher-researchers from the public and private sectors, health professionals;
- develop and run world-class clinical research and translational research infrastructures that are open both to projects from public or private partners - French or international - harbouring the range of skills necessary to capitalise upon discoveries made in the public sector, and to partnership research programmes;
- be centred on one or more hospital departments or department groupings that are fully integrated in the project, describing the interactions with the other departments or department groupings concerned;

[2] The IHU project shall focus on a defined thematic area, corresponding either to an existing thematic perimeter that will have to be developed, or an emerging and federating thematic area.

- develop, insofar as possible, a partnership with a competitiveness cluster, explaining how the IHU project relies on the regional cluster or, if applicable, how it establishes links with other clusters;
- plan for the value-creation activities stemming from the research work to be ensured by a single representative relying on existing structure(s)[3] pooling, where appropriate, their services, and having a high level of service to accelerate and streamline the promotion of work from the IHU;
- provide the possibility of having additional private and public partners other than a university, a healthcare facility or a research organisation.

2.3. Mission and particularities of the IHUs

In terms of research activities, the IHUs shall be capable of closely interlinking basic, translational and clinical research, and healthcare, and shall do so by:

- formulating research questions stemming from healthcare or prevention;
- exploring their fundamental aspects (TRL 1-3);
- developing translational research that leads to new products and preventive, diagnostic or therapeutic processes (TRL 4-6);
- performing the proof of concept and the clinical evaluation of these products and processes;
- taking advantage of this translational process and the clinical research capacities to create partnerships with the private sector and to attract projects proposed by national, European or international research institutions;
- transferring these innovations into healthcare practices or into prevention;
- developing an innovation approach at the end of the research itself, until the marketing of products and processes (TRL 7-9);
- allowing the experimentation of new medical or preventive practices, new healthcare protocols, new organisations and their assessment, with a view to allowing their transfer and dissemination in standard practice;
- ensuring the dissemination to the health professionals, patients and the general public;
- proposing high-level training courses for research and development professionals in the public and private sectors;
- developing very high-level care, prevention and teaching and proposing initial and continuous training courses for health professionals;
- transfer the results of its work to technology.

2.4. Governance

The governance of the IHU shall be simple, responsive, robust, open and adapted to its objectives, its missions, its partnerships, its regional, national and international impact. The governance must imperatively be part of a common site policy in research, care, prevention, training and value creation. It must allow the IHU to be fully integrated to the strategic vision and the establishment's projects of its public partners. It shall also include a simplification of the relationships between public and private actors and promote as far as possible an alignment of their interests, in a logic of accountability, sustainability of the actions implemented by the IHU and maximum amplification of their structuring effects.

[3] Creation of an *ad hoc* structure must be justified and supported by founding members of the IHU.

It should be a legal entity. If the site would already have existing entities, the use of these structures should be preferred (for example, through the constitution of a sub-foundation under the umbrella of an existing Foundation). In particular, new foundation cannot be created specifically for a project of IHU.

Whatever the case, the proposed governance shall meet the following requirements:

- be balanced and egalitarian between the healthcare facility, university and research organisation;
- include a governing board or a similar body, comprising in particular the university, the healthcare facility, the research organisations and representatives of the partners, an international scientific council and an executive committee which would allow an efficient relationship between researchers and physicians of the IHU to the scientific strategy and to the setup of a constructive management dialog;
- include in the board of directors or equivalent body, a representative of the State responsible for financing with a right of veto[4];
- have the necessary flexibility, particularly with regard to the delegation of management to the executive committee;
- guarantee that the IHU management board has effective strategic, financial and managerial responsibility over the IHU project and its implementation;
- allow the executive committee and the IHU director to effectively manage the human and financial resources and facilities specific to the IHU, and the distribution of these resources between the various operational units and research programmes. The leadership of the healthcare facilities, universities and research organisations shall continue to manage their own resources;
- the management of the equipment, particularly technological facilities, has to provide for the sharing conditions with the partners and the coordinating strategies of investment;
- associate, within the governing board or the similar body, a balanced representation of outside personalities, such as representatives of health services user associations and of economic sphere or regional authorities;
- allow the IHU to receive material and/or financial support from private sources;
- be capable of attracting a significant number of projects emanating from private partners. The structure shall be open to the potential participation of private and public partners other than a university, a healthcare facility or a research organisation;
- allow the scope of the IHU to evolve according to its strategy of scientific excellence and the partners' expectations, so that the required elements and skills - especially multidisciplinary - can be gathered;
- allow a good coordination of training with the university partners;
- ensure gender parity in the bodies set up;
- describe the process for renewing or replacing the IHU director at the end of or during the mandate. A job description will be established, guaranteeing the scientific and medical skills at the highest level and the managerial qualities of the IHU director. Her/his selection will necessarily involve an *ad hoc* selection committee including a majority of scientific personalities from outside the IHU, including international

