

CALL FOR PROPOSALS 2023

Call for research proposals – Psychoactive substances and behaviours with addictive potential

Open to the research continuum

Psychoactive substances – behaviours with addictive potential (PAS-BAP)

The French Institute for Public Health Research (IReSP) and the French National Cancer Institute (INCa) are implementing the research component of the Fund to Combat Addictions.

Deadline for submission: 6th March 2023 – 4 p.m.

Online submission:

Categories 1, 3 and 4

<https://eva3-accueil.inserm.fr/sites/eva/appels-a-projets/Pages/AAP-SPA.aspx>

Category 2

<https://projets.e-cancer.fr/>

CONTENTS

- 1. Background and objectives of the call for proposals 4**
- 1.1 Background..... 4
- 1.2 Objectives 5
- 2. Scope of the call for proposals..... 5**
- 3. Terms and conditions of participation 9**
- 3.1 Project types..... 9
 - 3.1.1 Full research projects..... 9
 - 3.1.2 Pilot research projects 9
 - 3.1.3 'Emerging' research projects..... 9
- 3.2 Structures receiving the funding 9
- 3.3 Project coordination..... 10
- 3.4 Eligible teams..... 10
- 3.5 Coordinator and team independence 10
- 4. Project selection and evaluation..... 11**
- 4.1 Selection process 11
- 4.2 Declaration of interests of evaluation committee members 11
- 4.3 Main stages of the evaluation 11
- 4.4 Admissibility criteria for proposals..... 11
- 4.5 Eligibility criteria for proposals..... 12
- 4.6 Evaluation criteria for proposals 12
- 5. Administrative management and terms and conditions for the funding of the selected projects
13**
- 6. Schedule 13**
- 7. Procedures for submission 13**
- 7.1 Categories 1, 3 and 4 13
- 7.2 Category 2..... 14
- 8. Publication of results..... 15**
- 9. Contacts..... 15**
- Appendix 16**
- 1. Terms and conditions for management of the call for proposals..... 16**
- 1.1 The partners: IReSP and INCa 16
- 1.2 Limitations of liability 16
- 2. General provisions and funding..... 16**
- 2.1 Terms and conditions of funding by the partners 16
- 2.2 General provisions..... 17
- 2.3 Funding allocation instrument 18
- 2.4 Funding 18
- 2.5 Eligible expenses..... 18
- 2.6 Payment and use of the funding 19
- 2.7 Financial management 19

3	Other undertakings of the coordinator and managing body.....	19
4	Scientific and financial reports	20
5	Intellectual property and contractual organisation	20
6	Publication and communication	20

1. Background and objectives of the call for proposals

1.1 Background

Psychoactive substance use and the addictive behaviours that may result from it constitute a health risk starting from the very first times that such substances are consumed.

Among them, tobacco and alcohol are two of the leading causes of avoidable mortality in France, with 75,000 deaths per year for tobacco^{1,2} and 41,000 for alcohol³ in 2015, caused by cancer, cardiovascular, digestive and nervous system diseases, as well as by injuries – particularly as a result of road accidents. It can be noted, for example, that among the 346,000 new cases of cancer diagnosed the same year in adults in France, 68,000 were attributed to smoking (20%)¹ and 28,000 to the consumption of alcohol (8%)².

In addition to the consequences in terms of morbidity and mortality, emphasis must be given to the considerable health and social impacts of using these legal drugs, the annual cost to society of which is estimated at 120 billion euros – for each of them – by the French Monitoring Centre for Drugs and Addictive Tendencies (OFDT).

These legal substances also include psychotropic medications, the use of which in France is considerable⁴.

In terms of illegal products, those most consumed each year include cannabis (11% of adults), cocaine (1.6% of adults) and to a lesser extent hallucinogenic mushrooms, ecstasy and heroin. According to the OFDT, the cost to society of illegal products is estimated at 9 billion euros per year.

These various addictive behaviours cause major social harms (implication in violent behaviours, road accidents, etc.) and deepen social inequalities, given that the vulnerable populations are particularly affected.

The practices of psychoactive substance users are evolving and are marked by polysubstance use as well as multiple diverse experimentations with practices and products that pose a risk to health. As such, it is necessary to design and implement strategies to address these practices.

Non-substance-related addictions, known as behavioural addictions, such as problem gambling or problem use of video games or screens, also present major public health challenges and have recently been recognised as being pathologies⁵. The most common are those related to gambling among adults⁶ and video games among young people. However, these addictions remain poorly quantified and with questions unanswered, particularly regarding the impact of screens on the cognitive and social development of young people and the general population⁷, and regarding the addictive potential of other behaviours (eating disorders, sex addictions, compulsive shopping, etc.) whose qualification, prevalence, associated comorbidities and therapeutic avenues have yet to be fully explored.

Research must therefore make it possible to participate in the establishment of suitable strategies, guide public health policies and document the various pathological (including carcinogenic) effects related to psychoactive substance use and addictive behaviours.

The French Interministerial Task Force for Combating Drugs and Addictions (MILDECA) drew up the 2018-2022 National Action Plan on Addictions in order to provide additional momentum in the fight against addictions, particularly by stepping up research on addictions (component 4 'Research and observation in the service of action').

