

SEPTEMBER 2022

# FRENCH NATIONAL CANCER INSTITUTE CODE OF ETHICS

/ In force from 1 September 2022



## TABLE OF CONTENTS

FOREWORD .....	4
Preliminary article. Definitions.....	6
Article 1. Purpose .....	8
Article 2. Scope .....	8
Article 3. Entry into force – Formalities and prior notice.....	9
<b>CHAPITRE 1. COMMON ETHICAL PRINCIPLES.....</b>	<b>9</b>
Article 4. Duties of probity and independence.....	9
Article 5. Duty of impartiality .....	9
Article 6. Duty of professionalism .....	9
Article 7. Duty of confidentiality .....	10
Article 8. Duty of discretion .....	10
<b>CHAPITRE 2. PARTIES SUBJECT TO THE DECLARATION OF INTEREST BASED ON THE FRENCH PUBLIC HEALTH CODE .....</b>	<b>11</b>
Article 9. Internal Associates.....	11
Article 10. Experts .....	12
Article 11. Representatives of public institutions in the health or research sector.....	12
Article 12. Members of bodies cited by the French Public Health Code in force appended to the present Code.....	13
<b>CHAPITRE 3. PARTIES SUBJECT TO OTHER ETHICAL PROVISIONS .....</b>	<b>14</b>
Article 13. Parties involved in proposal evaluation .....	14
Article 14. Other Members of bodies not cited by the French Public Health Code.....	15
Article 15. Individuals employed by a legal entity working with the Institute within the framework of a public contract.....	15
Article 16. Individuals employed by a legal entity working with the Institute within the framework of a partnership.....	15
<b>CHAPITRE 4. ADDITIONAL RULES APPLICABLE TO INTERNAL STAFF .....</b>	<b>15</b>
Article 17. Obligation to declare any links when expressing an opinion.....	15
Article 18. Favours and gifts .....	16
Article 19. Holding multiple posts .....	17
Article 20. Participation in work events.....	17
Article 21. Participation in bodies.....	18
Article 22. Participation in expert opinions .....	18
Article 23. Scientific publications.....	19
Article 24. Participation in the review of the proposal for grant allocation.....	20
Article 25. Participation in the launch or execution of a public contract .....	20
Article 26. Relationships with the Healthcare Industry .....	21
Article 27. Obligations on termination of an employment contract .....	21
Article 28. Failure of Internal Associates to comply with obligations .....	21

# FOREWORD

As the reference health and scientific expertise body in the field of oncology, the French National Institute (“**the Institute**”) holds essential roles in combating cancer, namely promoting scientific and medical innovation; reviewing and funding research projects; issuing reviews and guidelines for best practices; structuring and facilitating regional oncology research, care and screening organisations or analysing data with a view to targeting action better.

The quality and independence of our work, our expertise and all our productions are inseparable objectives. They are essential if we are to meet, to our utmost ability, the expectations of our fellow citizens, users, health care professionals, the research sector and health authorities as a whole.

With a strong commitment in the area of ethics, since 1 January 2018, we have adopted a code of ethics to bring together various separate documents, in order to reiterate and clarify the main ethical principles to be applied by persons involved in the fulfilment of the Institute’s roles (internal associates, experts, evaluators, national reviewers, stakeholder representatives, and body members). We have sought to produce an exhaustive, readable document, to facilitate appropriation of the many rules, which can sometimes be difficult to apply in everyday scenarios.

Ongoing changes in the Institute’s activities and, in particular, the creation of the Artificial Intelligence and Cancer Programme led to the Institute finalising, on 29 March 2021, a framework entitled “Framework for Independence and Transparency in relation to the Healthcare Industry”.

It was hence deemed necessary to incorporate a specific chapter in the present Code relating to our dealings with the Healthcare Industry in order to be able to include the provisions of this framework. At the same time, it was deemed necessary to restructure and update some provisions.

The result of several months of work involving many Institute associates, the updated code has been approved by our Ethics Officer, our Ethics Committee, the French National Commission for Ethics and Whistleblowing in matters pertaining to public health and the environment, and staff representative bodies. It was subsequently approved by our Board of Directors.

To further encourage appropriation of this new code and its effective implementation, it shall be the subject of mandatory training for all internal associates and an annual review shall be presented to the ethics committee.

Norbert IFRAH  
President

Thierry BRETON  
Director General

*In view of the French Public Health Code and particularly Articles L.1415-2 et seq., D.1415-1-1, L. 1451-1 et seq., L. 1452-3 and R 1451-1;*

*In view of the French Labour Code and particularly Article L.1321-5 et seq.;*

*In view of law 2013-316 of 16 April 2013 relating to the independence of expertise in matters pertaining to health and the environment and to the protection of whistle-blowers and particularly Article 2 thereof;*

*In view of Articles L.121-1 to L.125-3 of the French General Civil Service Code relating to requirements in respect of the prevention of conflicts of interest and rules applicable to holding multiple posts;*

*In view of Decree No. 2020-69 of 30 January 2020 relating to ethical oversight in the civil service;*

*In view of the founding agreement of INCa approved by interministerial decree dated 18 December 2019;*

*In view of the Framework for Independence and Transparency in relation to the Healthcare Industry, approved by the Board of Directors as of 29 March 2021;*

*In view of the Ethics Committee review dated 4 May 2022*

*In view of Ethics Officer review No. 2022-1 dated 10 May 2022;*

*In view of French National Commission for Ethics and Whistleblowing review CNDA/FG/2022-13 dated 25 May 2022;*

