

CREC INTERNAL OPERATING RULES  
OF THE BARCELONA OCULAR  
MICROSURGERY INSTITUTE

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## Introduction

The CREC of the Ocular Microsurgery Institute, accredited for the first time on 10 October 2006 by the Directorate General for Health Resources of the Catalanian Regional Government Health Department, renewed its accreditation on 15 February 2008.

According to Decree 406/2006, article 10.2, this re-accreditation is valid for four years. Therefore, on 25 October 2011, re-accreditation was again requested by the Clinical Research Ethical Committee of the Ocular Microsurgery Institute.

The accreditation was renewed on 12/7/2012 and its composition modified on 12/3/2013.

The IORs of the CREC were modified due to RD 1090/2015, in force since 13 January 2016, which establishes a new procedure for evaluating clinical trials with drugs and medical devices and a period of two years for accrediting Drug Research Ethical Committees. Decree 406/2006 was still in force during this period, which is why re-accreditation of the IMO's CREC is again requested for this two-year transitory period.

On 10 March 2016, the Ocular Microsurgery Institute's CREC joined the Memorandum for Collaboration and Information Exchange between the Spanish Drug and Medical Device Agency (AEMPS) and the Drug Research Ethics Committees, 3 February 2016 version, appearing in the List of Clinical Research Ethics Committees that have joined the collaboration memorandum, in their next update of the AEMPS.

## Scope of action and composition

### Scope of action

The scope of the CREC is: Barcelona Ocular Microsurgery Institute

### Composition

**The CREC for the Ocular Microsurgery Institute comprises:**

1. Dr Rafael Navarro – Ophthalmologist – President
2. Dr Marcela Manríquez – Clinical Pharmacologist – Vice President
3. Carmen Mas – Person outside the health professions – Secretary

### Voting members

1. Dr Làia Pascual – Ophthalmologist
2. Dr Anniken Bures – Ophthalmologist
3. Dr Miriam Barbany – Ophthalmologist
4. Dr Mercè Morral – Ophthalmologist
5. Leandro Martínez-Zurita – Legal expert
6. Pilar Sabin – Hospital Pharmacy
7. Carol Rovira – Primary Care Pharmacy
8. Esther Canals – Diploma in Nursing
9. Raquel Ramos – Diploma in Optics and Optometry and Member of the User Care Unit

### Members outside of the Centre are:

- Dr Marcela Manríquez
- Leandro Martínez-Zurita
- Pilar Sabin
- Carol Rovira

For CREC accreditation, prospective members were contacted directly in order to explain the intention of accrediting a CREC within the IMO; whereas they have signed a written statement that they have no direct or indirect relation with the industrial manufacture, distribution or marketing of medicines, medicines in clinical research phase or medical devices (document signed by committee members attached).

Dr Rafael Navarro Alemany has been proposed as President and his functions are: Convene CREC meetings, notifying the exact date and time of the meeting, open the session and begin assessing the clinical trials proposed to the CREC. To moderate the meetings so that the other CREC members, in alphabetical order, can discuss the content of the trials. To make the final decision about the work being evaluated, if there is no consensus among attendees at the corresponding meeting, counting as many votes for as against.

Dr Marcela Manríquez Tapia is proposed as Vice President. The functions of the Vice President are to replace the President, in case of absence or inability to attend. The Vice President informs the President of possible defects or strengths of the work submitted to the Committee.

Carmen Mas Crespi is proposed as Secretary, and her functions are: To take notes of everything discussed in the meeting and record the minutes. To compile the documentation of clinical trials evaluated, archive the documentation and convene CREC meetings.

Once the CREC has been accredited by the Directorate General for Health Resources of the Catalanian Regional Government Health Department, a meeting of its members will be convened to approve the internal operating rules (IOR or SOP). The decisions will be made pursuant to the provisions of the point *Decision-making*. Members will be asked to sign the rules to ensure continued operation. The members of the CREC must sign a confidentiality document regarding the content of CREC meetings (document signed by committee members attached).

The procedure for appointing and renewing the positions of President, Vice President and Secretary takes place every two years. The President, Vice President and Secretary will hold their positions for two years, beginning on the renewal date. At the CREC meeting in the month following the renewal, the new majority positions will be appointed (*see Decision-making*).

