VHIR CODE OF CONDUCT AND GOOD PRACTICES

(REGULATORY COMPILATION)

updated January 2023

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1.- PURPOSE AND SCOPE

This document contains the **basic and most relevant aspects** of the regulations relating to the CODE OF CONDUCT and GOOD PRACTICES of the VALL D'HEBRON UNIVERSITY HOSPITAL FOUNDATION - RESEARCH INSTITUTE (hereinafter, "**the Foundation**" or "**the VHIR**") which applies to all those who conduct research, work, collaborate or provide services to the VHIR (hereinafter, the set of persons referred to will be generically referred to as VHIR "**staff**").

Additionally, there are regulations that only affect certain areas of VHIR work or certain groups. Although applicable when appropriate, these have not been included in this document.

All the internal VHIR regulations comply with various legal aspects that from an institutional perspective we must protect and respect. Therefore, **this regulatory body (in its entirety) is incorporated into the employment, affiliation, or collaboration relationship that the Foundation establishes with all its workers, affiliates, and collaborators. All VHIR staff have the obligation to know and respect the internal regulations that apply to them.**

The regulations cited in this compilation are duly indexed and updated on the VHIR Intranet and, when applicable, are also included on the VHIR Transparency Portal.

Finally, the VHIR Legal Unit remains at your disposal to clarify any doubts you may have. You can contact this unit via e-mail: legal@vhir.org.

2.- DECALOGUE

1.- Hired or affiliated staff, as well as collaborators, must **know and comply with all VHIR regulations** (accessible on the **Institution's Intranet**). All persons related to the VHIR undertake to refrain from carrying out any of the behaviours identified as banned or prohibited in said regulations.

2.- The VHIR is a **public sector foundation**. The governing bodies of the VHIR and the main aspects that regulate the activity and operation of the Institution are defined in the **By-laws of the VHIR**, which can be found in the **Transparency** section of the Institution's website.

3.- In terms of public procurement, we are subject to the **Public Sector Contracts Act** *(Law 9/2017, of 8 November)*.

4.- In terms of **intellectual and industrial property**, it should be noted that the VHIR has its own internal regulations:

- The **research data and samples belong to the VHIR**.
  Regarding the data generated in the research process, researchers must deliver them to the VHIR in such a way that they are intelligible and useful for the result of the research carried out.
- **VHIR owns the intellectual property of the results** of any research project carried out by VHIR researchers.

5.- The **computer media we use in our workplace are owned by the VHIR** and therefore cannot be used privately. E-mail is a work tool and as such can be **reviewed by the VHIR**.

6.- It is the responsibility of each worker and collaborator to **comply**, where applicable, with the existing regulations on **compatibility**. However, everyone must comply with the regulations so as to avoid **conflicts of interest**.

7.- An **IP is a researcher who has a current and active competitive research project** (or during the previous two years), who **signs their articles as corresponding or senior author, and who directs and trains other researchers** in his/her scientific field.

8.- **The author of an article must meet the following 4 ICMJ criteria:** having made a substantial contribution to the conception or design of the work; or in the acquisition, analysis, or interpretation of work data; to have written the work or to have made a critical review of its own intellectual content; have approved the final version to be published; and accept that he/she can be held accountable for the parts of the work he/she has done.

9.- We have a **Transparency Portal** and **several mechanisms for channelling incidents** that may arise regarding compliance with VHIR regulations, such as the VHIR Ombudsperson or the Legal-Criminal Compliance Committee.

10.- **The principles of HRS4R apply to us.**

3.- REGULATIONS RELATING TO ETHICAL ASPECTS IN THE RESEARCH

CERCA CODE OF CONDUCT

Source and access route	CERCA Code of Conduct, approved by the VHIR Board of Trustees on 11/12/2018. *http://cerca.cat/wp-content/uploads/2018/11/Codi-de-conducta-CERCA_nov2018.pdf*	
Main aspects	*Scope of application*	To all the CERCA CENTRES, such as the VHIR, and to all the activities that these centres perform. Therefore, the research activity in the VHIR must respect the provisions of this code of conduct.
	Decalogue of Principles	- Honesty and transparency. - Open access to the research data. - Custody of research data, materials, and substances. - Management of industrial property in CERCA centres. - Individual commitment to good scientific practice and respect for ethical standards. - Commitment and responsibility in scientific activity and publications. - Coordination with the CERCA Institution and with the CERCA Ombudsperson. - Application of recruitment and promotion rules. Avoid any kind on conflict of interest in the activities performed within the scope of the CERCA centre. - Collaboration with the media. - Development of an action plan with the HRS4R recognition of the European Commission.
	Ombudsperson	The CERCA centres undertake to inform the CERCA Institution of the existence of a conflict of scientific integrity that is of sufficient relevance at the initial moment in which it arises and, in parallel, raise it to the CERCA Ombudsperson, under parameters of strict confidentiality and respect for the people allegedly involved. These relevant cases may be those that have to do with the revision or retraction of articles and that may lead to disciplinary measures or that involve the administration or management of the centre.
	Data custody	**Raw data, substances** (biological, chemical, or otherwise), **informed consents, surveys or research results or technological activities must be sorted and stored**, securely, to allow their retrieval or consultation during a minimum period, which is recommended to be 10 years, calculated from the date of publication of the results or from the protection of the industrial property. **Researchers must use laboratory notebooks or any other equivalent means of custody** that record the original experimental work and authorship. These notebooks or documents are the property of the CERCA centre where the work has been carried out.
	Research integrity	All the scientific and technical staff of each CERCA centre are required to undertake to their compliance with good scientific practice by signing a document when they start their professional relationship with the centre (including attached researchers). At the same time, the workers of a CERCA centre must know and comply with the current legislation applicable to their work.