*In view of the Social and Economic Committee review dated 9 June 2022;*

*In view of the approval of the Board of Directors of 14 June 2022;*

## Preliminary article : Definitions

1. **“The Institute”**: French National Cancer Institute
2. **“Healthcare Industry” or “Health Compagny”**: According to the Framework for Independence and Transparency in force<sup>1</sup> this term includes:
  - a) under the French Public Health Code: organisations, producing, marketing or providing services associated with the products cited in Section II of Article L. 5311-1 of the French Public Health Code<sup>2</sup> with the exception of those cited in Paragraphs 14, 15, and 17;
  - b) organisations providing services, producing or marketing medical equipment hardware (sequencer, imaging, etc.) or software (prescription assistance software, etc.);
  - c) organisations in which the majority of the capital is held by companies falling under a) or b) above or, failing capital, in which the majority of the votes of its decision-making body are held by companies falling under a) or b) above (foundation of a pharmaceutical firm, etc.).
3. **“Internal Associate”**: any person employed by the Institute in particular through an employment contract, an internship agreement or a staff provision agreement<sup>3</sup>.
4. **“Member of a body”**: refers to a member of a body, committee or commission :
  - **subject** to the terms under Section I of Article L.1451-1 of the French Public Health Code<sup>4</sup> identified by the President’s decision set out in Section V of Article R.1451-1 of the French Public Health Code appended hereto, namely: the Board of Directors (CA); the General Assembly (AG); the Ethics Committee (CDE); the Scientific Board (CS); the Health Democracy Committee (CDS); the Expert Opinion Commission (CE); hereinafter referred to as **“Members of bodies cited by the French Public Health Code”**
  - **not subject** to the terms of Article L.1451-1 of the Public Health Code because it is not in their remit to make decisions, issue recommendations or reviews **on public health or sanitary safety matters**: commissions or committees established by the rules of procedure or, in the case of proposal evaluation committees, by an internal procedure: the Scientific and Ethics Committee of the Oncology Data Hub; the Strategic Advisory Board of the Oncology Data Hub; the Audit Committee; the Public Contract Committee and the Evaluation Committees (as set out in Paragraph 8 hereinafter; hereinafter referred to as **“Members of bodies not cited by the French Public Health Code”**

---

<sup>1</sup> On the date of entry into force of the present Code, this refers to the Framework approved by the Institute’s Board of Directors on 29 March 2021.

<sup>2</sup> Medicinal products, including insecticides, acaricides and antiparasitics for human use, extemporaneous, hospital and officinal preparations, narcotic, psychotropic substances or other venomous substances, essential oils and medicinal herbs, pharmaceutical starting materials; Contraceptives and contragestives; Biomaterials and medical devices; In-vitro diagnostic medical devices; Labile blood products; Organs, tissues and products of human or animal origin; Cell products for therapeutic purposes; Breastmilk collected, qualified, prepared and stored by human milk banks; Products intended for contact lens care or application; Products and devices intended for disinfecting premises and vehicles in the cases set out in Article L. 3114-1; Microorganisms and toxins cited in Article L. 5139-1; Software programs which are not medical devices and which are used by medical biology laboratories, for the management of medical biology investigations and for validation, interpretation, appropriate communication under Paragraph 3 of Article L. 6211-2 and archival of results; Devices for not strictly medical purposes used in medical biology laboratories for conducting medical biology investigations; Prescription assistance software and dispensing assistance software; Stools collected by establishments or organisations cited in Article L. 513-11-1 and intended for the manufacture of a medicinal product

<sup>3</sup> Pursuant to Article L. 1415-6 of French Public Health Code stating, “French National Cancer Institute staff include: 1) Staff governed by headings II, III and IV of the general civil service statutes or public service staff governed by specific statutes; 2) Contract staff under public law provided by parties according to the terms laid down by the founding agreement; 3) Staff governed by the Labour Code.”

<sup>4</sup> Article L.1415-1 I.-Members of commissions and boards sitting with the French Ministers for Health and Social Security, members of the Ministers’ office, as well as directors, managers and executives and members of the collective bodies, commissions, working groups and organisations cited in Articles L. 1123-1, L. 1142-5, L. 1142-22, L. 1222-1, L. 1313-1, L. 1413-1, L. 1415-2, L. 1418-1, L. 1431-1, L. 1462-1, L. 3131-19 and L. 5311-1 of the present Code, in Article L. 161-37 of the French Social Security Code, in Article L. 592-45 of the French Environmental Code and in Article L592-2 of the French Environmental Code are required, on taking up their duties, to draft a declaration of interest.

**5. "External Associate": when these persons are acting within the framework of the assignments entrusted by the Institute:**

- experts,
- stakeholder representatives,
- national reviewers,
- representatives of public institutions in the health or research sector,
- external evaluators,
- reviewers reporting to the evaluation committee,
- user representatives taking part in the evaluation of proposals,
- Individuals employed by a legal entity working with the Institute within the framework of a contract or partnership.

**6. "Associate":** when this title is used on its own, it encompasses internal and external associates.

**7. "Ethics Officer":** under Section II of Article L. 1451-4 of the French Public Health Code, the role of the Ethics Officer<sup>5</sup> is to ensure adherence to the requirements in respect of declaring any interests and preventing conflicts of interest among directors, management personnel and executives, members of collective bodies of the French National Cancer Institute and commissioned experts.

**8. "Evaluation Committee"** (hereinafter referred to as "ECs"): provide the Institute, within the framework of a call for proposals or applications, with a ranking of the proposals for which institutional or financial support from the Institute is requested.

**9. "External evaluators":** are considered as such if they are evaluating a proposal with regard to criteria set out in an evaluation form and, where applicable, in the wording of a call for proposals or applications.

**10. "Expert":** any person requested by the Institute to provide their expertise for health-related expert opinions.

**11. "Specific Website":** website <https://dpi.sante.gouv.fr/> for inputting declarations of interest.

**12. "Framework for Independence and Transparency":** Framework for Independence and Transparency in relation to the Healthcare Industry in force. On the date of entry into force of the present Code, this refers to the Framework approved by the Board of Directors on 29 March 2021.

---

<sup>5</sup> Role taken from R.1451-10 et seq. of the French Public Health Code.

## Article 1. Purpose

The purpose of the present Code is to define the ethical framework governing the French National Cancer Institute hereinafter referred to as “**the Institute**” and to lay down the rules to be applied by persons working with the Institute in carrying out their assignments.

## Article 2. Scope

The Code applies to all individuals involved with the Institute in conducting its assignments, under the following conditions.