[4] Relating to the use of France 2030 funding for purposes other than the missions of the IHU or derogating from the financial regulations.

members, in accordance with international best practices. A mandate may not exceed 4 years and shall be renewable.

These governance principles must be described in a specific appendix, which will complete the scientific document (see 3.1 admissibility criteria). They shall be transposed in the statutes, internal regulations and agreements.

2.5. SPECIFIC PROVISIONS

- The selected projects shall be assessed by an international panel, every five years or more regularly if necessary, within the framework of interim assessments. This assessment shall concern all the activities of the IHU (scientific programme, economic model, governance, transfer to healthcare and prevention, value creation, etc.).
- ANR will verify the financial soundness of the selected beneficiaries and their ability to report regularly on the implementation of the investment.
- The benefit for patients and the medical and socio-economic impacts shall be taken into account, as will questions of ethics and of the societal acceptance of the research conducted within the IHU.

3. EXAMINATION OF THE PROJECT PROPOSALS

The IHU projects shall be selected by an international and independent panel comprising exclusively foreign or working abroad members of recognised standing in scientific and technological fields and personalities from the business world. The members shall collectively have experience in research, teaching/training, clinical and translational research, healthcare, prevention and value creation. The panel will be chaired by a recognised personality who is familiar with the organisation of the French system of higher education, research and innovation but has no conflict of interest with the submitted projects.

The selection procedure comprises the following main steps:

- examination of the **admissibility** of the projects by ANR in accordance with the criteria stipulated **§ 3.1** « Admissibility criteria ».
- examination of the **eligibility** of the projects by the panel;
- **evaluation** of the projects by the panel after having carried out a preselection and heard the project leads of the preselected projects and, where applicable, requested external expert appraisals;
- **handing over to the health ministerial steering committee of France 2030 of the evaluation panel's report** containing:
    - a list of A-rated projects that have been heard - indicating the reasons why - that it considers potentially fundable, subject if applicable to modifications that it shall indicate as recommendations;
    - a list of projects - indicating the reasons why - that it considers cannot be recommended for funding due to insufficient quality in at least one of the criteria or in the evaluation panel's overall perception of the project.

The ministerial steering committee,

- on the basis of the international evaluation panel's report, proposes the designation of the beneficiaries and the corresponding funding amounts to the General Secretariat for Investment: the final decision lies with the Prime Minister;
- after the Prime Minister's decision, asks the CEO of ANR to sign the ANR/beneficiary agreements detailing the mutual obligations of the parties;
- ensures that all or part of the funding is paid under the conditions provided for in the agreements, if the Prime Minister's decision is favourable.

The persons involved in project evaluation, particularly the evaluation panel, shall comply with the ANR code of ethics and scientific integrity[5]. ANR shall in particular verify compliance with non-disclosure agreements and that there are no ties or conflicts of interest. If noncompliance is observed, ANR reserves the right to take any remedial measures it deems necessary. The ANR code of ethics and scientific integrity can be downloaded from the ANR web site.

The composition of the international evaluation panel shall be posted on the call for proposals publication website at the end of the evaluation procedure.

3.1. ADMISSIBILITY CRITERIA

IMPORTANT

Files that do not satisfy the admissibility criteria will not be submitted to the evaluation panel and may not under any circumstances receive any funding.

1) The complete submission file shall be uploaded to the ANR submission website before the call for proposals closing date and time indicated page 3, including the administrative and financial appendix and the commitment letters, all signed by each Founding partner.

