INSTRUCTION FOR REQUESTING ETHICAL PERMISSIONS FOR RESEARCH PROJECTS IN BIOMEDICINE

JUNTA DE ANDALUCIA
Fundación Progreso y Salud
CONSEJERÍA DE SALUD

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1.- Introduction

This document aims to inform about different ethical issues to consider and the steps to be followed by those researchers who will carry out a research project in the field of biomedicine.

Ethics is crucial for the development of these projects as it is necessary to ensure that all research activities included within the project obey fundamental ethical principles and relevant ethical standard to ensure the freedom of research and the need to protect the physical and moral integrity of persons and animal welfare.

In Spain, all these matters are regulated by the Spanish law 14/2007 of 3 July, on Biomedical Research, which states that for the development of any project involving research on human beings and/or using biological material, a permission froma Committee on Research Ethics is mandatory.

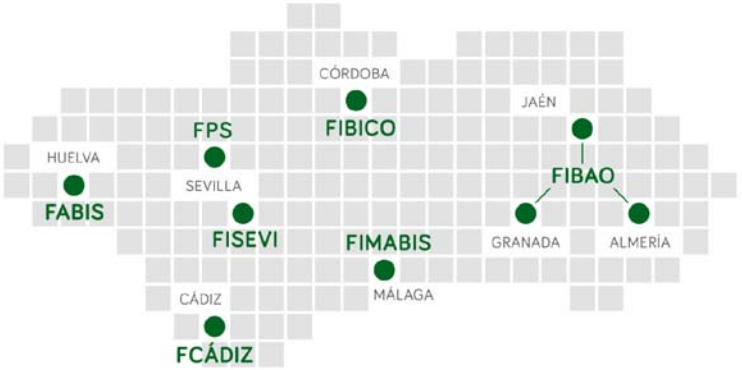
These Ethics Committees should ensure the adequacy of the methodological, ethical and legal aspects of research involving humans or the use of human biological samples.

2.- Who can help you to get a proper ethical permission for your project

Andalusian Public Health System (APHS) is supported by the Andalusian Network of Foundations for Research Managament, consisting of **7 Foundations which manage R&D+ i** in Biomedicine in Andalusia (hereinafter APHS - RMF) at local and regional level. Among them, the **Fundación Pública Andaluza Progreso y Salud (FPS)** is the coordinating entity. ***(see map)***.

A list of services in R&D+i provided by APHS – RMF is shown below::

- Support for fund raising
- **Funds management**
- Support and management of clinical trials and observational studies
- Consultancy of International Projects
- Methodological and Statistical Support
- Advice and management of protection and transfer of results



Within the "Funds management" , FPS gives support in all phases of the project, from its start to the end. Prior to start the project it must get the proper ethical approval. For this purpose, detailed steps depending on the type of the project are described as follows:

1- TECHNICAL ADVICE:

1.1. The Coordinating Investigator contacts with the project manager belonging to his Foundation showing the project.
1.2. The project manager assesses the type of the project in order to request the documents needed to submit them to the corresponding Ethic Committee
1.3. The Coordinating Investigator provides to the project manager this documentation
1.4. The Project manager submits the project documentation to the Ethic Committee

2- ETHICAL COMMITTEE ASSESSEMENT: The Committee assesses the project and gives a favorable or negative opinion.

3- RESOLUTION:

3.1. There is a rectification period where the coordinator can re-submit missing documents. Once the study has been assessed, clarifications or the final report will be issued.
3.2. In case of negative opinion, declaration of disagreement will be submitted within a period of 15 days.

4- FOLLWING:

4.1. Any study change has to be submitted to the Committee.
4.2. In case of projects assessed by the CAEI, a yearly report will be submitted to this Committee.

5- END: Once the study has been finalized, a final report will be submitted to the corresponding Committee.

* See Flow chart
* See table 1 & 2. Below there are 2 summary tables where we can see, depending on the type of the project, the corresponding Committee, the period, the regulation and links to guides detailing more information and documentation to submit depending on the Committee.

