INCLIVA COMPLAINTS CHANNEL

PROCEDURE FOR RECEIVING AND HANDLING COMPLAINTS

1. INTRODUCTION

INCLIVA's reputation for prestige and scientific excellence, which has been built up since its inception, is the result of a collective daily effort that must be safeguarded by everyone involved in the project.

INCLIVA, as a Foundation and Health Research Institute, adheres to the highest standards of transparency, honesty and accountability. One way of fulfilling this commitment is by ensuring that anyone associated with INCLIVA – whether members of its governing bodies, staff or affiliated researchers, patients, students, or third parties and organisations with which the organisation has dealings – who has concerns regarding any of the Foundation's activities and/or specific actions, can effectively raise such concerns.

Generally, employees and managers are the first to notice an irregularity within the organisation for which they work. However, they may decide not to voice their concerns, believing that doing so would constitute a breach of loyalty towards both their colleagues and the Foundation. They are also likely to fear reprisals. In such circumstances, they may feel it would be easier to ignore the conduct they consider irregular than to report what may be merely a suspicion of unlawful action.

The purpose of INCLIVA's Whistleblowing Channel is to make it clear to everyone associated with the organisation that they can and should report unlawful activities without fear of being persecuted, discriminated against or suffering any other form of reprisal.

This Channel reaffirms INCLIVA's commitment that any unlawful activity on the part of the Foundation or any person associated with the Foundation will be treated confidentially and thoroughly investigated, with appropriate measures being taken in accordance with internal and external regulations.

The procedure also entails a commitment on the part of all those associated with INCLIVA to act responsibly, with a view to upholding the Foundation's good reputation, and to act honestly in the event of a potential breach that could harm the Institute.

2. OBJECTIVE

The objective of the whistleblowing channel is to raise awareness amongst all persons associated with the Foundation so that, in the event of certainty or reasonable suspicion that unlawful conduct is taking place within the Foundation—relating to the list of acts of criminal relevance set out in this document—they may report such matters confidentially, so that they may be investigated.

Its purpose is to ensure that, should any conduct arise that may pose a criminal risk, it is handled professionally and confidentially, with appropriate measures taken to protect the interests of the Foundation and the whistleblower, and to ensure effective compliance with the law.

3. WHAT IS THE WHISTLEBLOWING CHANNEL?

People working within an organisation and its management are the first to become aware of irregularities. Choosing to 'turn a blind eye' to such conduct means ignoring the problem and making it impossible to act before irreparable damage occurs, with consequences for the organisation and those who have committed or colluded in the offence.

The Whistleblowing Channel provides a platform for reporting potential illegal and/or unlawful activities.

4. UNLAWFUL ACTIVITIES

An unlawful activity is any unlawful and/or illegal behaviour that falls within any of the categories set out in Organic Law 10/1995 of 23 November, the Criminal Code, and which entails criminal liability for the Foundation within which and for the benefit of which it has been carried out. Specifically, Article 31 bis reads as follows:

> *"1. In the cases provided for in this Code, legal persons shall be criminally liable:*
>
> > *(a) For offences committed in their name or on their behalf, and for their direct or indirect benefit, by their legal representatives or by those who, acting individually or as members of a body of the legal person, are authorised to take decisions on behalf of the legal person or hold powers of organisation and control within it.*
> >
> > *b) For offences committed in the course of the legal person's business activities, on its behalf and for its direct or indirect benefit, by persons who, being subject to the authority of the natural persons referred to in the preceding paragraph, were able to carry out the acts because those persons seriously failed to fulfil their duties of supervision, oversight and control of their activities, having regard to the specific circumstances of the case.*

2. If the offence is committed by the persons referred to in point (a) of the preceding paragraph, the legal person shall be exempt from liability if the following conditions are met:

> *1. the governing body has, prior to the commission of the offence, adopted and effectively implemented organisational and management models that include appropriate monitoring and control measures to prevent offences of the same nature or to significantly reduce the risk of their commission;*
>
> *2. supervision of the operation and compliance with the prevention model put in place has been entrusted to a body within the legal person with autonomous powers of initiative and control, or which is legally entrusted with the function of supervising the effectiveness of the legal person's internal controls;*
>
> *3. the individual perpetrators committed the offence by fraudulently circumventing the organisational and prevention models; and*
>
> *4. there has been no omission or insufficient exercise of its supervisory, monitoring and control functions by the body referred to in condition 2*

In cases where the above circumstances can only be partially substantiated, this fact shall be taken into account for the purposes of mitigating the sentence.