2) The scientific document shall be in unprotected PDF format and not exceed 25 pages (minimum character font size: 11, Times New Roman or equivalent). Any scientific document that exceeds 25 pages will automatically render the project inadmissible.
The scientific document may be supplemented by any appendix deemed relevant by the project lead. The maximum length of all the scientific appendices combined shall not exceed 50 pages (minimum character font size: 11, Times New Roman or equivalent).

3) The appendix dedicated to the governance in the last paragraph of the 2.4 complete the scientific document and shall be uploaded to the ANR submission website before the call for proposals closing date and time on page 3. This appendix shall be imperatively in unprotected PDF format and not exceed 5 pages (minimum character font size: 11, Times New Roman or equivalent). Any appendix dedicated to the governance in the last paragraph of the 2.4 that exceeds 5 pages will automatically render the project inadmissible.

4) The project duration shall be 120 months.

[5] https://anr.fr/en/anrs-role-in-research/commitments/scientific-integrity/

5) The project shall be presented by a project leader, the future director of the IHU.

6) No member of the future IHU shall be a member of the ministerial steering committee.

7) The amount of the requested funding shall be equal to or lower than €50 M.

3.2. ELIGIBILITY CRITERIA

IMPORTANT

The files examined by the evaluation panel that do not satisfy the eligibility criteria may not under any circumstances receive any funding.

The project must **fall within the scope** of the call for proposals described in § 2.

3.3. EVALUATION CRITERIA

IMPORTANT

The files that satisfy the admissibility and eligibility criteria shall be evaluated against the following criteria:

3.3.1. COHERENT AND ORIGINAL NATURE OF THE PROJECT, AND THE QUALITY OF ITS SCIENTIFIC, CLINICAL, TEACHING, AND VALUE CREATION GOALS AND DRAWING POWER

Research

- Originality, quality and relevance of the research programme and its implementation plan;
- Coherence of the proposed scientific program with the IHU mission and particularities as stated in 2.3 section;
- Coherence of the proposed scientific project with the research units, the healthcare facilities and with the strategy of the site;
- Coherence of the proposed project with the *Healthcare Innovation 2030* and the *France 2030* Plans.

Healthcare and prevention

- Quality of the healthcare environment in the area of the IHU;
- Links healthcare – research or prevention – research, particularly how issues arising from clinical experience are taken into account in the IHU's research strategy;
- Coherence and links with clinical activities of the founding healthcare facility, and its strategic priorities.

Teaching and training

- Innovating and multidisciplinary nature of the courses offering proposed under the IHU, particularly for clinicians and health professionals, including MD-PhD degree courses;

- Coherence of the proposed training courses with the life sciences, medical, pharmaceutical, paramedical, engineering, social sciences and humanities curricula etc. which exist locally, nationally or internationally;
- Consistency of the proposed training courses with the current and future needs of the health industries;
- Policy for promoting and training students, researchers and healthcare personnel in market-based logics and expectations as well as in the culture of intellectual property and entrepreneurship;
- Training in the regulatory and ethical aspects of clinical research for students and research and health personnel, as well as scientific integrity training;
- National and international attractiveness of the courses proposed for students and research and health personnel in the IHU thematic area.

Value creation and transfer

- Measures and organisation proposed to ensure valorisation, in particular through start-up and SME creation and development;
- Quality and coherence of the skills present within the IHU project;
- Credibility of the organisation of the technology transfer which should be entrusted to a single agent based on one or more existing structures, if necessary mutualised, offering a high level of service to accelerate and streamline the valuation of the work resulting from the 'IHU, consistent with the site policy;
- Defining of a technology transfer policy, more specifically with guidelines concerning the filing of patents, obtaining support for start-ups and the prevention of conflicts of interest;
- Presence of areas dedicated to hosting companies and entrepreneurial projects within the IHU premises;
- Envisaged contribution or role in the implementation of health policies.

Network and partnerships

- Quality and relevance of the IHU scientific and clinical network;
- Quality of the proposed scientific and clinical partnership research program;
- Proposed measures and resources to play the role of network pilot: shared platforms, data aggregator, city-hospital links, etc.;
- Capacities and resources provided for the dissemination of knowledge to health professionals beyond the IHU: animation of thematic or territorial networks, organisation of training for hospital professionals and private practitioners, etc.