ICS GUIDE TO GOOD PRACTICES IN RESEARCH

Source and access route	ICS guide to good practices in research in health sciences. 2nd edition, 2015 *http://ics.gencat.cat/web/.content/documents/recerca/GBP_recerca.pdf*	
Main aspects	*Scope of application*	In the health sciences research centres that manage ICS hospital research, as is the case of the VHIR.
	Knowledge and dissemination by research staff	The research staff of the ICS undertakes to rely on this Guide, in addition to relying on widely recognised existing laws, standards and other documents (see Appendix I), and to make the Guide known for their entire team.
	Authorship	Only those people who have made a significant contribution to the research and who agree to be so in writing must be listed as authors. In this sense, the recommendations of the ICMJE, International Committee of Medical Journal Editors, are adopted.
	Projects subsidised by the industry	**Agreements between the two parties must be in writing, and must establish intellectual property and publication rights.**
	Research on human beings	**Whenever the execution of a research project modifies the usual practice in the assistance of a patient, this person must give consent**, before starting the research, through their signature or that of the person who legally represents the patient. Research cannot begin until the relevant ethics committee has given its final approval to the protocol subject to its evaluation.
	Ownership of the results	The law states **that research data and samples belong to the institution and not to the researchers, of which they must be aware.** The intellectual property of the data that is the result of a research project is owned by the institution that hires the person, may however be subject to agreements that transfer it to third parties (for example, from the ICS to associated institutes or to the promoter).
	Research mediator	The research mediator, a figure equivalent to the Ombudsperson, is an independent person, duly qualified and of great personal integrity. It must be a person appointed by the management of each research institute at the proposal of the internal scientific committee, from among the institution's scientific staff. The research mediator must be available to all research staff in cases where there is a suspicion of a potential violation of the principles of good scientific practice. **In the case of the VHIR, the designated person is Dr Morell.**
	Research misconduct	Misconduct is deemed as the invention, falsification, plagiarism of data or other actions that entail a significant deviation from the practices that are commonly accepted by the scientific community for the proposal, performance, or presentation of research results. This does not include errors or *bona fide* differences in the interpretations or prosecution of the data. It is the task of the scientific directorate of the research centre, directly and through the research mediator, to receive and investigate allegations of scientific misconduct presented by a fully identified person or group.

AUTHORSHIP OF PUBLICATIONS

Source and access route	"Guidelines for the authorship of the publications of the Vall d'Hebrón Research Institute (VHIR)". *VHIR Intranet > Institutional info > Internal regulations > Research Management > Authorship guidelines*
Comments	The author of an article must meet the following 4 ICMJE criteria in force at the time of writing these recommendations (2015): 1.) Must have made a substantial contribution to the conception or design of the work; or to the acquisition, analysis, or interpretation of work data; and 2.) Must have written the paper or made a critical review of its own intellectual content; and 3.) Must have approved the final version for publication; and 4.) Must accept that he/she can be held accountable for the parts of the work that he/she has done, ensuring that questions related to the accuracy or completeness of any part of the work have been properly investigated and resolved. **Researchers who do not meet all 4 criteria must appear in the acknowledgements chapter**. The author responsible for the study is also in charge of identifying the authors who meet the criteria to be considered authors; ideally, this should be done at the time of planning the work. It should be noted that raising money for the study does not justify the fact of being considered an author. **Honorary or courtesy authorship (that is, one that does not meet the 4 criteria) is inconsistent with the principles of this authorship policy** and is therefore unacceptable. In the event that there is a conflict, the senior author or study leader is responsible for initiating discussions in order to reach an agreement; in the event that this agreement does not materialise, it is the Head of the Research Group who must try to reach a consensus and, if not, it will be the Institution who will be responsible for finding the most reasonable solution, **via the Research Integrity Committee (CIR).**

