AIRC

Associazione Italiana per la Ricerca sul Cancro

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Call for Applications 2018

International Cancer Research Fellowships iCARE-2

History of changes of Call for applications 2018				
Version	Publication date	Changes		
1.0	1 June 2018	 Page 18: the threshold coefficient reported in section 25. Financial support has been corrected to 0,8481 and is now consistent with the one reported on page 8. 		
		 Addendum B: edited to correctly mark with a (*) all countries with a coefficient lower than 0,8481. 		
		None of these typos had any impact on the online application system.		

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Foreword

The Italian Association for Cancer Research (AIRC) is inviting applications to the International Cancer Research Fellowships (iCARE-2) program, a funding scheme intended to promote the mobility of experienced researchers to and from Italy. This program is open to highly qualified post-doctoral fellows or equivalent who wish to broaden their experience in oncologic research, and consists of 3 different types of fellowships, each for a duration of 3 years:

Outgoing fellowships: for researchers who have worked in Italy for more than 3 years out of the last 4 years, interested in a research experience in a scientific institution located in a different country than Italy.

Incoming fellowships: for non-Italian scientists interested in a research experience in a scientific institution located in Italy.

Reintegration fellowships: for Italian researchers who have worked in a country outside Italy for at least 2 out of the last 3 years, and who wish to return and work in a research center in Italy.

A total of 15 fellowships will be awarded.

iCARE-2 fellowship program has received funding from the European Union's Horizon 2020 research and innovation program under the Marie Skłodowska-Curie grant agreement Nr.800924.

Experience eligibility criteria for applicants

At the time of the relevant deadline for submission and regardless of the type of fellowship, applicants MUST either be in possession of a doctoral degree, independently of the time taken to acquire it, or have at least 4 years of full-time equivalent research experience (including the period of research training) after the degree which formally allowed them to embark on a doctorate in the country in which the degree was obtained or in the country where the fellowship is taking place. Example: Italian applicants not holding a PhD must have at least 4 years of full research experience after the attainment of a "laurea magistralis" in order to be eligible; candidates who only have a "laurea breve/triennale" are not eligible.

Mobility eligibility criteria for applicants

Support cannot be awarded to researchers who are already permanently employed by the Hosting Institution. In addition, the following mobility eligibility criteria specific for each type of mobility fellowship MUST be met:

Outgoing fellowships:

- Applicants must have legally resided and have had their main activity (work, studies, etc.) in Italy for at least 3 out of the last 4 years prior to the relevant deadline for submission.
- The Hosting Institution's premises must be located in a different country than Italy.
- Applicants must not have resided or carried out their main activity (work, studies, etc.) in the country of the Hosting Institution for more than 12 months in the 3 years prior to the relevant deadline for submission.

Incoming fellowships:

Applicants must be non-Italian.

- The Hosting Institution's premises must be located in Italy.
- Applicants must not have resided or carried out their main activity (work, studies, etc.) in Italy for more than 12 months
 in the 3 years prior to the relevant deadline for submission.

Reintegration fellowships:

- Applicants must be Italian.
- The Hosting Institution's premises must be located in Italy.
- Applicants must not have resided or carried out their main activity (work, studies, etc.) in Italy for more than twelve
 months in the 3 years prior to the relevant deadline for submission.
- Eligibility based on mobility criteria will be verified in the Mobility Check form (see <u>section 14</u>).

3. The Hosting Institution

The research activity must be carried out in a Hosting Institution, *i.e.* a **research organization** (such as university, hospital or other research center), irrespective of its legal status (organized under public or private law), whose primary goal is to independently conduct non-economic biomedical research and to disseminate its results. Possible revenues coming from non-economic research activity must be completely reinvested in the non-economic research activities. Where the Hosting Institution also pursues economic activities, the financing, the costs and the revenues of those economic activities must be accounted for separately. Shareholders, members or other individuals that can exert a decisive influence upon the Hosting Institution cannot enjoy a preferential access to the intellectual property of the results generated by the non-economic research activity.

Hosting Institutions must assure **optimal working conditions** to the fellows, both technical and contractual. More specifically, they must be committed to:

- provide appropriate facilities, equipment and infrastructure, as well as training resources in complementary skills, e.g. seminars/workshops on Intellectual Property Rights (IPR) knowledge and skills, grantsmanship, ethical issues etc. Details on resources and trainings opportunities will have to be included in the letter of acceptance of the fellow, written and signed by the head of the hosting lab;
- comply with national or sectoral regulations concerning health and safety in research;
- 3. take on fellows under a full employment contract, with adequate and equitable social security provisions (contribution to pension funds, health and accident insurance, parental leave, etc.) in accordance with existing national legislation and with national or sectorial collective bargaining agreements. After the awarding of a fellowship, a "Declaration of conformity" certifying that these conditions are met will have to be signed by the Hosting Institution's Legal representative and by the fellow. A template of the Declaration of conformity is included in this Call (see Addendum A).

The Hosting Institution must promote the highest standards of integrity in research, in compliance with the <u>AIRC policy on research integrity</u> available on the AIRC website.

4. The research project

Research plan

Applications must include a detailed research plan, agreed with the head of the hosting lab, with a clear **focus on cancer**. The proposed research plan should be highly innovative, feasible, internationally competitive and with the potential to advance the field. In addition, it must be doable in the 3-year time frame of the fellowship.

Intellectual property rights

Intellectual property and patents resulting from research carried out during an iCARE-2 fellowship appointment will be solely owned and managed by the grantee and the Hosting Institution.

Ethics rules

All proposals must comply with the ethics directives of H2020, as detailed in the "Guide for proposal preparation", and clearance from the competent Ethics Committee(s) must be obtained and communicated to AIRC before the beginning of the research activity arising ethical issues.

What we do not fund

Research proposals falling under any of these categories cannot be funded and applications will be automatically rejected:

- Research activity aiming at human cloning for reproductive purpose;
- Research activity intended to modify the genetic heritage of human beings, which could make such changes heritable (research related to cancer treatment of the gonads can be funded);
- Research activity intended to create human embryos solely for the purpose of research or for the purpose of stem
 cell procurement, including by means of somatic cell nuclear transfer.

Originality

The proposal must be original and cannot contain copied texts, ideas and figures from other sources unless properly referenced. At AIRC we are aware that plagiarism may be accidental and that parts of an application (e.g. material and methods) may include material originally produced by the applicant. However, AIRC may verify documents with antiplagiarism software and proposals that contain blatantly and substantially copied materials will be rejected.

5. The review process

5.1. Eligibility check

All applications undergo an initial administrative review by the staff of the AIRC Peer Review Office for compliance with guidelines and eligibility, to be confirmed by the AIRC Scientific Fellowship Committee (see below). Applications that do not conform will not be admitted to the peer review process and will be rejected as ineligible.