Attractiveness

- Simple and clear measures and organisation implemented to attract talent, in particular the policy of attractiveness, mobility and human resources;
- Simple and clear measures and organisation implemented to attract European and international projects and funding whether public, private or in partnership;
- Simple and clear measures and organisation implemented to promote the clinical studies, in connection with local promotion structures (Clinical research department, Centre of clinical investigation, Centre of Clinical research, Integrated Cancer Research Sites, etc.);

- Measures implemented for the management of data and samples in connection with local existing structures;
- Simple and clear measures and organisation implemented for the unique management of intellectual propriety and technology transfer, in connection with the local valorisation structures.

International recognition of the teams

- Profiles of the researchers, teacher-researchers and health professionals, coherence of skills;
- Publications, prizes and awards;
- Patents filed in the last 10 years, company creations, funds raised by these companies, revenue from licenses;
- Funding obtained for national, European and international projects;
- Any other competence bearing witness to international recognition.

Founding partners commitment

- Policies of the Founders to strengthen the financing of the IHU either in cash or in kind (operation, general expenses, personnel, rents, chairs of excellence, contribution to competitive financing, etc.);
- Measures and minimal commitment to be IHU Founder.

Questions relating to ethics and concerns regarding the societal acceptability of the research work shall be taken into account.

3.3.2. EFFECTIVENESS AND FLEXIBILITY OF THE PROPOSED GOVERNANCE AND ORGANISATION

- Proposals for implementation of governance principles described in 2.4;
- Appropriateness and composition of the proposed structure and governance bodies;
- Integration within the site strategy;
- Composition of the international scientific council and its expected role on the scientific strategy;
- Profile of the director and process for her/his renewing or replacing (compliance with international best practices);
- Description of the administrative resources necessary for the smooth running of the IHU;
- Relations established with the main partners/Founders:
  - University;
  - Healthcare facility, in particular the planned legal and financial relationship between the healthcare facility and the IHU with regard to the organisation of care activities (if relevant);
  - Research organisations;
- Relations established with the socio-economic world:
  - Industrial partners;
  - Competitiveness cluster;

- Relations with patient networks or associations if applicable, and doctors and other health professionals in the outpatient sector, in relation with the thematic area of the IHU;
- Relationship with public and opening up to society.

3.3.3. Soundness of the development plan

- Detailed road map describing the 5-year objectives and the 10-year ambitions;
- Level of detail and appropriateness of the planned use of the allocated France 2030 funding, and in particular:
  - research equipment and infrastructure,
  - research projects
  - teaching/training programmes
  - human resources
  - research network
- Expected revenues from the partnership projects and technology transfer activities;
- Other expected sources of funding (including sponsorship, legacies, etc.);
- Drawing up of the articles of association (constitutive agreement between the IHU partners, etc.);
- Drawing up of a multi-year commitment of resources and functioning agreement between the IHU and its Founders, defining the conditions of managing the costs and revenues resulting from partnership projects, technology transfer activities and from other sources and guaranteeing the transparency of the financial flows and the process for assigning them to the healthcare, research, teaching and innovation activities;
- Balance of the funding and value creation plan;
- Prospective management of employment;
- Expected advances in medical practices or in public health;
- Putting in place specific support actions for new funding methods based on the research activity developed in the hospital departments or department groupings participating in the IHU;
- Ability to attract private or regional authority funding;
- Defining of the scientific and financial conditions of access to the translational research infrastructure for projects emanating from the public or private sector;
- With regard to the translational research infrastructure: quality and coherence of the development plan, of the proposed channel of services and of the monitoring bodies;
- Organisation of clinical research;
- Proposal of an investment master plan approved by the founding members;
- Defining of the conditions of financial sustainability of the project.

3.3.4. Expected impacts

- Envisaged and estimated medico-economic and socio-economic impacts (improvement in health professionals' practices and public health policies, reduction in health costs, etc.);
- Lasting and expected development of the biomedical industrial sector;

- Transforming effect of the IHU for the founding members in terms of healthcare, prevention, teaching/training and research.

3.4. Submission of projects to the various France 2030 initiatives and other funding programmes

The project leader and the various partners shall mention all the "Investments for the Future" calls for proposals in which they are, or envisage, participating.