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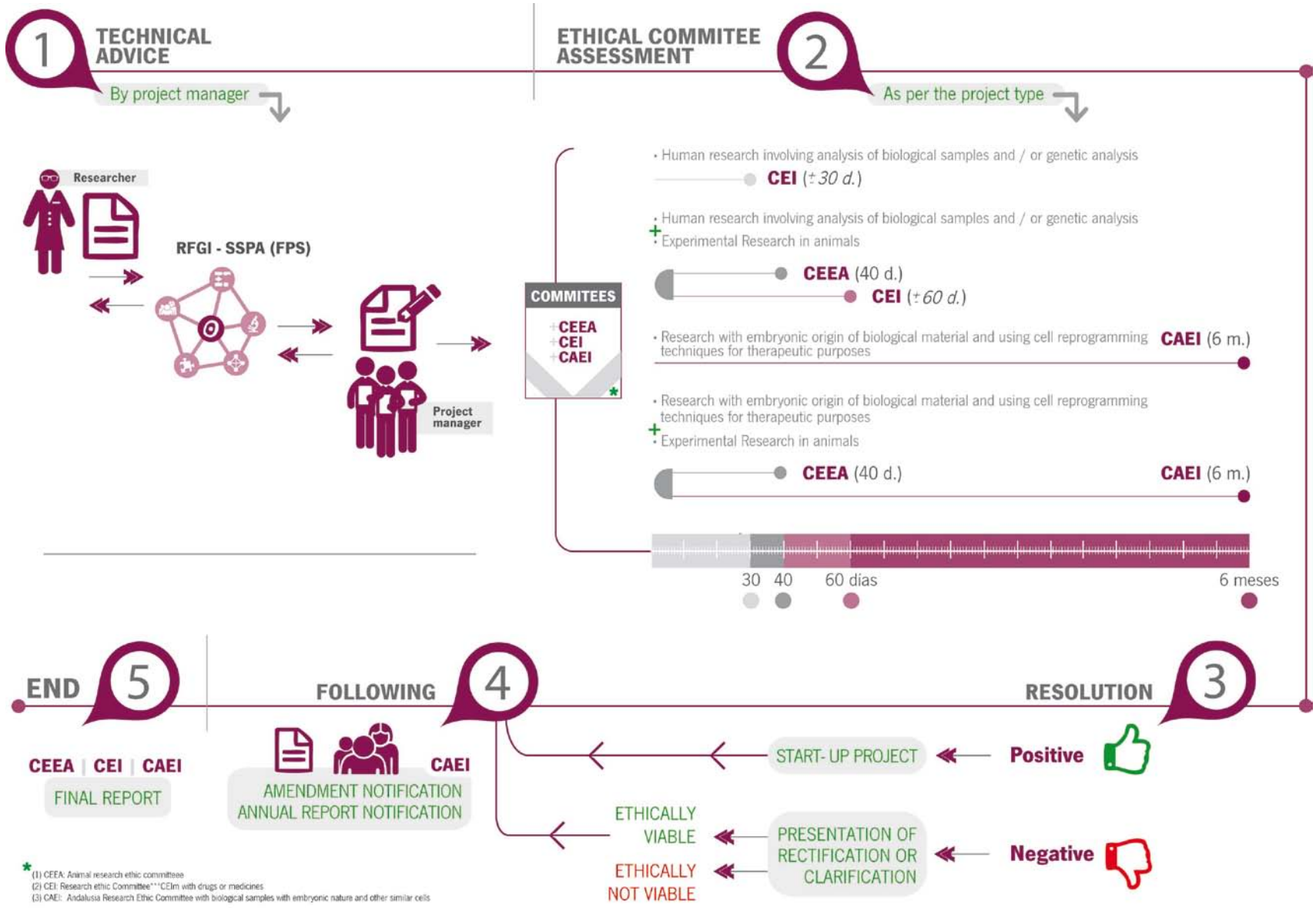
1
TECHNICAL ADVICE
By project manager
Researcher
RFGI - SSPA (FPS)
Project manager
COMMITEES
+CEEA
+CEI
+CAEI
*
ETHICAL COMMITEE ASSESSMENT
2
As per the project type
• Human research involving analysis of biological samples and / or genetic analysis
CEI (± 30 d.)
• Human research involving analysis of biological samples and / or genetic analysis
+ • Experimental Research in animals
CEEA (40 d.)
CEI (± 60 d.)
• Research with embryonic origin of biological material and using cell reprogramming techniques for therapeutic purposes
CAEI (6 m.)
• Research with embryonic origin of biological material and using cell reprogramming techniques for therapeutic purposes
+ • Experimental Research in animals
CEEA (40 d.)
CAEI (6 m.)
30 40 60 días
6 meses
RESOLUTION
3
START- UP PROJECT
Positive
ETHICALLY VIABLE
PRESENTATION OF RECTIFICATION OR CLARIFICATION
Negative
ETHICALLY NOT VIABLE
FOLLOWING
4
CAEI
AMENDMENT NOTIFICATION
ANNUAL REPORT NOTIFICATION
END
5
CEEA | CEI | CAEI
FINAL REPORT
* (1) CEEA: Animal research ethic committeee
(2) CEI: Research ethic Committee***CEIm with drugs or medicines
(3) CAEI: Andalusia Research Ethic Committee with biological samples with embryonic nature and other similar cells