¹ Bonaldi C, Boussac M, Nguyen-Thanh V. Estimation du nombre de décès attribuables au tabagisme, en France de 2000 à 2015. *Bull Epidémiol Hebd.* 2019;(15):278-84. http://beh.santepubliquefrance.fr/beh/2019/15/2019_14_2.html

² OFDT. Tabagisme et arrêt du tabac en 2021. OFDT. April 2022. 20p.

³ Bonaldi C, Hill C. La mortalité attribuable à l'alcool en France en 2015. *Bull Epidémiol Hebd.* 2019;(5-6):97-108. http://invs.santepubliquefrance.fr/beh/2019/5-6/2019_5-6_2.html

⁴ OFDT.fr: <https://en.ofdt.fr/products-and-addictions/psychotropic-medicines/> (accessed in August 2019)

⁵ Inclusion of video game and gambling addictions in the DSM-5 in 2013; inclusion of video game addictions in the 11th revision of the WHO International Classification of Diseases (ICD-11) in 2019

⁶ Prevalence of problem gambling: 1% of players aged 15 to 75 in the past year (based on the Canadian Problem Gambling Index (Ferris et al., 2001))

⁷ OFDT. Drogues et addictions, données essentielles 2019. OFDT, (2019), 200 p.

In addition, the 2021-2030 Ten-Year Cancer-Control Strategy has reaffirmed the objective of developing research on tobacco and alcohol (action I.1.3 'Enhance the tobacco and alcohol call for proposals with the strategy's priority themes'), particularly regarding the mechanisms of addiction and the trajectories of the individuals affected, the effects of the new products and new modes of consumption, as well as the interactions between risk factors and their potentiation.

This is the background against which INCa and IReSP are publishing a new call for research proposals on psychoactive substances and behaviours with addictive potential, financed by the Fund to Combat Addictions and continuing the initiative established in previous calls⁸. This latest call for proposals includes, for the first time, behavioural addictions and forms part of the establishment of an ambitious, dynamic, multiannual research policy, mobilising a broad spectrum of disciplines, to take into account factors of vulnerability, high-risk usage and its associated disorders, including the question of addiction.

1.2 Objectives

This call for proposals aims to support research projects in the field of psychoactive substance use and behaviours with addictive potential, whether or not they are classified as use disorders.

Its objective is to support research and the production of knowledge on, as a priority, **tobacco, alcohol and cannabis**, identified as known risk factors for cancer, but also **other psychoactive substances and polysubstance use**. Concerning research on non-substance-related uses and addictions, priority is given to **gambling and video games**, which are the subject of scientific consensus, but also other behaviours that remain poorly documented.

This call for proposals aims, in particular, to promote research that contributes to:

- the documentation of all pathological (including carcinogenic) and social effects of the entire spectrum of psychoactive substance use and behaviours with addictive potential, whether or not they are classified as use disorders.
- the implementation of appropriate strategies.
- the direction of public health policies.

This call for proposals aims to span the entire research continuum from fundamental sciences to interventional research, covering the human and social sciences, economics, epidemiology, addiction studies, psychiatry, psychology and the disciplines of public health. This call for proposals is also open to genetic studies, pharmacoepidemiology, clinical research on acute and chronic health effects, and the neurosciences.

Consideration of the multiple factors of health behaviour (biological, psychological, societal, environmental, economic, sociological, cultural, etc.), the trajectories of individuals and social groups, and the deciphering of industry strategies is encouraged.

The involvement of the human and social sciences in the study of public health policies, prevention and primary management strategies in the field of addiction is particularly desirable.

Multidisciplinary approaches are strongly encouraged.

2 Scope of the call for proposals

This call for proposals is open to all research themes and disciplines relating to use and/or addictions, with and/or without substances.

The list below as well as the fields discussed in the 4 categories are not an exhaustive list.

⁸ Calls for proposals Tobacco 2018 and 2019 (INCa/IReSP); Call for applications for doctoral grants Tobacco 2019 (INCa/IReSP); Call for proposals Addictions 2019 (IReSP/AVIESAN); Calls for applications for doctoral grants Psychoactive substances (PAS) 2020, 2021 and 2022 (INCa/IReSP); and Call for proposals PAS 2021 and 2022 (INCa/IReSP).

In relation to the aforementioned objectives, special attention will be paid to projects that concern the following topics, which span the four categories of the call for proposals:

- understanding and reducing social inequalities.
- gendered approach.
- vulnerable populations (young people in school or who have dropped out; people in trouble with the law; people in situations of disability and/or social marginalisation; people who are unemployed; people in situations of major economic insecurity; migrants, etc.).
- particularities of the French overseas territories.
- use of digital technologies in the strategies and interventions of prevention, risk reduction and treatment support (methods, relevance, effectiveness and efficiency).
- polysubstance use and/or multiple diseases.

In addition, regardless of the themes addressed, the utilisation of existing databases, epidemiological and cohort data, data from research infrastructures, particularly open data, is encouraged⁹, as well as the participation of other players in the research process (participatory and community research).

Finally, projects that incorporate workstreams centred around the implementation sciences are encouraged.¹⁰

The expected projects must come under one of the 4 categories that make up this call for proposals.