This principle of transparency also obliges indicating any link with the national public health plans or any other research funding programme, while avoiding redundancy in the funding applications.

4. General provisions for funding

4.1. Funding

The call for proposals funded under the France 2030 Plan is of an exceptional nature and stands out from recurrent funding of hospital, university or research institutions. It aims, by creating synergies, to give maximum six centres at the most worldwide visibility in the area of healthcare and to place translational research at the centre of the project by giving it very substantial resources.

The allocated funding represents additional resources intended for new actions. It will allow the purchase of equipment, in particular for the creation of the translational research infrastructure, the launching of innovative research projects, improving the teaching/training offering, and the expenses of personnel assigned specifically to the IHU (under the conditions specified in the financial regulations).

The IHU 3 (University Hospital Institutes 3) call for proposals funding is defined within the programme 425.

The conditions of payment of the grants to the final beneficiaries shall be described in the agreements concluded with the beneficiaries. Their signing shall be dependent on transmission by the coordinating entity of the following documents signed by all the partners:

- articles of association giving a precise description of the governance;
- consortium agreement and/or multi-year commitment of resources and functioning agreement with Founders;
- agreement instituting a single agent for technology transfer management;
- agreement for clinical studies promotion, data and sample management;
- business plan presenting all the contributions necessary to accomplish the project (e.g. funding conditions for the fitting out or construction of a building) signed by all the funding sources identified in the document;
- commitment of coordinating partner and Founders;
- appendix describing the analysis of the socio-economic impact of the project;
- agreement on the setting up of specific supports for new funding methods based on the research activity developed in the hospital departments participating in the IHU, provided for in article 3.3.3.
- agreements relative to the administrative and financial conditions necessary for the implementation of the project;
- Research Data Management Plan and Open Science policy.

Whatever the case, the agreements with the final beneficiaries shall be signed no later than six months following the Prime Minister's funding decision, otherwise they will be null and void.

4.2. Type of funding

The funding allocated by ANR shall be provided in accordance with the provisions of the "Regulations relative to the allocation of grants for the IHU 3 call for proposals" for the France 2030 Plan, available on the call for proposals website. The funding will be paid in the form of annual schedules. The winners will receive 10% of the total funding at the beginning, upon signing the agreement with the ANR. The following annual payments will be conditional on the effective completion of the project, in particular on the fulfilment of financial commitments or contributions from the founders or partners, as well as on the respect of contractual commitments in terms of monitoring and evaluation.

4.3. Interim audits and assessments

ANR may conduct audits of the IHUs as part of the annual project monitoring actions. If it is found that the appropriations are not used in accordance with the agreements made with the beneficiaries, ANR will inform the ministerial steering committee. This later may decide, after consulting the Secretariat-General for Investment, to suspend or stop the payments of the following instalment, or even to abandon the project.

ANR will also organise interim assessments (ideally every three years) following the same principles as those applied during project selection (international and independent evaluation panels, etc.). On completion of this interim assessment, the steering committee might, after consulting the Commissariat-General for Investment, decide to suspend or stop the payments of the following tranches, or even to abandon the project.

4.4. Open science

As part of ANR's contribution to the promotion and implementation of open science, and in connection with the national plan for open science (PNSO) and the European cOAlition S (Plan S), the coordinating institution, the Founders and the partners must commit to ensure immediate open access to peer-reviewed scientific publications and to implement a FAIR data vision (data that is Findable, Accessible, Interoperable and Reusable) in accordance with the principle: "as open as possible, as closed as necessary". All scientific publications resulting from projects in the framework of the IHU will thus be made available in open access under the Creative Commons Licence (CC-BY) or equivalent via one of the following routes:

- Publication in a natively Open Access journal;
- Publication in a subscription journal that is part of a transformative agreement or in a transformative journal;
- Publication in a subscription journal. Version of Record or version Author Accepted Manuscript will be submitted by authors to the open archive HAL under the CC-BY licence and zero embargo (Right Retention Strategy) according to the terms communicated in the funding agreement.

Moreover, the coordinating institution must commit to submit, at the time of publication at the latest, the full text of the scientific publications (version Author Accepted Manuscript or

Version of Record) in the national open archive HAL, and mention the ANR research project reference.