5.2. Scientific evaluation

Applications that meet all eligibility requirements undergo a peer review process that ensures an expert, fair and independent evaluation of their scientific merit and competitiveness. For the scientific evaluation of iCARE-2 applications AIRC relies on the expertise of internationally recognized Italian scientists members of the AIRC Scientific Fellowship Committee and a panel of about 600 well-established international investigators working in institutions outside of Italy. Applications are independently evaluated by at least 3 reviewers (one from the AIRC Scientific Fellowship Committee and two from the international panel) with expertise in the specific area of the research plan. Reviewer assignments are made in compliance with conflict of interest rules to ensure a review free from inappropriate influence. The AIRC policy on the Conflict of Interest is available on AIRC website.

When accepting to evaluate an application, reviewers and members of the AIRC Scientific Fellowship Committee agree to maintain the confidentiality of applications and associated materials they have received.

3 review criteria are used to evaluate applications. Reviewers assign a score to each section; for each evaluator, the global score of an application (range: 0-100; 100 for the most competitive) is calculated as the sum of the 3 sub-scores.

The review criteria are:

Quality of the Hosting Institution and training (score range: 0-45, with 45 to be used for the most competitive)
The quality of the Hosting Institution (especially in terms of training potential), and of the head of the hosting laboratory (*i.e.* the fellow's supervisor) are evaluated according to the following parameters:

- Supervisor's expertise in the field;
- Supervisor's experience in training researchers in the field, and ability to provide mentoring/tutoring;
- Supervisor/group's international standing and track record;
- Laboratories/facilities and availability of research grants;
- Frequency and availability in the Hosting Institution of scientific seminars and training opportunities (courses, seminars or workshops) on transferable skills intended to widen the competences of the fellows.

Curriculum vitae of the applicant (score range 0-35, with 35 to be used for the most competitive)

The CV of the applicant are assessed based on the following elements:

- Education;
- Track record and scientific accomplishments (publications, patents, awards, datasets, etc.);
- Previous mobility (transnational and/or inter-sectorial);
- Participation to international meetings and/or specific courses;

Research proposal (score range: 0-20, with 20 to be used for the most competitive. Funding threshold on the average of the reviewers scores: 10)

The following aspects of the research project are assessed:

- Significance and impact on cancer;
- Originality and innovation of the project, and relationship to the 'state of the art' of the research area at an international level;
- Proposed research methodology and feasibility;
- Overall scientific/technological quality.

For each application the global scores received from the 3 scientific reviewers are averaged to calculate the final score. Proposals are ranked according to the final scores.

The 15 top scoring applicants are identified as "finalists", and undergo a second step of evaluation. The 5 applications ranking immediately below the finalists are kept in a "reserve list" to allow for eventualities such as the withdrawal of an application or the availability of additional budget from other sources. When equally qualified, preference is given to:

- younger candidates and/or researchers at their early post-doctoral level (taking into consideration career breaks, if present):
- applicants from less favoured countries;
- applicants and/or heads of the hosting labs who that ensure a more balanced gender ratio;
- applicants with a refugee status.

All applicants receive a communication from AIRC ("Notification of results") that includes the indication on whether they are in the finalist list, in the reserve list, or in the not-approved list, the final score, the funding cut-off and the reviewers comments. The identity of the reviewers is not disclosed.

5.3. Ethical review and interview

Finalists and their applications are subjected to further scrutiny: an interview and an ethical review.

Applications by finalists undergo an ethical review by ethics experts. Ethics reviewers do not revisit the scientific

evaluation, but assess the Ethics Self-Assessment documentation, in order to determine whether the applicants:

- respect the H2020 ethical standards;
- clearly indicate how the proposal meets the national legal and ethical requirements of the country where the research will be performed;
- have sought or are planning to seek the approval of relevant local/national (ethics) committees.

Ethics experts prepare an Ethics Review Report which may include requests of clarifications or additional documentation. Applicants must respond and provide the requested supplementary information, which is analyzed by the ethics experts to determine whether it adequately addresses the relevant ethical issues. Ethics reviewers then make a final recommendation. The identity of the ethics experts is not disclosed. A proposal may be rejected on ethical grounds following the ethical review.

An **interview** with the finalists is organized, via telephone or video-conference, with 2 of the 3 scientists who evaluated their proposals, in order to obtain information on the commitment of the applicants, their timelines, the enthusiasm they bring to their research, and career plans. Reviewers write a brief summary of the interview and submit it to the AIRC Peer Review Office and to the other reviewer, together with their final recommendation.

If there are no issues with the research proposal after the ethical review, and if the interview of the candidate is successful, finalists are awarded the fellowship; otherwise the first member of the reserve list is invited for an interview and the application is subjected to an ethical review, and so on, until all fellowships are assigned. Successful finalists receive an official award letter with the terms and conditions of the award, together with instructions on how to activate the fellowship.

5.4. Redress procedure

Applicants may request an "evaluation review" when they receive the communication that their application has been considered ineligible (section 5.1) and when they receive the communication that their application has been considered not fundable and is in the not-approved list (section 5.2 and 5.3). In all cases, applicants' request of "evaluation review" can **only** refer to the procedural aspects of the evaluation (not the scientific merits of the proposal). This request must be submitted by the applicant within 15 business days after receiving the communication (redress deadline). A reply is provided within 15 business days after the redress deadline. In each case, the official communication from AIRC with the final decision on the application includes also information on the redress procedure and deadlines.

6. Funding

The financial support provided comprises:

Living and mobility allowance

- This allowance is calculated multiplying a flat rate of € 52.000/year by the correction coefficient of the country of the Hosting Institution. The correction coefficients are those established for the Marie Skłodowska-Curie Work Program 2018-2020, listed in the <u>Addendum B</u> at the end of this Call. For countries with a correction coefficient lower than 0,8481, the Living and mobility allowance is € 44.100/year, consistent with the EC requirements for COFUND Fellowship Programmes (€ 3.675/month).
- It will be used by the Hosting Institution to pay the fellow's stipend monthly, applying the local taxes in place. In addition, in conformity with the conditions set forth in the **full employment contract**, the Hosting Institution will also deduct the mandatory employer's contributions (e.g. pension provision): the amount remaining from the Living and mobility allowance, after the employer's contributions have been paid and the income taxes deducted, is the fellow's net salary. For Incoming and Reintegration fellowships: the fellow must be hired under a regular work contract. For

all types of fellowships, in case the award is granted, the Legal representative of the Hosting Institution and the fellow will have to sign the "Declaration of conformity" (see Addendum A) which certifies that the fellow is hired with a full employment contract. The Living and mobility allowance will be transferred by AIRC to the Hosting Institution, after a specific agreement between the 2 parties is set up and the Declaration of conformity has been signed.

Travel allowance

- Up to € 1.200/year, to cover one roundtrip ticket/year from the place of origin (or the home country, whichever applies) to the country of the Hosting Institution.
- It will be directly refunded by AIRC upon presentation of appropriate documentation.

Research and dissemination cost contribution

- € 3.000/year to cover research costs, publication of research papers and patent deposition.
- It will be used by the Hosting Institution to cover the costs of research and dissemination activities, including fees for the publication of scientific articles in the mandatory open access mode, and patents. It is a flat rate transferred by AIRC to the Hosting Institution on a yearly basis. At the end of the fellowship a financial reconciliation on how this contribution has been spent will be requested.