Category 1: Psychoactive substances and the general population

The objective of Category 1 is to elicit general-population projects among people with no comorbidities or no health consequences detected from the use of (legal or illegal) psychoactive substances, and excluding the social and economic consequences of psychoactive substance use (Category 3).

It supports projects related to:

- the use and trajectories of psychoactive substance consumption and poly-consumption¹¹, high-risk behaviours (occasional consumption of large quantities of alcohol, use in festive environments, vaping, etc.).
- the mechanisms of addictions⁹ (fundamental mechanisms, mechanisms of onset of psychoactive substance use and mechanisms of stopping – including pharmacological avenues for recovery from addiction or for the prevention of relapse).
- the effects of new products and new modes of consumption (particularly vaping)⁹.
- the risk profiles (individual risk factors and vulnerabilities)⁹ and protective factors.
- the strategies and interventions to prevent and delay the onset of psychoactive substance use.
- the strategies and interventions for the identification, care, support and withdrawal of people who are addicted to one or more psychoactive substances, including within the field of risk and harms reduction, unless the population studied consists exclusively of patients with cancer (Category 2) or diseases other than cancer resulting from psychoactive substance use (Category 3).

⁹ These databases and research infrastructures enable the scientific community to have access to information and data for use in secondary analyses (e.g. SNIIRAM, PMSI, SNDS, CépiDC, PROGEDO, Vican 2, Vican 5, Constances, Nutrinet, Epipage, E3N/E4N, etc.).

¹⁰ This means projects focused on how to integrate and adapt research findings in policies and practices.

¹¹ Priority areas for the 2021-2030 Ten-Year Cancer-Control Strategy

- the impact on a population level of public interventions in terms of regulating the psychoactive substance offering, including through modification of the legislative framework.
- the links between psychoactive substance use, addictions and COVID-19 epidemics: links between certain uses and COVID-19, modifications of psychoactive substance use during periods of lockdown, changes in the treatment conditions (proactiveness of medical staff, remote monitoring...), etc.

Category 2: Psychoactive substances and cancers

Category 2 is dedicated to projects concerning the field of cancers linked to psychoactive substance use, patients with cancer, and the holistic management of those patients: their families, socioeconomic environment, support initiatives, social representations, vulnerable populations, quality of life, social inequalities, etc.

It supports projects related to:

- the strategies and interventions for the identification, care, support and withdrawal of cancer patients who are addicted to one or more psychoactive substances, including within the field of risk and harm reduction.
- the strategies and interventions for the identification, care, support and withdrawal of people participating in cancer screening, particularly lung cancer, and who are addicted to one or more psychoactive substances, including within the field of risk and harm reduction.
- interventions to improve the quality of life and support of patients with cancer linked to psychoactive substance use (and their families):
 - interventions to improve the quality of life of patients and their families (patient therapeutic education, support, learning, nudging, disease management, supportive care, initiatives to reduce complications and risks of recurrence, etc.).
 - support with palliative care (quaternary prevention).
 - post-cancer support initiatives, including the maintenance of and return to employment.
- descriptive and comprehensive approach by the human and social sciences to cancer linked to tobacco, alcohol and/or other psychoactive substances: representations, experiences of cancer, impact of new treatments (e.g. immunotherapy) and screening initiatives, sociology of cancer, stigmatisation processes, psycho-oncology, environment and consumption-related quality of life scale, role of caregivers.
- screening for smoking and alcohol-related cancer, and innovative research concerning new modes of screening related to psychoactive substances.
- biology of cancer related to psychoactive substance use, early diagnosis and clinical-biological impacts.
- cancer and polysubstance use (tobacco, alcohol, cannabis, cocaine, heroin, etc.).

Category 3: Psychoactive substances and impacts other than cancers

Category 3 is dedicated to projects concerning populations of patients with any diseases, disabilities and/or chronic conditions resulting from the use of psychoactive substances, excluding cancer. This category also covers projects concerning social and economic consequences of psychoactive substance use.

It supports projects related to:

- the pathological consequences (other than in the case of cancer) of psychoactive substance use.
- the prevention, identification, care and support in psychoactive substance use and addictions related to specific public health issues requiring specific interventions:

- foetal alcohol syndrome, disability and developmental malformations related to use during pregnancy or during the perinatal period.
- mental and psychiatric disorders caused or made worse by use.
- infectious diseases related to the modes of administration and sharing of equipment.
- etc.
- strategies to stop use and reduce risks and harms in patients suffering from pathologies linked to psychoactive substance use, other than cancer:
 - respiratory diseases (COPD, emphysema, etc.).
 - cardiovascular diseases (infarction, stroke, atherosclerosis, etc.).
 - mental and psychiatric disorders.
 - infectious diseases (related to the mode of administration and sharing of equipment, injection, inhalation, sniffing).
 - etc.
- the impacts of psychoactive substance use and their biological and clinical-biological aspects in the context of diseases other than cancer.
- the non-pathological social and economic consequences resulting from psychoactive substance use (road accidents, physical violence, death through overdose, etc.).

Category 4: Non-substance-related addictions and behavioural disorders with addictive potential

Finally, Category 4 concerns projects on non-substance-related addictions or behavioural disorders whose addictive potential is confirmed. Non-substance-related addictions are those recognised by the WHO¹² as being addictions to gambling or video games. Exploratory research on behaviours not yet recognised as having addictive potential (e.g. sexual practices, food, screens, work, sport, etc.) also falls within the scope of this area.

