VJ-IISFJD
V.4

TRANSFER AND TRANSLATION PLAN

RECORD OF CHANGES SINCE LAST VERSION		
Version	**Date**	**Modification**
3	March 2020	Update of procedures and structure.
4	October 2024	Update of references to organisational structure and participation in the ITEMAS Platform.

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1. INTRODUCTION AND OBJECTIVES

The Fundación Jiménez Díaz Health Research Institute (IIS-FJD), certified by the ISCIII in 2010 and certified again in 2015 and 2020, is a centre conceived as a operational structure for multidisciplinary and translational biomedical research oriented towards basic, clinical, epidemiological and health services research, committed to the promotion of innovation, the translation of research findings into clinical practice and their efficient exploitation.

Its core is located at the Fundación Jiménez Díaz University Hospital (HUFJD), and it is made up of research staff from the Hospital, teaching and research staff from the Autonomous University of Madrid, and research groups from IDCSalud Villalba, IDCSalud Valdemoro, IDCSalud Móstoles, CIEMAT and the Primary Care area in the Fundación Jiménez Díaz's area of influence.

In relation to innovation, the IIS-FJD has set up an Innovation Unit aimed at disseminating a culture for protecting the knowledge generated at the Institute, identifying technological and health innovation that facilitates an increase in the number of patent applications and grants, as well as facilitating strategic collaborations with academic, health and industrial partners to license patents and obtain possible returns. This unit carries out the duties of the OTRI (*Research Transfer Office*), and manages research results within the Institute.

In addition, in recent years, increasing importance is being given to aspects related to the translation of research findings into routine clinical practice in healthcare centres. The innovation carried out in the Health Research Institutes is no longer restricted to the registration and exploitation of patents and other technology transfer models, but now also encompasses improvement and innovation in healthcare processes and other results that can be directly applied in clinical settings.

The objectives set out in this IIS-FJD Transfer and Translation Plan are the following:

- To define the scope of application of this Plan.
- To set out the background of the IIS-FJD that has led to the development of this Transfer and Translation Plan.

- To describe and identify the structures currently available to the IIS-FJD for the development of activities in this field.
- To develop the procedure for transferring research results into the productive sphere.
- To specify the ownership of the rights and the distribution of the benefits obtained from the exploitation of the results.
- To define the procedure for translating results into routine clinical practice at the HUFJD.
- To define the actions and channels for dissemination and training in the areas of innovation, transfer and translation of results.
- To identify the improvement objectives to be evaluated periodically in order to carry out the annual follow-up of the Transfer and Translation Plan.

2. SCOPE OF APPLICATION

This document applies to research results obtained by IIS-FJD staff. For these purposes, research results are understood to be those that can be legally protected by means of patents, utility models, computer programmes, databases and brands, as well as all results obtained that can be translated into routine clinical practice thanks to their cost-effective benefits or their advances in diagnostic, therapeutic or rehabilitative processes, among other improvements.

Results that, although not susceptible to protection according to the previous section, may be subject to economic exploitation, such as industrial secrets and know-how, are also understood to be research results.

Concepts relating to the patentability of new inventions are set out in Law 24/2015, of 24 July, on Patents, which identifies the industrial property titles that may be protected:

- Invention patents.
- Utility models.
- Supplementary protection certificates for medicines and phytosanitary products.

The requirements for an invention to be patentable are defined below:

- In all fields of technology, patentable inventions are those that are novel, involve an inventive step and are industrially applicable.
- The inventions referred to in the previous paragraph may relate to a product composed of or containing biological material, or to a process by which biological material is produced, transformed or used.
- Biological material isolated from its natural environment or produced by means of a technical process may be the subject of an invention, even if it previously existed in its natural state.

The following, in particular, shall not be regarded as inventions within the meaning of the preceding paragraph:

a) Discoveries, scientific theories and mathematical methods.

b) Literary, artistic or any other aesthetic creation, and scientific works.

c) Plans, rules and methods for the exercise of intellectual activities, for games or for commercial-economic activities and computer programs.

d) Ways of presenting information.

Methods of surgical or therapeutic treatment for the human or animal body and diagnostic methods applied to the human or animal body shall not be regarded as industrially applicable inventions, with the exception of cases involving products, in particular substances or compositions, or inventions of apparatuses or instruments for the implementation of such methods.

There are a number of prior considerations that researchers must take into account when initiating the process of protecting research results:

- It is very important to maintain the utmost confidentiality of the research results to be patented. To this end, any form of written or oral disclosure in contacts with third parties must be avoided, given that if they have been disclosed in publications or orally, they cannot be protected by patent, because the disclosure prior to the filing of the patent application deprives the object of the invention of the requirement of novelty.

  This includes, in particular, publications, abstracts, communications to conferences, doctoral theses, etc.

- If you try to establish contracts with third parties, either for further development or continuation of the R&D project, or for technical assistance or licensing, or even in preliminary contacts, it is advisable to use Confidentiality Agreements, before transmitting any information related to R&D results.

- The description of the invention for the patent application must be drafted in such a way that it can be carried out with the information contained in the specifications.

Trademarks can also be registered, which are included in Law 17/2001, of 7 December:

Trademark: all signs, especially words, including personal names, drawings, letters, numbers, colours, the shape of the product or its packaging, or sounds, may constitute trademarks, provided that such signs are appropriate for:

a) Distinguishing the goods or services of one company from those of other companies.

b) Being represented in the Register of Trademarks in such a way as to enable the competent authorities and the general public to determine the clear and precise subject matter of the protection granted to its owner.