Training cost contribution

- € 1.800/year to cover costs of participation to international conferences and training activities.
- It will be used by the Hosting Institution to cover the fellow's expenses to participate to either international scientific meetings on a cancer-related topic or to recognised transferable skills events. It is a flat rate transferred by AIRC to the Hosting Institution on a yearly basis after receipt of a certificate of attendance to the meeting.

A renewal request must be submitted at the end of the first and of the second year of funding (first/second year progress report), and a detailed final report (scientific and administrative) must be prepared at the end of the funding period.

Deadlines 7.

Deadlines are strictly enforced: applications submitted after the deadline will not be accepted.

Deadlines (by 17:00 Central European Time, of the indicated dates).

Online form release	May 14, 2018
Online submission deadline	June 25, 2018
Online submission with digital signatures of the candidate and of the Legal Representative	July 5, 2018
Papers in press (*)	July 22, 2018
Notification of results	September 17, 2018
Notification of award	October 22, 2018
Start of fellowships	From January 2, 2019

^(*) Communications received by July 22 2018 will be forwarded to all reviewers evaluating the proposal.

Deadlines for renewal requests and final reports will be communicated in the award letter.

Guide to proposal preparation

Access to our website

Researchers who already have an AIRC account

Login your AIRC account with your username and password at:

https://www.direzionescientifica.airc.it/Default.aspx

This website can also be reached clicking on the "Area ricercatori" of the website www.airc.it

First-time applicants

Only registered users can access the application form. Click on "Register (for applicants only)" at: https://www.direzionescientifica.airc.it/Default.aspx

Provide the requested information, including your Italian tax code ("codice fiscale") and ORCID (Open Researcher and Contributor ID - https://orcid.org) identifier. The registration will be confirmed by e-mail and a username and password will be provided. Login your AIRC account with your username and password. Applicants without a tax code can select the corresponding box and proceed with the application.

To launch the application form for the first time: click on "Calls", select "Fellowships", then click on "Apply" in the iCARE-2 Fellowships 2018 section. In the next window, click on "Access the application form".

To access the application in progress: click on "Submissions" and then click on "Access the application form".

General features of AIRC online application system

- All forms that must be filled out are listed on the left side of the page. Click on each one of them and fill in all the mandatory fields (in bold). Click on "SAVE" after completing each form.
- The forms can be filled out in different sessions and the work can be interrupted/resumed at anytime.
- A number of forms must be submitted as PDF files. Files exceeding 2Mb and secure PDF files cannot be uploaded. Documents submitted as PDF files must be written using an A4 format, single spaced, with margins not less than 2 cm and a font not smaller than 12 point (preferably Palatino, Times, Arial). When available, make sure to use the Word templates provided by the system. Do not exceed the page limit indicated for each section: the system will not allow the upload of a number of pages beyond the limit.
- For free text forms, either type in the text directly into each box, or use a Word processor and then cut and paste each section into the corresponding box; the system allows plain text only.
- The status of each form is shown on the left: red cross for mandatory forms that are incomplete; yellow circle for not mandatory forms; green mark for completed forms. These same symbols are used in the "Check and Submit" section.
- The "Check and Submit" section can be accessed anytime in order to:
 - a) check and see whether each form has been correctly filled out; for mandatory forms that are incomplete, the information that must be provided is listed;
 - b) view and print the application in its incomplete/complete state. By clicking on "Create draft" and then on "Open submission draft" you can download the PDF draft generated by the system;
 - c) submit the application. Once all mandatory forms are complete, please click on "Submit". Be aware that after clicking on "Submit" it will not be possible to make any further modifications.
- The complete proposal is automatically assembled as a PDF file at the end of the online procedure. For full submissions: the PDF file will be available only after the document has been digitally signed by the applicant.

Applicants may designate a Grant Officer from the Hosting Institution to assist in the preparation and submission of the application. However, the applicant is fully responsible of the entire proposal content. See the "Head of the Hosting Lab" form for further details.

The application must be written entirely in English.

Applications that do not conform to all the requirements in these instructions will be rejected.

1. Applicant's personal data

Most fields are automatically filled out with information provided during the registration to the AIRC website; to modify the information in any of these fields, please click on "My profile" at the top of the page and edit the information from the popup window.

In the "Address" field, please indicate the postal address (home or workplace) where documents related to the fellowship can be mailed to.

2. Type of fellowship

In the upper part of the form: please enter the title of the research proposal; it must not exceed 120 characters, lowercase, spaces included.

In the lower part of the form, please select the fellowship you are applying to (only one can be chosen), making sure that all eligibility requirements indicated are met. Applications from researchers who do not meet the eligibility criteria will not be admitted to peer-review and will automatically be rejected.

3. Head of the hosting lab

Please fill in the requested fields with information on the head of the hosting lab (i.e. the person who will supervise and mentor the fellow) and on the Hosting Institution.

4. Legal representative

The Legal Representative ("Legale rappresentante") of the Hosting Institution will be responsible, along with the head of the hosting lab, of all the legal and administrative duties of the fellowship award.

Incoming and Reintegration Fellowships

The information regarding the Legal Representative is provided automatically by the system based on the Hosting Institution selected in the "Head of the hosting lab" section. In case the Director of a Department within the Hosting Institution is duly authorized to sign as Legal Representative of the Department, check the box: "By flagging this check box you are declaring that the Director of the Department is duly authorized to sign on behalf of the Legal Representative of the Institution". Please note that by flagging this box the applicant certifies that the Director of the Department has power of attorney. Please make sure that all data are correct and up-to-date, then click on "Save". If they aren't, please notify AIRC by e-mail (administrative.office@airc.it) and provide an official record (e.g. copy of Appointment Decree) as supporting documentation.

Outgoing Fellowships

Please fill out the requested fields with contact data of the Legal Representative of the Hosting Institution. Please make sure that all data are correct and up-to-date.

5. Head of the laboratory of origin

Please fill in the requested fields with information on the head of the laboratory of origin and the Institution of origin.

6. Letter of presentation

Please attach a letter of presentation by the head of the lab of origin. The letter must be in letterhead paper, dated and signed, must not exceed 1 page in length, and must be uploaded as PDF file.

In case the head of the lab of origin wants to maintain confidentiality, the applicant must select the "The letter of presentation will be sent by the deadline indicated in the Call" option. By the Call deadline the letter should be sent by e-mail to AIRC (airc.direzione-scientifica@airc.it), with the e-mail subject line "iCARE-2 Fellowships — Presentation letter_Surname of the applicant". A pending action "Waiting for reference letter" will remain visible in the personal area of the applicant until AIRC receives the letter. The AIRC Peer Review Office will then forward the letter to the reviewers assigned to the application.

If the letter of presentation is not included in the application, or if AIRC does not receive it by the deadline of this Call, the application will not be sent out for review.

7. Education of the applicant

In this section list all degrees the applicant holds or is enrolled in. While Master's degree ("laurea") is mandatory, doctoral degree and clinical training or specialization sections can be filled if applicable. Each applicant can add only one master degree, one PhD degree and one specialty.

