IISPV
INSTITUT D'INVESTIGACIÓ SANITÀRIA PERE VIRGILI

IISPV CODE OF GOOD SCIENTIFIC PRACTICES

14-. IISPV code of good scientific practices. Meeting of the Governing Board of 10 July 2020

CONTENTS:

1. INTRODUCTION

The Pere Virgili Health Research Institute (IISPV, in its initials in Catalan), is an organisation set up in 2005 within the framework of inter-institutional scientific collaboration among: the ICS Camp de Tarragona (University Hospital of Tarragona Joan XXIII), ICS Terres de l'Ebre (Verge de la Cinta Hospital, Tortosa), the Sant Joan de Reus University Hospital, Grup Pere Mata and the Rovira i Virgili University to coordinate health and biomedical research and research training in the Camp de Tarragona and Terres de l'Ebre.

The IISPV is accredited as a CERCA centre.

The IISPV Code of Good Practice (CdPC IISPV) is a set of recommendations and commitments regarding research-related activities, innovation in scientific practice to ensure the integrity of research staff behaviour and the quality of knowledge generated.

Its goal is to create an environment conducive to high-quality research, as well as foreseeing integrity issues in the behaviour of scientists The content of this code supplements that already provided for in existing legal regulations.

The document complies with the laws and regulations currently in force.

2. GENERAL RESEARCH PRINCIPLES

2.1. Methodical doubt exercise

The principle of scientific knowledge is the capacity to question why facts are as they are. Science seeks objective knowledge that can be accepted as true in a socio-cultural context. To achieve it, one follows a reflective process with two phases: methodical doubt and the validation of an explanatory hypothesis. Methodical doubt implies independent judgement and non-acceptance of any idea as absolute or definitive. To validate a hypothesis, one has to find evidence or arguments that consolidate it. This inquisitorial attitude at the forefront of the scientific task must is something that researchers must always bear in mind.

2.2. General rules that regulate scientific practice

- Observation and experimentation in clinical practice, in the laboratory or the natural environment, are directed at the obtaining of data that can provide answers to scientific questions that are formulated a priori. Research must follow well-defined and well-designed protocols with rigour, that can be replicated, examined, evaluated and understood by any other researcher. The design has to be done with care to optimise the use of resources, always taking into account the rules for work of the centre where the research is conducted.
- One must maintain a systematically sceptical approach and be open to doubt, especially when it comes to one's own results. One of the principal forms of evidence to validate a scientific study is it replicability. The more surprising or desired a result is, the more important it is to reproduce it within a research group, before announcing it externally.
- Vigilance of any form of expectation motivated by self-interest or prejudices of any kind must be exercised at all times. The critical faculty must be maintained to foster a state of systematic alertness that can detect erroneous interpretations as a result of the limitations of experimental design, excessive generalisation and superficiality in interpretation.
- It is crucial to make a systematic, controlled and safe collection of primary data, and guarantee the storage of the documentation generated during the period established by the type of study itself. The data have to be clear and comprehensible, and include the methods used to generate them.

2.3. Application to the IISPV

- IISPV staff are committed to abiding by this Code, also including the laws and regulations enumerated in other documents (see Annex 3 "Law, regulations and documents") and to ensure that it is known by its whole team.
- The researchers will be able to determine freely the methods to solve problems, as long as the principles and recognised ethical practices are respected, and the limitations that are derived from the circumstances of the investigation or for operational reasons are accepted.
- IISPV staff must provide financing agencies with guarantees that the resources allocated to research are used in the most efficient way possible and comply with ethical principals.
- Before the scientific community, one must ensure that results are disseminated, including negative results, to prevent unnecessary duplication of effort.
- Scientific malpractice must be prevented, both in the realisation of the research process and in its dissemination to the scientific community.
- The necessary means must be used to ensure that the resources allocated to research are put to the best possible use and that the rights of sick people are protected.