In a similar way to trademarks, industrial designs can also be registered, as provided for in Law 20/2003, of 7 July, on the Legal Protection of Industrial Designs.

Industrial design: the appearance of the whole or part of a product, resulting from the characteristics of, in particular, the lines, contours, colours, shape, texture or materials of the product itself or its ornamentation.

In utility models, the shape of an object is protected because it determines a technical advantage of the object, whereas in industrial designs, the shape of the object is protected, but only for its originality, for the aesthetic effect it produces and this applies only to the ornamentation and presentation of commercial products. The duration of industrial design rights varies from country to country. In general, the maximum duration is between 10 and 25 years.

Finally, the scope of application of this Transfer and Translation Plan includes the registration and management of intellectual property developed by IIS-FJD professionals.

As stated in Royal Legislative Decree 1/1996, of 12 April, the latest revision of which dates from 2 March 2019, all original literary, artistic or scientific creations expressed by any means or medium, tangible or intangible, currently known or to be invented in the future, are the subject of intellectual property rights.

Collections of third-party works, data or other independent elements such as anthologies and databases which, through the selection or arrangement of their contents, constitute intellectual creations, are also subject to intellectual property rights under the terms of Book I of this Law, without prejudice, where appropriate, to the rights that may subsist over such contents.

3. MEDICAL HISTORY

The IIS-FJD was created through the signing of a collaboration agreement between its parties in December 2009. This association was also created under Order SCO/1245/2006, of 18 April, which implements Royal Decree 339/2004, of 27 February, on the accreditation of Health Research Institutes (IIS), legislation that was applicable thereto at the time of its creation.

Since its creation, the aim of the IIS-FJD has been to consolidate its strategic positioning to lead healthcare research and raise the level of scientific and technological excellence.

As a result of the lines defined in its initial strategic plan, and in subsequent reformulations, to promote the translation and exploitation of research findings, and as a sign of the IIS-FJD's commitment to promoting innovation, the Technosanitary Innovation Unit was created in 2013, and from 2014 until 2021, participated in the Platform for Innovation in Medical and Healthcare Technologies (ITEMAS). From 22 February 2022, the Fundación Jiménez Díaz Health Research Institute became a member of the ITEMAS Platform under the following nodes: '12 de Octubre Biomedical Research Foundation', 'Hospital La Paz Biomedical Research Foundation', 'Hospital Ramón y Cajal Biomedical Research Foundation' and 'Hospital Gregorio Marañón Biomedical Research Foundation'. The creation of the Innovation Unit was an important milestone in the Institute's innovation activity, managed by its OTRI (registration 171 under the old law, currently pending registration under the new law). The unit was created with the aim of disseminating a culture for protecting the knowledge generated at the Institute, identifying technological and health innovation that facilitates an increase in the number of patent applications and grants, as well as facilitating strategic collaborations with academic, health and industrial partners to license patents and obtain possible returns. This unit carries out the duties of the OTRI (*Research Transfer Office*), and manages research findings within the Institute.

In order to regulate the activity of this Technosanitary Innovation Unit, the IIS-FJD draws up a Procedure for the Transfer of Research Results, which includes an action plan:

- Detection of ideas: by capturing ideas and inventions from professionals for their subsequent transfer to the market.
- Valuation and protection: through the evaluation of the different opportunities for new inventions and ideas and the assessment of the suitability of protecting them, defining the best property strategy and carrying out a market and evaluation report for each of them.
- Project management: if the valuation strategy so determines, the project maturity stage is carried out. To implement this, a development plan is defined, including the business plan, the operational plan and the financial plan.
- Transfer of technology: once the development and protection plan has been finalised, the technology, product or knowledge is transferred to the market by means of a licence to a research-based start-up or an established company.
- Promotion of a culture of innovation and entrepreneurship: by informing and training healthcare professionals in aspects of innovation and entrepreneurship, through various actions such as training and information activities.

Therefore, the IIS-FJD's Procedure for the Transfer of Research Results focuses on the identification and management of results obtained that might be protected as industrial property.

With the increase in activity at the Institute's Innovation Unit, in recent years work has been carried out to standardise and homogenise operations and tasks in relation to transfer. As a result of this, the IIS-FJD has been able to certify its R&D&I management system under the UNE166002:2021 standard. This has enabled a quantitative and qualitative leap in the services offered and the quality of the results obtained by the IIS-FJD in terms of innovation.

Finally, in view of the new regulatory framework governing the accreditation process for Health Research Institutes, it was considered important to broaden the IIS-FJD Innovation Unit's service portfolio to include the identification, management and analysis of aspects related to the translation of the results obtained by the Institute's professionals into routine clinical practice.

This new orientation of the Innovation Unit's activity has given rise to the present IIS-FJD Transfer and Translation Plan.

4. INNOVATION, TRANSFER AND TRANSLATION MANAGEMENT STRUCTURES AT THE IIS-FJD

As mentioned in the background section, the IIS-FJD has a structure that acts as the OTRI responsible for the management of research results generated within the Institute through its Innovation Unit, which was created in 2013 as a cross-disciplinary unit to support the Institute's innovation management.

This unit originated in the Fundación Jiménez Díaz's OTRI, registered under record No. 171 with the Ministry of Science and Technology since 2003. On 13 September 2010, a change in the ownership of the Fundación Jiménez Díaz OTRI was requested, in the name of the IIS-FJD as the new owner. It is currently in the middle of a registration process under the new regulations.

