FRENCH NATIONAL CANCER INSTITUTE
CODE OF ETHICS

In force from 1 January 2018

Ethics Officer approval No. 2017-04 dated 28 June 2017
Ethics Committee approval No. 2017-01 dated 7 July 2017
French National Commission for Ethics and Whistleblowing in matters pertaining to Public Health and the Environment approval dated 8 November 2017
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As the reference health and scientific expertise body in the field of oncology, the French National Cancer 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, we have decided to define 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 (Institute staff, experts, evaluators, national reviewers, stakeholders 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.

The result of several months of work involving many Institute associates, this code has been presented to our Audit Committee and 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 the code and its effective implementation, it shall be the subject of mandatory training for all staff and an annual review shall be presented to the Ethics Committee.
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 the founding agreement of INCa approved by the interministerial decree dated 6 August 2013

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 persons involved with the Institute in conducting its assignments including:

2.1 internal staff, who are subject to chapters 1 and 2 of the present code, that is to say any person employed by the Institute in particular, through an employment contract, an internship agreement or a staff provision agreement;

2.2 external associates, who are subject to chapters 1 and 3 of the present code, that is to say, experts, stakeholders, national reviewers, representatives of public institutions in the health and research sector, external evaluators, reviewers reporting to the evaluation committee, user representatives involved in proposal evaluation;

2.3 members of its bodies, who are subject to chapters 1 and 4 of the present code, that is to say, members of the bodies, committees or commission, the list whereof is laid down by the Institute CEO's decision No. 2017-01 of 18 January 2017 appended to the code.

Article 3: Entry into force – Formalities and prior notice

The code comes into force on 1\textsuperscript{st} January 2018 and, on that date, replaces the Institute's ethics charter.

It was submitted to staff representative bodies for review on 12 December 2017 (combined staff representative body) and on 13 December 2017 (Health, Safety and Working Conditions Committee). It has been made available to the labour inspector along with the reviews and filed with the labour court registry.

It is forwarded to the persons mentioned in Article 2 and is broadcast 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 Officer who issued approval No. 2017-04 dated 28 June 2017;
- to its Ethics Committee who issued approval No. 2017-01 dated 7 July 2017;
- to its Board of Directors who approved it at the meeting on 15 December 2017.

\footnote{Pursuant to Article L. 1415-6 of the 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."}
CHAPTER 1: COMMON ETHICAL RULES APPLICABLE TO INTERNAL STAFF, EXTERNAL ASSOCIATES AND MEMBERS OF BODIES

The ethical rules under the present chapter apply to all persons defined in Article 2 (apart from external associates defined in Article 2.2 in the case of Articles 9 and 10) collectively referred to, in the present chapter, using the term "associate".

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. Any and all associates should not be in any situation liable to cast doubt on their independence. Concerning the declaration of any interests, the present code:
- reiterates the applicable rules when the associate is governed by the framework of the French Public Health Code;
- sets forth those to be complied with when the associate's assignments do not fall within the scope of this framework.

Article 5: Duty of impartiality
Impartiality infers maximum neutrality, advice based on arguments and, where applicable, thorough methodology. Lack of impartiality may invalidate any individual contribution, discredit all the work in which they have taken part and even discredit other work conducted by the Institute.

Article 6: Duty of professionalism
6.1 Personal completion of the assignment
All associates working on behalf of the Institute 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 Institute associates 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, in particular with dated and numbered successive document versions. In the event of a dispute, this will make it possible to establish that the assignment was carried out according to the state of the art of the discipline.

Article 7: Duty of confidentiality
All Institute associates 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; however, a duty of discretion shall remain applicable in any case after publication.

The duty of confidentiality shall not impede whistleblowing under the terms set forth by the law.

**Article 8: Duty of discretion**

No Institute associates 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 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 view.

All associates 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.

**Article 9: Prohibition to receive favours**

The present article is not applicable to external associates defined in Article 2.2 of the code.

The persons mentioned in Article L. 1451-1 of the French Public Health Code (namely Institute directors, members of its collaborative bodies, commissions, committees and its internal staff listed in the Institute CEO’s decision No. 2017-01 of 18 January 2017 appended to the code) and persons contributing occasionally to the work of these commissions are subject to the prohibition, set forth in paragraph 1 of Article L. 1451-2 of the French Public Health Code, to receive favours offered by companies providing services, producing or selling products covered by compulsory social security schemes.²

**Article 10: Obligation to declare any links when expressing an opinion**

The present article is not applicable to external associates defined in Article 2.2 of the code.