Master's degree: click on "Add degree information" to enter the details of the degree obtained (*i.e.* the degree that formally allows one to enrol in a doctorate in the country where the degree was attained or in the country where the fellowship will take place; in Italy, this would be a "laurea magistralis" or a "laurea specialistica"). Fill in all the requested fields.

Doctoral degree: click on "Add PhD information" to enter the details of the degree. Fill in the requested fields. If you are enrolled in a PhD by the Call deadline, please indicate the expected date of PhD attainment.

Specialty: click on "Add Clinical Training or specialization information" to enter the pertinent details. If you are enrolled in a Specialty Program ("Scuola di Specialità") by the Call deadline, please indicate the expected date of the degree attainment.

The form automatically shows the information inserted in previous applications and stored in the "My Profile" section of your AIRC account. By selecting some or all of these records, they will be uploaded in the current application; please check that all information is present and up-to-date. A record can be modified or updated anytime by clicking on the "Degree" column and filling in the pop-up window.

Certificate of graduation

Please upload a copy, in PDF format, of the highest degree obtained. Please include a page with a description (and English translation, if necessary) of the certificate provided and of the score range (e.g. for Italian applicants uploading a certificate of "laurea magistralis", please explain that the final score or "voto di laurea" can go from 80 to 110, 110 being the best score. As an alternative to the above document, Italian candidates can upload the official Diploma Supplement). **Self-certifications will not be accepted**.

9. Applicant research and professional experience

Click on "Add new record" and list all position held by the applicant after the attainment of the highest degree (e.g. PhD) indicated in the "education of the applicant" section; use this section to list post-doctoral trainings. It is assumed that each entry refers to a full time position. To list part time positions, please contact AIRC (airc.direzione-scientifica@airc.it). Research interruptions will have to be justified in a different form, see point 13.

Additional courses of the applicant

In this non mandatory form, list up to 5 training events you participated (courses, workshops, ...). Click on "Add new record" to indicate the name of the course, the organizer (University/Research center, Country, City), field of research and time frame, then click on "Save".

Participation of the applicant to scientific conferences

In this non mandatory form, list up to 5 conferences attended by the applicant, with an active contribution (poster or oral presentation). Click on "Add new record" to indicate the name, the location (Country and city), the starting date of the conference and the title of the contribution. Select the type of contribution among poster and oral presentation, then click on "Save".

12. Awards of the applicant

In this non mandatory form, list up to 5 awards the applicant has been honoured with. Click on "Add new record" to indicate the name and the date of the award, and the name of the awarding body, then click on "Save".

13. Research interruptions and justifications

This section should be completed in case the applicant's research activity has been interrupted due to parental leave, children care, illness or other personal issues. Click on "Add new interruption" and fill out the requested fields.

This section allows applicants to report **prolonged periods of absence** from work that may have had a negative impact on their track record. Use this form to report interruptions due to refugee status. Reviewers are instructed to take this information into account when assessing the scientific productivity of an applicant.

14. Mobility check

This form is meant to summarize where the applicant has spent the 4 years previous to the call deadline. The data inserted in this section will be used to check if the applicant meets the mobility criteria listed in section 2 of this Call.

The system automatically shows the first and the last day of each period, starting from June 25, 2014 and ending on June 25, 2018 (submission deadline), in order to cover the last 4 years.

Please insert all the occupations held, without leaving any period unaccounted for; do not enter overlapping periods. For transition phases (e.g. in between positions), please indicate "Unemployed" in the Position field; do not include holidays. The system will automatically calculate how many days the applicant has spent in each country. Click on "Update" to submit each single entry.

For additional help with this form, please refer also to the video tutorial.

15. Publications of the applicant

Provide the list of papers published in the last 5 years (from January 2013 to 2018). Do not include poster abstracts, conference papers, book chapters and papers published in journals without Impact Factor (IF), unless they are new journals. To do so, a number of options is available; click on any that applies:

Add PubMed publications

Within this interface the system launches a PubMed search and provides a list of PubMed-recorded publications spanning from 2013 to 2018. Enter the Pl's first and middle initials, and click on "Find". If the applicant has published with a different last name than that used to register into the AIRC account (e.g. married vs maiden name), check the "Change surname" box, and then click on "Find". Alternatively, search for a specific article by entering its PubMedID in the corresponding box. Once the list of all PubMed publications has been generated, please follow these steps:

- a) Select papers to be included in the application: from the list of all PubMed publications, select the papers published by the applicant and that the applicant wants to include in the proposal by clicking on the box at the left side of each article. Pay special attention to potential homonyms.
- b) Indicate acknowledgement to AIRC: for each publication, please indicate whether it has an acknowledgement to AIRC by checking the box (the default is unchecked).
- c) Certify accuracy of flags, and save records: once all selected publications have been flagged, scroll down to the bottom of the page and check the certification box ("I, the undersigned, certify that all publications have been carefully checked and correctly flagged for authorship. I am aware that any mistake or inaccuracy may impact the evaluation of my track record"). The system automatically recognizes the position of the applicant in the list of authors in each publication and assigns it as first, middle or last author (if not, the box "not assignable" will be checked). It is possible to amend this information, if incorrect, by providing supporting documentation from the main page of the Publications (max 2 pages - see below). Click on "Add selected publications" and then on "Close" to complete the process.

Add Web of Science Core Collection publications

From this section it is possible to enter articles that are included in Web of Science Core Collection® but not in PubMed (most journals are present in both databases, but there are few exceptions; the drop-down menu does not list PubMed journals). For each record, please provide the title, list of authors, journal, year and month of publication, volume, pages. Select the journal from the drop-down menu, which provides all journals listed in Web of Science Core Collection®. Mark each paper for authorship and acknowledgement to AIRC. Please upload as a single PDF file (max 2 pages) the first page of the article and, in case the applicant is co-first/co-last/co-corresponding/corresponding author, the page of the article where the role of the author in the published work is certified. Make this information clearly visible by highlighting the name of the applicant. Finally, check the certification box and click on "Save" to complete the process.

Add papers in press

Use this section to submit articles already accepted for publication but not yet available online. For each record, please provide the title, list of authors, journal, year. Select the journal from the drop-down menu, which lists all Web of Science Core Collection® indexed journals. Mark each paper for authorship and acknowledgement to AIRC. Please upload the letter of acceptance from the journal and the page(s) of the manuscript that report the authorship of the applicant as a single PDF file (max 3 pages). Make this information clearly visible by highlighting the name of the applicant. Do not attach the entire manuscript. Finally, check the certification box and click on "Save" to complete the process.

Add from My Profile - Publications

This interface lists all publications previously entered into the system (either when submitting an application, or when submitting a grant renewal request, or directly into the publication section of the My Profile Area). By selecting some or all of these publications, they will be uploaded in the current application; please make sure the flags are correct.

All publications entered from any of the above sections will be listed in the "Publications" main page. From here, it is possible modify the authorship information relative to each paper by clicking on the title of the publication. For PubMed papers, once in the "Edit publication flags" window, please check the appropriate authorship box and, if different from the default provided by the system, upload a PDF file with the first page of the article and the page where the role of the author in the published work is certified (e.g. for a second or third author who is in fact a co-first author, the page where it is stated that the applicant "equally contributed to this work"). To complete the process, click on the certification box and click on "Save" to complete the process. For Web of Science Core Collection® publications and for papers in press simply check the correct authorship box, the certification box and then on "Save".