3.- Overview of correspondence between ethical aspect to be considered and type of proyect (table 1)

Type of study				Facilities released	Informed consent	COMMITTEE					DEADLINES	Regulation	+ Info
						CEEA (1)	CEI (2)	CCEIBA (3)	CAEI (4)	AEMPS (5)			
Basic and preclinical research	Research with Genetically Modified Organisms (GMO)			Ministry of Agriculture and Fisheries - authorized by the Andalusian Committee GMO Control Center								Ley 9/2003, de 25 de abril	
	Experimental Research in animals			Animal-housing authorized by Ministry of Agriculture and Fisheries		yes					*40 days*	Real Decreto 53/2013, de 1 de febrero, por el que se establecen las normas básicas aplicables para la protección de los animales utilizados en experimentación y otros fines científicos, incluyendo la docencia	Guide application for approval of projects with animal experiments
	Research with embryonic origin of biological material and using cell reprogramming techniques for therapeutic purposes				Yes (embryo donations)				yes		*6 months*	Ley 14/2007 de Investigación biomédica Decreto 368/2015, de 4 de agosto que regula el Comité Andaluz de ética de Investigación con muestras biológicas de naturaleza embrionaria y otras celulas semejantes, el procedimiento de autorización y el registro de proyectos de investigación	Practical Guide to management and processing
Clinic investigation	Research with human	Human research involving analysis of biological samples and / or genetic analysis			Yes		Yes				*30 days*	Ley 14/2007 de Investigación biomédica Ley 11/2007 de 26 de noviembre	
		Research in humans with invasive procedures			Yes		Yes				*30 days*	Ley 14/2007 de Investigación biomédica	
		clinical research with drugs	clinical trials	*Clinical trials*	Yes		Yes***			Authorization	*104 days*	Real Decreto 1090/2015, de 4 de diciembre, por el que se regulan los EECC con medicamentos , los Comites de Ética y el REec (6) Reglamento nº536/2014 sobre EECC de uso humano Modelo de contrato económico para la realización de ensayos clínicos	Spanish Agency for Medicines and Health Products Memorandum of Collaboration List of Clinical Research Committees attached to the memorandum
			Observational post-authorization studies (EPA) and Observational no EPA studies	*EPA-LA= EPA linked to Authorizaton*	Yes		Yes	Si multicentric		classification + authorization	*60 days*	Orden SAS/3470/2009 de 16 de diciembre Modelo de contrato económico para la realización de ensayos clínicos	Spanish Agency for Medicines and Health Products RESEARCH MANAGEMENT FOUNDATIONS NETWORK (APHS-RMFN).
				EPA-AS= EPA-promoved by Health Authorities and public funds	Yes		Yes	Si multicentric		classification + authorization	*90 days*		
				EPA-SP= EPA- prospective follow-up	Yes		Yes	Si multicéntrico		classification + authorization	*90 days*		
				EPA-OD= EPA-Other designs : cases and controls, transversals, restrospective cohorts, etc.	Yes		Yes	Si multicentric		Classification	*60days*		
				NO-EPA= No EPA observational studies	Yes		Yes	Si multicéntrico		Classification	*30 days*		
		Clinical research with medical devices			Yes		Yes	Si multicentric		Yes	*90 days*	Real Decreto 1591/2009 de 16 octubre Circular 7-3004 Investigación con Productos sanitarios	Spanish Agency for Medicines and Health Products