Currently, the structures with competencies assigned in the field of innovation, transfer and translation of results in the context of the IIS-FJD are the following:

- IIS-FJD Innovation Unit.
- IIS-FJD Quality and Innovation Committee. From 2025, this committee will be split into two separate committees: Quality Committee and Innovation Committee.
- HUFJD Innovation Classroom.

4.1. IIS-FJD Innovation Unit

The IIS-FJD Innovation Unit was created in 2013 as a cross-departmental Unit to support innovation management. It is directed by the Scientific Director of the IIS-FJD, Dr. Carmen Ayuso MD, PhD, and coordinated by Dr. Alberto Ortiz.

Currently, the Innovation Unit is a member centre of the Spanish Platform for Medical and Healthcare Technologies (ITEMAS), promoted by the ISCIII, and holds the Quality Certificate in R&D&I Management Systems under the UNE166002:2014 Standard.

The Innovation Unit has a multidisciplinary support team of professionals that includes basic scientists and clinical researchers with an innovative profile who, together with project management staff, technology platforms and services staff, are responsible for identifying technological and healthcare innovation at the centre, and promoting collaboration agreements with the academic, healthcare and industrial environments.

- Innovation Unit Director: Dra. Carmen Ayuso García
- Innovation Unit personnel:
    - Coordinator: Dr. Alberto Ortiz Ardúan.
    - Research staff: Victoria del Pozo Abejón, Dr. Damián García-Olmo, Raquel Largo Carazo.
    - Technology transfer management personnel: Isabel Orbis Ramírez
- Clinical and basic scientific personnel to advise and support the Innovation Unit: Dr. J. Esteban, Dr. P. Llamas, Dr. A Celdrán, Dr. Cenjor, Dr. Jiménez Alfaro, Dr. S. Jiménez de los Galanes, Dr. I. Fernández Navamuel, Dr. C. Gómez Guerrero, Dr. L. Blanco Colio, Dr. Mariano García Arranz, Dr. Juan Antonio Bueren, Dr. Marcela del Río, Dr. Ruiz Tovar, Dr. Francisco Javier Ruiz Hornillos.
- Technology platform personnel: Dr. G. Álvarez Llamas, Dr. R Fernández, M González García-Parreño, Dr. Lucía Llanos, Dr. Sandra Zazo.
- Person responsible for research management: Alberto Montero Manso

Objectives of the Innovation Unit

The strategic objectives of the unit are:

- Facilitate the transfer of research results to society and health in general by continuously improving the quality of patient care as well as commercial returns.
- Promote innovative culture in the IIS-FJD health sector and field
- Promote the internationalisation of R&D+i projects.
- Provide training to personnel in innovation.
- Identify innovative ideas that can be converted into products or services.

- Support the development of innovation projects (support services for the projects generated, management of intellectual and industrial property, technology transfer)
- Support the intellectual and industrial protection of innovations.
- Promote collaboration agreements in R&D+i projects with agents of the scientific-technological field, universities, companies, etc., both nationally and internationally.

Duties of the Innovation Unit

To fulfil these objectives, the Unit performs the following functions:

1. Detection of ideas.
2. Valuation and protection of ideas.
3. Support in the implementation and development of ideas.
4. Protection of the results obtained.
5. Transfer to the market of the results obtained.

Service portfolio of the Innovation Unit

- Information on funding calls for projects in the field of innovation.
- Guidance on industrial and intellectual protection of research results.
- Support in the search for partners to develop projects and their transfer to the business sector.
- Support in the management of confidentiality agreements, other agreements, service provision contracts, material transfer agreements, innovation licensing and so on with other entities.
- Support in the management of international projects.
- Training in innovation management.

4.2. IIS-FJD Innovation Committee

In 2017, following the Institute's R&D+i Management Systems Certification under the UNE166002 Standard, the Innovation Committee established action guidelines for ideas, projects, and actions carried out within the Institution being taken up by the Innovation Support Unit.

Objectives of the Innovation Committee

The specific objectives to be developed by this Committee are the following:

- Review of innovation proposals.
- Analysis of ongoing project portfolio.
- Decision about the continuity and inclusion of projects.
- Decision-making on technology transfer and/or protection of results.

Composition of the Innovation Committee

The Innovation Committee is composed of:

- Chair: Scientific Directorate of the IIS-FJD.
- Members: Coordination of the Innovation Support Unit, 2 Representatives of the Research Committee, Head of IIS-FJD Management, Quality Director of the HUFJD.
- Secretary: Technology Transfer Manager. Innovation Unit.

Exceptionally, the Committee may have advisers and representatives from other Units, both external and internal to the Institution.

Duties of the Innovation Committee

The duties of the Innovation Committee shall include:

a) To encourage the involvement of all the Institute's staff in the innovation process, especially in the dissemination of the culture of innovation and the identification of opportunities.

b) To analyse, select and prioritise proposals for innovation ideas/projects.

c) To evaluate the degree of development of the various innovation projects and decide on the advisability of their continuity or cancellation.

d) To ensure the documentation, protection and exploitation of the project results.

e) To systematically define and assess a set of indicators for measuring the combined results of innovation.

f) To promote regular internal audits of the innovation process for its evaluation and improvement.

4.3. HUFJD Innovation Classroom

The HUFJD Innovation Classroom is the tool that the Hospital makes available to all its professionals to increase the capturing of innovative ideas that can be transferred or translated into routine clinical practice. The Innovation Classroom came about in the context of the 2017-2020 HUFJD Strategic Plan, which includes the need to promote innovation and creativity among professionals. An innovative idea is any idea that serves to improve the way things are done, and for this reason, it can arise from any worker and area of the Hospital.