3. In the case of small legal persons, the supervisory functions referred to in condition 2 of paragraph 2 may be carried out directly by the administrative body. For these purposes, small legal persons are those which, under the applicable legislation, are authorised to submit an abridged profit and loss account.

4. If the offence is committed by the persons referred to in paragraph 1(b), the legal person shall be exempt from liability if, prior to the commission of the offence, it has adopted and effectively implemented an organisational and management model that is suitable for preventing offences of the nature of that committed or for significantly reducing the risk of their commission.

In this case, the mitigation provided for in the second subparagraph of paragraph 2 of this article shall also apply.

5. The organisational and management models referred to in condition 1 of paragraph 2 and in the preceding paragraph must meet the following requirements:

> *1. They shall identify the activities within the scope of which the offences to be prevented may be committed.*
>
> *2. They shall establish protocols or procedures that set out the process by which the legal person forms its will, takes decisions and implements them in relation to such offences.*

3. They shall have in place appropriate financial resource management models to prevent the commission of the offences to be prevented.

4. They shall impose an obligation to report potential risks and breaches to the body responsible for monitoring the operation and compliance with the prevention model.

5. They shall establish a disciplinary system that imposes appropriate sanctions for non-compliance with the measures set out in the model.

6. They shall carry out a periodic review of the model and amend it where necessary should significant breaches of its provisions come to light, or where changes occur in the organisation, the control structure or the activities carried out that make such amendments necessary."

Our current Criminal Code sets out a list of offences for which the Foundation may be charged alongside those who have been involved; however, only some of these are likely to be committed, as the rest—either due to the nature of the Foundation's own activities or because they are offences typically committed by organised crime networks—have not been deemed likely.

Among the types of offences most likely to be committed within INCLIVA's sphere of activity are the following:

1) Discovery and disclosure of secrets

- Seizing papers, letters, emails or any other document or personal effect with the aim of infringing on a third party's privacy or uncovering their secrets without their consent. Intercepting their telecommunications using technical devices for listening in on, transmitting, recording or reproducing sound or images, or any other communication signal.
- Unauthorised access to, use of or alteration of confidential personal or family data belonging to another person, whether stored in computer, electronic or telematic files or media, or in any other type of public or private archive or register.
- To disclose or pass on to third parties the data, facts or images referred to in the preceding paragraphs. To engage in the conduct described in this paragraph whilst being aware of its unlawful origin and without having taken part in its discovery.
- Any person who, by any means or procedure, in breach of the security measures established to prevent it, and without being duly authorised, accesses or facilitates another person's access to all or part of an information system, or remains within it against the will of the person who has the legitimate right to exclude them.

- Acquiring for one's own use, importing or providing to third parties, with the intention of facilitating the commission of any of the offences referred to above, a computer programme or a computer password, access code or similar, which allows access to the information system.

2) Scams and fraud

- Using deception for financial gain to induce someone to dispose of property, whether by means of computer systems, credit cards, traveller's cheques or the data contained therein.
- Fraudulent disposal of movable and immovable property, concealment of encumbrances or the execution of a sham contract.
- Entering into a sham contract.

3) Obstruction of enforcement and punishable acts of insolvency

- Diverting one's assets to the detriment of one's creditors.
- Carrying out any act of disposal of assets or creating obligations that delays, hinders or prevents the effectiveness of a seizure or of judicial, extrajudicial or administrative enforcement or coercive proceedings, whether already commenced or likely to be commenced.
- Submitting to the authority or official responsible for enforcement an incomplete or false statement of assets or estate in judicial or administrative enforcement proceedings, thereby delaying, hindering or preventing the satisfaction of the creditor's claim.
- This expressly includes acts carried out within insolvency proceedings that favour certain creditors or that cause or exacerbate the economic crisis or insolvency.
- Making use of assets seized by a public authority that have been placed in custody without being authorised to do so.
- Punishable acts of insolvency: Whilst in a state of current or imminent insolvency, engaging in any of the following acts:
    - Concealing, damaging or destroying assets or property that are included, or would have been included, in the insolvency estate at the time of the commencement of proceedings.
    - Carrying out acts of disposal by handing over or transferring money or other assets, or by assuming debts, which are disproportionate to the debtor's financial position or income, and which lack economic or business justification.