3. DIFFERENTIATING ASPECTS OF HEALTH SCIENCES RESEARCH

- Clinical care practice and health treatments are based on a body of scientific knowledge, skills, techniques and attitudes of the professionals in the field. This knowledge is gained by means of systematic research. its transfer is conducted through scientific publications and teaching.
- The research that is conducted in basic settings, in clinics or in the public health service, makes it possible to renew and increase the existing knowledge base through an orderly procedure. This consists in a sequence of processes aimed at an ultimate goal, which is the improvement of the professional practice and public health.
- Quality research makes it possible for the professionals to keep their knowledge up to date and to have an open-minded attitude to change, which results in improvement in healthcare. To achieve it, what is needed is to bring together all the resources available, such as the effort, the time and the dedication of the research personnel.
- An especially important aspect is that when efforts are directed to a project and none to a particular direction, other options are rejected, hence the importance of deciding correctly.
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- Communication of the results allows knowledge to be transferred and science to progress. It is therefore essential, once it is in the public domain, to avoid duplication and to promote improvements in procedures and development of new technology. In this way, society as a whole benefits.
- In order that all of this process is accepted by society, which provides the resources used to develop it, a set of ethical postulates must be fulfilled and specific conditions must be met. It is the scientific community that evaluates and determines the validity of our knowledge.
- The research environment is competitive when it comes to obtaining resources and funding. These resources may come from external funding source, not-for-profit organisations, profit-driven enterprises or the health service itself. The search for funding must not undermine the moral imperative that underpins the process.
- Today, research is conducted in increasingly wide spheres. Multi-site studies are increasingly common. The centre and the research staff must be committed, on the one hand, to reviewing with keen interest the participation in this type of study and, on the other hand, they must not participate in it until they have carried out this review.
- The IISPV"s Guide to Good Practices in Research constitutes a commitment of the institute and the research staff in terms of the realisation of all scientific processes, to the highest possible standard.

4. PLANNING A RESEARCH PROJECT

To stand a chance of success, a research project needs to meet a minimum standard of planning. Without these elements in place, no project can be considered and it cannot be registered as such with any research bodies, as it will lack the elements of assurance and protection that are referred to in this document.

Any research that directly involves humans, experimental animals, or material of human embryonic origin must first be set out in a written research plan. The text of the research plan must have been independently reviewed by an ethics committee for clinical research and/or animal testing. This text is generally accompanied by the requisite report to obtain permissions and resources[1].

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3.1 Project design phase

1. Appointment of the lead researcher
2. Review of pre-existing information. Establishment of a hypothesis
3. Discussion of the aims.
4. Selection of the focus, variables and the observational and experimental methodology
5. Determination of the sample size
6. Definition of data analysis plan and the statistical methodology
7. Determination of the minimum resources necessary for the viability of the project
8. Definition of the data collection and custody system
9. Task planning

3.2 Design of the protocal in the case of clinical trials

1. It is compulsory to draw up a protocol
2. Minimum required content
3. Research team
4. Publication rights and financial agreements

3.3 Approval of the protocol

1. Inter-services collaboration agreements
2. Scientific approvals
3. Ethics approval
4. Legal approval
5. Undertaking of the research team
6. Existence of a contractual agreement

Financial conditions

If there is a financial compensation, there must be a contractual agreement, in the form of a written document, that sets out the conditions agreed upon by the parties. This must at least be signed by the promoter or funding body as the case may be, the responsible executive of the IISPV, the lead researcher and the health institution where the study is to be conducted. The financial management of the funds obtained shall be conducted via the IISPV and all of its recommendations must be followed. In the event that a project is not managed directly through the IISPV, as a result of alliances or agreements with other institutions, the IISPV must be aware of it.

5. RESEARCH ON HUMANS

5.1 Prior informed consent document

Research projects that have the participation of patients or volunteers will have to have their informed consent before they begin, either through their signature or that of their legal representative.