It is against this backdrop that the Innovation Classroom has been created as a tool to stimulate, collect, study and support or develop innovative ideas to improve the quality of patient care and/or the work of professionals.

To this end, the Innovation Classroom provides professionals with a simple form to propose ideas. The form containing the idea is then evaluated and, if necessary, tutoring is provided to complete its development. If the idea is ultimately accepted and selected, it is finally approved by the Hospital's Central Quality and Innovation Committee.

This committee is mainly responsible for managing innovations in processes and those related to e-health. Coordination with the IIS-FJD's Innovation Unit is excellent. When ideas are received from the Unit's area of activity, they are forwarded to this body for management. This guarantees the correct management of the idea by the department with competencies in the corresponding areas.

Composition of the Hospital's Central Quality and Innovation Committee

This committee is currently made up of members of the management team involved in the corresponding area (care, research, teaching, administration, maintenance, etc.), who together provide the necessary global vision to decide on the suitability of the implementation of the project and provide the necessary support.

The composition of the committee is the following:

- Juan Antonio Álvaro de la Parra.
- Eva Sáez Martín.
- José Gómez Moreno.
- Ana Leal Orozco.
- Marta del Olmo Rodríguez.
- Ana Gloria Marcos Moreno.
- María Dolores Martín Ríos
- Álvaro Gándara del Castillo.
- José Ángel Cortés Márquez.
- José Miguel Arce Obieta.
- Alberto Pardo Ortiz.

5. PROCEDURE FOR THE TRANSFER OF RESULTS

All the activity carried out by the IIS-FJD Innovation Unit, and specifically that relating to the transfer of research results obtained by its professionals, is included in the Institute's general Process Map, drawn up in the context of the UNE166002:2021 Standard.

This Process Map defines the three main blocks of processes carried out:

- Strategic processes
- Operational processes
- Care support processes

STRATEGIC PROCESSES					
STRATEGIC PLANNING	PATIENT EXPERIENCE	COMMUNICATION	INT. SYSTEM MANAGEMENT	PATIENT SAFETY	IIS-FJD
PEOPLE MANAGEMENT	CONTINUITY OF CARE	MANAGEMENT CONTROL	OCCUPATIONAL HEALTH AND SAFETY	SYSTEMS AND ICTs	TEACHING

OPERATIONAL PROCESSES											
CONTEXT AND RISKS		VISION AND STRATEGY	→	SURVEILLANCE AND STRATEGIC INTELLIGENCE	→	IDEAS	→	PROJECTS		PROTECTION AND EXPLOITATION OF RESULTS	
KNOWLEDGE MANAGEMENT											
		1	KNOWLEDGE M.		COLLABORATIONS		INTELLECTUAL PROPERTY		INTANGIBLE ASSETS		

CARE SUPPORT PROCESSES											
	IMAGING DIAGNOSIS							MEDICAL LABORATORIES			
	Radiodiagnosis	Interventional radiology		Nuclear Medicine		Radiation Protection		Clinical Analyses		Anatomical pathology	
	TRANSPLANT UNIT	INTRAVENOUS THERAPY		USE OF THE DRUG		PROA (*Antimicrobials Stewardship Programmes*)	INFECTION PREVENTION AND CONTROL	USE OF HAEMOCOMPONENTS		STERILISATION	

As part of this Process Map, the IIS-FJD has developed a series of procedures with the aim of standardising and homogenising the entire process of transferring the results obtained by the Institute's researchers during their daily scientific activity.

The procedures developed under the UNE166002:2021 Standard, linked to the detection and transfer of results, are the following:

- Procedure for the management of ideas.
- Procedure for the development of projects and project portfolio management.
- Procedure for knowledge transfer, protection and exploitation of results and placing on market/collaborations.
- Patent and utility model procedure.
- Procedure for the management of intangible assets and knowledge.

Below is a brief description of each of these procedures. The full breakdown can be found in the documentation attached to this document.

5.1. Procedure for the management of ideas

The purpose of this procedure is to establish the working system to promote the generation of new innovative ideas and to identify and establish the general criteria for the evaluation and selection of ideas to be developed at the IIS-FJD.

This procedure is applicable to R&D&I activities carried out at the IIS-FJD.

The IIS-FJD fosters a culture of innovation and, therefore, the generation of ideas by innovative staff through various activities.

When an innovator or group of innovators at the IIS-FJD has a proposal for an innovative idea that may generate a scientific innovation, they communicate this fact to the Innovation and Transfer Area. This communication can be done either by providing documentation describing the idea to the area's email address (innovacion.invest@quironsalud.es, or by filling in the Declaration of Invention form available on the IIS-FJD website (https://www.fjd.es/iis-fjd/es/innovacion/2-idea).

Once the Declaration of Invention has been completed, the proposed idea is evaluated based on the degree to which the proposed idea meets the innovation criteria established by the IIS-FJD, its level of maturity and its potential to be protected. The Innovation Unit carries out this evaluation based on the results reported by the State of the Art searches in terms of patent documents and scientific literature, and it is detailed in the Ideas Evaluation Report based on the criteria contained therein.