	Chapter 1 Common ethical principles (Articles 4 to 8)	Chapter 2 Parties subject to the PDI requirement of the French Public Health Code (Articles 9 to 12)	Chapter 3 Parties subject to other ethics provisions (Articles 13 to 16)	Chapter 4 Additional rules for Internal Associates (Articles 17 to 28)
Internal Associates	Articles 4 to 8	Article 9		Articles 17 to 28
Experts		Article 10		
Members of bodies featured in appended list		Article 12		
Members of bodies not featured in list			Article 14	
Stakeholder representatives				
National reviewers				
Representative of public institutions		Article 11		
External evaluators				
Reviewers reporting to the evaluation committee				Article 13
User representatives				
Persons working within the framework of a contract or partnership				Articles 15 and 16



### **Article 3.** Entry into force – Formalities and prior notice

The Code comes into force on **1<sup>st</sup> September 2022** and, on that date, replaces the previous code.

It was presented to the Social and Economic Committee on 10 May 2022, who issued a review on 9 June 2022. It has been made available to the labour inspector along with the review and filed with the Labour Court Registry of Nanterre.

It is forwarded to the persons mentioned in Article 2 and is published on the Institute's Intranet site and website.

Furthermore, in that it consists of a document of general scope relating to ethics in the public health sector, the Institute has also submitted the present Code:

- to its Ethics Committee who issued a review dated 4 May 2022;
- to its Ethics Officer who issued a review dated 10 May 2022;
- to the French National Commission for Ethics and Whistleblowing who issued review CNDA/FG/2022-13 dated 25 May 2022;
- to its Board of Directors who approved it at the meeting on 14 June 2022.

## **CHAPITRE 1. COMMON ETHICAL PRINCIPLES**

The ethical rules under the present chapter apply to all persons defined in Article 2.

### **Article 4.** Duties of probity and independence

Complete honesty is required in carrying out assignments. No financial or other benefits may be received in exchange for influence on the work carried out at the Institute.

No Associates or Members of bodies may, when carrying out their assignments on behalf of the Institute, be in any situation liable to cast doubt on their independence in relation to undue external influences.

Concerning the declaration of any interests, the present Code:

- reiterates the applicable rules when the Associate or Member of a body is governed by the framework of the French Public Health Code;
- sets forth those to be complied with when the assignments of the Associate or Member of a body do not fall within the scope of this framework.

### **Article 5.** Duty of impartiality

Impartiality infers handling issues with neutrality, advice based on objective arguments and, where applicable, thorough methodology. Lack of impartiality may invalidate any individual contribution, discredit all of the work in which they have taken part, and even the work conducted by the Institute.

### **Article 6.** Duty of professionalism

#### 6.1 Personal completion of the assignment

All Institute Associates or Members of bodies are appointed in their personal capacity for recognised expertise. They may not delegate the assignment to a third party, unless a delegation of authority has been granted subject to the terms set forth by the Institute's rules of procedure.

In an evaluation or expert opinion, the Associate acts in their own name. Opinions expressed during or at the end of their assignment and relating to the assignment shall not be expressed in the name of the host organisation unless they have been appointed as a representative of that organisation.

## 6.2 Obligation of due diligence

All Associates or Members of bodies are required to make their best efforts to complete the assignment using the resources available to them.

As such, they must carry out the assignment using rigorous and, if applicable, scientific methodology. It is important that the manner in which the assignment was carried out is fully documented, for the purposes of proof, in the event of a dispute, that the assignment was carried out according to the state of the art of the discipline.

## **Article 7. Duty of confidentiality**

All Institute Associates or Members of bodies are bound by professional discretion. As such, unless previously authorised, they shall not disclose any facts, information or documents, of which they have been made aware in or when carrying out their assignments.

Likewise, they shall not disclose their individual work, or individual or collaborative work produced by other Institute associates, unless authorised to do so by the Institute.

The results of work published by the Institute may be presented by Associates or Members of bodies; however, a duty of discretion shall remain applicable in any case after publication.

The duty of confidentiality shall not impede whistleblowing<sup>6</sup> as set forth by the law<sup>7</sup> or the mandatory reporting, as set forth by the law,<sup>8</sup> to the Public Prosecutor in the event of any offence or crime that the Associate is privy to in carrying out their duties.

## **Article 8. Duty of discretion**

No Institute Associates or Members of bodies may speak in the name of the Institute, including on their assignments, without being authorised to do so. On the other hand, they may speak on behalf of the Institute on a subject pertaining to their assignment if the Institute requests them to do so.

The duty of discretion does not detract from freedom of opinion, but imposes some restrictions on freedom of expression.

The Associate or Member of a body shall make an explicit distinction between information validated by the Institute and their own views liable to result, which do not involve the Institute. They shall not use their association with the Institute to support or bolster their own personal view.

In any case, all Associates or Members of bodies shall ensure that their personal participation in public debates pertaining to their assignments does not include any criticism or view which could detract from the public service for which they are working.

---

<sup>6</sup> The whistleblowing procedure is available at: <https://www.e-cancer/Institut-national-du-cancer/Qui-sommes-nous/Missions>

<sup>7</sup> Law No, 2016-1691 of 9 December 2016 on transparency, combatting corruption and modernisation of economic life (referred to as "Sapin Law 2") and its Enforcement Decree No. 2017-564, amended by Law No. 2022-401 of 21 March 2022 aimed at improving protection for whistle-blowers (the enforcement decree of which is currently being drafted)

<sup>8</sup> Article L.221-11 of the French General Civil Service Code: "Civil servants adhere to the terms of Paragraph 2 of Article 40 of the Criminal Procedure Code for any crime or offence of which they are made aware in carrying out their duties."

## **CHAPITRE 2. PARTIES SUBJECT TO THE DECLARATION OF INTEREST BASED ON THE FRENCH PUBLIC HEALTH CODE**

The declaration of interest (DI) cites any links of interest of any kind, whether direct or indirect, that the Associate or Member of a body has, or has had in the five years prior to commencing their assignment, with companies, firms or bodies whose activities, technologies or products fall within the Institute's remit, or with consulting companies or bodies working in the same sector.