Since the renewal of positions implies a change in the functioning of the CREC, the Internal Operating Rules (IOR) will be updated, and this information will be sent to the Directorate General for Health Resources of the Catalanian Regional Government Health Department for approval. This information will be communicated at the next CREC meeting.

The CREC's internal operating rules will also be updated according to the needs of the CREC's activity, and the corresponding changes will be communicated to the Directorate General for Health Resources.

The CREC's internal operating rules are public. They can be requested on the IMO website ([www.imo.es/](http://www.imo.es/) on [imo/crec](http://imo/crec)). The versions will be updated, if there is any change due to re-accreditation, renewal of members and/or positions or other reasons.

CREC members are renewed every four years (last renewal July 2012), submitting the request to the Directorate General for Health Resources, enclosing a brief CV of the persons proposed and a written statement that they have no direct or indirect relation with the industrial manufacture, distribution or marketing of medicines, medicines in clinical research phase or medical devices. The regular renewal shall involve at least one quarter of members and at most half of them.

This information will be communicated at the next CREC meeting.

Once appointed by the Directorate General for Health Resources, they will sign a confidentiality document regarding the content of CREC meetings. They will also sign the CREC internal operating rules to ensure they continue to be adhered to.

This will also apply, if a new member is included. The proposed new member must have the appropriate training, experience and skills, and shall be evaluated by the other

members of the committee. A CV must be sent to the committee and an interview will be conducted.

If a member is excluded, the application must be submitted to the Directorate General for Health Resources, enclosing a letter with the reasons for such action: not attending meetings, conflict of interest, non-compliance with the CREC's operating rules or others.

To ensure that all CREC members have sufficient time to combine their usual activity and the tasks derived from the CREC, the IMO's CREC meeting will take place from 20:00 to 21:30. Appendix II

A written guarantee is presented from the director of the centre to respect the CREC's independence and to enforce the resolutions and opinions issued by the CREC within the scope of its competences Appendix I and Appendix III.

The Centre has the following material resources: computer equipment with internet connection, infrastructure: office located on the second floor for the secretary and meetings, and space to store documents, as well as personnel to carry out its activity. Material resources are updated according to the needs of the committee. Attached is a written guarantee from the director of its suitability for the needs and activities of the CREC. Appendix IV

The Centre has an annual budget for material, personnel and infrastructure resources. It also includes continuing education activities for its members. In relation to the budget, overtime will be paid to CREC members according to the rate of the professional association of their specialisation, and an hourly rate will be agreed for those who are not members of an association.

## Functions

The CREC's activities are governed based on the principles established in the Declaration of Helsinki (2008), the rules of Clinical Best Practices, the CREC Guide of the OMS to ensure protection of the rights, safety and wellbeing of the people participating in research projects that may entail a physical or psychological risk, evaluating the methodological, ethical and legal correction of these projects and monitoring them in the centres included in the scope of action.

To evaluate the methodological, ethical and legal aspects as well as relevant modifications of clinical trials with medicines, pursuant to Royal Decree 1090/2015, 4 December.

To evaluate the ethical, methodological and legal aspects as well as the relevant modifications to the clinical research with medical devices, pursuant to RD 1591/2009, 16 October.

To evaluate the methodological, ethical and legal aspects of post-authorisation studies with medicines and observational studies, pursuant to SAS Order 3470/2009, 16 December.

To evaluate the methodological, ethical and legal aspects of pharmacogenomic and pharmacogenetic studies, pursuant to RD 1090/2015, 4 December.

To evaluate the methodological, ethical and legal aspects of other biomedical research projects that may be commissioned, pursuant to RD 1090/2015, 4 December.

The ruling models will follow those indicated by the AEMPS attached to the Memorandum, v3/2/2016.

To monitor clinical trials with medications and clinical research with medical devices. Also the other studies that are undertaken at the IMO. (*See Follow-up of Clinical Trials*).

## **Notice of meetings**

The CREC will meet once per month to evaluate new clinical trials and changes to the trials already presented. The meeting date will be between the 21st and the end of the month and also between the 4th and the 15th of the month, if CREC of reference.