It supports projects related to:

- defining, qualifying – on a scientific basis – and measuring (prevalence) these disorders, addictions, risk or problem behaviours, which takes into account the severity continuum (to focus not only on manifest disorders and thus take into account the strong heterogeneity of behaviours).
- studying the trajectories of individuals, before and after the use of healthcare, with the aim of observing changes in behaviour and thereby better visualising the prevention efforts needed.
- strategies and interventions for preventing these addictive behaviours.
- identifying and diagnosing these disorders and addictions, help with access to healthcare, as well as care pathways and therapies.
- studying the links between non-substance-related addictions and comorbidities (other addictive behaviour whether or not substance-related, mental illnesses, pre-existing conditions that may lead to an excessive engagement).
- studying the health and social impacts of these behaviours.
- advertising/marketing impacts.

¹² World Health Organization (2019). International Classification of Diseases (11th revision). <https://icd.who.int/en>

3 Terms and conditions of participation

It should be noted that the funding allocated within this call for proposals does not cover these. The call for applications for doctoral grants is scheduled to be published in the first half of 2023.

Please note: it is mandatory that all selected projects start within 8 months of notification of results.

3.1 Project types

For this edition of the call for proposals, the following types of projects are expected:

3.1.1 Full research projects

Conditions	Duration: 36 or 48 months	Projected budget: €100,000 minimum
------------	---------------------------	------------------------------------

The purpose of this funding is to support research projects that can involve several teams. These are research projects with an advanced design, founded on a strong methodological approach and successful partnerships, based notably on data from pilot studies, emerging projects or feasibility evaluations. Interventional research projects may also be funded.

3.1.2 Pilot research projects

Conditions	Duration: 18 or 24 months	Projected budget: €150,000 maximum
------------	---------------------------	------------------------------------

A feasibility assessment phase is necessary when preparing certain full research projects. Therefore, this involves funding a small-scale preliminary study in order to determine feasibility, time-frames, costs and risks before conducting a similar project on a larger scale. These pilot projects may also support interdisciplinary and inter-establishment cooperation between researchers and field workers in order to develop common research projects.

3.1.3 'Emerging' research projects

Conditions	Duration: 12 or 18 months	Projected budget: €60,000 maximum
------------	---------------------------	-----------------------------------

Emerging projects are aimed to structure, for example, a partnership between research teams and field players/practitioners, in order to develop research questions and the design of the intervention. The funding should enable researchers and their partners to develop a project intended for submission to subsequent editions of the call for proposals (as a pilot or full research project).

3.2 Structures receiving the funding

The funding allocated as part of this call for proposals is intended for the following legal entities established in France (referred to hereafter as 'structures'):

- public research institutions (public scientific and technical research establishments [EPSTs], industrial and commercial public undertakings [EPICs], etc.).
- institutions of higher education (universities, etc.).
- non-profit organisations with a health research, health promotion, prevention or screening mission, or working in the health and social sector.
- public or private non-profit healthcare institutions (hospitals, teaching hospitals, regional cancer centres [CRLCCs], etc.).

Ineligible for funding in whole or in part and ineligible to participate in this call for proposals are legal entities with links to the tobacco industry (article 5.3 of the FCTC¹³), operators in the alcohol and cannabis sectors, and the pharmaceutical industries. Any links to commercial or for-profit companies must be stated in the application. INCa and IReSP reserve the right to use an ethics committee, if needed.

For each project, the funding will be paid to one structure that will be responsible for distributing the funds to the other structures for the benefit of the teams taking part in the project. This coordinating structure receiving the funding must have a public accountant. This recipient structure will also be responsible for justifying the expenditure to the body that allocates the funding.

3.3 Project coordination

The project coordinator is the principal manager of the project. Only one coordinator is the referent for the submitted project.

The coordinator must hold a research or practice doctorate (medicine or pharmacy) and be:

- a permanent staff member (statutory in the civil service or on a permanent contract governed by private or public law) or,
- a staff member on a fixed-term contract governed by private or public law only if the contract covers the entire duration of the project in one of the structures eligible for coordinating the project. The coordinator must verify the compatibility of his or her status with the performance of the project and, if necessary, obtain the authorisation of his or her employer.

The coordinator must be involved in the project for at least 30% of his or her time and must not be a member of the evaluation committee of the call for proposals.

In addition to his or her scientific and technical role, the coordinator is responsible for the entire deployment of the project and for setting up the modes of collaboration between the teams participating in it, producing the required documents (scientific and financial reports), holding meetings, overseeing the project's progress, and communicating the results.

3.4 Eligible teams

There is no limit to the number of teams participating in the project or the number of people involved. However, **a maximum of 5 teams per project can request funding** for full or pilot projects, and **a maximum of 2 teams** for emerging projects.

The participation of industrial partners (excluding the tobacco industry, operators in the alcohol and cannabis sectors, and the pharmaceutical industries), territorial authorities, regional health agencies (ARS) and/or foreign institutions is possible provided they fund their own work in the project. They will then be associated with the project (referred to hereafter as 'associates') and receive no funding within the framework of the call for proposals.

Please note: projects wholly carried out abroad and/or those which do not entail any positive impact for public health in France will not be eligible.

