CATÓLICA
INSTITUTE
OF BIOETHICS

PORTO

ETHICS IN RESEARCH

CRITICAL SKILLS IN RESEARCH

Ana Sofia Carvalho | IB UCP

Joana Araújo | IB UCP

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RESEARCH ETHICS

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ETHICS IN RESEARCH

SCIENTIFIC INTEGRITY

- RESEARCH MISCONDUCT
  - FFP
  - PERSONAL MISCONDUCT
  - PUBLICATION MICONDUCT
- OTHER ETHICALLY OBJECTIONABLE PRACTICES RESEARCH PRACTICES

RESEARCH ETHICS

- RESEARCH WITH HUMANS
  - RESEARCH ETHICS MISCONDUCT
- RESEARCH WITH ANIMALS
  - RESEARCH ETHICS MISCONDUCT

HUMANS EMBRYOS

(1) demonstrate that the project serves important research aims to advance scientific knowledge, the origin of the embryos and the justification to use embryos and not validated appropriate alternatives

(2) Approval of Comissão Nacional de Procriação Medicamente Assistida must be submitted

(3) the origin of the cell lines and, if commercially available, details on the provider.

(4) origin of human foetal tissues/cells.


RESEARCH PARTICIPANTS
HUMAN HEALTHY VOLUNTEERS
PERSONS NOT ABLE TO CONSENT
PATIENTS
VULNERABLE PARTICIPANTS
COGNITIVE
MEDICAL
ALLOCATIONAL
DEFERENTIAL

RESEARCH WITH HUMANS

(1) recruitment criteria (e.g. detail information on the participants, number, inclusion/exclusion criteria, direct /indirect incentives for participation, the risks and benefits for the participant)

(2) informed consent procedures and Informed Consent Forms and Information Sheets (incidental/ unexpected findings policy should be included)

(3) Copies of Ethics Approvals must be submitted

(4) justification for the participation of adults unable to give informed consent; details of the procedures for the consent of the legal representative

(5) details on the recruitment and inclusion/exclusion criteria and the measures to prevent the risk of enhancing vulnerability stigmatization of individuals/groups

(6) justification for the participation of children, the assent procedures for children and the procedures for obtaining the consent from the guardian/legal representative

RESEARCH WITH HUMANS CELLS/TISSUES

(1) details on the cells or tissue types and of provider

(2) source and amount of the material and the procedures for collection. Details on the storage and destination, reuse of the material at the end of the research.

(3) if the material will be collected only for the purpose of the project further information must be provided about recruitment criteria

(4) informed consent procedures and Informed Consent Forms and Information Sheets (incidental/unexpected findings policy should be included) and Copies of Ethics Approvals must be provided

(5) Confirmation that the material is full anonymised or that consent for secondary use has been obtained. Copies of authorisations for using/processing the cells or tissues

(6) Details on the biobank (name and country), Confirmation that the material is full anonymised or that consent for secondary use has been obtained. Copies of authorisations for using/processing the cells or tissues.

PROTECTION OF PERSONAL DATA

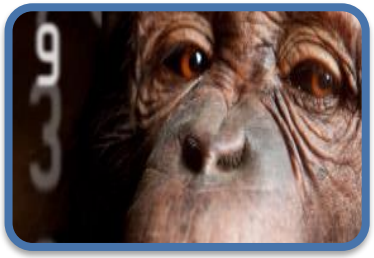
Details of procedures for data collection, storage, protection, retention, transfer, destruction or re-use (including, collection methodology (digital recording, picture, etc.), methods of storage and exchange (LAN, cloud, etc.), data structure and preservation (encryption, anonymisation, etc.), data merging or exchange plan, commercial exploitation of data sets, etc.)

Details of data safety procedures (protective measures to avoid unforeseen usage or disclosure). Copies of notifications/authorisations for collecting and/or processing the personal data (CNPN – Comissão Nacional de Proteção de Dados) must be provided.

Details on the database used or of the source of the data. Details of procedures for data processing. Details of data safety procedures.

Confirmation that data is openly and publicly accessible or that consent for secondary use has been obtained. Permissions by the owner/manager of the data sets. Copies of notifications/authorisations for collecting and/or processing the personal data (CNPN) must be provided.

ANIMALS



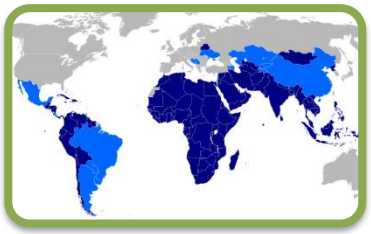
Justification of animal use (including the kind of animals to be used) and why alternatives cannot be used. Details of species and rationale for their use, numbers of animals to be used, nature of the experiments, procedures and techniques to be used. Details on how the Principle of the Three Rs will be applied.

Copies of relevant authorisations (for breeders, suppliers, users, and facilities) for animal experiments. Copy of project authorisation (covering also the work with genetically-modified animals). Copies of training certificates/personal licenses of the staff involved.

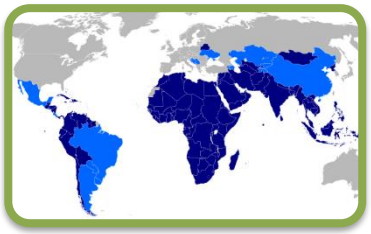
Detailed justification for the use of NHPs and details on the provenience of the animals. Personal history file of NHP.

Copies of GMO authorisations; Copies of authorisations for cloning (if required). Copies of authorisations for supply of endangered animal species (including CITES)

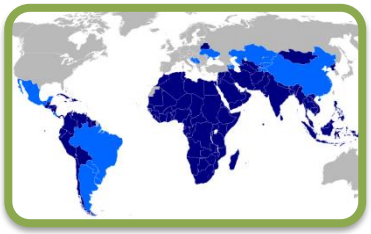
THIRD COUNTRIES



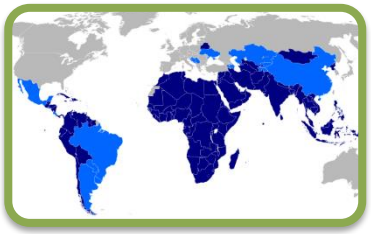
Risk-benefit analysis (if applied). Copies of ethics approvals and other authorisations or notifications (if required). Confirmation that the activity could have been legally carried out in an EU country (for instance, by submitting an opinion from an appropriate ethics structure in an EUcountry).



Copies of Ethics Approvals for humans; For animals, plants, microorganisms and associated traditional knowledge: documentation demonstrating compliance with the UN Convention on Biological Diversity (e.g. access permit and benefit sharing agreement).



Details on the materials to import/export. Copies of import/export licences must be provided.



Details of benefit sharing and capacity building and details on safety measures must be provided.

Details on safety measures. DOCUMENTS TO BE PROVIDED: Safety classification of laboratory. Copy of GMO authorisations (if required).

Specific authorisations (if required)

Details on health and safety procedures. DOCUMENTS TO BE PROVIDED: Safety classification of laboratory.

DUAL USE

- Details on potential dual use implications of the project and risk-mitigation strategies must be provided and copy of export licences

EXCLUSIVE FOCUS ON CIVIL APPLICATIONS

- Explanation of the exclusive civilian focus of research. Justification for the inclusion of military partners or military technologies.

MISUSE

- Details on potential misuses and details on measures to prevent abuse of research findings.

DOCUMENTS TO BE PROVIDED: Copies of authorisations (if required). Copies of security clearances (if applicable). Copies of ethics approvals (if applicable).