CREC members will be summoned to the IMO at 8 p.m., in writing and with seven days' prior notice, requesting written confirmation within three days, specifying the agenda, so that members can review the corresponding documentation.

In the event of an extraordinary call, members will be contacted by telephone directly and within a maximum period of two weeks.

The meeting notification, as well as the agenda, will be archived in the CREC's operational documentation.

If expert advice is required, the expert will also be notified in writing and with seven days' prior notice, requesting written confirmation within three days. This expert will only advise and not vote. To ensure the confidentiality of the information, the expert must sign a document of obligation to respect such confidentiality.

CREC members must confirm their attendance to ensure that there are sufficient numbers to enable decisions to be made (at least half plus one of the members, including at least one person not associated with the institution and another who is not in the health sector).



## Receiving protocols and notifications

According to RD 1090/2015, 4 December, a clinical trial's documentation must be divided into Part I and Part II.

The Instruction Document from the Spanish Drug and Medical Device Agency for conducting clinical trials in Spain, 3 February 2016 version, and the Memorandum for Collaboration and Information Exchange between the AEMPS and the Drug Research Ethics Committees, 3 February 2016 version, establish that the documents that must be sent to the committee for evaluation are the following and must be grouped according to whether they belong to the first or the second part:

### PART I

1. Letter from the applicant promoter identifying the protocol to be evaluated with the protocol code for the promoter, title, version and EudraCT number and list of documentation presented
2. Application form
3. Protocol
4. Protocol summary
5. Researcher's manual or technical data sheet for the drug being researched
6. The researcher's technical file or manual of the drugs not researched
7. Scientific advice and paediatric research plan.

### PART II

1. Selection procedure
2. Patient Information Sheet, Informed Consent Form and Informed Consent Procedure
3. Suitability of the researcher (Instructions Document, version 3/2/2016, point 37, Appendix II)
4. Suitability of the facilities (Instructions Document, version 3/2/2016, point 38, Appendix III)
5. Proof of insurance coverage or financial guarantee
6. Financial report
7. Documents related to biological sample management
8. Proof of fee payment to the committee, where applicable
9. Declaration of compliance with Organic Law 15/1999, 13 December, on personal data protection and its implementing regulations.

In the case of substantial modifications:

1. Letter from the applicant promoter identifying the protocol to be evaluated with the protocol code for the promoter, title, version and EudraCT number and list of documentation presented
2. Relevant modification form
3. Summary of changes

4. All the documents with the changes highlighted so that they can be evaluated.  
All the documents with the changes incorporated indicating the corresponding version.

All documents can be submitted in English, except the documents listed below, which must be submitted in SPANISH:

- Presentation letter
- Protocol summary
- Patient Information Sheet, Informed Consent Form and Informed Consent Procedure
- Proof of insurance coverage or financial guarantee

The promoter must submit 12 + 1 copies of the documents mentioned to:

Instituto de Microcirugía Ocular  
ETHICAL COMMITTEE  
Attn. Carmen Mas  
Josep Maria Lladó, 3  
08035 Barcelona

The CREC must receive 12 + 1 sets of documentation required to evaluate a clinical trial; one for each member and one more for the committee archive. The documents will be marked with a stamp (black) to indicate the date received by the CREC.

In the evaluation of part I, the division of responsibilities between the AEMPS and the Committee is as follows:

Data related to quality	AEMPS
Non-clinical, pharmacological and toxicological data	AEMPS
Clinical Data	
Clinical trial qualification in low intervention level	CEIm
CT justification and relevance	CEIm
CT design	CEIm
Treatment	CEIm
Characteristics of the population	CEIm
Contraceptive measures	CEIm
Identification of risks and measures to minimise damage	CEIm
Criteria for managing subject interruption and withdrawal	CEIm
Cecum masking and breaking	CEIm
Data security monitoring	AEMPS
Defining the end of the trials	AEMPS
Criteria for advance finalisation of the CT	CEIm
Statistics	AEMPS
Compliance with CBP Standards	AEMPS
Valuation of the charge for CT subjects	CEIm
Access to treatment once the trial is over	CEIm

Overall benefit/risk assessment CEIm/AEPMS

The evaluation of part II is as follows:

Informed Consent	CEIm
Compensation to the subjects for their participation	CEIm
Compensation to researchers	CEIm
Methods for selecting the subjects for the trial	CEIm
Personal data protection	CEIm
Researcher suitability	CEIm
Facility suitability	CEIm
Compensation for damages	CEIm
Compliance with the rules for collection, storage and future use of the test subject's biological samples.	CEIm

According to the guidelines established by the Memorandum for Collaboration and Information Exchange between the AEMPS and the Drug Research Ethics Committee, 3 February version, points 5.1 and 5.2.