3.5 Coordinator and team independence

The coordinator and the leader of each participating team declare, in the application, to have no link of interests within the framework of the project's conduct and that there is no fact or element, past, present or liable to appear in the foreseeable future, which could compromise their independence, particularly in relation to the tobacco industry, operators in the alcohol and cannabis sectors, and the pharmaceutical industries.

¹³ FCTC: WHO Framework Convention on Tobacco Control. Guidelines for implementation of Article 5.3 on the protection of public health policies with respect to tobacco control from commercial and other vested interests of the tobacco industry: https://www.who.int/fctc/guidelines/article_5_3.pdf?ua=1

4 Project selection and evaluation

4.1 Selection process

In order to evaluate the submitted proposals, IReSP and INCa convene four international evaluation committees (ECs) whose members, renowned for their expertise, examine the eligible projects. For each category, one committee will be convened.

The full research projects will also be examined by external evaluators.

4.2 Declaration of interests of evaluation committee members

The two institutes have established a system in terms of professional ethics and transparency of interests. The examiners and external evaluators undertake to respect the professional ethics provisions of the two institutes¹⁴.

An examiner cannot be a coordinator or a project team member. The examiners and external evaluators must declare their direct and indirect interests relating to each project submitted to the evaluation committee and relating to a project coordinator or a member of a project team.

The composition of each EC will be published on the IReSP and INCa websites at the end of the evaluation process of the call for proposals.

4.3 Main stages of the evaluation

The main stages of the procedure for selecting applications are as follows:

- electronic submission of the application (scientific documents and financial appendix).
- verification of the admissibility and eligibility criteria.
- evaluation:
 - external evaluators (international and French) are asked to provide a project evaluation report (only for full research projects).
 - the examiners (specific to each EC) provide a project evaluation report.
- evaluation meeting for each EC: based on external evaluations and examiners' assessments, the members of the EC collectively discuss the quality of the projects. Please note that we are aiming for:
 - two external evaluations and two examiners per project in the case of **full projects**.
 - three examiners per project in the case of **pilot projects**.
 - two examiners per project in the case of **emerging projects**.
- At the end of the session, the EC will propose a list of projects to receive funding.
- INCa and IReSP will make their final decision on the projects selected for funding.
- INCa and IReSP will publish the results.

4.4 Admissibility criteria for proposals

Applications must be submitted:

- **within the deadline** (see section 6).

¹⁴ For Categories 1, 3 and 4, refer to the IReSP rules and regulations: <https://iresp.net/liresp/linstitut/>
For Category 2, refer to the INCa provisions: <http://www.e-cancer.fr/Institut-national-du-cancer/Deontologie-et-transparence-DPI>.

- **in the required format** (see section 7).
- and with nothing missing.

The application file (Word scientific document and Excel financial document) must be submitted in **full and containing all the required information** (the signatures of the undertakings and the bank details are included in the Word file).

4.5 Eligibility criteria for proposals

To be eligible, the projects and the coordinators must satisfy the following conditions:

- the project must fulfil the scope and objectives of this call for proposals.
- the project must be of a duration of 12, 18, 36 or 48 months depending on the project type selected.
- a given project may not be simultaneously submitted to several INCa or IReSP calls for proposals.
- the project may not already be in progress or be receiving funding from INCa, IReSP, or any other public body.
- the project coordinator may not be a member of an evaluation committee (EC) for the call for proposals or be a stakeholder in preparing this call for proposals.
- the teams receiving the funds must belong to the structures that are eligible for this call for proposals (see section 3.2).
- the performance of the project is not limited in terms of the number of partner teams, belonging to different research units and/or institutions. However, a maximum of 5 teams may request funding for pilot projects and full research projects, and a maximum of 2 teams for emerging projects.
- since the evaluation committee is international, the application must be written in English.
- the application must contain all the information necessary for the overall assessment of the project's quality, including statistical analyses, logistical aspects where these are important for proper analysis, justification of the requested budget (as a minimum the principal cost items envisaged), etc.
- the project coordinator and the team leaders must have no interests or conflicts of interest within the framework of the project's performance and they will make an undertaking to this effect in the application.

4.6 Evaluation criteria for proposals

Applications that meet the eligibility criteria will be evaluated on the basis of the following general criteria:

Scientific quality:

- excellence in relation to current scientific knowledge.
- position of the proposal in the national and international context.
- relevance and originality of the proposal.
- clarity of the objectives.

Coordinator and partner teams:

- quality and synergy of the partnership between researchers and field players.
- quality of the teams involved (capabilities, experience, complementarity...).

Methodology and feasibility:

- methodological quality and relevance of the technologies envisaged.

- suitability and justification of the suggested schedule in relation to the objectives of the proposal.
- feasibility of the research (access to data, schedule for performing project tasks, detailed programme, deliverables, respect of ethical rules and regulatory aspects, status of authorisation requests, declaration of access to databases or to cohorts...).
- technical, financial and legal-administrative feasibility (budget in line with the request, compatibility of the funding obtained through the call for proposals with any other funding that the structure will receive).

Impact of the proposal:

- scientific, technical, or medical impacts.
- potential impacts on public health (consequences for public health, participation in the direction of public health policies and the implementation of appropriate strategies).
- innovative characteristics.