ANR encourages depositing pre-prints in open platforms or open archives and using permanent or unique identifiers (DOI or HAL Id, for example). ANR recommends giving priority to publication in journals and books that are natively open access.

4.5. Other provisions

The funding of a project does not relieve its participants of their obligations concerning the regulations and the rules and code of ethics applicable to their area of activity.

The project leader (the future IHU director) undertakes in the name of all the founding members to keep ANR informed of any change that could modify the content, the partnership or the schedule of project performance between the time of project submission and the publication of the list of selected projects.

5. Submission conditions

5.1. Content of the submission file

The submission file shall include all the elements necessary for the scientific and technical assessment of the project. It shall be complete when the call for proposals closes, the date and time of which are indicated on page 3.

Important

No additional elements will be accepted after closing of the call, the date and time of which are indicated on page 3

The documents shall be uploaded to a submission website, the address of which is indicated on page 3. To gain access to this service an account must be opened beforehand (login and password). To obtain these elements it is recommended to register as early as possible.

The complete submission file comprises the following fully completed documents:

- **the "administrative and financial document" which describes the administrative and budgetary aspects of the project**;
- **the "scientific document" and its appendices which describe the scientific and clinical thematic area and the teaching and value creation objectives of the project;**
- **the governance appendix**
- **the commitment letters signed by the person with legal responsibility from each of the project founding members.**

The elements of the submission file (administrative and financial document in Excel format / templates of scientific document, appendices and commitment letters in Word format) shall be accessible from the publication website page of this call for proposals (see address on page 1).

As the projects are evaluated by an international panel, it is recommended to produce a scientific and technical description of the project **in English**. If the scientific and technical

description is written in French, an English translation may be requested within a time frame compatible with the evaluation process deadlines.

5.2. Submission procedure

The submission file documents shall be transmitted by the project leader:

IN ELECTRONIC FORMAT, without fail:

- before the closing date indicated on page 3 of this call for proposals,
- on the submission site in accordance with the recommendations of 5.1.

Prior registration on the submission website is a prerequisite for project submission.

Only the electronic version of the submission documents present on the submission website when the call for proposals closes is taken into consideration for the evaluation.

AN ACKNOWLEDGEMENT OF RECEIPT in electronic format will be sent to the project leader when the documents are submitted.

N.B.: The signing of the commitment letters certifies that the project partners agree to submit a project in accordance with the conditions described in the administrative and financial document and in the scientific document and its appendices.

5.3. Submission recommendations

It is strongly recommended:

- to open an account on the submission website as early as possible;
- not to wait for the project submission deadline date to enter the data on line and upload the files (warning: it is mandatory to comply with the submission deadline time);
- to verify that the documents uploaded to the dedicated spaces under the "submission documents" and "signed documents" headings are complete and are indeed the required documents. The submission file and the deposition of signed documents can only be approved by the project leader if all the documents have been uploaded;
- to regularly consult the call for proposals website at the address indicated on page 1, which contains updated information concerning the applicable procedures;
- to contact the correspondents by e-mail if necessary, at the addresses indicated on page 3 of this document.

6. Appendices

6.1. Definitions relative to project organization

Coordinating entity: endowed with legal personality, it is the chief point of contact with ANR for administrative matters. It is responsible for setting up and formalizing the collaboration between the partners, producing the project deliverables, holding the progress meetings and communicating the results. It is assisted in these tasks by a project leader, director of the IHU. It signs the grant award agreement with ANR and receives the grant awarded to the project.

Project leader: this is the natural person who ensures the scientific, clinical and technical coordination of the project on behalf of the Coordinating entity. This person is the future director of the IHU. This person is the chief point of contact with ANR.

Founders: entities with legal personality involved in the IHU governance. A university, a healthcare facility, and one or more research organisations are at once involved as founding members. Other private and public entities shall be involved as additional founding members.

Partner: research unit of a research organisation, a university, a company or a department in a healthcare facility, or a project stakeholder. Each of the partner units designates its own scientific investigator, who will be the chief point of contact with the project leader, the IHU director.

Partner institution: parent university, research organisation or healthcare facility of a partner unit, or a research organisation or a healthcare facility allocating resources to the partner unit or company on which a partner unit depends.