- Carrying out sales or the provision of services at a price below their acquisition or production cost, which, in the circumstances of the case, lack economic justification.

- Falsifying third-party claims or recognising fictitious claims.

- Engaging in speculative business ventures, where this lacks economic justification and, in the circumstances of the case and in light of the economic activity carried out, is contrary to the duty of care in the management of economic affairs.

- Failing to comply with the legal duty to keep accounts, keeping two sets of accounts, or committing irregularities in their keeping that are relevant to understanding the business's financial or asset position. The destruction or alteration of accounting records shall also be punishable where this significantly hinders or prevents an understanding of the business's financial or asset position.

- Concealing, destroying or altering the documentation which the business owner is obliged to retain before the expiry of the period to which this legal duty applies, where this significantly hinders or prevents the examination or assessment of the debtor's actual financial position.

- Preparing annual accounts or accounting records in a manner contrary to the regulations governing commercial accounting, in such a way as to hinder or render impossible the examination or assessment of the debtor's actual financial position, or failing to fulfil the duty to prepare the balance sheet or inventory within the prescribed time limit.

- Engaging in any other active or omissive conduct that constitutes a serious breach of the duty of care in the management of financial affairs and which is attributable to a reduction in the debtor's assets or through which the debtor's actual financial situation or business activity is concealed.

- Causing a state of insolvency through any of the acts referred to in the preceding paragraph.

- Favouring any of the creditors by carrying out a dispositive act or creating a liability, with the aim of paying a claim that is not yet due or providing a guarantee to which the debtor was not entitled.

4) Cyber damage

- ➢ Recording, deleting, damaging, corrupting, altering, removing or rendering inaccessible another person's data, computer programmes or electronic documents without authorisation, where the resulting consequences are serious.

- Obstructing or disrupting the operation of another person's computer system by introducing, transmitting, damaging, deleting, impairing, altering, suppressing or rendering inaccessible computer data without authorisation, where the resulting consequences are serious.

- Facilitating the commission of the above offences by means of computer programmes, passwords or codes that allow access to an information system.

5) Intellectual and industrial property, the market and consumers

- With the intention of obtaining a direct or indirect financial gain and to the detriment of a third party, reproducing, plagiarising, distributing or publicly communicating, in whole or in part, a literary, artistic or scientific work, or its adaptation, interpretation or artistic performance, fixed on any type of medium or communicated through any means, without the authorisation of the holders of the relevant intellectual property rights or their assignees.

- For industrial or commercial purposes, without the consent of the holder of a patent or utility model and with knowledge of its registration, to manufacture, import, possess, use, offer or place on the market objects protected by such rights.

- To use or offer to use a process covered by a patent, or to possess, offer, place on the market or use the product directly obtained by the patented process.

- Disclosing a trade secret by obtaining data, documents and computer media, as well as the dissemination or disclosure of a trade secret.

6) Corruption in business

- Promising, offering or granting to directors, managers, employees or associates of a commercial enterprise or company, either directly or through an intermediary, an unjustified benefit or advantage of any kind, for themselves or for third parties, in return for them unduly favouring the person in question or a third party over others in the purchase or sale of goods, the contracting of services or in commercial relations.

- Receiving, soliciting or accepting an unjustified benefit or advantage of any kind, for oneself or for a third party, in return for unduly favouring another person in the purchase or sale of goods, the procurement of services or in commercial dealings.

7) Environmental offences

- Contravening laws or other general provisions designed to protect the environment, by directly or indirectly causing or carrying out emissions, discharges, radiation, extractions or excavations, landfilling, noise, vibrations, injections or deposits into the atmosphere, the soil, the subsoil or surface, groundwater or marine waters, including the high seas, with an impact extending even to cross-border areas, as well as water abstraction which, by itself or in conjunction with other factors, causes or is likely to cause substantial damage to the quality of the air, soil or water, or to animals or plants.