5 Administrative management and terms and conditions for the funding of the selected projects

The provisions relating to the administrative management of the call for proposals and the terms and conditions of funding allocation are set out in the appendix.

6 Schedule

Month of publication of the call for proposal	December 2023
Deadline for electronic submission of the application (scientific, financial and administrative documents)	6th March 2023 – 4 p.m.
Evaluation Committee meetings (1 EC per category)	June - July 2023
Provisional date for announcement of the results	Summer 2023

7 Procedures for submission

The finalised application must contain all the required elements necessary for the scientific and technical evaluation of the project (application form and financial appendix).

The finalised application must be submitted in electronic form (online) only.

The procedures relating to the chosen project category must be respected.

7.1 Categories 1, 3 and 4

For Categories 1, 3 and 4, the required documents must be uploaded to the EVA3 platform: <https://eva3-accueil.inserm.fr/sites/eva/appels-a-projets/Pages/AAP-SPA.aspx>

Recommendations for applicants:

- creating/activating an EVA3 account: to log in, use your reference email address as your login on the EVA3 platform login page (<https://www.eva3.inserm.fr/login>).

- if you have not yet registered, create your account.
- if you already have an account but have forgotten your password, click on 'Forgot password?' and follow the instructions.

Application submission: all applications **must be submitted solely in the name of the coordinator and with his or her contact details**. Applications submitted under another name/email address will be **inadmissible**.

Applications

Each application is submitted by one person only.

If several researchers from the same team are submitting an application, one of them must be designated as the contact.

The applicant logs into his or her account on the EVA3 platform, and:

- enters the data requested online.
- downloads the application document templates (Word scientific file and Excel financial appendix).
- submits the required documents completed and signed.
- validation/submission: the final validation generates an email acknowledging receipt and confirming submission of the application. Please note: once validated, you will no longer be able to return to the contents of your application.

7.2 Category 2

For Category 2, projects are submitted directly from the PROJECTS portal: <https://projets.e-cancer.fr>

Creating/activating an account: to log in, use your reference email as your login on the PROJECTS portal home page.

- If you have not yet registered, create your account and enter your contact details and work profile.
- If you are already registered, a message tells you that your email address already exists. In this case, simply click on 'Forgot password?' and follow the instructions.
- Finally, if you think that you are already registered and your email address is not recognised, contact us at: assistanceprojets@institutcancer.fr

Applications

Each application is submitted by one person only.

If several researchers from the same team are submitting an application, one of them must be designated as the contact.

The applicant logs into his or her account in the PROJECTS portal, and:

- enters the data requested online (supplementary sections).
- submits the required documents: project description in the 'Project overview' section.
- submits any optional documents: it is possible to add supplementary attachments to the application: 'Supplementary attachments' section.
- submits signed documents – undertakings of the participating teams: compilation of all the scanned undertakings of all the participating teams. The submitted document must contain the project no. as assigned by the Portal in the 'Project submission' menu (e.g. 'SPA23-001').
- validation/submission: the final validation generates an email acknowledging receipt and confirming submission of the application. Please note: once validated, you will no longer be able to return to the contents of your application.

8 Publication of results

The results of the evaluation will be emailed to the project coordinators.

The list of the selected projects will be published on the INCa and IReSP websites.

In addition, IReSP and INCa reserve the right to post details of the projects submitted, funded or otherwise, on their websites.

9 Contacts

	INCa	IReSP
For any information of a scientific nature	Coline Bancel: cbancel@institutcancer.fr	IReSP Addictions Unit: addictions.iresp@inserm.fr
For administrative and financial aspects	tabac-info@institutcancer.fr	iresp.daf@inserm.fr
For technical aspects	PROJECTS portal: assistanceprojets@institutcancer.fr	EVA3: eva@inserm.fr

Appendix

Additional administrative, organisational and financial elements concerning the call for proposals

1 Terms and conditions for management of the call for proposals

1.1 The partners: IReSP and INCa

This call for proposals has been jointly organised by IReSP and INCa.

The Institute for Public Health Research (IReSP) is a consortium with a specific legal status in France (GIS). Its principal objective is to develop, structure and promote public health research. This takes place in conjunction with the various players in the field, in line with the knowledge requirements of its members and, more broadly, those of the various players concerned and society as a whole, in order to reinforce interventions and policies aimed at improving the population's health and well-being. More information can be found at iresp.net.

The French National Cancer Institute (INCa) is a public institution and the preeminent health and science agency dedicated to cancer. It is tasked with giving impetus to and coordinating the fight against cancer in France, with implementing a cancer research policy, and with ensuring equality of patient access to healthcare. More information can be found at e-cancer.fr.

Depending on the project category, the funding and evaluation process will be conducted by one or both of the institutes.

IReSP is responsible for evaluating Category 1, 3 and 4 projects.

INCa is responsible for evaluating Category 2 projects.

1.2 Limitations of liability

In responding to the call for proposals, the structures, associates, coordinators, team leaders and, generally speaking, all legal entities or natural persons involved in a project recognise and accept, without any possible redress or claim for compensation against Inserm or INCa, that:

- Inserm, as managing establishment of IReSP or INCa reserve the right to terminate the call for proposals at any time, should Inserm or INCa be unable to or no longer be able to receive funding from the Addictions Fund.
- Inserm, as managing establishment of IReSP or INCa reserve the right to suspend or terminate the funding of the selected projects in the event of non-payment or insufficiency of Addictions Fund funding or should Inserm or INCa become ineligible for that funding.