(1) CEEA: Animal research ethic committeee
(2) CEI: Research ethic Committee***CEIm with drugs or medicines
(3) CCEIBA: Andalusia biomedical research Ethic coordinator committee.
(4) CAEI: Andalusia Research Ethic Committee with biological samples with embryonic nature and other similar cells
(5) AEMPS: Spanish Agency of Medicines and Medical Devices
(6) REec: Clinical research spanish register

4.- Documentation to be presented by committee (table 2)

CEEA — Animal research ethic committeee

GENERAL DOCUMENTATION

1. Protocol or Scientific Report

ESPECIFIC DOCUMENTATION

1. Patient information sheet and Informed Consent form, if apply
2. Vitae Curriculum signed and dated
3. Insurance Policy, if apply
4. Facilities and research team suitability

CEI — Research ethic Committee ***CEIm with drugs or medicines

GENERAL DOCUMENTATION

1. C professional certificate of study responsible or research coordinator.
2. Animal research Ethic committee report
3. Copy of the study assessment application address to authorized body.
4. Annex V corresponding to the study information.

ESPECIFIC DOCUMENTATION

1.No-technical summary for studies Type II and III.

CAEI — Andalusia Research Ethic Committee with biological samples with embryonic nature and other similar cells

GENERAL DOCUMENTATION

1. Application form
2. Curriculum Vitae of each investigator team member.
3. Hospital Management authorization where the research will take place

ESPECIFIC DOCUMENTATION

EMBRYONIC ORIGIN CELL LINES

1. Original Authorization signed by site transfering the biologic material (specifying the title and PI name)
2. Lines transfer document without pre-embryos completed and signed (Anex II)

PLURIPOTENT CELL LINES INDUCED

1. Original Authorization signed by site transferring the biologic material (specifying the title and PI name)
2. Cell lines transfer document completed and signed (Annex II)

PRE- EMBRYOS CRYOPRESERVED

1. Transfer informe consent of all pre-embryos used (Anex III)
2. Lines transfer document with pre-embryos (Anex IV) completed and signed.
3. Sworn statement keeping the cell lines register in order to guarantee an appropriate traceability

VOLUNTARIEE DONORS SOMATIC CELLS

1. Information sheet and consent form for donors. (Annex IV)
2. If the point 1 is not met a PI agreement will have to be included to provide, wherever necessary, a sworn statement of that the donors informed consent form carries out according the current regulation.

OOCYTES CRYOPRESERVED

1. Document detailing:
   - Oocytes number
   - Source
   - Origen center
2. Donation information sheet and consent form (Annex III)
3. PI agreement to provide, wherever necessary, assisted human reproduction site responsible sworn statement.
4. PI or files responsible sworn statement where are keeping the personal data.
5. Cell lines transfer document completed and signed (Annex III)

If you have any cuestions, please contact us :

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