5.2 Ethical principles

Biomedical research in the centre must be based on universally recognised ethical postulates of autonomy and the principle of benefit. The principle of autonomy must be respected especially in the case of disabled persons, for whom their guardian(s) will be responsible.

5.3 Prior information to informed consent

The information that has to be given to the patient that participates in a project has to provide before he or she signs the acceptance document. This information has to be given to the participant in the most clearly intelligible terms possible, respecting the cultural values of each person. Patients must be given the time they need to be able to study the proposal and take a decision that is well-grounded.

5.4 Written information

Patients must be provided with a document specifying the potential benefits and risks of their participation in the study, and the full name of the person who informed them and the lead researcher of the study . Their express acceptance must be recorded, or that of his/her legal guardian(s).

5.5 Financial compensation

If the project allows for financial compensation for the participants, be they patients or healthy volunteers, this fact must be recorded, as well as the relationship with the extraordinary expenses that their participation may entail.

5.6 Approval by the research ethics committee or the body that performs this role.

The research cannot be initiated until the research ethics committee has evaluated and approved the protocol. This committee ensures that the rights of patients', healthy volunteers and other persons who participate in a research project are respected, The requisite documents must be sent to this committee on a yearly basis and on the completion of the study.

5.7 Notice and action to be taken in the event of possible adverse effects

If adverse effects occur, the promoter must be informed immediately. If they are potentially serious, the patient must be withdrawn from the study.

5.8 Biobank

The setting up and operation of the biobanks and their basic organisational requirements are set out in the current specific regulations. It is essential to have the relevant informed consent in accordance with the type of sample and use one wishes to make of it (see the annex on relevant law).

6. RESEARCH ON ANIMALS

Research involving animals must be in accordance with the '3Rs ("replace, reduce and refine"), and each aspect must always be justified.

6.1 Animal model justification

There must always be a rationale of the need to use animals as experimental subjects, and indicate the non-existence or contra-indication of alternative methods that could replace them.

6.2 Deciding on the number of animals

The sample size of the study must be determined, and it must be kept as small as possible.

6.3 Mitigation of discomfort

The procedures to prevent animal suffering and the method of termination must be specified, which must be the most appropriate possible, according to the principle of refinement.

6.4 Approval of the animal testing ethics committee

The research may not start until the animal testing ethics committee has given its final approval. When the study comes to an end, the requisite yearly and final reports must be sent to the ethics committee.

7. SAFETY, HEALTH AND THE ENVIRONMENT

The research staff must be aware of the safety, occupational health and environmental protection measures that must be taken into account in conducting research activities.

Each centre will ensure that the research is carried out ensuring the safety and health of the staff involved, as well as respecting the environment. Research groups must ensure that their activities are carried out within the framework of policies for the prevention of occupational risks and environmental protection, both the centre's and those established by current law, which includes specific sections for genetically modified organisms.

8. DEVELOPING PROJECTS

8.1 Responsibility of the Lead Researcher

The lead researcher is the person responsible for the project. In the event that he or she is replaced, the replacement must be authorised by the funding agency and the management of the centre, before going on with the research. In these circumstances, the person put forward must have at least the same capacity as the person replaced.

8.2 Supervision of the study

The lead researcher must ensure that his or her research team follows the authorised protocol, including the meticulous monitoring of the pre-doctoral research personnel and any other personnel who are in training, to ensure that they comply with the protocol and receive the appropriate instruction.

8.3 Modifications

If significant changes need to be made to the project, these must be formally stated in writing. If they are major importance, they must be authorised by all of the bodies that approved them in the first instance.

8.4 Audits

The lead researcher must cooperate in all inspection visits and checks that the centre and/or the external agency may decide to carry out, and in the preparation of the progress reports as required, with the periodicity planned.

8.5 Record of expenditure

The research team is responsible for the efficient use of the budget allocated to the project. Financial management must be transparent and detailed of all payments and receipts. These must enable the requisite reports to be made and checked by the funding agencies.