Based on the results of the Ideas Evaluation Report, the Innovation and Transfer Area will inform the researcher of the points for improvement identified, if the conclusions of the report are unfavourable, or the next steps to be taken, in the event that the conclusions of the report are favourable. The Innovation Committee is regularly informed of the progress of the projects/ideas and the needs that arise for each of them, so that the members of the Innovation Committee can provide advice and counsel in case of complex situations.

5.2. Procedure for the development of projects and project portfolio management

The purpose of this procedure is to establish, in the field of Innovation, the working system for planning, developing, monitoring and controlling R&D&I projects carried out by the IIS-FJD, as well as the management of the R&D&I project portfolio.

This procedure applies to the different R&D&I projects in the field of innovation that make up the IIS-FJD's project portfolio.

Once the projects are registered by the Innovation Support Unit (UGIDI) in the Innovation Projects Portfolio, the UIDI (R&D&I Unit) is constituted. The UIDI is made up of one or several innovators, although there will always be a lead innovator, who will be responsible for the design and development of the project as well as for the management and coordination of the UIDI. These selected ideas registered in the innovation project portfolio are only developed if funding (both internal and external) is secured.

The UIDI designated for the development of each project is responsible for drawing up a scientific and economic report of the project. This report may be made up of one or more documents, although it must include the minimum content required by the terms and conditions of the call for funding to which it is to be submitted.

Once the scientific-economic report has been approved, the innovative leader of the UIDI is responsible for submitting the documentation required to process the application for funding and/or grants in accordance with the terms and conditions published in collaboration with the UGIDI. The process is supervised by the Research Administrative Area.

The UIDI assigned to the project carries out the work for the development of the project in accordance with the planning established in the project report. The development of the project, up until its completion, will be documented through different records generated throughout the life of the project and until it is finalised.

The monitoring and control of the project is carried out on the basis of two aspects: technical and economic-administrative.

The UGIDI monitors the Portfolio of R&D&I projects in the field of Innovation on a six-monthly basis. The agreed decisions are submitted to the Innovation Committee for approval and are documented in the Minutes of each meeting. Deviations detected during project implementation are analysed by the UIDI assigned to the project and, if necessary, the appropriate non-compliance reports are issued.

5.3. Procedure for technology transfer, protection and exploitation of results and placing on market/collaborations

The purpose of this procedure is to create the system for maintaining and documenting technology transfer methods, as well as protecting and exploiting the results obtained in the R&D&I process developed by the IIS-FJD in accordance with the UNE 166002 Standard.

This procedure is applicable to the results obtained from the innovation projects that make up the IIS-FJD's project portfolio and assumes all the points included in the IIS-FJD's Procedure for the management of ideas.

A preliminary identification, evaluation and selection of internal and/or external collaboration needs is carried out during the stage of analysis and selection of ideas, in accordance with the Procedure for the Management of Ideas.

The UIDI identifies the needs for both internal and external collaborations for the suitable development of the project, considering the project objectives, and will make an initial proposal/list of possible collaborators.

The need to require the participation of internal and/or external collaborations for the development of R&D&I projects in turn gives rise to the need to transfer technology to these collaborators. The technology transfer actions carried out by the organisation are regulated through different types of records depending on the type of technology transferred. These include licensing contracts, collaboration agreements, confidentiality agreements, material transfer agreements and so on, as well as any other type of document regulating technology transfer between the IIS-FJD and its collaborators.

During the procedure for the management of ideas or at any time during the development of an R&D&I project, results may be generated that can be legally protected or be subject to economic exploitation. The protection and exploitation of results is carried out by the Innovation Support Unit acting as OTRI.

If, during the implementation of the project, results with potential for protection and/or exploitation arise, the principal investigator must inform the Innovation Support Unit as soon as possible to initiate the procedures, where appropriate, for ownership, management, assessment and possible ways of exploitation through the Declaration of Invention document. This is documented in the entity's Transfer of Results procedure, and in the Standard Operating Procedure for Patents and Utility Models.

Once the results protection stage has been completed, where applicable, the next step towards the valuation of the invention consists of defining a customised Plan for the exploitation of the results.

5.4. Patent and utility model application procedure

The general outline that the IIS-FJD will follow when considering the process of analysing the best strategy for the protection of an invention is as follows:

			Optional	

The IIS-FJD Innovation Unit is the entity in charge of advising and, where appropriate, protecting the research results of IIS-FJD researchers through the most suitable form of industrial property.

The IIS-FJD Innovation Unit has agreements with legal technical consultancy firms in the field with which it collaborates in the management of industrial property, as well as in the management, filing and monitoring of the IIS-FJD's industrial property titles (patents, utility models, trademarks, intellectual property, etc.).

Summary process for the filing of an industrial property title

CREATION	PROTECTION	EXPLOITATION	DEFENCE

Supervision by a technical **expert in the field**	Pre-assessment through **Preliminary Technical Questionnaire**	IEA Optional	**Optimisation** of the **drafting** of specifications

State Of The Art Report

A more exhaustive description of this procedure can be found in the Patent and Utility Model Application Procedure SOP itself.

5.5. Procedure for the management of intangible assets and knowledge

The purpose of this procedure is to establish the management of intangible assets, intellectual and industrial property and the knowledge generated in the development of R&D&I activities by the IIS-FJD.

This procedure shall apply to intangible assets and knowledge available at the IIS-FJD.

The Innovation Support Unit is the unit responsible for identifying the Organisation's intangible assets, which will include at least intellectual and industrial property, industrial or trade secrets, the results of R&D&I projects developed, computer applications and publications, papers or results of participation in R&D&I forums.