4.- RULES RELATING TO TRAVEL EXPENSES

Source and access route	"Guidelines for the authorship of the publications of the Vall d'Hebrón Research Institute (VHIR)". *VHIR Intranet > Institution info > Internal regulations > Tenders and Purchases*
Comments	**Any payment of per diem/travel expenses must conform to the content of the regulations.** The main novelties, applicable from 01/01/23, include: 1. Incorporation of the following platforms into the Regulations: - Air B & B - Pilot test for those cases of: journeys involving a minimum stay of 3 nights outside the place of work // journeys in which involve travelling in a group of at least 3 people and all staying in the same "Air B&B" establishment. - Booking: One can search for the cheapest trip and flights and send the link for the agencies that offer this service. 2. Justification of Travel for Actual Costs with documentary justification. Only for per diem expenses when the bases of the Project Call expressly establish this possibility. 3. Incorporation of explanation for expenses of +15,000 in travel and/or catering orders. 4. Incorporation of the possibility to carry out training and team building activities, complying with the requirements indicated in the regulations. 5. Incorporation of the option to directly book congresses with accommodation in those establishments that are designated directly by the Congress Organiser. 6. Update of the table of economic limits (per diem and accommodation): Any queries that may arise can be addressed to the VHIR Tenders and Purchases Unit: gestiodeviatges@vhir.org.

5.- RULES APPLICABLE TO DATA PROTECTION

Source and access route	"Appendix to the internship agreement and contract". *VHIR Intranet > Institutional info > Internal regulations > Data protection > Appendix to the internship agreement and contract*
Comments	**The Appendix contains the rules for the use of computer media, intellectual property, information processing and confidentiality that must be respected in our institution.** The document regulates: - Identification of the user and passwords - Use of computer systems - Confidentiality of the Information - Data protection - Use of the Internet - Access to e-mail - Intellectual and Industrial Property - Professional Secret All in relation to the professional activity of VHIR workers. In relation to **e-mail and computer equipment**, please bear in mind that: - The IT system, the corporate network and the terminals used by each user are, in general, the property of the Foundation. - No e-mail message will be considered private. Both internal e-mails, between terminals in the corporate network, and external e-mails, addressed to or originating from other private or public networks, especially the Internet, will be considered as e-mails. - That the VHIR reserves the right to review, without prior notice, the e-mail messages of users of the corporate network and the log files of the server, in order to check compliance with these rules and prevent activities that affect the VHIR for subsidiary civil liability. On the other hand, it must be considered that it **is mandatory to take the basic LOPD training programme** (which can be carried out online and is offered periodically for all members of staff).

GUIDELINES ON DATA PROCESSING IN CLINICAL RESEARCH

In order to clarify what is considered personal data and how it should be protected in the context of VHIR research activity, three guides have been prepared:

- CREATION OF PERSONAL DATABASES IN THE FRAMEWORK OF CLINICAL TRIALS
- PROCESSING OF PERSONAL DATA IN RESEARCH
- HUVH DATA ACCESS GUIDE, agreed with all the institutions that make up the VH Campus.

All three can be consulted on the Intranet, following the access route: *VHIR Intranet > Institution info > Internal regulations > Data protection.*

Each person must be familiar with their content before conducting clinical research in the VHIR. Any queries can be addressed to: legal@vhir.org and lopd@vhir.org

6.- REGULATORY COMPLIANCE AND PROCEDURES COMMITTEES

RESEARCH INTEGRITY COMMITTEE (CIR)

Source and access route	https://vhir.vallhebron.com/es/instituto/transparencia *VHIR Intranet > Institution info > Research Management > Internal regulations > CIR (Research Integrity Committee/Ombudsperson*	
Main aspects	*Scope of application*	To all VHIR workers and researchers regardless of their position and hierarchical level.
	Code of Ethics	Its mission is to **promote knowledge and the internal adoption of good practices and ethics in research, as well as to ensure compliance with the regulations that in general terms affect the VHIR** (except Legal-Criminal Compliance (Compliance) and Data Protection).
	Functions regarding integrity in research	1. Ensure compliance with the good practice guides of the ICS, the CERCA Institution and the European Commission (ALELLA). 2. Act as an arbitral institution in the face of uncertainties or conflicts that may arise in relation to the integrity of the research; at the request of the interested parties or at the direction of the VHIR Management. 3. Inform and sensitise the scientific community of the institutions on the events, needs and guidelines relating to the ethical and deontological aspects of biomedical research. 4. Promote measures aimed at improving the quality of research and training within this field. 5. Be attentive and receptive to developments and new problems related to the integrity of research, as well as proposing the drafting of internal regulations necessary for good scientific practice and identifying bad behaviours and unacceptable practices in research. 6. Learn about the conflicts that may arise between the scientific community as a result of potential non-compliance with the regulations that apply to us and submit reports, proposals and opinions related to said conflicts to the Centre's Management. For any query, please contact the following email: cir@vhir.org or the Legal Directorate of the VHIR (which acts as Technical Secretariat of the CIR): legal@vhir.org
	Ombudsperson	This figure, which is part of the CIR, ensures the scientific integrity of the VHIR and specifically corresponds to Dr Ferran Morell Brotad.