In the case of substantial modifications, the AEMPS and the CEIm will evaluate the documentation on which they have already ruled in the initial assessment.

Once the promoter's documentation is received, the evaluation schedule is as follows:

10 days maximum for validating the CEIm documentation (from part II) received and inform the promoter, if it needs to be corrected.

10 + 1 days maximum for the promoter to submit the requested documentation to the AEMPS (from part I) and the CEIm (from part II). If a response is not received, it will be understood that the complete application for the trial will not be submitted.

5 days maximum for the CEIm and the AEMPS to notify the promoter whether or not the request is valid. The application is only considered VALID if Part I of the AEMPS and Part II of the CEIm are valid. If one of them is not, the complete application will be considered INVALID.

35 days from the date of receipt of a valid application. If there is a request for correction, it is counted from when the promoter's response is received. The CEIm will send its opinion to the AEMPS:

10 days for the AEMPS to integrate and send the conclusions to the promoter

12 days for the promoter to respond

10 days for the CEIm to send the conclusions on the response to the AEMPS

9 days for the AEMPS to integrate and send the conclusions to the promoter.

### **In summary**

Initial application: It will take 10 days from the initial date of receipt to validate the request. Several cases are presented:

- With no corrections or clarifications: 35 days from the initial date of receipt of the application for the CEIm's evaluation of part I and II (*RULING*), + 10 days for integration and sending the promoter the conclusions, + 5 days the AEMPS will send the resolution integrating the conclusions of part I and part II.
- With correction The promoter must respond to the correction within 10 days from the initial date of receipt. Once the response is received, it will take 35 days from the date of receiving the correction for the CEIm's evaluation of part I and II (*RULING*), + 10 days for integration and sending the promoter the conclusions, + 5 days the AEMPS will send the resolution integrating the conclusions of part I and part II.
- With clarifications: It will take 35 days from the initial date of receipt of the application for the CEIm to evaluate part I and II (*RULING clarifications*), + 10 days for integrating and sending the conclusions to the promoter, + 12 days the promoter has to answer, + 10 days for the CEIm to send its conclusions to the AEMPS (*Final RULING*), + 9 days for the AEMPS to integrate the CEIm response, + 5 days the AEMPS will send the resolution integrating the conclusions of part I and part II.
- With correction and clarifications The promoter must respond to the correction within 10 days from the initial date of receipt. Once the response is received, it will take 35 days from the date of receiving the correction for the CEIm to evaluate part I and II (*RULING clarifications*), + 10 days for integrating and sending the conclusions to the promoter, + 12 days the promoter has to answer, + 10 days for the CEIm to send its conclusions to the AEMPS (*Final RULING*), + 9 days for the AEMPS to integrate the CEIm response, + 5 days the AEMPS will send the resolution integrating the conclusions of part I and part II.

The AEMPS will inform the promoter whether part I of the application is valid and the evaluation schedule, as well as the result of the integrated evaluation of part I by the AEMPS and the CEIm. It will also adopt the decision on the trial, expressed as a resolution of

- Authorisation: if it is the conclusion on part I and on the opinion of the CEIm on part II
- Authorisation with conditions: if it is the conclusion on part I and in the opinion of the CEIm on part II
- Rejection

The CEIm ruling models for initial requests and for relevant modifications are those indicated in the Memorandum dated 3/2/2016.

The principal researcher will be contacted in writing to attend on the day the CREC meets, in order to ask questions about the clinical trial that members believe are appropriate. This meeting is estimated to last for 10 minutes per clinical trial. If the principal researcher cannot attend, a co-researcher may do so.