The Innovation Support Unit prepares and updates an inventory of intangible R&D&I assets using the Innovation Management format.

The Innovation Support Unit is responsible for identifying and managing the organisation's R&D&I knowledge, so that it is available to the persons determined and is suitably protected with the different levels and means of confidentiality. To this end, the Innovation Support Unit is responsible for identifying different key elements.

The Management and Scientific Directorate will periodically review the suitability of the inventory and the different areas of knowledge within the framework of the annual review of strategic planning and, depending on this review, may update the different records.

6. OWNERSHIP OF PROPERTY RIGHTS

This section contains the basic criteria for the assignment of industrial and intellectual property rights for research results arising from the joint activity of IIS-FJD researchers. We have based these criteria on the aspects covered in the initial agreement for the creation of the IIS-FJD, signed in 2009, which includes the guidelines related to ownership and property rights and which are ratified in the Agreement for the development of the activity of the Fundación Jiménez Díaz Health Research Institute, signed on 18 May 2021.

In this sense, all intellectual property rights belong jointly to the signatory institutions. However, in the event that any of the researchers participating in the work intends to publish or disseminate the results of the research, the parties will transfer the exercise of the exploitation rights, subject to prior written consent of all the parties involved. The publication will refer to the IIS-FJD and may require including the corporate image of the Institutions involved.

With regard to the criteria related to the ownership, transfer and exploitation of research results, the approved guidelines are the following:

“If the research activities carried out within the scope of the IIS-FJD by researchers participating in them give rise to results that may be protected by patents or other forms of industrial or intellectual property, the ownership of these shall correspond to the signatory members, taking into account the current regulations of their Institution.”

“Patent applications shall be made in the name of the members, irrespective of who processes the application.”

“The management of the protection and transfer of research results shall be carried out by the majority member in the authorship, who will give an account of their actions to the minority members. These actions shall be agreed by the members in the event of equal authorship.”

"The costs involved in the management of the protection and eventual transfer of results shall be paid by the members in proportion to their participation. If no member is interested in the ownership of any of the results, the other members may continue, in their own name, to assume all the rights and obligations in respect of their own research staff."

"The parties undertake to collaborate in establishing suitable procedures to identify the origin of results and to collaborate, in accordance with the principles of good faith and efficiency, in ensuring the successful protection and exploitation of results. The Institutions that make up the IIS-FJD will be subject to the applicable internal regulations in terms of ownership, notification, distribution of benefits and management of rights susceptible of economic exploitation."

The IIS-FJD patent policy was drawn up and approved by the Governing Council and ratified by the External Scientific Committee in October 2013 and summarises the general guidelines to be followed in the IIS-FJD patent strategy, specifying the aspects related to authorship and benefit sharing.

6.1. Authorship and benefit-sharing issues

The IIS-FJD states that the moral rights of authorship correspond in all cases to the authors of the works that have given rise to those rights in accordance with the applicable legislation.

In the case of results susceptible of economic exploitation, protected by industrial property, industrial secret, intellectual property and so on, the ownership, management and exploitation thereof will belong to the IIS-FJD.

If other institutions are jointly involved in the research activities that give rise to the results, it is necessary to establish a specific agreement signed to this effect by the aforementioned parties, reflecting how the economic exploitation will be carried out. This agreement will take into account, among other factors, the participation of the institution's staff and other workers, such as grant holders, in obtaining the results.

IIS-FJD researchers who have obtained research results that are susceptible of economic exploitation must inform the contacts established at the IIS-FJD and the Institutions involved with rights over the research as soon as possible, and always prior to their dissemination, in order to initiate the procedures, where appropriate, for ownership, management, valuation and possible ways of exploitation.

In addition, in accordance with the agreement adopted by the Governing Council dated July 2013 and ratified by the External Scientific Committee on 30 October 2013, the provisions of the IIS-FJD regulations on the exploitation and assignment of inventions shall apply, pursuant to the provisions of article 21 of Law 24/2015, of 24 July, on Patents, with the following particularities:

- All economic exploitation rights, such as industrial property, industrial secrets, intellectual property, shall be exercised by the IIS-FJD.
- Participation in the rights relating to ownership, management, exploitation and so on will belong to the IIS-FJD.

As specified in the IIS-FJD Patent and Utility Model Application Procedure, in reference to Ownership of research and publications:

- Rights generated by the IIS-FJD's own staff (direct employment relationship) belong to the IIS-FJD.
- Rights generated by collaborating staff will be defined according to the entity requesting the project:
    - If the applicant has a direct employment relationship with the FJD, HUIE, HRJC and HGV hospitals, applications will be processed through the IIS-FJD and will be defined in a similar way to staff with an employment relationship with the IIS-FJD.
    - If the applicant is the institution of the collaborating staff, then the rules of that institution shall apply.
- All scientific publications related to the activities carried out at the IIS-FJD must expressly mention this, and also list the researchers and the centre to which they belong.

- Rights generated by IIS-FJD staff, understood as described above, belong to the IIS-FJD.
- Rights generated by grant holders will be defined according to the specific regulations to be developed.
- Rights generated by collaborating staff will be defined according to the entity co-owning the rights.

Distribution of benefits:

- One third for the IIS-FJD.
- One third for the author or authors of the invention.
- One third to be distributed in accordance with the criteria established by the IIS-FJD Governing Council, taking into account the importance and significance of the patent, the benefits it may generate and the participation or collaboration of staff other than the author or authors of the invention. This last third can be used to cover the costs of maintaining the patent or be allocated in part to the researcher depending on strategic value, opportunity criteria, etc.