2 General provisions and funding

2.1 Terms and conditions of funding by the partners

Funding will be allocated by INCa or by Inserm, as managing establishment of IReSP, and according to the additional financial terms and conditions set out in the Appendix.

The selected coordinators will be contacted by IReSP or INCa to update or supplement the documents required for allocation of the funding:

- the detailed budget.
- the undertakings of the legal representative of the coordinating structure receiving the funding.

- the additional documents required for the funding of private non-profit bodies (signed copies of the up-to-date statutes, copy of the publication in the French Official Gazette of the declaration of the body's constitution, activity report, list of members of the directors board and executive committee, and extract from the official report approving the accounts of the previous closed financial year).

The rules concerning the use of the funding will be specified in the funding allocation instrument between INCa or Inserm and the body receiving the funding and completed by the 'additional financial terms and conditions' described in the Appendix hereafter.

For Category 1: funding will be attributed by INCa or by Inserm, as managing establishment of IReSP (by INCa for projects concerning psychoactive substance use as a known risk factor for cancer (tobacco, alcohol, cannabis)¹⁵; by IReSP for projects concerning all types of substances).

For Category 2: funding will be allocated by INCa.

For Category 3: funding will be allocated by Inserm, as managing establishment of IReSP.

For Category 4: funding will be allocated by Inserm, as managing establishment of IReSP.

Terms and conditions specific to funding by INCa (Categories 1 and 2):

Funding will be allocated in accordance with regulation no. 2021-01, which the coordinator and the body receiving the funds must undertake to respect (accessible at: <https://www.e-cancer.fr/Institut-national-du-cancer/Appels-a-projets/Reglement-des-subventions>)

Terms and conditions specific to funding by IReSP (Categories 1, 3 and 4):

- funding will be allocated according to the provisions of the funding allocation instrument, which the coordinator and the body receiving the funds must undertake to respect.
- unless otherwise provided in the funding allocation instrument, a first activity report must be provided to IReSP 6 (six) months after the start of the project. Depending on its duration or any specific monitoring provisions recommended by the Evaluation Committee, other reports must be submitted during the course of the project. A final report will be provided no later than 2 (two) months after the end of the project. The details of the reports expected will be described in the funding allocation instrument.

2.2 General provisions

The funding allocated within the framework of the call for proposals may cover all or part of the project budget.

Those participating in the project must undertake to respect the rules of allocation by signing the undertakings listed in the application ('Undertakings' section).

These undertakings concern:

- the legal representative or person responsible (duly authorised) for financial management within the managing body of the project coordinator.
- the project coordinator.
- the director of the affiliate laboratory to which the coordinator belongs, if applicable.
- the legal representative or person responsible (duly authorised) for financial management within each body receiving a share of the funding as a participating team (only if the funds are shared).
- the leader of each participating team in all cases.

¹⁵ Research on opioids may be considered, given the studies showing an increased cancer risk in opium users (Sheikh M. Opium use and subsequent incidence of cancer: results from the Golestan Cohort Study. The Lancet Global Health, vol 8, May 2020)

2.3 Funding allocation instrument

The funding by INCa/IReSP is determined by the creation of a funding allocation instrument through which INCa or Inserm, on behalf of IReSP, notifies the managing body of its rights and obligations regarding the performance of the selected project. The funding allocation instrument can take the form of an agreement, a decision to allocate aid or in the case where the managing establishment of the funding is Inserm, a notification letter.

The funding allocation instrument is produced on the basis of the elements in the application and the text of the corresponding call for proposals. It contains the following information:

- the title of the project.
- the duration of the project.
- the duration of the funding allocation instrument.
- the teams participating in the project and the coordinator.
- the amount of funding and its payment terms.
- the obligation to provide scientific and financial reports to INCa/IReSP.
- the appendices of the funding allocation instrument.
 - Appendix 1: Project abstract as written in the application.
 - Appendix 2: Project budget.

Inserm or INCa drafts and signs the funding allocation instrument and sends notification by mail to the managing body. Any modifications to the provisions of the funding allocation instrument will lead to the drafting and signing of an amendment.

2.4 Funding

The amount of funding allocated, when it is identical to that requested in the application, takes into account the budget appendix completed by the coordinator when submitting the application.

If the amount allocated by INCa/IReSP differs from that requested in the application, INCa/IReSP will inform the coordinator by email, of the amount of the overall funding that it plans to allocate for conduct of the project. A new financial appendix is then drawn up, dated and signed by the managing body. In this case, the coordinator must carry out the research project according to the terms and conditions notified by INCa/IReSP. In the event of refusal to complete a new financial appendix or failure to respond within one month of the sending of the email by INCa/IReSP, no funding will be allocated.

Due to the absence of any consideration for INCa/IReSP's financial support, and in accordance with the provisions of Tax Instruction 3A-4-08 of 13 June 2008 of the General Directorate of Public Finance, the funding allocated by INCa/IReSP is not subject to VAT.