The applicant is responsible for uploading the most accurate information regarding publications and authorship. The IF assigned to each article, regardless of the publication date, is the latest provided by the Journal of Citation Reports (JCR) by Clarivate Analytics (previously the Intellectual Property and Science business of Thomson Reuters). For this Call, the 2016 JCR IF list will be used.

Candidates are required to check all the information and to contact the AIRC Peer Review Office (<u>airc.direzione-scientifica@airc.it</u>) before the deadline of the Call in order to correct any possible inaccuracy or mistake.

Papers accepted for publication after the Call deadline

In case additional papers are accepted for publication after the submission deadline, the applicant may ask the AIRC Peer Review Office to add this supplementary information to his/her application.

Please prepare a **single PDF file** containing a copy of the acceptance letter and a copy of the manuscript, and e-mail it to: airc.direzione-scientifica@airc.it

All communications made in this regard **by July 22 2018** (23:59 Central European Time) will be forwarded to all reviewers evaluating the proposal. Any communication received after July 22 2018 (23:59 Central European Time) will not be taken into consideration.

16. Personal Statement

Please write a brief statement in the following sections (max 250 words each)

- **Motivation and interest in a career in cancer**: applicants are invited to explain how their education and early experiences in a research lab have shaped their motivation and interest in pursuing a career in cancer research.
- Expected impact of the fellowship on the applicant's career: applicants are invited to explain how they will
 benefit from working in the selected hosting lab and why it represents the most suitable place to for their personal
 and professional development.

17. Project keywords

Project keywords will be used by the AIRC Peer Review Office to assign each application to the most appropriate reviewers. Therefore, a good choice of keywords is extremely important to ensure that reviewers with the most adequate expertise will evaluate the application. Avoid keywords that are too generic or too similar with each other; pick a set of keywords that clearly define the key aspects of your research plan. Keywords are listed here.

To enter the project keywords (at least 1, maximum 5) please click on the button "Enter/Edit Keywords". In the "Manage Project Keywords" pop-up window, keywords are grouped by their first letter: for example, by clicking on the letter "C" in the menu it is possible to visualize all keywords beginning with the letter C, and to select one. Alternatively, type in a specific keyword in the "Search a specific keyword" box and click on "Search". To select a keyword, click on it (the keyword box will turn from grey to blue) and then click on "Save". Repeat this process for each keyword. To exit the window, click on "Close". You will be automatically redirected in the main keywords page: click on "Save" at the bottom of this page to save the record.

18. Abstract and Proposal main body

Abstract

Abstract must be structured into the following sections: Background, Hypothesis, Aims, Experimental Design, Expected Results and Impact on Cancer. The total number of words must not exceed 500.

It must provide an immediate understanding as to why the research plan is proposed, which approach will be undertaken and the potential impact on cancer of the whole line of research. Avoid long introductions and do not include references. When all sections have been filled out, click on "Save". All sections will be assembled automatically into one page in the PDF file of the application.

Please note: the Abstract of all iCARE-2 fellowships funded may be made public on AIRC or European Union journals and websites.

Proposal main body

A single PDF file of max 6 pages (including figures and tables) must be uploaded. The text, agreed with the head of the hosting lab must be organized in the following sections:

- background (suggested length 1 page);
- proposal main body (suggested length 3 pages): The research project must have a clear relevance to cancer;
- feasibility (suggested length 1 page): This section can be used to provide: preliminary data, if not already included in the Proposal main body; statistical power calculation, if applicable; explanation on how relevant biological variables, such as sex, are factored into the research designs and analyses; description of key facilities or resources instrumental for the success of the research plan; discussion on pitfalls and caveats; etc.;
- references (suggested length 1 page): for any reference, give the title and list all authors. For articles with more than 6 authors, list the names of the first 6 authors, followed by "et al.". Example: Hanahan D, Weinberg RA. Hallmarks of cancer: the next generation. Cell 2011; 144:646-74. When available, we strongly encourage to include a paper identification code (PubMedID or doi). We recommend employing the format used by the journal Cancer Research (http://aacrjournals.org/content/authors/article-style-and-format):

Please make sure to propose a research plan that is consistent with the work of one person for the 3-year duration of the fellowship. Proposals that look like a 5-year grant requiring the work of several people will be judged not feasible and will be rated very low.

19. Letter of acceptance by the Hosting Institution

Please download the template available in this form and fill in the requested fields. Do not modify or delete any of the letter's sections. Once completed, upload the letter, on letterhead paper, signed by the head of the hosting lab (max 2 pages).

In the letter the head of the hosting lab MUST address the following points:

full employment contract: the head of the hosting lab confirms that the applicant will be offered an employment contract (or other direct contract with equivalent benefits, including social security coverage) in agreement to the

terms and conditions set forth in the "Declaration of conformity" (see Addendum A). Only in case the fellowship is awarded, the fellow and the Legal representative of the Hosting Institution will have to sign the Declaration and send AIRC a copy of such document;

- Hosting Institution: describe what the Hosting Institution will offer as research environment to the fellow (in terms of facilities, infrastructure, activities, internationality, and scientific environment);
- Lab space and research group composition: describe what the hosting lab will offer to the fellow;
- **Resources**: describe which resources (e.g. research grants held by the supervisor) are available to carry out the proposed research plan, for the entire duration of the fellowship;
- Mentoring activities and complementary skills training: describe the mentoring activities that the supervisor will organize specifically for the fellow (e.g. frequency of one-to-one meetings, lab meetings, participation to seminars and international congresses etc.) and the training in complementary skills the fellow will have access to (e.g. writing grants and papers, knowledge of ethical issues, research integrity, intellectual property rights, etc.);
- Freedom to publish: declare that the applicant will be free to publish as a first author, where appropriate, the results of the research carried out during the fellowship appointment; please note open access is mandatory for papers stemming from the research supported by an iCARE-2 fellowship;

Please note that this document is particularly important as it represents the major source of information for reviewers on the mentoring and training opportunities that the fellow will receive. As such, it will impact the assessment of the "Quality of the Hosting Institution", one of the major review criterion (see "The review process" above).

20. Education and training of the head of the hosting lab

Click on "Add new record" and list degrees and post-doctoral trainings of the head of the hosting lab (only the most relevant).

21. Research and professional experience of head of the hosting lab

Click on "Add new record" and list the most relevant positions held by the head of the hosting lab.

22. Experience of the head of the hosting lab as a research supervisor

Describe how many people (undergraduate and PhD students, post-doctoral fellows,...) the head of the hosting lab has supervised in his/her career (max 200 words). When appropriate, indicate how many of the former trainees have become independent scientists.

23. Publications of the head of the hosting lab

A list of maximum 10 selected publications of the head of the hosting lab, spanning January 2013 to 2018, must be included. Click on "Add publications" and follow the prompt.

Ethics Self-Assessment 24.