- Contravening laws or other general provisions, collecting, transporting, recovering, processing, disposing of or utilising waste, or failing to adequately control or monitor such activities, in a manner that causes or is likely to cause substantial damage to air, soil or water quality, or to animals or plants; death or serious injury to persons; or is likely to seriously impair the balance of natural systems.

- Contravening laws or other general provisions by operating facilities in which a hazardous activity is carried out or in which hazardous substances or preparations are stored or used, in such a way as to cause or be likely to cause substantial damage to air, soil or water quality, to animals or plants, death or serious injury to persons, or to seriously impair the balance of natural systems.

8) Offences against public health and drug trafficking

- Manufacturing, dispatching, supplying or marketing, without the necessary authorisation, substances harmful to health or chemicals capable of causing serious harm.

- Dispatching or supplying substances harmful to health or chemicals capable of causing widespread damage, whilst holding the necessary authorisation for their trade, but without complying with the formalities laid down in the relevant laws and regulations.

- Manufacturing, importing, exporting, offering, supplying, acting as an intermediary for, marketing, offering for sale or placing on the market, or storing for these purposes medicinal products, including those for human and veterinary use, as well as medicinal products under investigation, which lack authorisation, or medical devices that do not have the conformity documents required by the general provisions, or which are spoiled, have expired or fail to meet the technical requirements relating to their composition, stability and efficacy, thereby posing a risk to human life or health.

- 1- To manufacture or produce, provided that they are intended for public consumption or for use by third parties and pose a risk to human life or health, a MEDICINAL PRODUCT, including those for human and veterinary use, as well as investigational medicinal products; or an active substance or excipient of such a medicinal product.

- 2- To manufacture or produce, provided they are intended for public consumption or for use by third parties and pose a risk to human life or health, a MEDICAL DEVICE, as well as any accessories, components or materials essential to its integrity, whilst misrepresenting its identity, including, where applicable, the packaging and labelling, the expiry date, the name or composition of any of its components, or, where applicable, their dosage; its origin, including the manufacturer, the country of manufacture, the country of origin and the holder of the marketing authorisation or conformity documents; information relating to compliance with legal requirements or obligations, licences, conformity documents or authorisations; or its history, including records and documents relating to the distribution channels used.

- To alter, during manufacture or production or at a later stage, the quantity, dosage, expiry date or genuine composition, as authorised or declared, of any of the above, in a manner that reduces its safety, efficacy or quality, thereby posing a risk to human life or health.

- Importing, exporting, advertising or promoting, offering, displaying, selling, providing, dispensing, dispatching, packaging, supplying (including acting as an intermediary), trafficking, distributing or placing on the market any of the aforementioned medicinal products, active substances, excipients, medical devices, accessories, components or materials, whilst knowing that they have been counterfeited or tampered with, thereby posing a risk to human life or health.

- Producing any false document or document containing false information relating to a medicinal product, active substance, excipient, medical device, accessory, component or material referred to above, including its packaging, labelling and instructions for use, in order to commit or facilitate the commission of such offences.

9) Bribery

- Offering or providing a gift or remuneration of any kind to a public authority or official so that they may perform an act contrary to the duties of their office or an act within the scope of their office, so that they may refrain from performing or delay the act they are required to perform, or in consideration of their office and function. This also applies if the provision is made at the request of the authority or official, including, in both cases, officials of the EU or of another Member State.

  Particular attention is drawn to cases where the intended action relates to a procurement procedure, grant or auction organised by the government or public bodies.

10) Trafficking in influence

- A public official or authority who influences another public official or authority by abusing their personal or hierarchical relationship with that person or another, in order to secure a decision that may directly or indirectly generate a financial benefit for themselves or for a third party.
- A private individual who influences a public official or authority by abusing their personal relationship with that official or authority, or with another person, in order to secure a decision that may directly or indirectly generate a financial benefit for themselves or for a third party.
- Soliciting bribes, gifts or any other form of remuneration from third parties, or accepting an offer or promise, in order to carry out the acts described in the preceding sections.