2.5 Eligible expenses

The expenses must relate directly to the project, be strictly necessary for the conduct of the project, comply with the regulations applicable notably in terms of public procurement, human resources, and prevention of conflicts of interest, and be duly justified.

Eligible are:

- non-permanent staff costs, with the exception of PhD contracts. For establishments governed by private law, permanent-staff costs are eligible when those personnel are assigned to the project within the strict framework of its implementation.
- operating costs (consumables; costs related to travel or assignments within the framework of and for the purposes of the conduct of the project by the permanent or temporary staff assigned to it; service provision

and costs justified by an internal invoicing system; intellectual property costs of patents or licences incurred by the conduct of the project; costs related to the publication of results as well as any additional costs applied for the publication of open access articles; costs of drafting a possible consortium agreement).

- equipment, excluding office automation and furniture, for an amount lower than €150,000, including VAT. This €150,000 threshold applies to individual items of equipment and not to the total amount spent on equipment. In addition, the total equipment costs may not exceed 30% of the amount of the grant allocated by INCa and IReSP; the purchase of computer hardware and software is only accepted if it is essential to the conduct of the project and that its use is precisely justified in the scientific description of the project highlighting its own properties. The support provided is not intended to equip the personnel assigned to the project with standard office automation. IReSP and/or INCa reserves the right to not respond favourably to the request if it is insufficiently substantiated.
- overheads, to a maximum of 8% of the total cost of eligible expenses actually paid (staff, operational costs, equipment). Management fees are applied on a flat-rate basis.

Budgetary items are interchangeable throughout the duration of project execution.

The funding allocated is not intended to contribute to the structural operation of the institution. INCa/IReSP reserves the right to not fund the submitted project in its entirety.

If the amount of funding paid by INCa/IReSP does not cover all the costs related to the completion of the project, the managing body undertakes to supplement the funding, enabling its proper execution, either from its own resources or through one or more co-funding arrangements. In the latter case, the managing body will inform INCa/IReSP, in the event of co-funding obtained after notification of the agreement, of the name of the co-funding party and the amount of its co-funding. The managing body also undertakes that this co-funding will not generate any conflicts of interest in the conduct of the project.

INCa/IReSP reserves the right to suspend, withdraw the funding granted or request the reimbursement of sums paid, without prejudice to any other action that INCa/IReSP could take in the event of non-compliance with the applicable regulations, particularly in terms of public procurement and management of human resources.

2.6 Payment and use of the funding

The amount of funding depends on the duration of the project in question.

The number of payments and the amount paid will be specified in the funding allocation instrument.

The funding paid by INCa/IReSP must be used by the managing body for the sole purpose of carrying out the project identified in the funding allocation instrument.

Following validation of the final reports, the sums not spent will be reimbursed to Inserm/INCa within 30 days of receipt of the revenue order (*titre de recette*) issued by the latter.

2.7 Financial management

Throughout the duration of the project, IReSP or INCa reserve the right to conduct a site visit in consultation with the managing body and project coordinator. The use of the funding paid under the funding allocation instrument may be subject, during the life of the project and for 5 (five) years after its expiry, to an inspection or audit on behalf of INCa/IReSP on and/or off-site.

It should be noted, given that these are public funds, that this funding may be subject to inspection by the various state supervisory bodies.

3 Other undertakings of the coordinator and managing body

The coordinator is required to inform INCa/IReSP of any substantial modification to the research project regarding the content of the application or funding allocation instrument, or difficulties impeding conduct of the research project.

The managing body will inform INCa/IReSP of any change of address or bank details.

The managing body must at any time during the project be able to justify the allocation to the project of the funded personnel as well as all expenditure made using the funding.

The managing body must be able to provide all documents and supporting documents of an administrative, accounting and legal nature relating to use of the funding.

4 Scientific and financial reports

The coordinator will make reports based on the template and procedures that will be defined in the funding allocation instrument. Failure to produce these reports may lead to the reimbursement of all or part of the sums paid by INCa/IReSP.

5 Intellectual property and contractual organisation

INCa and IReSP do not acquire any intellectual property rights solely for financing calls for proposals and providing funding.

The management of intellectual property arising from the project is a matter for the structures and, if applicable, the project associates.

The drafting of a consortium agreement is strongly recommended when:

- the total amount of the grant is more than €250,000.
- more than three structures are involved in the project.

In principle, the structure in charge of coordinating the project is tasked with drafting the consortium agreement.

6 Publication and communication

Within the scope of the rollout of the French National Plan for Open Science, the body receiving the funds and the project coordinator must take care to:

- complete the 'General abstract' and 'Scientific abstract' sections of the application. The abstracts (scientific and general) of the funded projects may be published on the INCa and/or IReSP websites.
- prioritise publication in open-access journals or publications. Failing that, the recipient and the teams involved in the project undertake to submit the scientific publications resulting from the funded research projects to an open-access archive.
- enter and update a data management plan on the DMP OPIDoR Portal: <https://dmp.opidor.fr/>. The funding allocation instrument will recap the schedule and procedure for updating this data management plan.
- it is mandatory that all written or verbal communications relating to funded projects mention the support given by INCa and IReSP. A reference containing the number to be mentioned will be provided once the project has been selected for funding. These publications will be sent to INCa and IReSP for information as soon as possible and no later than 5 (five) days after publication.