The CREC's ruling, together with the centre's letter of agreement, will be sent to the promoter in writing. Copies will be sent by fax or e-mail to the promoter and will be filed along with the corresponding trial documentation. The CREC's opinion must include the numbered and dated modifications to the protocol.

If unfavourable, the deadline for submitting an appeal to the CREC decision is 10 days. The documentation provided will be included in the next CREC meeting.

The sending date of the documents must be verified with a stamp purchased for this purpose.

## Evaluating projects

The methodological, scientific, ethical, economic and insurance aspects of the suitability of research personnel and facilities will be evaluated. Clinical trials and clinical research protocols approved by the CREC must also be evaluated in terms of changes made, distinguishing between relevant and non-relevant ones. A Research Project Evaluation Guide form will be used. Appendix VI

The procedure is to send the corresponding documentation to committee members, so that they can review it before the committee meeting. During the meeting, the President will ask attending members to speak in alphabetical order, who will provide the evaluation that they believe appropriate. The decisions will be made as described in the section *Decision-making*.

## Decision-making

The committee may issue a favourable or unfavourable opinion on or a clarification of the clinical trial

In order for decisions to be made in committee meetings, there must be a quorum; that is, half plus one of committee members must attend and be able to vote. The attendance of at least one doctor and of a member outside of the health professions is mandatory. If these requirements are not met, the meeting will be suspended and convened on another date, which must comply with the expected time limits for contributions and opinions, if there are multi-centre clinical trials.

Decisions will be made by consensus of the attendees. The President shall make the final decision about the work evaluated, if there is no consensus among attendees, counting as many votes for as against, at the corresponding meeting.

The advisors convened will not have the right to vote; in other words, the people who can attend committee meetings as experts to advise on the evaluation will not have voting rights.

The minutes of each meeting include the date and location, attendees and those absent at the committee meeting and the aspects evaluated, the agreement reached and the reason for the evaluated project. The minutes will be read and approved at the beginning of the next meeting and will be signed by all those attending the meeting. The committee meetings will take place in the meeting room on the 2nd floor of the IMO. In the event that a committee member is a researcher or co-researcher of the trial being evaluated, this must be expressly recorded in the minutes, and he/she must not participate in the evaluation of this trial. Nor will any remuneration, directly or indirectly, be received by the promoter of the clinical trial.

Each member of the committee is responsible for destroying their documents, giving them to the Secretary of the committee, who is responsible for hiring a company to destroy them. The container for destroying the committee's documentation is located on the second floor.

## Follow-up activities

Once a year, the clinical trial promoter must provide a report on the evolution of the trial, pursuant to RD 1090/2015.

This report must include the following information:

- Date of inclusion of the first patient
- Number of patients included and who abandoned, indicating the reason
- Adverse events
- Further information on the progress of the relevant trial

This documentation will be archived with the protocol. The protocol modifications and information on the risk/benefit balance of the project will also be evaluated.

The principal researcher or coordinator of the IMO study is also asked to complete a form and update the information every six months, i.e. in June and December of each year, delivering it to the committee from the 1st to the 5th of the following month. If not delivered, the committee will make the claim in writing. Appendix VII

The follow-up of the trials will be managed with a proprietary application created for this purpose by the IMO's IT department.

The registered clinical trial follow-up information will be included in the agenda and minutes of the meetings. This information will be updated every six months and will continue to be given to committee members at least twice a year. A copy of this documentation will also be archived with each clinical trial.

This documentation will be evaluated at the committee meeting in June of the current year and at the first committee meeting of the following year.

The committee activity report must not contain confidential data and must contain at least information on:

- Scope of action.
- The number of meetings.
- The number of projects evaluated.
- A sense of opinions issued.
- The current situation of the different types of projects evaluated by the committee.



## Archive

Clinical trials will be archived by protocol number. The archive must have a security system to guarantee the confidentiality of the information. The documents must be kept for three years after the end of the trial.