Pursuant to paragraph 2 of Article L. 1451-2 of the French Public Health Code, the persons or members cited in Article 9 are required to make known to the public the links that they have with companies and firms producing or operating health care products, with advisory bodies involved with these products or with companies involved in the Institute’s remit, when speaking on said products at:

- a public event;
- a university lecture;
- a continuous training or therapeutic education action;
- in the press or audio-visual media or through any written or online publication.

² Pursuant to Article 3 of order No. 2017-49 of 19 January 2017 pertaining to favours offered by parties manufacturing or selling health care products or services, the products shall be, from the date stipulated by the application decree and from 1 July 2018 at the latest, those mentioned in Section II of Article L. 5311-1 (products for health purposes intended for humans and products for cosmetic purposes) with the exception of those mentioned in Sections 14), 15) and 17).
CHAPTER 2: ADDITIONAL RULES APPLICABLE TO INTERNAL STAFF

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

Article 11: Declarations of interest (DI)

11.1 The internal staff defined in Article 2.1 complete, prior to taking up their duties, a declaration of interest (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 their DI at least annually.

The DI is drawn up and updated online on the specific website: https://dpi.sante.gouv.fr, under the authority of the French Ministry for Health.

11.2 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, if applicable, decide on the course of action required.

According to the nature, depth and persistence of the declared interests, the decision whether to allow the associate to take up their duties may be submitted to the Institute CEO's office for review.

11.3 Following the analysis of the links and pursuant to Article L. 1451-1 and Section I and III of Article R. 1451-1 of the French Public Health Code, DIs of internal staff whose roles are listed in the Institute CEO's decision No. 2017-01 of 18 January 2017 appended to the code are published on the specific site, after concealing parts not suitable for publication.

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

11.4 DIs of internal staff not listed in the CEO office decision cited in 11.3 are not published.

11.5 In the conduct of their duties, internal staff 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 practise their expertise. Should the management deem necessary to assign the project to another person, the removed associate may not attend any meetings, or express any opinion pertaining the matters in question.

Moreover, internal staff 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 12: Holding multiple posts

All internal staff are prohibited from concurrently holding a remunerated position with the companies referred to in Article 9 of 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 17.

**Article 13: Favours and gifts**

13.1 Favours or gifts are understood to mean in particular:
- a. sums of money, bequests and discounts;
- b. trips;
- c. personal invitations to non-work events (sports competitions, performances, etc.);
- d. any service or object having a market value;
- e. 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);
- f. perishable or shareable foodstuffs;
- g. low-value "promotional" items;
- h. work-related meals ("business meals").

13.2 The prohibition, set forth in Article 9 of the present code, on receiving favours from companies providing services, producing or selling products covered by compulsory social security schemes, is applicable to all internal staff.

13.3 All internal staff shall likewise not accept favours offered by public or private bodies other than those mentioned in 13.2 (particularly institutional partners, members of the Institute's public interest group, contract holders).

However, in exceptional cases, an internal associate may accept gifts or favours defined under f) perishable or shareable foodstuffs, g) low-value "promotional" items and h) work-related meals ("business meals") in Article 13.1, subject to the dual requirement:
- that they are low in value in the category of the favour in question;
- that the internal associate notifies their management by any means.

In any case, these accepted favours or gifts shall remain one-off or occasional occurrences and the acceptance thereof shall not detract from the independence or impartiality of the associate, or from the appearance of independence and impartiality.

Any attempted corruption must be reported to the associate's management.

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.

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3 Pursuant to Article 3 of order No. 2017-49 of 19 January 2017 pertaining to favours offered by parties manufacturing or selling health care products or services, the products shall be, from the date stipulated by the application decree and from 1 July 2018 at the latest, those mentioned in Section II of Article L. 5311-1 (products for health purposes intended for humans and products for cosmetic purposes) with the exception of those mentioned in Sections 14), 15) and 17).
Article 14: Participation in work events

Within the scope of their assignments, internal staff may be required to take part in work events (particularly congresses, symposia, seminars, conferences) organised by public or private bodies, as a speaker or as an audience member.

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.

14.1 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.

14.2 Coverage of expenses by the organiser

Coverage by the organiser of registration costs, travel and accommodation expenses is not permitted for organisers whose activity is referred to within the framework of Article L. 1451-2 of the French Public Health Code and described in Article 9 of the present code.

For other organisers, this coverage is also not permitted, with the Institute being under obligation to pay for all of said expenses, except under exceptional circumstances for organisational reasons. In any case, these coverages shall remain one-off or occasional occurrences and the acceptance thereof shall not detract from the independence or impartiality of the associate.

