**Formulari de sol·licitud d’avaluació d’estudis al CEIm-PSMAR**

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| **Sol·licitant /Applicant** |
| Nom i cognoms / Nameand Surname |  |
| Nom CRO (si aplica)Name of CRO (if applicable) |  |
| Telf. |  | E-mail |  |
| **Promotor / Sponsor** |
| Nom / Name |  |
| Adreça / Adress: |  |
| Telf. |  | E-mail |  |

**Evaluation Request Form to the EC - PSMAR**

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| **Dades d’identificació de l’estudi / Study Identification** |
| Títol / Title |  |
| Codi protocol / Protocol Code |  |
| Investigador Principal / coordinador (en estudis multicèntrics)Principal Investigator / Coordinator(in multicentre studies) |  |
| Investigador principal del centre /Local principal Investigator |  |
| Servei/departamento/grup recercaService/department/research group  |  |
| E-mail |  |
| Versió i data del protocolVersion and date of the protocol |  |
| Versió i data del FIP/CIVersion and date of the ICF |  |
| [ ]  Unicèntric / Unicentre [ ]  Multicentre. Llistat de centres / list of sites participanting in the study (in the member state): |
| Nº total de participantsTotal number of subjects  |  |
| Nº participants previst al centreNº subjects planned in the centre |  |
| 1. **RESUM DE l’ESTUDI / SUMMARY OF THE STUDY**
 |
| ***en llenguatge planer, en Català o castellà / in lay language, in catalan or Spanish (MANDATORY)*** |
| **Tipus d’estudi** /**Study type** | \*\*\* Els Assajos clinics amb medicaments s’han de presenter d’acord amb els requisits del Reglament UE 536/2014 i el RD1090/2015, a través del portal CTIS / Clinical Trials with medicines must be submitted in accordance with the requirements of the Regulation (EU) 536/2014 and RD1090/2015, through the CTIS portal.[ ]  Investigació Clínica amb Producte Sanitari / Clinical Investigadtion with Medical Device (Reglamento (UE) 2017/745). [ ]  sense marcat CE / without CE mark [ ]  amb marcat CE. Ús segons instruccions i finalitat prevista autoritzada / with CE mark. Use according to instructions and authorized intended purpose. [ ]  sense marcat CE o amb marcatge, però al marge de la seva finalitat prevista / Medical devices without CE marking or with marking, but outside their intended purpose [ ]  estudi amb intel·ligència artificial / Artificial intelligence study [ ]  estudi observacional amb producte sanitari / observational Studies with medical devices[ ]  estudi clínic amb un producte alimentari o nutricional / nutritional intervention studies[ ]  estudi clínic que requereix la realització de proves o intervencions fora de la práctica clínica habitual / clinical study with tests or interventions outside of routine clinical practice[ ]  estudi observacional amb medicaments d’acord amb el RD 957/2020 (EOm) / Post-authorization studies (PAS) according to RD957/2020.[ ]  estudi observacional (sense medicaments) / observational studies (withouth human medicines)[ ]  estudi de recerca bàsica amb mostres biològiques d’origen humà / research studies with human samples[ ]  Other:………………………………………………………………………………. |
| Si es tracta d’un estudi acadèmic, indicar / Specify if this is an academic study:[ ]  Yes[ ]  No If yes, specify (TFG, TFM, PhD, ...): …………………………………………………………… |
| L’estudi està aprovat per un altre Comitè d’Ètica? / The study has the approval of another Ethics Committee?[ ]  Yes[ ]  No If yes, specify: ……………………………………………………………\*\* *adjuntar el certificat d’aprovació amb la presentació de l’estudi / attach the certificate of approval with the study submission* |