LEGAL-CRIMINAL COMPLIANCE

Source and access route	Code of Ethics, Code of Ethics Procedure, Code of Conduct, approved by the VHIR Board on 06/13/2017. *VHIR Intranet > Strategy and Policies > Policy >* Code of Ethics, Code of Ethics Procedure, Code of Conduct	
Main aspects	*Scope of application*	All the people related to the VHIR, regardless of their position, hierarchical level or type of relationship, including all members of the Board of Trustees, of the Executive Commission, of the External Scientific Committee (Scientific Advisory Board - SAB), of General Management, of the Executive Management Committee, the Deputy Directors, of the Internal Scientific Council (CCI), the Directors, Employees and collaborators, as well as to those third parties and organisations with which the entity is related.
	Code of Ethics	It is an instrument that serves to protect the identity and mission of the VHIR in each of its areas of activity. According to this Code, the mission and vision of the VHIR are identified.
	Procedure Code of Ethics	It establishes the procedure for reporting possible illegal and/or illicit activities, which may lead to criminal civil liability for the VHIR in accordance with the provisions of the Criminal Code (currently Article 31 bis). **Any person who has a concern regarding a specific action must contact the person in charge of the Ethical Channel**, informing them in a summarised and specific manner of the action in question, the person or persons involved and the documents or information that, in their case, supports the complaint, via the e-mail canaletic@vhir.org The communication of possible illegal or illicit behaviour must meet the following requirements: 1. The complaint must be made in good faith. 2. The complainant must believe it to be substantially true. 3. False accusations must not be made. 4. The complainant must not be motivated by revenge and/or seek personal gain.
	Code of Conduct	**All persons related to the VHIR undertake to refrain from performing any of the behaviours identified in the Code of Conduct**, personally or through an intermediary, and to also refrain from giving orders to other people to perform these same behaviours. Likewise, they undertake to refrain from providing means or information, helping, cooperating, or participating to any degree, not even by omission of the duty to report through the Ethical Channel, for its commission or they will be equally responsible.

ANTI-FRAUD MEASURES PLAN

The VHIR has an **Anti-Fraud Measures Plan for the management of Next Generation funds**. In this regard, on 16 June 2022 the VHIR Board of Trustees adopted the following institutional resolution:

Declaration of the fight against fraud, corruption, and conflicts of interest of the Vall d'Hebrón University Hospital Foundation - Research Institute (VHIR)

Through this Declaration, the VHIR, within its powers, wants to strengthen its Anti-Fraud Policy, in its broadest sense, in the development of its functions.

This is why it expressly expresses its highest commitment to compliance with legal, internal, and ethical standards as well as compliance with the principles of integrity, honesty, impartiality, and justice as well as all those applicable to the systems of integrity and more demanding regulatory compliance.

All of the above is established with the aim of guiding its actions, as well as that of all its members (workers, collaborators, associates, management, and governing bodies), under the principles of good practices, ethics, and good governance. Principles, all of them, which are also assumed by all the members of the different departments of the VHIR, so that all of them and also the third parties that relate to the VHIR perceive that all their activity will always be opposed to any form of fraud, corruption, and conflict of interest.

The VHIR Anti-Fraud Policy aims to establish a culture of regulatory compliance, significantly opposed to fraud, corruption, and conflicts of interest, so that means are provided to prevent and detect such situations as well as to manage and prosecute them appropriately.

We also want to make it clear that anti-fraud instruments have already been put in place in the VHIR, the most recent being the Antifraud Measures Plan (hereafter, the PMA) in the management of the European Next Generation EU fund (hereafter NGEU), notwithstanding that this may also be applied to other VHIR procedures.

This PMA contains, among others, an analysis of the risk of fraud in the management of NGEU funds; the identification of the activities in which situations of fraud may be committed (process and department); the establishment of measures to prevent, detect, correct and prosecute fraud; the adoption of control measures on the risks detected; provision of training for VHIR workers so that they become aware of the fraud risks detected and communication channels to be used when detecting suspected cases of fraud.

It is thus intended to reinforce through this Declaration, from the highest level of the VHIR, zero tolerance to fraud, corruption, and conflicts of interest, thus forming part of a fraud, corruption, and conflicts of interest management system whose purpose is to prevent and detect such situations in order to be able to correct and improve, where appropriate, these types of issues.

The VHIR Intranet provides a training session, related to the PMA, that all members of staff can view in order to have the relevant information.

The VHIR Compliance Committee is responsible for monitoring the Anti-Fraud Measures Plan.