

INVESTMENTS FOR THE FUTURE

UNIVERSITY HOSPITAL INSTITUTES

IHU 2

2017 Edition

Call for proposals closing date
12/10/2017 at 13h00 (1 pm)

Call for proposals publication address
<http://anr.fr/IHU2-2017>

KEY WORDS

Biomedical research, clinical research, translational research, public health research, high-level higher education, improvements in healthcare and prevention, 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

The aim of this call for proposals is to create a maximum of three new University Hospital Institutes (IHU), future centres of excellence in research, healthcare, 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 university hospital centre or healthcare facility, and one or more research organisations.

The appropriateness of the economic model and the governance; the capacity to create a dynamism that fosters excellence and integrate the project into the policies of the institutions

IHU 2

- particularly the hospital and the university; the 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 files, in addition to the 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:

THURSDAY 12/10/2017 AT 13H00 (1 P.M.) (PARIS TIME)

to the website:

<https://investissementsdavenir.agencerecherche.fr/ihu>

CONTACTS

ihu@agencerecherche.fr

CORRESPONDENT:

Aude-Marie LEPAGNOL-BESTEL aude-marie.lepagnol-bestel@agencerecherche.fr

IHU PROGRAMME SUPERVISOR

Emmanuelle SIMON emmanuelle.simon@agencerecherche.fr

**You must read carefully the
"Regulations governing the conditions of awarding grants for the IHU2 Programme"¹
before submitting a file.**

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

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

CONTENTS

1. Context and objectives of the call for proposals .	5
1.1. Context	5
1.2. Objectives of the call for proposals.....	5
2. Scope of the of call for proposals	6
2.1. Scope.....	6
2.2. Partners	7
2.3. Mission and particularities of the IHUs	7
2.4. Governance	8
2.5. Specific provisions	8
3. Examination of the project proposals	9
3.1. Admissibility criteria	10
3.2. Eligibility criteria.....	10
3.3. Evaluation criteria.....	11
3.3.1. Coherent and original nature of the project, and the quality of its scientific, clinical, value creation and teaching goals	11
3.3.2. Effectiveness and flexibility of the proposed governance and organisation	12
3.3.3. Soundness of the development plan	13
3.3.4. Expected impacts	13
3.4. Submission of projects to the various investments for the future initiatives and other funding programmes	14
4. General provisions for funding	14
4.1. Funding	14
4.2. Interim audits and assessments	15
4.3. Other provisions	15
5. Submission conditions	15
5.1. Content of the submission file	15
5.2. Submission procedure	16
5.3. Submission recommendations	16
6. Appendices	17
6.1. Definitions relative to project organization	17
6.2. Definitions relative to the structures.....	17
6.3. Definitions relative to the different research categories.....	18

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. 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 six 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.

The proposal today is to supplement the IHU programme by launching a second 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 six IHUs.

The "University Hospital Institutes - IHU 2" initiative will allow the creation of up to three centres of excellence in research, healthcare, training and technology transfer in the area of health thanks to an allocation of 200 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 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 cognitive, 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 ways of organising healthcare, 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 national scale, more specifically in clinical research, translational research and the discovery research which fuels them. On this account, the proposed projects shall fit into the National Strategy for Research and the National Strategy for Health.

IHU 2

The IHU programme must allow:

- the consolidation of the leading French centres for research, healthcare and training by creating centres of excellence of international standing which will have to:
 - give themselves the means to attract, develop and retain the world's leading talents;
 - develop healthcare and teaching of a high standard, geared to the new needs of research, create new professional activities and improve the training of research and healthcare professionals;
 - foster research and multidisciplinary courses.
- lastingly stimulate the competitiveness of France by encouraging the development of the biomedical industrial sector:
 - by bringing greater visibility, legibility and thus greater attractiveness for the talents and partners;
 - by permeating the economic fabric;
 - by making courses and infrastructures evolve to encourage partnership research.
- stimulate research beyond the perimeter of the IHUs:
 - by encouraging the research actors to organise themselves around the exemplary centres that the IHUs will epitomise;
 - by fostering the emergence and dissemination of a new culture that ties in with the new research and development models.

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 and healthcare 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.

IHU 2

2.2. PARTNERS

The projects presented shall:

- involve, as founding members, a university, a university hospital centre or a healthcare facility, and one or more research organisations;
- display scientific and medical coherence² ;
- be limited to one main site, possibly associated with satellite sites that can reinforce its potential by constituting an integrated whole and not a thematic network;
- 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;
- 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, from the creation of the IHU, by a mutualised structure on the same site;
- provide the possibility of having additional private and public founding members other than a university, a university hospital centre, 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;
- developing translational research that leads to new products and preventive, diagnostic or therapeutic processes;
- 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;
- allowing the experimentation of new medical practices, new healthcare protocols, new organisations and their assessment, with a view to facilitating 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;

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.

IHU 2

- developing very high-level care 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, and its regional, national and international impact. It may for example take the form of a foundation, a Foundation for Scientific Cooperation (FCS), a hospital foundation, etc. 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 comprising in particular the founding members, an international scientific council and an executive committee;
- 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;
- guarantee within the governing board a balanced representation between founding members and outside personalities (such as representatives of health services user associations);
- 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 founding members other than a university, a university hospital centre, 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;
- describe the process for renewing or replacing the IHU director at the end of or during the mandate. A mandate may not exceed 4 years and shall be renewable.

These governance principles shall be transposed in the articles of association and rules of procedure.

2.5. SPECIFIC PROVISIONS

- The selected projects shall be assessed by an international panel, ideally every three years, 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.