Please download the Ethics Self-Assessment template available in this form and fill in the requested fields. You must use a Word version compatible with the .docx format (Office 2007 or above). For each question you answer YES insert all information required (I) and describe how you will obtain the necessary documents (D). A facsimile of the template of the Ethics Self-Assessment is available in the Addendum C of this Call. Do not modify or delete any sections. Once completed, upload the form maintaining the word format (no page limit).

The completed questionnaire will be inserted in the PDF application.

You will be requested to obtain the required documents and provide them to AIRC only if the fellowship is funded and only before the beginning of the experiments arising ethical issues.

Please note that the compliance with ethics regulations will be carefully evaluated. Make sure to thoroughly address all the issues indicated in the template. A proposal may be rejected on ethical grounds; any proposal that contravenes fundamental ethical principles will not be selected.

25. Financial support

This is a "read-only" section.

The Living and mobility allowance is automatically calculated by the system based on the country where the Hosting Institution is located and entered in the "Head of the hosting lab" section of the application form, and is the product of the base rate of € 52.000/year multiplied by the correction coefficient of the country selected (see <u>Addendum B</u>). For countries with a correction coefficient lower than 0,8481 the Living and mobility allowance is € 44.100/year.

The Travel allowance indicated is the maximum allowed (€ 1.200).

The Research and dissemination cost contribution and the Training cost contribution are indicated as flat rate contribution of € 3.000/year and € 1.800/year, respectively.

26. AIRC Policy on Research Integrity

Please read the <u>AIRC policy on research integrity</u> and check the corresponding box. By signing the application the applicant and the Legal Representative of the Hosting Institution certify that they will comply with ethical principles of good scientific practice and engage in honest behaviour, as described in this policy.

27. FEA ("Firma Elettronica Avanzata")

This form applies only to candidates who hold an Italian tax code ("codice fiscale"). Applicant must sign the submitted application with the digital signature tool provided by AIRC: refer to the <u>FEA instructions</u> for details.

Proposal Submission

Proposal PDF draft

At any time during the application process a PDF draft file of the proposal can be generated and checked: go to "Check and Submit", click on "Create draft" and then on "Open submission draft".

Online submission

Applicants are advised not to leave submission to the last minute, as heavy server load might affect system performance. To submit the application, go to "Check and Submit" (on the lower left of the main page). All mandatory sections of the application form must be completed and must have a green flag before finalizing the submission.

Only after having ascertained that all data are correctly reported in the PDF Draft of the proposal, please proceed to proposal submission by clicking on "submit".

Applicants will receive a confirmation of the submission by e-mail. The final PDF file will be available in the "Your submissions archive" section of the Personal Area, and a copy should be saved for future reference.

Two documents will be generated and stored in the "Your submissions archive" section of the Personal Area:

- PDF file of the application: this is the document that will be sent to the reviewers.
- Publications addenda: contains the list of publications of the fellow (also present in the PDF file of the
 application) and supporting documentation for papers in press, Web of Science Core Collection® publications
 and authorship certifications.

A copy of the above documents should be saved for future references.

The application cannot be modified after the submission deadline.

The evaluation of the proposal is only based on the information present in the application.

Submission of digitally signed application

Both the applicant and the Legal Representative must digitally sign the submitted application:

Applicants: if the applicants hold an Italian tax code ("codice fiscale"), they must sign the application with the digital signature tool provided by AIRC: refer to the <u>FEA instructions</u> for details. If the applicants do not hold a tax code, they can use a digital signature of their choice or print the application and manually sign it.

Legal Representatives: legal representatives of an Italian Hosting Institution must use a certified digital signature. Legal representatives of a foreign Hosting Institution can use a digital signature of their choice.

The submitted proposal with the 2 signatures must be uploaded by the deadline indicated in the Calls.

Addendum A: Declaration of conformity (template)

This document must be signed ONLY in case the fellowship is awarded

DECLARATION OF CONFORMITY

OF THE AGREEMENT BETWEEN HOSTING INSTITUTION AND FELLOW WITH THE PROVISIONS SET FORTH FOR iCARE-2 FELLOWS (International Cancer Research Fellowships-2, iCARE-2 2018)

The undersigned (name of Legal representative) as Legal representative of (Hosting Institution) declares, for the recruitment of the Fellow, that an agreement has been entered into force between the:
(Hosting Institution)
and
(name of Fellow)
and the state of t

and that the terms and conditions of the award are in conformity with the provisions set forth in: the Call for Applications "International Cancer Research Fellowships-2, iCARE-2 2018"; the letter of award to the Fellow;

the Agreement between the Italian Association for Cancer Research (AIRC) and the Hosting Institution.

The undersigned declares that the above mentioned agreement consists of a **full employment contract** between the Hosting Institution and the Fellow, detailing all the following information:

- a) the conditions for implementing the research project "......." (title of application) and the respective rights and obligations of the Fellow and the Hosting Institution under the project;
- b) the name of the scientist supervising the research project activities (*i.e.* the head of the hosting lab) as well as a description (abstract) of these activities;
- c) the amounts that the Fellow is entitled to receive from the Hosting Institution and the arrangements for payment of the amounts due to the Fellow;
- any additional contribution paid to the Fellow by the Hosting Institution for the purpose of this project and the arrangements for payment of this amount;
- e) any amount deducted, subject to a legal justification;
- f) that the Fellow shall not be allowed to receive, for the activities carried out in the frame of the fellowship project, other incomes than those received from the Hosting Institution;
- g) the law applicable to the agreement;
- h) the social security coverage provided to the Fellow; the Hosting Institution must ensure that the Fellow is covered under the social security legislation, applicable according to Title II of Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004. Where the Fellow will carry out the research project activities in a non-EU Member State, each Hosting Institution shall ensure that the Fellow is covered under a social security scheme providing protection at least equivalent to those of local researchers holding a similar position;
- i) the provisions for annual and sickness leave according to the applicable law and the internal rules of the

Hosting Institution;

- j) that the Fellow must devote him/herself full-time to his/her research project;
- k) the description and the timetable for the implementation of the research project activities;
- I) the total duration, the nature and the date of entry into force of the agreement, provided that the working conditions are comparable to those applied to local researchers holding a similar position. The agreement must cover the entire duration of the fellowship award (2 years); it must be effective on the official start date of the fellowship; and it must be valid at least until the official termination date of the fellowship.
- m) the location(s) where the research project activities will take place;
- n) that the Fellow shall inform the Hosting Institution and AIRC as soon as possible of circumstances likely
 to have an effect on the research activity or the agreement, such as a pregnancy, or a sickness that may
 directly have an effect on the implementation of the project or the agreement;
- o) the arrangements between the Hosting Institution and the Fellow during and after the research project activities relating to intellectual property rights;
- p) that each publication, press release, patent or other documents or media communication citing results from the research carried out during the fellowship appointment must include the following sentence to acknowledge AIRC and the European Union: "This project has received funding from the European Union's Horizon 2020 research and innovation program under the Marie Skłodowska-Curie grant agreement No 800924".

The payment arrangements referred to in paragraph c) shall be based on the principle of monthly payments in arrears unless this is contrary to the applicable law mentioned in paragraphs g) and h).