6.2. DEFINITIONS RELATIVE TO THE STRUCTURES

Enterprise (Company): the term "enterprise" or "company" includes Large Companies and Small and Medium-size Enterprises (SMEs). The definition of small and medium-sized enterprises (SME) is that of regulation (EC) No. 70/2001 of the European Commission of 12th January 2001 and figures in recommendation 2003/ 361/CE of the European Commission of 6th May 2003 on the definition of micro, small and medium-sized enterprises and any community text that replaces it. Within the meaning of European Community law, any entity - irrespective of its legal form - that conducts an economic activity is considered to be an enterprise (company). Economic activity means any activity consisting in offering goods and/or services on a given market.

Research organization: the term "research organization" must be taken in the sense defined in point 2.2 of the EU Framework. It means an entity, such as university or research institute, irrespective of its legal status (organised under public or private law) or way of financing, whose primary goal is to conduct fundamental research, industrial research or experimental development and to disseminate their results by way of teaching, publication or technology transfer; all profits are reinvested in these activities, the dissemination of their results or teaching; undertakings that can exert influence on such an entity, in the quality of, for example, shareholders or members, shall enjoy no preferential access to the research capacities of such an entity or to the research results generated by it.

Regional authorities: endowed with **legal persons of public law independent of the State** and benefiting as such from **legal and patrimonial autonomy.** They are designated under the name of "local authorities". The two terms are used as equivalents in everyday language. For example, the following are defined as regional authorities: municipalities; the administrative "départements", including the five overseas départements (DOM), the regions, including five overseas regions; communities with special status; overseas communities (Com).

Healthcare facility: structures ensuring the diagnosis, surveillance and treatment of the sick, injured and pregnant women, who deliver care and treatments on an inpatient or outpatient basis and in the home, who participate in the coordination of treatments in collaboration with members of the health profession exercising in town practices and with the medical/welfare institutions and services. They participate in the implementation of the public health policy and the oversight mechanisms intended to guarantee safety in health. They conduct internal reflections on the ethics associated with the reception and management of patients (L6111-1 et seq. of the Public Health Code).

6.3. DEFINITIONS RELATIVE TO THE DIFFERENT RESEARCH CATEGORIES

These definitions figure in the EC Framework of Government aids to research, development and innovation[6].

Basic or Fundamental research: experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundations of phenomena or observable facts, without any practical application or use in direct view.

Industrial research: planned research or critical investigations aimed at acquiring new knowledge and skills for developing new products, processes or services or for bringing about a significant improvement in existing products, processes or services. It includes the creation of components of complex systems, necessary for industrial research, and notably for the validation of generic technologies, but excludes prototypes covered in the definition of experimental development below".

Experimental development: the acquiring, combining, shaping and using of existing scientific, technological, business and other relevant knowledge and skills for the purpose of producing plans, devices or drawings for the design of new, modified or improved products, processes or services. These may also include, for example, other activities aiming at the conceptual definition, planning and documentation of new products, processes and services. These activities may concern the production of drafts, drawings, plans and other documents, provided that they are not intended for commercial use.

The development of commercially usable prototypes and pilot projects is also included where the prototype is necessarily the final commercial product and where it is too expensive to produce for it to be used only for demonstration and validation purposes. In case of a subsequent commercial use of demonstration or pilot projects, any revenue generated from such use must be deducted from the eligible costs.

The experimental production and testing of products, processes and services are also eligible, provided that these cannot be used or transformed to be used in industrial applications or commercially.

Experimental development does not include the routine or periodic changes made to products, production lines, manufacturing processes, existing services and other operations in progress, even if such changes may represent improvements.

6.4. DEFINITIONS RELATIVE TO THE MEDICAL SECTOR

Prevention: set of measures aimed at avoiding or reducing the number and severity of diseases, accidents and disabilities (WHO 1948)

Healthcare: coherent set of actions and practices implemented to help restore or maintain a person's health (HAS 2007)

Public health: set of knowledge, know-how, practices and legal rules which aim to know, explain, preserve, protect and promote the state of health of people (Public Health Treaty 2016).

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[6] Cf. JOUE 30/12/2006 C323/9-10
http://www.agence-nationale-recherche.fr/documents/uploaded/2007/encadrement.pdf