11) Labour disputes

- Mobbing/Harassment: Psychological harassment at work, also known as 'mobbing', is any conduct, practice or behaviour which, in a systematic and recurring manner over time, constitutes, within the context of the employment relationship, an affront to or attack on the dignity of the employee, seeking to subjugate them emotionally and psychologically and aiming to undermine their capacity, career progression or continued employment, thereby creating a hostile environment and negatively affecting the workplace. The concept of workplace harassment does not include temporary interpersonal conflicts confined to a specific moment, which may arise within the context of human relations and affect the organisation and conduct of work, but which are not intended to destroy the parties involved in the conflict, either personally or professionally.
- Sexual Harassment: Any unwanted behaviour of a sexual nature that may be perceived as, or cause, offence or humiliation to a person. This applies where such behaviour interferes with work, or creates an intimidating, hostile or offensive working environment. Whilst it generally involves a pattern of behaviour, it may also take the form of a single incident. A distinction must be made between 'sexual harassment' and 'harassment on grounds of sex', as the latter constitutes a form of discriminatory harassment in relation to effective equality between women and men, defined as 'any behaviour based on a person's sex or gender identity, with the purpose or effect of violating their dignity and creating an intimidating, degrading or offensive environment'.
- Discrimination: Any unfair treatment or arbitrary distinction based on a person's race, sex, religion, nationality, ethnic origin, sexual orientation, disability, age, language, social background or any other social condition. Discrimination may be

an isolated incident affecting one person or a group of people in a similar situation.

- Inappropriate behaviour and other workplace conflicts: Occasional or recurring behaviour involving the abuse of power, whether by management or company officials towards their subordinates, or mistreatment of an employee occurring between individuals who do not have a relationship of authority or hierarchy between them, or where such a relationship, if it existed, would not be relevant.

- Working conditions: Errors in the process of remunerating employees (payment of wages, overtime, bonuses, etc.) that are not linked to fraud. This also includes situations that pose a health and safety risk to the worker (unhealthy working conditions, fire hazards, etc.).

12) Accounting fraud:

- Accounting irregularities relating to internal controls over financial information or audit matters.

Furthermore, the offences listed below are considered to be excluded due to the low or zero probability of their occurrence within INCLIVA's remit:

- Illegal organ trafficking (Section 156 bis).
- Trafficking in human beings (Art. 177 bis).
- Prostitution, sexual exploitation and corruption of minors (Articles 187 to 189)
- Illegal financing of political parties (Article 304 bis).
- Offences against the rights of foreign nationals (Article 318 bis).
- Offences against land-use planning and town and country planning (s. 319).
- Offences relating to nuclear energy and ionising radiation (Article 343).
- Offences involving risks caused by explosives (Article 348).
- Offences relating to the counterfeiting of currency and means of payment (Articles 386 and 399 bis).
- Offences against fundamental rights and public freedoms (Art. 510).
- Terrorist financing (Art. 576).
- Price-fixing in public tenders and auctions (Article 262).
- Corporate offence in the form of obstructing an inspection (Article 294).

- The offence of smuggling (Article 2 of Organic Law 12/1995 of 12 December on the suppression of smuggling).
- Money laundering (Article 301)
- Offences against the Treasury and Social Security (Articles 305 to 308)

5. SCOPE OF APPLICATION

This procedure applies to all staff and activities carried out within the INCLIVA organisation.

Any person employed by the Foundation or attached to INCLIVA has a duty to report, via the mechanisms provided for this purpose through this Channel, any conduct, incident or information which they consider may constitute a criminal offence or involve the materialisation of a risk of such a nature.

Furthermore, this channel may be used by INCLIVA users to report any conduct they consider may constitute a criminal offence.

For the purposes of this document, 'User' refers to any natural or legal person who may use INCLIVA's facilities or services, any supplier or client, researcher, student, patient and any other person who has a direct or indirect relationship with the Institute.

The Supervisory Body shall ensure that all reports, enquiries or complaints received are examined independently and confidentially. It shall also guarantee the confidentiality of the identity of the person making the report and of the person or persons against whom the report is made, informing only those persons strictly necessary for the process. In accordance with the Organic Law on Data Protection, anonymous complaints may be submitted under the terms described in this document.

6. T CONTROL BODY

The Supervisory Body is the body to which any potential breach may be reported, whether it affects individuals personally or third parties, and to which enquiries or complaints may be made regarding events or situations that may constitute a breach.

Option 1: The Supervisory Body shall be the Management of INCLIVA.