Date:

Signature of Legal representative:

Date:

Signature of Fellow:

Addendum B: country correction coefficients

Incoming or Reintegration Fellowships
Italy 1,044

Outgoing Fellowships

Outgoing Fellowships		
Albania	0,653	*
Algeria	0,740	*
Angola	1,281	
Argentina	0,656	*
Armenia	0,754	*
Australia	1,044	
Austria	1,067	
Azerbaijan	0,883	
Bangladesh	0,611	*
Barbados	1,125	
Belarus	0,595	*
Belgium	1,000	
Belize	0,770	*
Benin	0,970	
Bermuda	1,515	
Bolivia	0,675	*
Bosnia and Herzegovina	0,690	*
Botswana	0,517	*
Brazil	0,979	_
Bulgaria	0,620	*
Burkina Faso	0,966	-
Burundi	0,742	*
Cabo Verde	0,742	*
Cambodia	0,717	*
Cameroon	0,743	-
Canada	0,900	-
Central African Republic	1.086	
	,	-
Chad Chile	1,178	*
	0,589	-
China	0,917	*
Colombia	0,779	*
Comoros	0,691	,
Congo (Democratic Republic of)	1,374	
Congo	1,206	*
Costa Rica	0,821	*
Côte d'Ivoire	0,983	
Croatia	0,839	*
Cuba	0,786	
Cyprus	0,827	*
Czechia	0,818	*
Denmark	1,350	
Djibouti	0,865	
Dominican Republic	0,629	*
Ecuador	0,755	*
Egypt	0,579	*
El Salvador	0,696	*
Eritrea	0,989	
Estonia	0,794	*
Ethiopia	0,851	
Faroe Islands	1,350	
Fiji	0,681	*
Finland	1,208	
France	1,157	
Gabon	1,078	
Gambia	0,690	*
	0,000	

Germany	0,970	
Ghana	0,641	*
Greece	0,887	*
Guatemala	0,826	*
Guinea	0,737	*
Guinea-Bissau	0,966	*
Guyana	0,622	*
Haiti	0,946	*
Honduras	0,734	*
Hong Kong	1,004	*
Hungary	0,774	*
Iceland	1,153	
India	0,634	*
Indonesia	0,698	*
Ireland	1,156	
Israel	1,061	
Italy	1,044	
Jamaica	0,920	
Japan	1,055	
Jordan	0,865	*
Kazakhstan	0,819	
Kenya	0,815	*
Korea (the Republic of)	0,976	
Kosovo, Republic of	0,655	*
Kyrgyzstan	0,803	*
Lao People's Democratic Republic	0,892	*
Latvia	0,777	*
Lebanon	0,863	*
Lesotho	0,483	*
Liberia	1,111	*
Libya	0,576	*
Liechtenstein	1,212	*
Lithuania	0,725	*
Luxembourg	1,000	*
Macedonia	0,600	*
Madagascar	0,860	
Malawi	0,680	*
Malaysia	0,688	*
Mali	0,944	*
Malta	0,844	*
Mauritania	0,625	*
Mauritius	0,744	*
Mexico	0,671	
Moldova	0,620	*
Montenegro	0,648	*
Morocco	0,754	*
Mozambique	0,715	
Myanmar	0,655	*
Namibia	0,614	*
Nepal	0,770	*
Netherlands (the)	1,079	_ _
New Caledonia	1,172	
New Zealand	0,994	
Nicaragua	0,565	*
Niger	0,848	*
Nigeria	0,926	

Norway	1,306	
Pakistan	0,519	*
Palestine, State of	1,108	
Panama	0,632	*
Papua New Guinea	1,015	
Paraguay	0,690	*
Peru	0,802	*
Philippines	0,734	*
Poland	0,755	*
Portugal	0,842	*
Romania	0,688	*
Russian Federation	1,054	
Rwanda	0,825	*
Samoa	0,830	*
Saudi Arabia	0,808	*
Senegal	0,947	-
Serbia	0,673	*
Sierra Leone	1,068	+
Singapore	1,130	
Slovakia	0,804	*
Slovenia	0,861	+
Solomon Islands		
	1,074	*
South Africa	0,508	
Spain	0,954	*
Sri Lanka	0,699	
Sudan	0,997	*
Suriname	0,560	*
Swaziland	0,535	*
Sweden	1,218	
Switzerland	1,212	
Syrian Arab Republic	0,772	*
Taiwan	0,827	*
Tajikistan	0,622	
Tanzania, United Republic of	0,654	*
Thailand	0,716	*
Timor-Leste	0,894	
Togo	0,844	*
Tonga	0,850	
Trinidad and Tobago	0,810	*
Tunisia	0,675	*
Turkey	0,821	*
Turkmenistan	0,634	*
Uganda	0,705	*
Ukraine	0,708	*
United Arab Emirates	0,915	
United Kingdom	1,398	
United States of America	0,991	
Uruguay	0,843	*
Uzbekistan	0,665	*
Vanuatu	1,080	
Venezuela	0,902	1
Viet Nam	0,533	*
Yemen	0,811	*
Zambia	0,774	*
Zimbabwe	0,774	+
ZITIDADWE	0,310	

Adapted from: http://ec.europa.eu/research/participants/data/ref/h2020/wp/2018-2020/main/h2020-wp1820-msca_en.pdf

0,753

To calculate the Living and mobility allowance, the base rate of € 52.000/year will be multiplied by the correction coefficient of the country where the Hosting Institution is located. Belgium and Luxembourg are the basis of the correction coefficient which is therefore always static at 1,000.

For Countries where the correction coefficient is not available, the European Commission will decide on a case-by-case basis.

^{*} indicates countries where the living and mobility allowance calculated as explained above is lower than the minimum set by the European Commission for COFUND Fellowship Programmes (€ 3.675/month). In these cases AIRC will give exactly € 44.100/year.

Addendum C: Facsimile of the Ethic Self-Assessment template

Ethics Self-Assessment

This form is adapted from the H**2020** Programme "Guidance How to complete your ethics self-assessment". Select YES or NO after each question.

For each question you answered YES insert all information required (I) and describe how you will obtain the necessary documents (D), as described in *italic*.

This document has no page limit.

1. HUMAN EMBRYOS/FOETUSES

1.1. Does your research involve Human Embryonic Stem Cells (hESCs)? Choose YES/NO

If YES:

1.1.1. Will they be directly derived from embryos within this project?

Choose YES/NO

I: Research not eligible for funding.

1.1.2. Are they previously established cells lines?

Choose YES/NO

- **I:** Origin and line of cells. Details of licensing and control measures by the competent authorities of the Member States involved.
- **D:** Copies of Ethics Approval. A statement that the human embryonic stem cell lines used in the project are registered in the European hESC registry (www.hescreg.eu) both for hESCs and human-induced pluripotent stem cell (hiPSC) lines. A statement confirming that the **6** specific conditions (see below) for research activities involving human embryonic stem cells are met.
- **1.2.** Does your research involve the use of human embryos?