6.2. Research in collaboration with other institutions

Any research results derived from the activities carried out by the research groups that are susceptible to economic exploitation or may give rise to an application for the ownership of industrial property rights must be notified to the IIS-FJD and to the Institutions involved in the research to which the authors of the results belong.

If any party renounces or loses its participation in the ownership, their right shall accrue to the others in accordance with their participation in same.

The protection of these rights shall be managed by whoever is duly designated, in accordance with the provisions of the specific agreement. If no agreement is reached, the procedure may be initiated by the party with a majority participation in the ownership, measured in terms of staff involved in the result. In no case shall this circumstance determine a subsequent distribution in the allocation of ownership.

A co-ownership agreement signed by all right holders will set out the terms of management and the financial conditions of the transfer. If no agreement is reached, these shall be determined according to majority participation of the entities incorporated in the consortium that holds the rights, as expressed in the previous paragraph.

Right holders, even when they have renounced or lost their right to participate in the ownership of the industrial property, shall retain a non-exclusive, non-transferable licence, free of charge, for the use of the results obtained from the development of the activity in research work.

Inventions for which an application for a patent or other exclusive protection title is filed within one year of the termination of the co-ownership agreement may be claimed under the terms set out in the agreement by the signatory parties, provided that the inventions have been generated because of research activity.

The co-ownership agreement shall contain a commitment on the part of the parties to collaborate in establishing suitable procedures to identify the origin of results and to collaborate, in accordance with the principles of good faith and efficiency, in ensuring the successful protection and exploitation of results.

The Institutions involved in the research and/or the Centres carrying out the research will act in accordance with the internal regulations applicable to them in terms of ownership, notification, distribution of benefits, and management of rights susceptible of economic exploitation."

7. PROCEDURE FOR THE TRANSLATION OF RESULTS

Translating the results of research and innovation into routine clinical practice is a key aspect in the development and evolution of healthcare, which has led to developments including cost reductions in treatments and diagnoses, optimisation of processes and improvements in patients' quality of life.

The IIS-FJD is aware of this fact and works closely with the healthcare sector to identify and assess the main findings that can be or have already been translated into routine clinical practice.

The procedure for translating results that is developed in this section consists of three sequential and complementary stages:

- Identification of translated results and of those with potential for translation into routine clinical practice
- Recording and evaluation of results with potential for translation
- Drafting and dissemination of follow-up reports.

7.1. Identification of translated results and of those with potential for translation into routine clinical practice

The first step in translating the results obtained by professionals into clinical practice is the identification of initiatives that have either already been incorporated into care or have the potential to do so in the short and medium term.

The IIS-FJD Innovation Unit has different strategies for obtaining information for this purpose.

Meetings between the Innovation Unit and Hospital Services

The main tool for identifying results with potential for translation in the context of the HUFJD are the periodic meetings and the Area Meetings that the Innovation Unit holds for the different Services of the Hospital. These meetings make it possible to identify and compile findings of potential interest or those already implemented, which are aimed at making better use of resources, saving costs in the organisation and which, in short, yield an improvement in the operation of Services.

These meetings give rise to a two-way communication channel in which healthcare

professionals and management staff can work on recording the translation of findings into clinical practice.

Forms to communicate ideas

The Innovation Unit makes an invention declaration form available to all the organisation's professionals, in which anyone can communicate an innovation that they consider to be of interest to the organisation.

This form, available on the IIS-FJD corporate website, in the section corresponding to the Innovation Unit, contains the following information:

- Title of the invention.
- Participants (inventors).
- Origin of the invention.
- Object of the invention.
- Description and applications of the invention.
- Other additional information.

Although the main aim of this form is to identify inventions that may be protected as industrial property, it is also an additional source for identifying possible ideas and results that may be translated into routine clinical practice.

In addition to this channel, as previously mentioned, the HUFJD's Innovation Classroom has a form available for all Hospital professionals to identify innovations, mainly in processes and e-health. This information is provided to the Innovation Unit for its knowledge and support in the translation process, if the evaluation is favourable.

Compilation of Clinical Practice Guidelines

This last channel makes it possible to identify research results that have already been implemented and translated into routine clinical practice. Periodically, the IIS-FJD management structure carries out a search to compile all the clinical practice guidelines published in scientific journals indexed in the Web of Science (WoS) and in which researchers from the Institute have participated.

After identifying these guidelines, researchers are consulted directly to verify their degree of implementation in their respective services and clinical units.

In this way, not only is information available on the generation of results with potential for translation into clinical practice, but also any protocols and actions that are currently being implemented in the context of the HUFJD.

7.2. Recording and evaluation of results with potential for translation

Once the results with potential for application and translation into routine clinical practice have been identified, the next step is to record them in the Innovation Unit information systems for their subsequent evaluation to determine the degree of implementation or potential implementation.

In the case of ideas arising from meetings with hospital services and invention declaration forms, the staff responsible for the Innovation Unit are responsible for registering these ideas in their available databases and following them up, either through innovation projects or under another model.

Regarding the identification of clinical guidelines developed by IIS-FJD professionals and which have been implemented in their respective clinical services, the Innovation Unit carries out an analysis of their impact and efficacy. A form has been designed and organised into the following sections for this purpose:

- General data (name, volume of population benefited and year of implementation).
- Benefits for the patient: improvement in prevention, diagnosis, treatment, etc.
- Benefits for the health system: optimisation of resources, other improvements, efficiency, etc.
- Benefits for the community: improvements or impacts on other ongoing research.