Option 2: It comprises the following members:

- Head of Finance / Human Resources
- Head of the Legal Department
- Head of Scientific Affairs

The Supervisory Body may call upon advisers who provide advice or who may assist on specific occasions.

7. PROCEDURE FOR REPORTING IRREGULARITIES

1) Identification of an irregularity

Any person who becomes aware of an irregular situation or conduct, non-compliance or breach must report it immediately.

The Whistleblowing Channel is the main means through which reports are to be made, although they may also be sent to any INCLIVA Department Head or to the Management, who will forward them to the Supervisory Body.

2) Submission and receipt of reports

Any person who becomes aware of an irregularity may report it via the following channels:

- By email to canaldedenuncias@incliva.es , which will be received by the Supervisory Body
- By letter or written communication addressed to the Supervisory Body
- By informing any INCLIVA Unit Manager or the Director General using any of the methods indicated in the preceding paragraphs. In this case, it shall be the responsibility of the Unit Manager or Director to report the matter to the Supervisory Body via the channels indicated above, whilst ensuring the utmost confidentiality at all times.

In any case, the report must be as descriptive and detailed as possible, thereby enabling the Supervisory Body to identify the potentially irregular conduct and the person(s) or department(s) involved.

3) Minimum requirements for a report

A detailed description of the suspicious incident or situation, stating:

- What the potentially or currently irregular conduct or situation consists of.
- Any individuals involved.
- Approximate dates on which it occurred.
- The means by which the possible unlawful conduct took place.

- The area of activity affected.
- Potential impact on INCLIVA (financial or otherwise)
- Where possible, documents or evidence of the facts should be provided.

The complainant may submit their complaint anonymously, in which case the supervisory body is obliged to initiate the relevant proceedings.

Should the complainant choose to identify themselves, the complaint must be treated with the special confidentiality as set out above, and in all cases, the applicable legislation on the protection of personal data must be complied with.

4) Classification of reports

In order to prioritise those reports which, due to their nature, may have a greater impact, the Supervisory Body must, upon receipt, classify them as follows:

- **Priority reports:** Reports alleging facts or well-founded suspicions regarding the preparation or commission of any conduct constituting a criminal offence identified as such.
- **Other communications**

Priority reports must be forwarded to the Supervisory Body as soon as possible and, in any event, within 5 working days of their receipt. The Supervisory Body shall make initial contact with the author of the report, also as soon as possible and in any event within 10 working days of receipt, with the aim of obtaining the best possible information by clarifying the details of the complaint and gathering any relevant additional details. Should the identity of the complainant not be disclosed, the Supervisory Body may investigate the alleged facts using the means of evidence admissible in law.

For other communications, the Supervisory Body shall make initial contact with the author within 10 working days of receiving the communication.

5) Action and investigation

Once all relevant information regarding irregular conduct has been obtained from the complainant, or once the information contained in the anonymous complaint has been verified, if the Supervisory Body considers that there are reasonable grounds to believe that an act or omission constituting a risk of a criminal offence has taken place, it shall initiate an investigation, taking the following measures:

Appointment of an investigator to open the investigation file and draft the investigation report. The investigator may or may not be an employee of INCLIVA

Establishing procedures for conducting the investigation that ensure both the preservation of evidence and respect for employees' rights. These procedures may include face-to-face interviews with the complainant to gather further information, face-to-face interviews with staff or the department involved in the reported irregular conduct, or other measures.

Determine which department or area should be informed of the investigation and at what level within the organisation, depending on:

The hierarchical level and number of people potentially involved.

The need to involve other departments (for example, Accounting or IT) to obtain supporting data (financial information, access to databases, server or email data, etc.).

The need to promptly inform senior management and the Supervisory Body and/or the Governing Board or the Board of Trustees about the investigation carried out.

Once the investigation has been completed, the investigator will draw up a draft report setting out the main conclusions, which will be sent to the Supervisory Body so that it may take the necessary measures.

The Supervisory Body shall at all times ensure the confidentiality of the investigation and its contents, as well as the confidentiality of the individuals involved in the investigation.

If, upon receipt of the report, the Supervisory Body considers that the facts alleged do not constitute an infringement or a criminal offence, it shall dismiss the report, close the case and notify the complainant of the reasons for the dismissal, provided the complainant has identified themselves.