Notwithstanding the above, if the associate is speaking at the event, the registration costs may be covered by the organiser.

Article 15: Participation in bodies

15.1 Internal bodies

All internal staff participating, in a capacity as a member or as a guest, in a body, commission or committee listed by the Institute CEO's decision No. 2017-01 of 18 January 2017 appended to the code is deemed to be a participant, subject to the same provisions in force in respect of prevention and management of conflicts of interest as for external members or guests.

The associate's declaration of interest is reviewed within the scope of the dedicated information system by the business officer of the body, committee or commission, prior to each meeting being held and with regard to the agenda.
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.

15.2 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 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 within the scope of Article L. 1451-1 of the French Public Health Code, the associate should update their DI.4

Article 16: Participation in expert opinions

16.1 Participation in internal expert opinions
Any internal staff taking part in an expert opinion5 is deemed to be an expert, subject to the provisions in force in respect of the prevention and management of conflicts of interest in relation to expert opinions. It is the responsibility of the internal associate's management to review the latter's interests prior to assigning expert opinion duties to the associate and to exclude the associate if the link is deemed to represent a conflict of interest. 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. The associate's participation in the expert opinion is published in the expert report.

16.2 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 within the scope of Article L. 1451-1 or L. 1452-3 of the French Public Health Code, the associate should update their DI.6

Article 17: 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 12 apply.

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4 This applies to cases where the body, commission or committee in which the internal associate is participating has been identified by a decision of the third-party organisation as a body subject to the declaration of interest obligation set forth by Article L. 1451-1.
5 Four scenarios: ☐ the associate produces an expert opinion ☐ he/she coordinates an expert opinion produced by an expert group ☐ he/she provides guidance to a sponsor within the framework of expert opinion accreditation by the Institute ☐ he/she participates in an expert capacity in an expert opinion coordinated by the Institute.
6 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
17.1 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 CEO'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.

17.2 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.

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 18: Participation in the review of the proposal for grant allocation

All internal staff 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 link with a proposal coordinator, a participating team or with the proposal under evaluation, the associate undertakes to notify it immediately to their management.

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 19: 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.

A conflict of interest\(^7\) 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\(^8\).

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

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\(^7\) Article 48 of Order No. 2015-899 of 23 July 2015: “A conflict of interest 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.”

\(^8\) 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.
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.

**Article 20: Obligations once the association has ended**

At the end of their association, internal staff shall comply with the principles of confidentiality and discretion arising from Articles 7 and 8.

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.

**Article 21: Failure of internal staff 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.

Furthermore, it should be noted that, pursuant to Article L. 1454-2 of the French Public Health Code, knowingly omitting to complete or update one's 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, particularly for the internal staff referred to in Article 11.1.

**CHAPTER 3: ADDITIONAL RULES APPLICABLE TO EXTERNAL ASSOCIATES**

The provisions of the present chapter apply solely to the Institute's external associates as defined in Article 2.2.

**Article 22: Experts**

In order to ensure that expertise complies with the principles of impartiality, transparency, plurality and full argument set forth by Article L.1452-1 of the French Public Health Code, the provisions of the present article apply to experts.

22.1 Pursuant to Article L. 1452-3 and Section II of Article R. 1451-1 of the French Public Health Code, experts invited to provide their expertise in the field of health to the Institute's expert opinion
commission 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 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: https://dpi.sante.gouv.fr, 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.

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

22.3 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 CEO appoints the expert.

The DI is then published on the specific site, after concealing parts not suitable for publication.

In the event of a conflict of interest with regard to the envisaged expert opinion, the Institute may, pursuant to the health-related expert opinion charter and if the terms stipulated thereby are fulfilled, collect the expert's expert opinion, particularly through a hearing or written contribution.

22.4 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 23: Stakeholders

Stakeholders (physical persons 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.

Consequently, and according to the review issued by its Ethics Committee, the Institute does not require them to complete a DI.

Article 24: National reviewers

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.

9 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.


11 Ethics Committee review No. 2016-02 of 9 November 2016 approved by the Board of Directors on 16 December 2016
National reviewers do not contribute to the findings and recommendations of the expert opinion but issue, retrospectively, an opinion on the consistency, readability and acceptability thereof. Consequently, and according to the review of its Ethics Committee, the Institute does not require them to complete a DI.

**Article 25: 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. According to the review of its Ethics Committee, the Institute does not require them to complete a DI.