This report, prepared jointly by the Innovation Unit and the person responsible for the implementation of the CPG (Clinical Practice Guideline), provides information on the benefits arising from the implementation of the guideline in routine clinical practice.

7.3. Drafting and dissemination of follow-up reports

Periodically, the IIS-FJD Innovation Unit compiles all the experiences and success stories of the results translated into clinical practice and drafts a report summarising all these initiatives, including the main benefits and findings. Once drafted, it is submitted to the Scientific Directorate for validation and approval.

After approval, the report is disseminated and made available to the following recipients on an annual basis:

- The Carlos III Health Institute, to report all results transferred to clinical practice. Whenever possible, this communication will coincide with the submission of the IIS-FJD corporate information requested by the ISCIII.
- To the Management and Medical Directorate of the HUFJD, with the aim of informing them of best practices that can be implemented in other Hospital Services and Units. This submission will also be used to include this report in the Hospital's annual reports.

8. DISSEMINATION OF TRANSFER AND TRANSLATION

One of the most important aspects in the process of transferring and translating research results is the dissemination of this information, with the aim of informing all interested agents of the new advances made and the possibility of incorporating these process innovations and improvements into their tasks and structures, resulting in an increase in the quality of the services offered.

The primary means of disseminating and publicising the transfer and translation activity in the context of the IIS-FJD is the publication of the technological offer on the Institute's own corporate website, as well as through the ITEMAS website; the Innovation Unit is a member of this Platform.

Meanwhile, activities aimed at the Institute's professionals are also carried out with the aim of promoting:

- An increase in the number of patents registered and licensed.
- The transfer of knowledge to the productive sector.
- The development of new healthcare products or marketable devices.
- The implementation of new clinical processes.
- The creation of spin-offs and start-ups.
- Academic clinical trials or studies.

The transfer and translation results obtained by the IIS-FJD are presented at different conferences and events in which the Innovation Unit participates, either as an attendee or a speaker. These events are attended by other agents from the healthcare sector and entities and companies from health-related sectors:

- National congresses.
- Training courses.
- Specific conferences.
- Investment forums.

In the specific area of translation, as mentioned in the previous section, each year the Innovation Unit prepares a follow-up report on the main initiatives and findings translated into routine clinical practice, which is disseminated mainly through the annual activity reports of both the HUFJD and the actual IIS-FJD.

Finally, in terms of training, specific courses have been planned to train IIS-FJD professionals in matters related to the mechanisms for translating their research findings into clinical practice.

9. OBJECTIVES AND FOLLOW-UP OF THE PLAN

All the activity carried out by the Innovation Unit is aligned with the guidelines of the UNE166002:2021 Standard. In this line, the Innovation Unit sets annual objectives, which are approved by the Innovation Committee for each year.

These annual objectives are set with the aim of covering all aspects and areas with which the Innovation Unit must align:

- Objectives of the Unit itself.
- Objectives aligned with the UNE166002:2021 Standard.
- Objectives of the IIS-FJD Strategic Plan.
- Objectives of the IIS accreditation regulations (Evaluation Guide).

Therefore, the follow-up of the IIS-FJD Transfer and Translation Plan is based on the measurement of the Innovation Unit's indicators, which are based on the aforementioned aspects.

These objectives are grouped into three main sections:

- Improvement objective No.1: To promote the development of innovative projects in the institution with a view to their transfer and implementation in routine clinical practice.
- Improvement objective No.2: To promote the recognition of clinical guidelines and innovative procedures developed that can be registered as intellectual property.
- Improvement objective No.3: To optimise the processes developed in the field of innovation management and position the entity as a reference in the field of Scientific Integrity management.

A breakdown of the annual objectives of the Innovation Unit can be found in the documentation attached to this Transfer and Translation Plan.

10. ANNEXED DOCUMENTATION

- Framework collaboration agreement between the Fundación Jiménez Díaz and the Autonomous University of Madrid for the creation and development of the Fundación Jiménez Díaz Health Research Institute (IIS-FJD).
- Agreement for the development of the activity of the Fundación Jiménez Díaz Health Research Institute, of 18 May 2021.
- IIS-FJD Foundation Statutes.
- Register of research results transfer offices: OTRI-FJD Register.
- OTRI-FJD change of ownership document.
- Minutes of the Governing Council meeting held in July 2013.
- Minutes of the External Scientific Committee meeting held in October 2013.
- 2024-2028 IIS-FJD Strategic Plan.
- 2019 IIS-FJD Results Transfer Procedure.
- Rules of operation of the Innovation Committee.
- Minutes of the Quality and Innovation Committee (2019-2023).
- R&D&I Process Map (IIS-FJD 4/P0).
- Declaration of Invention Form (IIS-FJD 4.1/P1/F1).
- Ideas evaluation report (IIS-FJD 4.1/P1/F2).
- Procedure for the management of ideas. (IIS-FJD 4.1/P1)
- Procedure for the development of projects and project portfolio management. (IIS-FJD 4.2/P1)
- Procedure for knowledge transfer, protection and exploitation of results and placing on market/collaborations. (IIS-FJD 4.2/P2)
- Patent and utility model procedure.
- Procedure for the management of intangible assets and knowledge. (IIS-FJD 4.4/P1)

- CPG Impact Assessment Form.
- Improvement objectives No.1.
- Improvement objectives No.2.
- Improvement objectives No.3.