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| 1. **HUMAN BEINGS**
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| **Does your research involve human participants?**If Yes (more than one option can be marked): | [ ]  Yes [ ] No |
| * Are they volunteers for social or human sciences research?
 | [ ]  Yes [ ] No |
| * Are they persons unable to give informed consent?
 | [ ]  Yes [ ] No |
| * Are they vulnerable individuals or groups?
 | [ ]  Yes [ ] No |
| * Are they children/minors?
 | [ ]  < 12 y[ ] 12 -17 y |
| * Are they patients?
 | [ ]  Yes [ ] No |
| * Are they healthy volunteers for medical studies?
 | [ ]  Yes [ ] No |
| **Detail the recruitment procedure and materials that are necessary (same as protocol, if applicable):** |
| **Describe the study intervention(s) (if applicable):** |
| **Define if the study is:**[ ]  prospective[ ]  retrospective[ ]  ambispective |
| **Do you provide an informed consent form (ICF)?**If yes (more tha one option can be marked):* General or main ICF
* For parents/legal representative
* Assent of the child (necessary if >12y to 17y)
* Sub-study
* Others: …………………………………………………………….

\*\*provide the ICFs in separate documents, with version and data (mandatory)If no, **justify the exception (the explanation must be included in the ethics section of the protocol)** to requiring the informed consent form:* The research poses no more than minimal risk to subjects (a record review or using data from medical records)
* The rights and welfare of the individual would not be adversely affected
* It is impracticable to obtain consent
* The research does not infringe the principle of self-determination
* The waiver of informed consent is needed for the study
* The clinical relevance and public health importance
* Patient/participant signed a previous ICF that permits the secondary use of data and/or samples to future studies of the same line of research, and the previous study was approved by the ethics committee.

**Other information of interest to the ethics committee (free text):***For example, if data or samples used in the present study were obtained in previous studies approved by the EC and have the ICF signed by participants…* | [ ]  Yes [ ] No[ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]  |
| 1. **HUMAN SAMPLES (if applicable)**
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| Does your research involve Human Embryonic Stem Cells (hESCs)? | [ ] Yes [ ] No |
| Does your research involve the use of human embryos? | [ ]  Yes [ ] No |
| Does your research involve the use of human foetal tissues / cells? | [ ]  Yes [ ] No |
| Does your research involve human cells or tissues (other than from Human Embryos/Foetuses)?If Yes: | [ ]  Yes [ ] No |
| * Are they available commercially?
 | [ ]  Yes [ ] No |
| * Are they obtained within this project?
 | [ ]  Yes [ ] No  |
| * Are they obtained from another project, laboratory or institution?
 | [ ]  Yes [ ] No |
| * Are they obtained from a biobank?
 | [ ]  Yes [ ] No |
| Detail of the cells or tissue type, the source of the material, provider (biobank, hospital, company…), amount to be collected, duration of storage what you will do with the material at the end of the research, or if you will destroy samples at the end of the study: |
| Detail if material is fully anonymised or that consent for secondary use will be obtained: |

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| 1. **PERSONAL DATA PROTECTION**
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| **Personal Data:** Information that can lead to the identification of an individual (or a group of individuals)* Direct identifiers: name, address, postcode, telephone number, photograph or image, or some other unique personal characteristic, id card/social security number, medical record number …
* Indirect identifiers: when certain information is linked together with other sources of information, including, their place of work, job title, salary, their postcode or even the fact that they have a particular diagnosis or condition, date of birth, gender ….