The documents to be saved are:

- Protocol, modifications and all documentation submitted by the promoter or legal representative
- The committee ruling
- Copy of any notification and correspondence with the researcher, promoter or legal representative: numbered and dated protocol modifications and reports of serious and unexpected adverse reactions
- Project monitoring document from the committee and progress reports from the promoter
- Copy of all notifications with the Spanish Medicines Agency and/or the Department of Health.
- In the case of multi-centre trials, a copy of all notifications with the AEMPS and/or the promotor.
- Annual safety and suspected adverse reaction reports sent by the promoter.
- The scheduled completion or early termination notification
- Summary of the final report of the clinical trial from the promoter
- All relevant documentation

The documentation entry will be recorded with:

Protocol number

Title

Promotor

Entry date (black stamp)

Evaluation date

To consult the documentation in the committee archive, the following information will be recorded:

Name

Consultation date

Release date

The documentation regarding the operation and activity of the CREC will be archived with a security system. A report on the committee's annual activity will be drafted and submitted to the Department of Health. This documentation will be kept as long as the committee is operational and five years longer, if its activity ceases.

The following information must be kept in the committee activity archive:

- Decision on accreditation and any changes to the composition or the scope of action accredited
- CV of current and previous committee members
- Meeting notification, agenda and minutes of all meetings
- Current and previous internal operating rules of the committee
- The committee's annual operating budget

Documentation associated with the inspection actions that have been carried out on the committee.

Only committee members can access the archive. Those who are no longer members of the committee will not have access to it.

If the committee ceases its activity, the institution responsible for its incorporation will maintain the file for five years after its cessation. If another committee, based in another institution, assumes the scope of action of the IMO committee, the transfer must be documented.

## **Fees**

The fees for evaluating a clinical trial are:

1,500 euros + 21% VAT for a new trial

1,000 euros + 21% VAT for a change

These fees are updated annually.

ANEXO I al contenido de las Normas de Funcionamiento Interno  
CEI Instituto de Microcirugía Ocular – Versión 10 Mayo 2016

Presentado en la reunión del CEIC del 17/11/2017

Habiéndose revisado el Memorandum de colaboración e Intercambio de Información entre la Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) y los Comités de ética de Investigación con Medicamentos, versión del 21/6/2017 de fecha de publicación el 5/7/2017 y atendiendo a la Instrucción 1/2017 sobre el procedimiento de acreditación de los Comités Éticos de Investigación Clínica (CEIC) como Comités Éticos de Investigación con Medicamentos (CEIm), se adjunta este anexo a las Normas de Funcionamiento Interno de referencia.

El CEI del Instituto de Microcirugía Ocular está ubicado en:  
calle Josep Maria Lladó, nº3  
Barcelona 08035  
Tel 93 253 15 00  
Fax 93 417 13 01  
E-mail Secretaría Técnica [imo@imo.es](mailto:imo@imo.es)

Se incorpora a la Secretaría Técnica la Dra Anniken Bures Jelstrup, cuyas funciones serán:

- Gestionar la actividad del CEIm.
- Actuar como interlocutora en nombre del CEIm en lo referente a la comunicación con todos los agentes interesados, incluyendo la Agencia Española de Medicamentos y Productos Sanitarios.
- Asegurarse de que se celebren las reuniones presenciales y no presenciales necesarias para que el CEIm cumpla con su cometido en los tiempos establecidos.
- Rendir, en colaboración con los miembros del CEIm, los informes que se le soliciten desde la Agencia Española de Medicamentos y Productos Sanitarios o cualquier otra autoridad competente para mantener su acreditación como CEIm.

La secretaria técnica tendrá voz pero no voto

La Secretaria técnica se incluye en el Organigrama del IMO

Además se incorpora como miembro externo la Sra. Ana Mas Crespi como miembro lego que represente los intereses de los pacientes.