Pursuant to article L. 1454-2 of the French Public Health Code, knowingly omitting to complete or update a DI in order to update the data featured therein or provide misleading information detracting from the honesty of the declaration is subject to a fine of €30,000.

### **Article 9. Internal Associates**

The Internal Associates defined in the Preliminary Article complete, prior to taking up their duties, a DI drawn up in accordance with the specifications of the template document provided in Section II of Article R. 1451-2 of the French Public Health Code.

They shall update their DI whenever a change occurs in their interests. Failing any changes, they are required to check and sign their DI at least annually.

The DI is drawn up and updated online on the specific website, under the authority of the French Ministry for Health.

The links are reviewed by the Institute's Human Resources Division prior to the associate taking up their duties and whenever the DI is updated.

In the event of declared interests liable to cause a conflict, the Human Resources Division notifies the associate's management to make the information available and, where applicable, decide on the course of action required.

According to the nature, depth and persistence of the declared interests, the matter may be referred to the Ethics Officer for review. The decision whether to allow the associate to take up their duties may be referred to the Institute President's office for review.

In any case, the Ethics Officer is consulted for complex matters and may issue a review.

Following the analysis of the links and pursuant to Article L. 1451-1 and Section I and III of Article R. 1451-1 and Section III of Article R.1451-2 of the French Public Health Code, DIs of internal associates whose roles are listed in the Institute's President's decision in force appended to the code are published on the Specific Website.

Pursuant to Article R. 1451-12 of the French Public Health Code, the Ethics Officer has direct access thereto.

DIs of Internal Associates not listed in the President's office decision cited are not published.

In the conduct of their duties, internal associates who deem themselves to be subject to a conflict of interest shall contact their management, specifying the elements of the matters for which they consider that they are required not to provide their expertise. Should the management deem necessary to assign the project to another person, the withdrawn Associate may not attend any meetings, or express any opinion pertaining to the matters in question.

Moreover, Internal Associates who have been granted a delegation of signing authority and who deem themselves to be subject to a conflict of interest shall refrain from using same and notify the delegating party.

## Article 10. Experts

**10.1** Pursuant to Article L. 1452-3 and Section II of Article R. 1451-1 of the French Public Health Code and to ensure that expertise adheres to the principles of impartiality, transparency, plurality and full argument, experts invited to provide their expertise in the field of health to the Institute<sup>9</sup> previously complete a declaration of interest (DI) drawn up in accordance with the template document provided in Section II of Article R. 1451-2 of said Code.

They shall update their DI whenever a change occurs in their interests. Failing any changes, they are required to check and sign their DI at least annually.

Pursuant to Section I of Article R. 1451-3 of the French Public Health Code, the DI is drawn up and updated online on the Specific Website, under the authority of the French Ministry for Health.

Pursuant to Article R. 1451-12 of the French Public Health Code, the Ethics Officer has direct access thereto.

All experts shall ensure that the links declared in relation to the expert opinion are declared in full and, where applicable, shall ensure consistency with the relevant data available in the public [Transparence-Santé](https://transparence.sante.gouv.fr) database ([transparence.sante.gouv.fr.](https://transparence.sante.gouv.fr))

The links declared in the DI are reviewed with regard to the subject matter of the expert opinion by the Institute's teams and submitted to the Institute's Expert Opinion Commission for review. On the basis of the review issued by the commission, the Institute's President appoints the expert.

The Ethics Officer is consulted for complex matters and may issue a review.

The DI is then published on the Specific Website.

In the event of a conflict of interest with regard to the envisaged expert opinion, the Institute may, by derogation, pursuant to the health-related expert opinion charter<sup>10</sup> and if the terms stipulated thereby have been met, collect the expert's expert opinion, particularly through a hearing or written contribution.

**10.2** Experts, according to the assignments carried out on behalf of the Institute, are, pursuant to Article L.1451-2 of the French Public Health Code:

- subject to the prohibition on receiving favours and gifts cited in Article L.1453-3 of the French Public Health Code, under the terms set out in Article 18 of the present Code;
- required to make known to the public the links that they have with companies and firms producing or operating healthcare products, with consulting bodies involved with these products or with companies involved in the Institute's remit, **when speaking about said products**, under the terms set out in Article 17 of the present Code.

## Article 11. Representatives of public institutions in the health or research sector

Representatives of public institutions in the health or research sector (health board, health insurance fund, scientific and technological body) are described as such if they attend an expert meeting in a capacity as an attendee, observer or cosponsor of the expert opinion.

---

<sup>9</sup> Pursuant to article 28 of the Institute's rules of procedure, Institute expert opinions coordinated by the Institute or carried out at its request are submitted to the Expert Opinion Commission.

<sup>10</sup> Decree No. 20123-413 of 21 May 2013 approving the health-related expert opinion charter stipulated in Article L. 1452-2 of the French Public Health Code

According to the review of its Ethics Committee <sup>(11)</sup>, the Institute requires them to complete a DI, which is reviewed with regard to the expert opinion envisaged and links prior to taking up their role as a public institution representative or relationships and published on the Specific Website.

**Article 12.** Members of bodies cited by the French Public Health Code in force appended to the present Code

**12.1** Members of bodies cited by the French Public Health Code complete, at the request of the Body's Business Officer, on taking up their duties, a declaration of interest (DI) drafted in accordance with the template document provided in Section II of Article R. 1451-2 of said Code.

Pursuant to Section I of Article R. 1451-3 of the French Public Health Code, the declaration of interest (DI) is drawn up and updated online by the Members on the Specific Website, under the authority of the French Ministry for Health. Non-French-speaking Members, insofar as the sections of the DI are not translated into English on the DPI Santé.gouv website, complete their DI in an English version of the DI produced and provided by the Institute.

The DI is published on said Specific Website, except for members of the Expert Opinion Commission given their status as Internal Associates, and for non-French-speaking Members for whom the English version of the PDI is published on the Institute's website.<sup>11</sup>

Members shall update their DI whenever a change occurs in their interests. Failing any changes, they are required to check and complete their DI on the Specific Website at least annually.