8.6 Use of equipment

It is a compulsory requirement that researchers maintain the research equipment in the best possible condition, and that they comply scrupulously with the rules for using it. The relevant periodic calibrations must be made, both to ensure the validity and accuracy of the results and to safeguard the physical safety of the persons that are going to use it.

8.7 Recording, documentation, storage, custody and sharing of the biological and chemical data and material resulting from the research.

8.7.1 Data collection and retention plan

All research protocols must make provision for a data collection system, and for the recording of the biological or chemical material resulting from the research, as well as a plan for their custody, conservation and eventual disposal and destruction, in accordance with current law.

8.7.2 Record of data and corrections

All of the data resulting from experiments and observations of the research must be collected, without exception. This information must be permanently recorded in databases or in any other relevant format, and in a condition to be reviewed by third parties. Records should also include changes, errors, and negative, unexpected, or discordant results, as well as the person making or observing them.

8.7.3 Retention of data and samples collected

It is necessary to provide the necessary means and infrastructures to guarantee the correct custody and conservation of the various documentation and of the resulting biological or chemical material. In the case of data recorded in electronic form, a specific backup plan and their physical location must be included.

8.7.4 Custody and access to the data

All persons that are part of the research team must be able to access the information of the data obtained and their interpretation. The person responsible for the research must have a single record of the various elements of data collection (notebooks, databases, etc.). and custody of samples, access to which must such that it can be made available to third parties.

8.7.5 e. Ownership of the data and samples

All of the primary documentation (data collection notebooks, databases, etc.) and the biological or chemical material obtained in the course of a research project is the property of the institution or institutions to which the person responsible for the project is bound by an employment relationship. In the event of a change of institution, the person responsible for the project may provide a replacement with a copy of the existing information.

8.7.6 Sharing data and samples with third parties

The data and materials resulting from a search must be public and must such that they can be shared by third parties, except in cases where restrictions have been imposed on their possible future sale. Any loan or transfer will require prior knowledge of the use to be made by the requester, knowledge of the application by the research team and a loan or transfer agreement with the approval of the person responsible for the research, as well as the willingness of the requester in order to take charge of the possible production and delivery costs. Loans may be limited due to reasons of availability, competitiveness or confidentiality.

8.7.7 Time limit for retaining data and samples

All primary and original information, as well as stored biological or chemical material resulting from any research project, shall be retained for at least ten years from the first publication of the results, except in those cases where the law allows for shorter periods or requires longer periods.

8.7.8 Falsification and fabrication

The falsification and fabrication of data are considered scientific malpractice and serious offences. Falsification is the tampering with or incomplete or inaccurate presentation of the results with the intent to deceive. Fabrication is the distortion of research results by the invention of data, results, or procedures that have not been performed.

8.8 Ownership of the results and intellectual property

The law states that the data and samples of the research are the property of the institution and not of the researchers, which is a fact they must be aware of. Intellectual property is regulated by the PPI regulations of the IISPV approved at the XXXX Board of Trustees meeting.

8.9 Personal data protection

At all times, the confidentiality of the clinical, biological and genetic data, as well as the samples that belong to the patients, must be safeguarded. The provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46 / EC (hereinafter, RGPD) and Organic Law 3/2018, of 5 December, on the Protection of Personal Data and the Guarantee of Digital Rights (hereinafter, LOPDGDD) will be followed.

8.10 Final report

At the end of each project a report must be filed that must include the following minimum information: the identity of the lead researcher and of the other people involved, the identity of the laboratory where the study was carried out, any circumstances that could have affected it, the start and end dates of the research , its results and possible modifications to the protocol.

The final report shall be sent to the Scientific Management of the Institute which will review and file it with the rest of the project documents.