La composición del CEI quedará:

Presidencia: Dr Rafael Navarro– Oftalmólogo

Vicepresidencia: Dra Marcela Manriquez - Farmacólogo Clínico

Secretaría Técnica: Dra Anniken Burés– Oftalmólogo (sin voto)

Secretaria Administrativa: Sra. Carmen Mas- Persona ajena a las profesiones sanitarias

#### Vocales

Dra Laia Pascual - Oftalmólogo

Dra Mercé Morral – Oftalmólogo- Miembro de Atención al Paciente

Dra. Charlotte Wolley Dod- – Oftalmólogo

Dra Cecilia Salinas - – Oftalmólogo

Sr Leandro Martínez- Zurita – Abogado

Sra. Ana Mas – Representante intereses de pacientes

Sra. Carolina Rovira – Farmacéutica de Hospital

Sra. Pilar Sabín – Farmacéutica de Atención Primaria

Sra. Esther Canals – Diplomada en Enfermería

Los miembros externos al centro son:

Dra Marcela Manríquez

Sr. Leandro Martínez- Zurita

Sra. Ana Mas

Sra. Carolina Rovira

Sra. Pilar Sabín

Se solicitará anualmente la renovación de la declaración de conflicto de intereses y el compromiso de confidencialidad a todos los miembros del comité.

En el caso de que se necesite el asesoramiento de expertos para la evaluación del estudio, se les solicitará y archivará, además del documento de confidencialidad, también la declaración de conflicto de intereses así como un Curriculum Vitae.

Firmo el presente anexo, a los efectos oportunos.

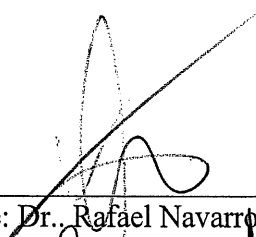
En Barcelona, a 6 de Marzo 2018

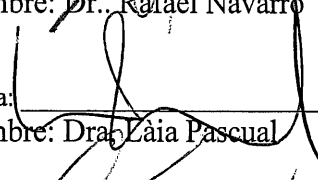


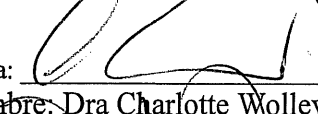
Dr. Rafael Navarro  
Presidente

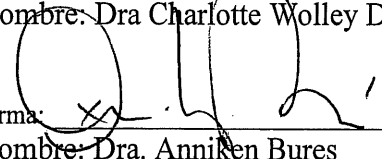


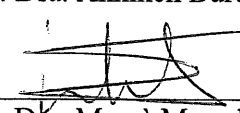
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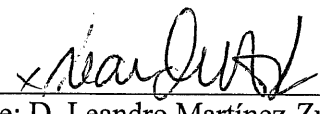
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Nombre: Dr. Rafael Navarro

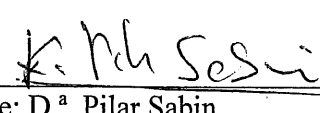
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Nombre: Dra. Laia Pascual

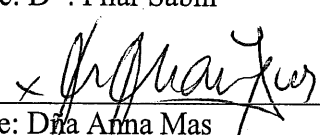
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Nombre: Dra. Charlotte Wolley Dod

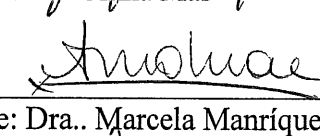
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Nombre: Dra. Anniken Bures

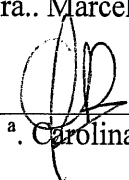
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Nombre: Dra. Mercè Morral

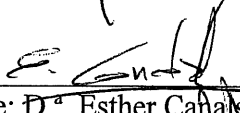
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Nombre: D. Leandro Martínez-Zurita Julià

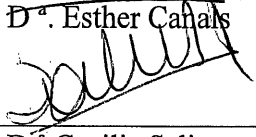
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Nombre: D.ª Pilar Sabin

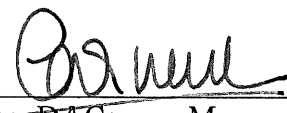
✕ Firma:  Fecha: 15/05/2018  
Nombre: Dra. Anna Mas

✕ Firma:  Fecha: 26/04/2018  
Nombre: Dra.ª Marcela Manríquez

✕ Firma:  Fecha: 26/4/2018  
Nombre: D.ª Carolina Royira

✕ Firma:  Fecha: 26/04/2018  
Nombre: D.ª Esther Canals

✕ Firma:  Fecha: 26/04/2018  
Nombre: D.ª Cecilia Salinas

✕ Firma:  Fecha: 26/4/18  
Nombre: D.ª Carmen Mas