All members of bodies shall ensure that the links declared in relation to the assignments thereof are declared in full and, if applicable, shall ensure consistency with the relevant data available in the public Transparence-Santé database ([transparence.sante.gouv.fr](https://transparence.sante.gouv.fr)).

Pursuant to Article R. 1451-12 of the French Public Health Code, the Ethics Officer has direct access thereto.

**12.2** Furthermore, for the duration of their mandate, on receipt of the agenda and no later than the start of each meeting, Members are requested to report any direct or indirect links, not cited in the DI, with any of the items of the agenda.

**12.3** The links declared in the DI are reviewed solely with regard to the public health items included in the meeting's agenda.<sup>12</sup>

The Ethics Officer is notified of complex cases and of their handling by the Institute by the Business Officer, with a copy being sent to the Ethics Coordinator. At the Institute's request, the Ethics Officer issues a review of the complex cases submitted.

Pursuant to Paragraph 6 of Section I of Article 1451-1 of the French Public Health Code, the persons referred to in the present Article may not, subject to the penalties set forth in Article 432-12 of the French Penal Code, take part in the work, decisions, or votes of these bodies if they have a direct or indirect interest in the project under evaluation.

**12.4** Members of bodies cited by the French Public Health Code are, according to the assignments carried out on behalf of the Institute and pursuant to Article L.1451-2 of the French Public Health Code:

---

<sup>11</sup> In this case, only the Internal Associate's involvement in the Expert Opinion Commission is published on the Specific Website under their "roles"

<sup>12</sup> N.B.: This targeted review was approved by the Ethics Officer on 4 May 2022 and the Ethics Committee on 10 May 2022, insofar as a review of the declared links with regard to the other items of the agenda is conducted according to the terms cited in the Institute's "Ethics for Bodies, Committee and Commissions" procedure

- subject to the prohibition on receiving favours and gifts cited in Article L.1453-3 of the French Public Health Code, under the terms set out in Article 18 of the present Code;
- required to make known to the public the links that they have with companies and firms producing or operating healthcare products, with consulting bodies involved with these products or with companies involved in the Institute's remit, **when speaking on said products**, under the terms set out in Article 17 of the present Code.

## CHAPITRE 3. PARTIES SUBJECT TO OTHER ETHICAL PROVISIONS

As a preliminary point: In accordance with the review of its Ethics Committee,<sup>13</sup> the Institute does not request national reviewers<sup>14</sup> and stakeholder representatives<sup>15</sup> to complete a DI.

### Article 13. Parties involved in proposal evaluation

Parties involved in proposal evaluation, namely external evaluators, evaluation committee (EC) reviewers set out in the Preliminary Article and user representatives involved in the EC must declare any direct or indirect links that they may have with the proposal submitted, the coordinator of the proposal or a member of the team for this proposal. They shall also declare any links they may have with any other person, including the Healthcare Industry, liable to result in them receiving a financial, professional or personal benefit from the project being selected or not.

The declared links are reviewed by the Institute with regard to each proposal. Should the findings of this review indicate that a declared link is liable to cause conflict, the party concerned may not take part in the evaluation of the proposal, and the proposal may be reassigned.

Furthermore, EC evaluators and reviewers undertake:

- not to receive any financial, professional or personal benefit due to the decision whether to allocate institutional support or funding to the proposal under evaluation, for themselves, their close family and friends, their colleagues, their laboratory or their organisation;
- not to come into contact with the coordinator or teams of the proposal under evaluation;
- and to guarantee the confidentiality of information and documents provided.

These undertakings or declarations are formalised in the information system developed by the Institute, entitled the "Projects Portal".

---

<sup>13</sup> Ethics Committee Review No. 2016-02 of 9 November 2016 on the management and prevention of conflicts of interest

<sup>14</sup> National reviewers of an expert opinion are described as such if they take part in a review on a national scale, comparable to a public consultation, as it is conducted with a panel of at least one hundred professionals. They do not contribute to the findings and recommendations of the expert opinion but issue, retrospectively, an opinion on the consistency, readability and acceptability thereof.

<sup>15</sup> Stakeholders (individuals or legal entities) are described as such if they represent a community, economic or professional interest in the envisaged expert opinion and their aim is to promote one or more interests (unlike an expert who expresses an argued, impartial opinion, based on scientific knowledge and experience, with no preference for a specific interest). They give their point of view but are not directly involved in expert opinion findings and recommendations.

#### **Article 14.** Other Members of bodies not cited by the French Public Health Code

On receipt of the agenda and no later than the start of each meeting, Members of bodies not cited by the French Public Health Code,<sup>16</sup> shall declare their direct or indirect links with any items featured in the agenda.<sup>17</sup>

The links are reviewed for the members present at the meeting by the body's Business Officer in relation to each item featured in the agenda.

Reported links and their review are mentioned in the meeting's minutes or report.

Should the findings of this review indicate that a declared link is liable to cause conflict, the Member should stand aside and may not take part in the work and review.

#### **Article 15.** Individuals employed by a legal entity working with the Institute within the framework of a public contract

Individuals employed by a legal entity working with the Institute within the framework of a contract, undertake to adhere to the contractual clauses arising from the public contract, and, where applicable, a specific confidentiality agreement relating to access to the Institute's sensitive data.<sup>18</sup>

#### **Article 16.** Individuals employed by a legal entity working with the Institute within the framework of a partnership

When individuals, employed by a legal entity working with the Institute within the framework of a partnership, have access to the Institute's sensitive data, particularly health data, they sign a confidentiality agreement specific to the partnership which must be carried out in concert with the Institute.

### **CHAPITRE 4. ADDITIONAL RULES APPLICABLE TO INTERNAL STAFF**

The provisions of the present chapter apply to the Institute's Internal Associates as defined in Article 2.1.