6) Conclusions

Once the investigation file has been compiled, the Supervisory Body shall issue a report of findings containing a clear account of the facts, decisions and recommendations. This report shall include:

a) The report received concerning the irregular conduct.

b) The procedures used in the investigation,

c) The documented results of the investigation,

d) Any corrective actions that may need to be implemented, as well as any disciplinary measures that may be appropriate, in accordance with the provisions of the disciplinary system (in the case of the Organisation's staff) or the terms set out in the contract (in the case of external parties),

v) Recommendations or proposals for preventive measures or improvements in the control, supervision, evaluation and updating of the internal procedures necessary to prevent a recurrence in the future.

The Supervisory Body shall forward the Report to the Management and to the Governing Board for the purpose of initiating the relevant administrative or judicial proceedings in each case. Furthermore, the Supervisory Body shall inform the complainant (should they have identified themselves) of the measures taken.

8. PROTECTION OF WHISTLEBLOWERS AND THOSE AGAINST WHOM COMPLAINTS ARE MADE

The Supervisory Body shall ensure that no form of reprisal is taken against those who have submitted enquiries, reports or complaints. If it is confirmed that such persons have been subjected to reprisals, the perpetrators shall be subject to investigation and, where appropriate, disciplinary action.

Similarly, the Supervisory Body will guarantee, in all cases, the utmost confidentiality in the investigation of complaints or other communications received, in order to protect the identity of both complainants and those against whom complaints are made, as well as their reputation within INCLIVA, informing only those persons strictly necessary to the process.

Furthermore, in compliance with data protection regulations, the right of INCLIVA's employees, collaborators or service users not to disclose their identity and for their identity not to be recorded in the relevant file is recognised.

9. RETENTION OF INFORMATION

The Supervisory Body shall maintain a record of the complaints received, investigation reports, reports of findings and any other reports issued by the Body, as well as the relevant documents included in each file.

Access to the data contained therein shall be restricted exclusively to those who, whether or not they are employed by the organisation, carry out internal control and compliance functions, or to any data processors who may be appointed for that purpose. However, access by other persons, or even disclosure to third parties, shall be permitted where necessary for the imposition of disciplinary measures or for the conduct of any relevant legal proceedings.

Without prejudice to the notification to the competent authority of facts constituting a criminal or administrative offence, access shall only be granted to staff with human resources management and control functions where disciplinary measures may be taken against an employee.

The necessary measures must be taken to protect the identity and ensure the confidentiality of the data relating to the persons affected by the information provided, particularly that of the person who brought the facts to the organisation's attention, should they have been identified.

The data of the person making the report, as well as that of employees and third parties, must be retained in the reporting system only for the time strictly necessary to decide whether to initiate an investigation into the reported facts.

In any event, three months after the data has been entered, it must be deleted from the whistleblowing system, unless the purpose of retaining it is to provide evidence of the functioning of the legal person's model for the prevention of criminal offences. Reports that have not been acted upon may only be retained in anonymised form.

Once the period referred to in the previous paragraph has elapsed, the data may continue to be processed by the body responsible for investigating the reported facts, but shall not be retained in the internal complaints information system itself.

10. FALSE OR UNFOUNDED ALLEGATIONS

The Foundation, mindful of its commitment to its good governance policy, will invest the necessary human and financial resources to implement and maintain the effectiveness of the Whistleblowing Channel, undertaking to investigate any report received.

Similarly, it will regard any false or malicious allegation made deliberately by one of its employees as a serious offence which may be sanctioned in accordance with the provisions of the rules on offences and sanctions, in line with labour and/or criminal legislation.

It should be emphasised that, first and foremost, under the Criminal Code, this could constitute the offence of making a false accusation or complaint (Article 456 of the Criminal Code) or the offence of slander (Article 205 of the Criminal Code).

Indeed, Article 456(1) of the Criminal Code, relating to the offence of false accusation or false complaint, provides that any person who, knowing the facts to be false or with reckless disregard for the truth, accuses another person of acts which, if true, would constitute a criminal offence, if such an allegation is made before a judicial or administrative official who has a duty to investigate it, shall be punished with imprisonment for a term of six months to two years and a fine equivalent to twelve to twenty-four months' earnings, if a serious offence is alleged; a fine equivalent to twelve to twenty-four months' earnings, if a less serious offence is alleged; and a fine equivalent to three to six months' earnings, if a minor offence is alleged.