9. DISCLOSURE, DISSEMINATION AND TRANSFER OF RESULTS

9.1 Obligation to disseminate and transfer of results

Without the dissemination/transfer of the results, the research process remains incomplete. The results must be communicated to the scientific community, whether they are positive or negative, and even if they are not consistent with the expected results. This stimulates scientific debate, prevents duplication and enables new hypotheses to be formulated.

The lead researcher has the duty to disclose his/her results and is the sole person who can authorise their publication.

9.2 Authorship of scientific work, publications and patents

Information related to the authorship of scientific work, publications and patents

The status of author does not depend on one's profession or hierarchical position, nor on the nature of the employment relationship established, but rather on the contribution to the research. To be considered the author of a publication or patent, it is necessary:

1. To have contributed substantially to its creative process, both in its conception and design and during the execution, as well as in the analysis and interpretation of the data derived.
2. To have contributed to the preparation of resulting communications, reports or publications.
3. To be able to present one's personal contribution and discuss the main aspects of the research.
4. The authors must accept in writing the final draft of the original manuscripts which are processed for registration or publication.
   Provision of data, findings or experimentation subjects

Acknowledgements and thanks to the IISPV are regulated by the rules of acknowledgements and thanks approved at a meeting of the Board of Trustees.

9.3 Partially responsible authors

When in a publication there is an author who cannot assume full responsibility for the content, his/her specific contribution must be identified, with the exception of cases in which this issue is already regulated by rules of publishing.

9.4 Honorary authors and unacknowledged authors (*ghost writing*)

Any person linked to the research group who, due to their hierarchical position or work relationship, as an author or ex-officio *author*, violates academic and research freedom, commits an act of injustice and can be regarded as an abuse of authority . The omission of any person who contributed to it is an act of misappropriation and an attack on the intellectual property of other authors.

9.5 Statement of authorship in reports

The publication of reports, work reports or technical documents, or any other writing addressed to third parties, should always include the relationship between the authors, the centre (or centres) involved, and the subsidies received, in the same terms as a scientific publication or a patent.

9.6 Rank order of authorship

As a general rule, the order of signing of authors involved in scientific publications must be as follows:

a) The first person named as author is the one who has made the most important effort during the research, the one that has done the experiment or the fieldwork and prepared the first draft of the article.
b) The latter is the senior person, responsible for the managing of the project, to whom the ultimate responsibility of the experimental design and the result of the search is entrusted. This is usually the person responsible for the conducting and supervision of the research programme of which the project is a part.
c) The other authors may appear in order of importance or, as the case may be, in alphabetical order. The author who is in charge of the correspondence is the one who has the main responsibility for the whole publishing process, as well as for any interactions derived from the publication.

9.7 Shared principal authorship

In scientific publications, there is the right to justify the order in which the authors sign. When in a study two or three more authors have devoted the same effort and shared the main work during the preparation of the manuscript, they must be given the same consideration as the principal authors. This will be made explicit in the publication of the original. The same criterion may be applied in the case of intermediate and senior authors.

9.8 Ethics in publications

Publications must not be redundant. They must not be fragmented in an arbitrary manner to increase their name. All of the data obtained must be supplied accurately. If any case or variable is deleted, the change must be explained.

9.9 Dissemination via the media.

Only after the communication or publication of the research results in a scientific journal, or by an equivalent system of review, may the research be publicised in non-expert media. Prior to this, one must have the formal consent of the institution (comunicacio@iispv.cat) and of the agency that funded the project, where applicable. If the project is a coordinated one, the approval of all participating persons and entities is required. Sensationalist formats that raise false expectations are to be avoided.

10. CONFLICT OF INTERESTS

10.1 Concept and origin

There is a possible conflict of interests when the lead researcher, or some member of the team has been influenced by (1) an undeclared economic compensation and/or (2) a personal interest, other than a scientific one, in the design, realisation, or communication of the results of a research [project]..