#### **Article 17.** Obligation to declare any links when expressing an opinion

Pursuant to Paragraph 2 of Article L. 1451-2 of the French Public Health Code, the Internal Associates cited in the appended list in force drawn up by the Institute's President are required to make known to the public the links that they have with companies and firms producing or operating healthcare products, with consulting bodies involved with these products or with companies involved in the Institute's remit, **when speaking about these products.**

This obligation applies when speaking in the following contexts:

- public events;

---

<sup>16</sup> This refers to commissions or committees established by the rules of procedure and not falling within the scope of Article L.1451-1 of the French Public Health Code, because it is not in their remit to make decisions, issue recommendations or reviews on public health or sanitary safety matters (Audit Committee, Public Contract Committee, Data Hub Scientific and Ethics Committee, Hub Strategic Advisory Board).

<sup>17</sup> Members of the Public Contract Committee sign a Declaration of No Conflict of Interest

<sup>18</sup> Sensitive data refers to personal health data, financial data obtained from employment or public contracts, data covered by professional or medical confidentiality, data obtained from documents not disclosed to the public

- university lectures;
- continuous training or therapeutic education initiatives;
- in the press or audio-visual media or through any written or online publication.

Moreover, Internal Associates must notify their management of any public speech in their own name, relating to public health matters.

## Article 18. Favours and gifts

Favours or gifts are understood to mean in particular:

- sums of money, bequests, and discounts;
- trips;
- personal invitations to non-work events (sports competitions, performances, etc.);
- any service or object having a market value;
- free invitations to a work event subject to an admission charge other than if the associate is speaking at said event (if the associate is speaking, refer to Article 14.2);
- perishable or shareable foodstuffs;
- low-value “promotional” items;
- work-related meals (“business meals”).

### 18.1 Favours and gifts from the Healthcare Industry

The Institute’s Internal Associates are prohibited from receiving gifts and favours in cash or in kind provided by the Healthcare Industry as set out in Paragraph 2 of the Preliminary Article of the present Code.<sup>19</sup>

The coverage of expenses inherent to participation in professional events organised by the Healthcare Industry, is governed by Article 20 of the present Code.

When an Internal Associate takes part in a committee or Board of Directors of a Healthcare Company, any food and beverage expenses are paid by the Institute on submission of the relevant invoice issued by said Healthcare Company.

### 18.2 Favours and gifts from other public or private organisations

The Institute’s internal Associates are also prohibited from receiving favours in cash or in kind provided by public or private organisations (particularly institutional partners, members of the Institute’s public interest group, contract holders).

However, an exemption is allowed in respect of :

- perishable or shareable foodstuffs;
- Low-value “promotional” items;
- Work-related meals (“business meals”)

Subject to the dual requirement :

- that they are low in value in their category;
- that the Internal Associate notifies their management by any means.

---

<sup>19</sup> This ban arises from Articles L.1451-2 and L.1453-4 of the French Public Health Code and applies for favours from firms marketing or producing products covered by statutory social security bodies. The Institute has extended this ban to the entire Healthcare Industry (as set out in Paragraph 2 of the Preliminary Article of the present Code)



Furthermore, it is specified that gifts or favours offered by a representative of a foreign country during an institutional visit are authorised, the latter being governed by an official framework.

### 18.3 Common rule

Any attempted corruption must be reported to the Internal Associate's management and to the Director of Human Resources and to the "Ethics" Coordinator.

## **Article 19.** Holding multiple posts

All Internal Associates are prohibited from concurrently holding a remunerated position within the Healthcare Industry as set out in the present Code.

For any other remunerated position that an Internal Associate seeks to hold concurrently, the latter shall request authorisation from the Human Resources Division, who shall notify the management with a view to determining whether this concurrent position is liable to cause a conflict of interest or not.

If the remunerated position is authorised, the Associate shall declare it in their DI.

Any other supplementary activity in connection with the Institute's assignments shall also be declared in the DI.

Remunerated writing or publication of articles shall also be subject to authorisation and the terms of application thereof are governed by Article 23.

## **Article 20.** Participation in work events

Within the framework of their assignments, Internal Associates may be required to take part, as a speaker or attendee, in work events (particularly congresses, symposia, seminars, conferences) organised by public or private bodies.

The present article does not apply to work events aimed at staff training, particularly due to the declaration of activity of instructors or training bodies of organisers and the coverage of the Institute of the registration costs, for which a specific framework applies.

### 20.1 Prior approval

Any participation of an Internal Associate in a work event shall be subject to prior approval from their management, formalised according to an internal procedure.

Once the approval has been granted, the Internal Associate shall register their absence for the purposes of their participation in a work event in the human resources information system.

If participating as a speaker, the associated documents (presentation, poster, publication in journals, etc.) shall be subject to prior validation by the management.

The Internal Associate shall report to their management and/or their department, in the days following their participation, the essential information and main discussions arising from the event.

If the participation is conducted within the framework and according to the terms set forth by the present article, the Associate is not required to complete their declaration of interest in this regard, as the participation is not in a personal capacity but on behalf of the Institute.

### 20.2 Coverage of expenses

When the event organiser falls under the Healthcare Industry as set out in Paragraph 2 of the Preliminary Article of the present Code, registration costs, travel and accommodation expenses shall be solely borne by the Institute.

When the event is organised by an organisation other than those falling under the Healthcare Industry, the Institute shall also cover expenses, other than in exceptional cases driven by organisational needs. In any case, these coverages by the organiser shall remain one-off or occasional occurrences and the acceptance thereof shall not detract from the independence or impartiality of the associate.

Notwithstanding the two paragraphs above, when the Associate is speaking as part of the event programme and after the Institute's prior approval, the organiser (Healthcare Industry or not) may waive or cover the payment of **registration costs**.

## **Article 21.** Participation in bodies

### 21.1 Internal bodies

All Internal Associates sitting or participating, in a member or guest capacity, in a body, is subject to the rules set out in Articles 12.2 pertaining to bodies cited by the French Public Health Code, Article 14 pertaining to bodies not cited by the French Public Health Code of the present Code, and, where applicable, the Regulations of the Expert Opinion Commission.

The Associate is not required to complete their declaration of interest in this regard, as the participation is not in a personal capacity but on behalf of the Institute.

### 21.2 Bodies, commission, committee of a third-party organisation involved in the Institute's remit

All participation of an Internal Associate in a body, commission or committee of a third-party organisation involved in the Institute's remit shall be subject to prior approval from their management.