Paragraph 2 of the aforementioned Article 456 goes on to state that "proceedings may not be brought against the complainant or accuser until after a final judgement or a final order of dismissal or closure of the case has been issued by the judge or court that heard the alleged offence" and adds that "the judge or court that has heard the case concerning the alleged offence shall order proceedings to be brought ex officio against the complainant or accuser whenever sufficient evidence of the falsity of the allegation emerges from the main proceedings, without prejudice to the fact that the offence may also be prosecuted following a complaint by the aggrieved party".

Furthermore, the offence of slander set out in Article 205 of the Criminal Code provides that "slander is the allegation of a criminal offence made with knowledge of its falsity or with reckless disregard for the truth" and may be punishable by imprisonment for a term of six months to two years or a fine equivalent to twelve to 24 months' earnings, if the allegations are disseminated publicly; otherwise, with a fine equivalent to six to 12 months' earnings.

Secondly, with regard to labour legislation, Article 58 of the Workers' Statute provides that "workers may be disciplined by the management of organisations for breaches of their employment obligations, in accordance with the scale of offences and sanctions laid down in the relevant legal provisions or in the applicable collective agreement."

In the case of INCLIVA, the disciplinary regime set out in current labour legislation shall apply.

11. ADVERTISEMENT

Without prejudice to employees' obligation to be aware of and act in accordance with their responsibilities in the performance of their duties, the existence of the Whistleblowing Channel will be promoted and its proper dissemination ensured.

12. ENTRY INTO FORCE

It shall enter into force on the day following its approval by the INCLIVA Governing Board.

ANNEX I

Form to be completed by the complainant

Date of complaint		
Complainant's details *(optional)*	First name and surname	
	Email	
	Contact telephone number	
Connection to INCLIVA *(optional)*	Staff on an employment contract ☐ Seconded staff ☐ Student ☐ INCLIVA service user ☐ Other:	
Detailed description of the irregularity and approximate date when it occurred		
Possible person or persons responsible for or involved in the irregularity *(indicating whether or not they are INCLIVA staff)*		

Areas of activity involved in the irregularity *(if known)*	Governing bodies ☐ Management ☐ Platforms ☐ Research Groups ☐ Clinical Trials ☐ CEIM ☐ Other:
List of documents provided *(if any)*	

☐ I have read and accept that the personal data provided in this registration form will be processed by INCLIVA, as the controller of the Whistleblowing Channel, in accordance with data protection regulations and INCLIVA's PROCEDURE FOR RECEIVING AND HANDLING COMPLAINTS.

Signed:

(not compulsory)

INCLIVA informs you that the personal data you provide on this registration form will be processed by INCLIVA, as the data controller for this website.

Purpose: Solely to handle the complaint submitted.

Legal basis: Legitimate interest

Retention periods: Once the reason for the complaint has been resolved, INCLIVA will keep your personal data on hold for ten years. After this period, we will destroy your data.

Rights: You may exercise your rights of access, rectification, restriction and erasure, as well as lodge a complaint with the Data Protection Authority (protecciondatos@incliva.es) at - dpdsectorpublico@gva.es

Further information:

You can find further detailed information on data protection in the Privacy Policy published at the following link: "https://www.incliva.es/aviso-legal-y-politica-de-privacidad/", or, if you wish, you may contact our Data Protection Officer at the INCLIVA FOUNDATION. Av. Menéndez y Pelayo 4, Acc, 46010 VALENCIA (VALENCIA) or by email atprotecciondatos@incliva.es or dpdsectorpublico@gva.es

ANNEX II

Form to be completed upon receipt of the complaint

Case No.		Date of complaint	
Complainant *(optional)*			
Recipient of the complaint			
Method of receipt of the complaint *(tick)*	Letter ☐ *(attach)*		
	Email ☐ *(attach)*		
	Website ☐		
	Other ☐ *(please specify)*		
Classification of the communication *(tick the box)*	Priority report ☐		
	Other ☐		
Description of the report			
Reported to *(tick the box)*	Supervisory body ☐		
	Director-General ☐		
	Governing Board ☐		
	Board of Trustees ☐		
	Other ☐ *(please specify)*		
Attached documents			