10.2 Notification

Depending on the case, any conflict of interests must be communicated to the funding agencies, the personnel that evaluate and certify the experimental validity of the project, or the publishers of the scientific journals at the time of the study's evaluation and the consequent decision-making.

11. PERSONNEL

11.2 Research personnel

The IISPV has a research career path that describes the positions: Team leader Lead researcher Post-doctoral researcher: Pre-doctoral researcher (See relevant documentation and regulations of the 'IISPV, http://www.iispv.cat/personal/documentació_rrhh-html).

12. RESEARCH INTEGRITY COMMITTEE

12.1. Research Integrity Committee (CIR, initials in Catalan)

The CIR is a body constituted freely and voluntarily by the members of the internal scientific committee, aimed at promoting knowledge and adapting the guide of good practices. In addition, the CIR arbitrates any consultations and conflicts that may arise, and the research mediator will assist when necessary.

The CIR operates independently and is at the service of the research personnel of the centres adhering to the compliance with this document of good practices, with the sole purpose of supporting the quality of research and contributing to preserving its integrity.

[2] For more details on conflicts of interest, see the current recommendations of the ICMJE, *International Committee of Medical Journal Editors,* http://www.icmje.org

Scope of action[3]:

In relation to the aforesaid functions, the CIR must guarantee at all times the diligence, independence and impartiality in its management and actions, as well as anonymity and confidentiality in the processing of personal data, and the solvency of the information generated. Objectivity must be ensured, deliberations must be supported by reasonable grounds and its resolutions must be fair and equitable. There must be an appeals mechanism. Communications with the CIR must be sent to this address: cir@iispv.cat

12.2 Research mediation person (Ombudsperson)

The research mediator (or Ombudsperson) is an independent person, duly qualified and of the utmost personal integrity.

The Ombudsperson and the CIR are obliged to defend and protect the informant and prevent any negative consequences that his or her accusation could entail. This is particularly important if the person filing the complaint belongs to the same group as the person reported.

The position of Ombudsperson will be occupied by the person who holds the chair of the Ceim of the IISPV with the approval of the Management Committee.

13. MISCONDUCT INRESEARCH

In accordance with the most widely established definition of misconduct, it is the invention, falsification and/or plagiarism of data, or other actions that deviate from the commonly accepted practices by the scientific community as regards the proposal, realisation and/or presentation of research results. Any errors or deficiencies made in good faith are not included in the interpretation of the data.

In order to prevent situations of scientific malpractice from arising, knowledge of the principles of scientific ethics should be encouraged, ensuring there is frequent supervision and monitoring by experts at all levels; avoiding excessive pressure to obtain results and promoting the exchange of information between groups. The Institution must implement the rules of good practice in research included in this document, with special emphasis on data collection systems. These

3 http://universitatsirecerca.gencat.cat/ca/01_secretaria_duniversitats_i_recerca/la_secretaria/organismes/comite-per-a-la-integritat-de-la-recerca-a-catalunya-circat/

rules not only reduce the risk of errors, as they also greatly facilitate the identifying of cases of scientific misconduct.

14. UNDERTAKING OF DISSEMINATION AND APPLICATION

The management of the IISPV will distribute the document of the Code of Good Scientific Practice to all its staff and to any new person who joins the center at the time of induction. In both cases an acknowledgement of receipt will be issued. This Code can be found on the IISPV's website, where it can be freely consulted.

REFERENCES

Documentation consulted for the revision of this code of good research practices:

- Guide to good practices in health science research of the ICS (July 2015)
- IISPV code of good scientific practices (2012 revised edition)
- IISPV code of good scientific practices (approved by the Board of Trustees, 2010)
- La biomedicina del segle xxi: nous paradigmes i noves responsabilitats dels científics (Biomedicine of the 21st century: new paradigms and new responsibilities of scientists). Author: Jordi Camí - Parc de Recerca Biomèdica de Barcelona, Universitat Pompeu Fabra i Fundació Pasqual Maragall.