Once the approval has been granted, the Internal Associate shall register their absence for the purposes of their participation in said body in the human resources information system.

The Internal Associate is not required to complete their declaration of interest in this regard, as the participation is not in a personal capacity but on behalf of the Institute, except in the following cases:

- any mandate carried out in a decision-making body of a third-party organisation or
- if this participation falls within the scope of Article L. 1451-1 of the French Public Health Code, and the third-party organisation requests them to do so.

## **Article 22.** Participation in expert opinions

### 22.1 Participation in internal expert opinions<sup>20</sup>

The provisions in force in respect of preventing and managing conflicts of interest in relation to expert opinions arising from the Rules of Procedure of the Expert Opinion Commission and the Framework for Independence and Transparency apply to all Internal Associates coordinating and contributing to an expert opinion.<sup>18</sup>

They are required to notify their management and the Expert Opinion Quality and Compliance Team **of any links liable to give rise to a conflict of interest<sup>21</sup> or cast doubt on their impartiality** during work. The line manager, the Quality and Compliance Team

---

<sup>20</sup> Five possible scenarios: ① the associate produces an expert opinion ② they coordinate an expert opinion produced by an expert group ③ they provide a sponsor with guidance within the framework of an expert opinion accreditation by the Institute ④ they participate in an expert capacity in an expert opinion coordinated by the Institute ⑤ they are requested to review an internal or external expert opinion within the framework of the Institute expert opinion institutional validation process.

<sup>21</sup> According to the Health-related Expert Opinion Charter published by Decree No. 2013-413 of 21 May 2013, a conflict of interest arises in a scenario wherein an expert's interests are liable, by their nature or depth, to cast doubt on their impartiality or independence in carrying out their expert opinion assignment with respect to the project to be dealt with.

and the Ethics Officer commissioned, where applicable, decides on the suitable measures for the conduct of health-related expert opinion work.

The Associate is not required to complete their declaration of interest for participation in internal expert opinions, as they are not participating in a personal capacity but on behalf of the Institute. It is included in the expert opinion report submitted to the sponsor or published on the Institute's website.

#### 22.2 Participation in external expert opinions

This consists of participation, in the Internal Associate's work hours, in expert opinions produced by national or international public institutions.

Any participation in such an expert opinion shall be subject to prior approval from the associate's management, formalised according to an internal procedure.

Once the approval has been granted, the Associate shall register their absence for the purposes of their participation in an external expert opinion in the human resources information system.

The Associate is not required to complete their declaration of interest in this regard, as the participation is not in a personal capacity but on behalf of the Institute.

However, if this participation falls with the scope of Article L. 1451-1 or L. 1452-3 of the Public Health Code, the associate should update their DI<sup>22</sup>, if the third-party organisation requests them to do so.

In accordance with the Health-related Expert Opinion Charter, any Associate, with regard to the expert opinion assignment commissioned, who believes themselves to be at a risk of a conflict of interest, or is of the view that they should withdraw due to their collaboration with the healthcare Industry within the framework of their assignments at the Institute, notifies the institution in question so that they can take the appropriate measures.

### **Article 23. Scientific publications**

It should be noted that if the publication is the subject of supplementary remuneration in addition to that paid by the Institute, the terms set forth in Article 19 apply.

#### 23.1 Publication produced by the Institute or on behalf of the Institute

Any Internal Associate producing a scientific publication on behalf of the Institute shall request approval from the Institute President's office on the appropriateness of publication.

This publication is then reported at the board of management meeting to notify its members and request for any cross-disciplinary contributions from other departments. Finally, the management validates the content prior to the definitive publication.

If the publication is produced within this framework, the Associate is not required to complete their declaration of interest in this regard, as the publication is not produced in a personal capacity but on behalf of the Institute.

#### 23.2 Publication produced by the associate in their own name

Internal staff may not be the authors, in their own name, of publications falling within the remit of the Institute, with the exception of publications produced within the scope of academic research activity and which cannot be categorised as the Institute's view.

In this exceptional case, said publications are subject to prior notification to the Associate's management.

---

<sup>22</sup> This applies to cases where the expert opinion in which the internal associate is involved is an expert opinion pertaining to the fields of health or sanitary safety submitted to an institution or the bodies referred to in Article L. 1451-1

If the scientific publication does not fall within the Institute's remit, the Associate shall notify their management thereof and complete their declaration of interest if deemed appropriate.

Publications falling within the remit of the Institute and initiated prior to taking up duties at the Institute shall mention the previously occupied position, without mentioning the Institute.

#### **Article 24.** Participation in the review of the proposal for grant allocation

All Internal Associates taking part in the selection of a proposal for grant allocation shall ensure that their impartiality cannot be called into question.

In the event of a direct or indirect connection with a proposal coordinator, a participating team or with the proposal under evaluation, the Associate undertakes to notify their management immediately.

The latter shall review the interest with regard to the relationship with the requested evaluation and withdraw the Associate from the selection procedure if the link is deemed to represent a conflict of interest.

#### **Article 25.** Participation in the launch or execution of a public contract

All Associates taking part in the launch or execution of a public contract shall ensure that their impartiality cannot be called into question.

As regards public contracts, a conflict of interest<sup>23</sup> arises when a person is unable to avoid the risk of partiality due to the existence of contradictory interests (personal interests versus the Institute's interests).

To launch a public contract process or take part in the execution thereof, the Associate signs a statement certifying the absence of any conflict of interests, whether actual or potential.<sup>24</sup>

They declare therein any fact or information, occurring previously or currently or liable to occur in a foreseeable future, which could cast doubt on their impartiality and independence.

Any change of situation shall be reported immediately to their management and to the department responsible for purchasing and contracts.

The Associate having a conflict of interest does not take part in the process (or contract execution follow-up) and is replaced. However, in the case of purchases with high financial and/or operational stakes, their management may decide to retain their participation in the process (or in execution follow-up) in view of their unique expertise, so that the establishment avails of an expert technical analysis such that the purchasing requirement is met in an appropriate manner and the risk of a defective purchase is restricted.