IHU 2

- 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 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 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 steering committee³ 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 B-rated projects that have been heard - indicating the reasons why - that it considers only partially meet the selection criteria but are sufficiently promising to receive a lower level of funding than the projects rated A, subject to modifications that it shall indicate as recommendations;
 - a list of C-rated 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 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 Commissariat-General for Investment: the final decision lies with the Prime Minister;
- after the Prime Minister's decision, asks the Director-General 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.

³ The steering committee is the authority designated as such in paragraph 2.4 of the State-ANR agreement governing this call for proposals.

IHU 2

The persons involved in project evaluation, particularly the evaluation panel, shall comply with the ANR code of ethics⁴. 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 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. The signed and scanned commitment letters shall also be uploaded to the ANR submission website by the date and time indicated on page 3.
- 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 appendices combined shall not exceed 50 pages (minimum character font size: 11, Times New Roman or equivalent).
- 3) The project duration shall be 120 months.
- 4) The project shall be presented by a project leader, the future director of the IHU.
- 5) No member of the future IHU shall be a member of the steering committee.
- 6) The amount of the requested funding shall be between €35 M and €55 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.

⁴ <http://www.agence-nationale-recherche.fr/CharteDeontologieSelection> and <http://www.agence-nationale-recherche.fr/missions-et-organisation/qualitedeontologie/politique-d-ethique-et-d-integrite-scientifique/>

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, VALUE CREATION AND TEACHING GOALS

Research

- Quality and relevance of the research programme and its implementation plan;
- Coherence of the proposed project with the strategy of the site;
- Coherence with the France Horizon 2020 strategic research agenda and the Health Well-Being societal challenges of the National Research Strategy;
- Ability to attract the world's leading talents, policy with regard to mobility and human resources.

Healthcare

- Quality of the healthcare environment in the area of the IHU;
- Coordination with the activities of the University Hospital Centre (UHC) and its strategic priorities;
- Envisaged legal and financial link between the UHC and the IHU with regard to the organisation of healthcare activities (for example: agreement to create a GIE (economic interest group) or a GCS (healthcare cooperation group), contract agreement between the UHC and the hospital department groupings or departments included in the perimeter of the IHU, etc.);
- Attractiveness of the clinical project and how healthcare and research are linked, particularly by the ways in which questions arising from clinical experience are taken into account in the IHU's research strategy;
- Capacity to disseminate knowledge to health professionals beyond the IHU perimeter: facilitation of thematic or regional networks, organisation of training courses for health professionals in hospitals and private practice, etc.;
- Coherence of the proposed project with the French National Health Strategy.

Value creation, transfer, partnerships

- Quality and coherence of the skills present within the IHU project to ensure continuity from discovery research through to application in healthcare;
- Attractiveness of the IHU for European, international, public, private or partnership projects and funding;
- Credibility of the organisation of technology transfer which shall be based on a mutualised structure situated on the same site;
- 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;

IHU 2

- Ability to disseminate - both locally and nationally - knowledge and practices in the discipline and networks associated with the IHU;
- Envisaged contribution or role in the implementation of health policies.

Teaching, training

- National and international attractiveness of the proposed courses for students, research and health personnel in the thematic area of the IHU;
- Innovating and multidisciplinary nature of the courses based on research training and research-led teaching proposed under the IHU, particularly for clinicians and health professionals, including MD-PhD degree courses;
- Ability to meet 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;
- Overall coherence of the university training offering with medical, paramedical, engineering, social sciences and humanities degree courses, etc.

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.

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 of the proposed structure and governance bodies;
- Composition of the international scientific council and its expected impact on the scientific strategy;
- Profile of the director;
- Description of the administrative resources necessary for the smooth running of the IHU;
- Relations established with the main partners:
 - University;
 - University hospital centre or healthcare facility;
 - Research organisations;
- Relations established with the socio-economic world:
 - Industrial partners;
 - Competitiveness cluster;

IHU 2

- 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.

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 PIA (Investments for the Future Programme) funding, and in particular:
 - research equipment and infrastructure,
 - research projects
 - teaching/training programmes
 - human resources
- 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 partners, 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;
- Expected advances in medical practices;
- 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, teaching/training and research.

3.4. SUBMISSION OF PROJECTS TO THE VARIOUS INVESTMENTS FOR THE FUTURE 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 action funded under the Investments for the Future programme 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 three 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).

Within programme 422 "New Innovation Ecosystems", €200 M (€150 M as a 10-year endowment and €50 M as grants) have been released through the Finance Act No. 2016-1917 of 29th December 2016 for 2017 to fund the IHU 2 (University Hospital Institutes 2) initiative.

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;
- agreement instituting a single mandate for technology transfer 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;
- 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.

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.

IHU 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 2 call for proposals" for the Investments for the Future programme, available on the call for proposals website. Payment of the grant is more specifically dependent on effective realisation of the project and transmission of the elements necessary for monitoring and evaluation.

4.2. 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 steering committee. The steering committee may decide, after consulting the Commissariat-General for Investment, to suspend or stop the payments of the following tranches, 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.

4.3. 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 three fully completed documents:

- **the "administrative and financial document" which describes the administrative and budgetary aspects of the project;**

IHU 2

- 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 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 and letter of undertaking 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 website 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 appendix, if applicable.

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 programme 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. 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.

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.

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 innovation⁵.

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.

⁵ Cf. JOUE 30/12/2006 C323/9-10

<http://www.agence-nationale-recherche.fr/documents/uploaded/2007/encadrement.pdf>