**Article 26: External evaluators**

External evaluators of proposals for which institutional or financial support from the Institute is requested are considered as such if they are evaluating a proposal with regard to criteria set out in an evaluation form and, if applicable, in the wording of a call for proposals or applications.

26.1 According to the review issued by its Ethics Committee, the Institute requires them to complete a declaration certifying that they have no direct or indirect conflicts of interest with the proposal.

26.2 Furthermore, they 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.

**Article 27: Reviewers reporting to an evaluation committee**

Reviewers reporting to an evaluation committee are considered as such, in particular, if they take part in an evaluation committee intended to 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.

27.1 According to the review issued by the Institute's Ethics Committee, reviewers shall declare any direct or indirect links with each proposal submitted to the evaluation committee, with the coordinator of a proposal or a member of the team of a proposal. 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 reviewer may not take part in the evaluation of the proposal.

27.2 Furthermore, reviewers are required to commit to the undertakings mentioned in Article 26.2.

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12 Ethics Committee review No. 2016-02 of 9 November 2016 approved by the Board of Directors on 16 December 2016
Article 28: User representatives taking part in the evaluation of proposals
User representatives taking part in the evaluation of proposals within the framework of an evaluation committee intended to rank proposals for which institutional or financial support from the Institute is requested complete a declaration certifying the absence of direct or indirect conflicts of interest with the proposals studied by the committee.

CHAPTER 4: ADDITIONAL RULES APPLICABLE TO MEMBERS OF BODIES

The provisions of the present chapter 4 apply solely to members of the Institute’s bodies as defined in Article 2.3.

Article 29: Declarations of interest (DI)

29.1 Pursuant to Section I of Article L. 1451-1 and Section I of Article R. 1451-1 of the French Public Health Code, members of the Board of Directors and of the general assembly, as well as members of the collective bodies, committees or commissions listed in the Institute CEO’s decision No. 2017-01 of 18 January 2017 appended to this code complete, on taking up their duties, 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 their DI at least annually.

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 on the specific website: https://dpi.sante.gouv.fr, 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.

29.2 All members of a body 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).

29.3 The declared links are reviewed by the Institute with regard to the remit of the body, and prior to each meeting with regard to the items on the agenda.

Pursuant to paragraph 6 of Section I of Article 1451-1 of the French Public Health Code, the persons referred to by paragraph 29.1 may not, subject to the penalties set forth in Article 432-12 of the French Criminal 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.

29.4 The DI, after concealing parts not suitable for publication, is published on the specific site.

29.5 Pursuant to Article L. 1454-2 of the French Public Health Code, knowingly omitting to complete or update one’s 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.
APPENDIX: French National Cancer Institute CEO's decision No. 2017-01 of 18 January 2018 published in the official journal of the French ministry of social affairs and health

MINISTÈRE DES AFFAIRES SOCIALES ET DE LA SANTE
MINISTÈRE DES FAMILLES, DE L'ENFANCE ET DES DROITS DES FEMMES

ADMINISTRATION

AUTORITES ADMINISTRATIVES INDEPENDANTES, ETABLISSEMENTS ET ORGANISMES

INCa
Institut national du cancer

Décision n° 2017-01 du 18 janvier 2017 remplacant la décision du 19 octobre 2012 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

NOR : AF201703035

Le président de l'Institut national du cancer,
Vu le code de la santé publique, et notamment ses articles L. 1415-2, L. 1451-1 et R. 1451-1 ;
Vu l'article 10 du règlement intérieur de l'Institut national du cancer (INCa) relatif aux déclarations publiques d'intérêts ;
Vu l'avant du comité de déontologie et d'éthique de l'INCa n°2016-02 en date du 9 novembre 2016, approuvé par le conseil d'administration de l'INCa le 16 décembre 2016 ;
Vu l'avant rondu par le déontologue de l'INCa le 18 janvier 2017,

Décide :

Article 1er

La présente décision remplace la décision du 15 octobre 2012 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 organismes 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 des usagers et des professionnels (COMUP) ;
- commission d'audit ;
- 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 ;
- adjoint au 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 (I), 1°)
du code de la santé publique, sont les suivantes : les personnes exerçant au sein du pôle santé publique et soins, de la direction des recommandations et du médicament, du pôle recherche et innovation, 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.

Art. 4

La présente décision prend effet à compter de sa signature.
Elle est publiée sur le site internet de l’INCa et au Bulletin officiel santé, protection sociale, solidarité.

Fait le 18 janvier 2017.

Le président,

N. IFRAH