---

<sup>23</sup>L2141-10 of the French Public Procurement Code: "The buyer may rule out of the public contract placement process persons who, through their application, give rise to a potential conflict of interest, if it cannot be resolved by other means.

Such a scenario is deemed to arise in any scenario in which a person involved in the public contract placement process or liable to influence the outcome thereof has, directly or indirectly, a financial or economic interest or any other personal interest liable to compromise their impartiality or independence within the framework of the public contract placement process

<sup>24</sup>The conflict of interest is potential when the associate cannot avoid the risk of partiality due to the existence of contradictory interests, but the tasks, activities, assignments, responsibilities or decisions involved are not carried out or the responsibilities are not taken up.

## **Article 26.** Relationships with the Healthcare Industry

Relationships established between Internal Associates and the Healthcare Industry shall adhere to the procedures relating to the organisation of meetings and “given” requests set out in Appendix 1 of the Framework for Independence and Transparency in force.

## **Article 27.** Obligations on termination of an employment contract

At the end of their association, Internal Associates shall comply with the principle of confidentiality arising from Articles 7.

Associates shall not divulge, to anyone, any of the plans, studies, designs, proposals, projects, software devised or used in carrying out their assignments at the Institute, either on behalf of members or partners of the Institute, or on behalf of the Institute itself.

The same applies for the information and results arising from research conducted in the Institute or by one of the partners or members thereof.

All materials or media containing any type of information and all Institute property in the associate’s custody or possession shall be returned, and the associate shall not retain any materials or media, copies, or property belonging to the Institute.

Should an Internal Associate plan to leave for the private sector, they shall notify the Institute’s Human Resources Division beforehand; the HR Division will conduct an ethics check,<sup>25</sup> no later than within ten days following receipt of the request.

In the event of serious doubt, the Human Resources Division may refer the matter to the French High Authority for Transparency in Public Life (HATVP).

## **Article 28.** Failure of Internal Associates to comply with obligations

Failure of an Internal Associate to comply with an obligation featured in the present Code may be subject to sanctions arising from the staff rules of procedure.

---

---

<sup>25</sup> The activity envisaged by the Associate shall not compromise or call into question the normal running, independence or neutrality of the department, or disregard any ethical principle cited in the French General Civil Service Code and shall not place the Internal Associate in a scenario of unlawful acquisition of interests (432-13 for the French Penal Code)

APPENDIX: Decision No. 2022-27 of 9 June 2022 replacing the decision of 18 June 2017 establishing the list of Institute posts and bodies concerned by the framework provided for by the law of 29 December 2011



**Décision n° 2022-27 du 9 juin 2022 remplaçant la décision du 18 janvier 2017 fixant la liste des emplois et des instances de l'Institut national du cancer concernés par le dispositif instauré par la loi N°2011-2012 du 29 décembre 2011**

*Vu le code de la santé publique et notamment les articles L. 1415-2 et suivants et D. 1415-1-1 ;  
Vu le décret du 17 juin 2021 portant nomination du président du conseil d'administration de l'Institut national du cancer ;  
Vu l'article 10 du règlement intérieur de l'Institut national du cancer (INCa) relatif aux déclarations publiques d'intérêts ;  
Vu l'avis du comité de déontologie et d'éthique de l'Institut en date du 4 mai 2022 ;  
Vu l'avis du déontologue de l'Institut N°2022-1 en date du 10 mai 2022*

**LE PRESIDENT DE L'INSTITUT NATIONAL DU CANCER  
DECIDE**

**Article 1**

La présente décision remplace la décision du 18 janvier 2017 fixant la liste des emplois et des instances de l'INCa concernés par le dispositif instauré par la loi N°2011-2012 du 29 décembre 2011.

**Article 2**

Les organes dirigeants, les instances collégiales, commissions ou groupes, dont les membres sont soumis aux obligations de l'article L. 1451-1 du code de la santé publique, incluant la remise de la déclaration publique d'intérêts prévue dans ledit article, sont les suivants :

- Conseil d'administration ;
- Assemblée générale ;
- Comité de déontologie et d'éthique ;
- Conseil scientifique ;
- Comité de démocratie sanitaire ;
- Commission des expertises.

Les personnes invitées à apporter leur expertise à titre individuel ou dans un cadre collectif, auprès des instances ou commissions visées au présent article sont soumises aux dispositions de l'article L. 1452-3 du code de la santé publique, incluant la remise de la même déclaration publique d'intérêts.

**Article 3**

Les personnes exerçant des fonctions de direction ou d'encadrement, visées par l'article R. 1451-1 I 3°) du code de la santé publique, sont les suivantes :

- Président ;
- Directeur général ;
- Directeur ;
- Responsable de département ;
- Responsable de service ;
- Responsable de mission.

Les personnes participant à la préparation des décisions, recommandations, références et avis relatifs à des questions de santé publique ou de sécurité sanitaire, visées par l'article R. 1451-1 III 1°) du code de la santé publique, sont les personnes exerçant au sein :

- de « la direction générale »
- du « pôle santé publique et soins »
- de la « direction des recommandations et du médicament»
- du « pôle recherche et innovation », de la « direction de l'observation des sciences des données et de l'évaluation »
- du « département campagnes de communication »

et dont l'emploi est le suivant :

- Chargé de mission ;
- Chargé de veille et de documentation ;
- Chargé de projet ;
- Chef de projet ;
- Responsable de projet.

**Article 4**

La présente décision prend effet à compter de sa signature.

Elle est publiée au registre des actes administratifs de l'Institut national du cancer.

Fait le 9 juin 2022  
En un exemplaire

Le Président  
Norbert IFRAH  
« Signé »

---

**CODE OF ETHICS**



52, avenue André Morizet  
92100 Boulogne-Billancourt  
France

Tel. +33 (1) 41 10 50 00  
[diffusion@institutcancer.fr](mailto:diffusion@institutcancer.fr)



For more information  
**e-cancer.fr**

French National Cancer Institute  
52, avenue André Morizet  
92100 Boulogne-Billancourt  
France

Tél.: +33 (1) 41105000  
diffusion@institutcancer.fr