**References:****Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales.**<https://www.boe.es/buscar/doc.php?id=BOE-A-2018-16673> **REGLAMENTO (UE) 2016/679 DEL PARLAMENTO EUROPEO Y DEL CONSEJO de 27 de abril de 2016 relativo a la protección de las personas físicas en lo que respecta al tratamiento de datos personales y a la libre circulación de estos datos.**<https://eur-lex.europa.eu/legal-content/ES/TXT/?uri=celex%3A32016R0679> <https://web.gencat.cat/ca/seu-electronica/sobre-la-seu/proteccio-de-dades> <https://salutweb.gencat.cat/ca/el_departament/proteccio-de-dades/><https://apdcat.gencat.cat/ca/documentacio/RGPD/altres_documents_dinteres/>  |
| **Does your research involve processing of personal data?**If Yes: | [ ]  Yes [ ] No |
| Does it involve the processing of special categories of personal data (e.g. genetic, health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)? | [ ]  Yes [ ] No |
| Does it involve profiling, systematic monitoring of individuals or processing of large scale of special categories of data, intrusive methods of data processing (such as, tracking, surveillance, audio and video recording, geolocation tracking etc.) or any other data processing operation that may result in high risk to the rights and freedoms of the researchparticipants? | [ ]  Yes [ ] No |
| **Does your research involve further processing of previously collected personal data** (including use of preexisting data sets or sources, merging existing data sets)?*Information to be provided in the protocol: details of the database used or of the source of the data, and data processing operations*. | [ ]  Yes [ ] No |
| **Is it planned to export personal data from the EU to non-EU countries?** | [ ]  Yes [ ] No |
| **Details of the technical and organisational measures to safeguard the rights of the research participants:**[ ]  **Informed Consent Form (ICF)**[ ]  **Anonymization:** Process of removing private or confidential information from raw data. Results in anonymous data that cannot be associated with any individual or company. For data to be truly anonymised, the anonymisation must be irreversible.[ ]  **Pseudonymization:** the processing of personal data in such a way that the data can no longer be attributed to a specific data subject without the use of additional information, as long as such additional information is kept separately and subject to technical and organizational measures to ensure non-attribution to an identified or identifiable individual.**Detail data protection officer (DPO) contact (of the institution)**: …………………………………………*for example, in Hospital del Mar Research Institute (HMRI) and Hospital del Mar the DPD contact is* *protecciodedades@imim.es***Detail Sponsor data protection officer (DPO) contact**: ………………………………………………………. |
| **Under the GDPR, a Data Protection Impact Assessment (DPIA) will be mandatory for any new high-risk processing projects. Type of research projects requiring a DPIA:*** **Observational: unicentre or multicentre, prospective or retrospective, without informed consent form and/or when data is transferred to third parties.**
* **Innovative technologies:** processing involving the use of new technologies, or the novel application of existing technologies. P. e: artificial intelligence, machine learning and deep learning, Smart technologies (including wearables), market research involving neuro-measurement (i.e. emotional response analysis and brain activity)
* **Large-scale profiling:** any profiling of individuals on a large scale. P.e.: data processed by Smart Meters, hardware/software offering fitness/lifestyle monitoring, social-media networks.
* **Biometric data**: any processing of biometric data for the purpose of uniquely identifying an individual. P.e.: facial recognition systems, workplace access systems/identity verification, access control/identity verification for hardware/applications (including voice recognition/fingerprint/facial recognition)
* **Genetic data**: any processing of genetic data. P.e.: medical diagnosis, DNA testing, medical research.
* **Tracking**: processing which involves tracking an individual’s geolocation or behaviour, including but not limited to the online environment. P.e.: social networks, software applications, hardware/software offering fitness/lifestyle/health monitoring, online advertising, web and cross-device tracking, data aggregation / data aggregation platforms, eye tracking, data processing at the workplace, data processing in the context of home and remote working, wealth profiling – identification of high net-worth individuals for the purposes of direct marketing.

**Different templates of DPIA are available in the Ethics Committee website.****The protocol must explain the data lifecycle (data creation, processing and storage, usage, archiving and destruction), and the procedure to minimize risk of re-identification of participants.**  |

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| 1. **Agreement and study budget**
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| An **agreement** will be necessary in multicenter studies.The study agreement will be managed through the Hospital del Mar Research Institute (IMIM Foundation)* E-mail: contractes@imim.es
* Telf. : 933160602
 |
| **Study Budget** *(the estimated amount of money that you need to accomplish the goal of a clinical trial or research study*):[ ]  Not available (not funded)[ ]  Funded study **Note**: study budget must be submitted in funded studies. |

**The requirements for submitting studies to the Ethics Committee are available on the website:**

<https://www.imim.es/comitesetics/ceic/index.html>

**Specify the list all the documents attached:**

* Request Form
* Protocol
* ICF
* Study Budget
* Reference ethics committee approval
* Investigator commitment
* …..
* …..
* …..
* …..

Submitted by: …………………………………

Date: …………………………………………..