Choose YES/NO

- **I:** Origin of embryos. Details on recruitment, inclusion and exclusion criteria and informed consent procedures. Confirm that informed consent has been obtained.
- **D**: Copies of ethics approval. Informed Consent Forms + Information Sheets.

If YES:

1.2.1. Will the research lead to their destruction?

Choose YES/NO

I: Research not eligible for funding.

1.3. Does your research involve the use of human foetal tissues / cells?

Choose YES/NO

- *I:* Origin of human foetal tissues/cells. Details on informed consent procedures. Confirm that informed consent has been obtained.
- D: Copies of ethics approval. Informed Consent Forms + Information Sheets.

If you answered YES to any of the questions in this section, your application is not eligible.

2. HUMANS

2.1. Does your research involve human participants?

Choose YES/NO

- 1: Confirm that informed consent has been obtained.
- D: Informed Consent Forms + Information Sheets. plus:

If YES:

2.1.1. Are they volunteers for social or human sciences research?

Choose YES/NO

- I: Details of recruitment, inclusion and exclusion criteria and informed consent procedures.
- **D**: Copies of ethics approvals (if required).
- **2.1.2**. Are they persons unable to give informed consent?

Choose YES/NO

- I: Details of your procedures for obtaining approval from the guardian/legal representative and the agreement of the children or other minors. What steps will you take to ensure that participants are not subjected to any form of coercion?
- D: Copies of ethics approvals.

2.1.3. Are they vulnerable individuals or groups?

Choose YES/NO

I: Details of the type of vulnerability. Provide details of recruitment, inclusion and exclusion criteria and informed consent procedures. These must demonstrate appropriate efforts to ensure fully informed understanding of the implications of participation.

D: Copies of ethics approvals.

2.1.4. Are they children/minors?

Choose YES/NO

I: Details of the age range. What are your assent procedures and parental consent for children and other minors? What steps will you take to ensure the welfare of the child or other minor? What justification is there for involving minors?

D: Copies of ethics approvals.

2.1.5. Are they patients?

Choose YES/NO

I: What disease/condition /disability do they have? Details of recruitment, inclusion and exclusion criteria and informed consent procedures. What is your policy on incidental findings?

D: Copies of ethics approvals.

2.1.6. Are they healthy volunteers for medical studies?

Choose YES/NO

D: Copies of ethics approvals.

2.2. Does your research involve physical interventions on the study participants?

Choose YES/NO

If YES:

2.2.1. Does it involve invasive techniques (e.g. collection of human cells or tissues, surgical or medical interventions, invasive studies on the brain, TMS etc.)?

Choose YES/NO

I: Provide the risk assessment for each technique and overall.

D: Copies of ethics approvals.

2.2.2. Does it involve collection of biological samples?

Choose YES/NO

I: What type of samples will be collected? What are your procedures for collecting biological samples?

D: Copies of ethics approvals.

3. HUMAN CELLS / TISSUES

3.1. Does your research involve human cells or tissues (other than from Human Choose YES/NO Embryos/Foetuses, i.e. section 1)?

I: Details of the cells or tissue types.

D: Copies of relevant ethics approvals. Copies of accreditation /designation/authorisation/ licensing for using, processing or collecting the human cells or tissues (if required), plus:

If YES:

3.1.1. Are they available commercially?

Choose YES/NO

I:Details of provider (company or other).

D: Copies of import licences (if relevant).

3.1.2. Are they obtained within this project?

Choose YES/NO

I: Details of the source of the material, the amount to be collected and the procedure for collection. Details of the duration of storage and what you will do with the material at the end of the research. Confirm that informed consent has been obtained.

D: Informed Consent Forms + Information Sheets.

3.1.3. Are they obtained from another project, laboratory or institution?

Choose YES/NO

- I: Country where the material is stored. Details of the legislation under which material is stored. How long will the material be stored and what will you do with it at the end of the research project? Name of the laboratory/institution. Country where the laboratory/institution is located. Confirm that material is fully anonymised or that consent for secondary use has been obtained.
- D: Copies of import licences (if relevant). Statement of laboratory/institution that informed consent has been obtained.

3.1.4. Are they obtained from biobank?

Choose YES/NO

- I: Name of the biobank. Country where the biobank is located. Details of the legislation under which material is stored. Confirm that material is fully anonymised or that consent for secondary use has been obtained.
- D: Copies of import licences (if relevant). Statement of biobank that informed consent has been obtained.

4. PERSONAL DATA

4.1. Does your research involve personal data collection and/or processing?

Choose YES/NO

- I: Details of your procedures for data collection, storage, protection, retention, transfer, destruction or re-use (including, collection methodology (digital recording, picture, etc.), methods of storage and exchange (LAN, cloud, etc.), data structure and preservation (encryption, anonymisation, etc.), data-merging or exchange plan, commercial exploitation of data sets, etc.). Details of your data safety procedures (protective measures to avoid unforeseen usage or disclosure, including mosaic effect, i.e. obtaining identification by merging multiple sources). Confirm that informed consent has been obtained. Details of data transfers to non-EU countries (type of data transferred and country to which it is transferred).
- D: Copies of notifications/authorisations for collecting and/or processing the personal data (if required). Informed Consent Forms + Information Sheets + Other consent documents (opt-in processes, etc.) (if relevant). Copy of authorisation for data transfer to non-EU country (if required)

If YES:

4.1.1. Does it involve the collection and/or processing of sensitive personal data (e.g: health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?

Choose YES/NO

- **D**: Copy of notification/authorisation for processing sensitive data (if required)
- **4.1.2.** Does it involve processing of genetic information?

Choose YES/NO

4.1.3. Does it involve tracking or observation of participants (e.g. surveillance or localization data, and Wan data, such as IP address, MACs, cookies etc.)?

Choose YES/NO

- 1: Details of methods used for tracking or observing participants.
- **D**: Copy of notification/authorisation for tracking or observation (if required).
- Choose YES/NO **4.2.** Does your research involve further processing of previously collected personal data (secondary use)?
- I: Details on the database used or of the source of the data. Details of your procedures for data processing. Details of your data safety procedures (protective measures to avoid unforeseen, usage or disclosure, including mosaic effect, i.e. obtaining identification by merging multiple sources). Confirm that data is openly and publicly accessible or that consent for secondary use has been obtained (and details of how this consent was obtained (automatic opt-in, etc.)). Confirm permissions by the owner/manager of the data sets.
- D: Evidence of open public access (e.g. print screen from website). Informed Consent Forms + Information Sheets + other consent documents (opt in processes, etc.). Copies of permissions (if required).

5. ANIMALS

5.1. Does your research involve animals?

Choose YES/NO

I: Details of species and rationale for their use, numbers of animals to be used, nature of the experiments, procedures and techniques to be used. Justification of animal use (including the kind of animals to be used) and why alternatives cannot be used. plus:

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5.1.1. Are they vertebrates?

Choose YES/NO Choose YES/NO

5.1.2. Are they non-human primates (NHP) (e.g. monkeys, chimpanzees, gorillas, etc.)?

I: Why are NHPs the only research subjects suitable for achieving your scientific objectives? Explain. What is the purpose of the animal testing? Give details. Where do the animals come from? Give details.

D: Personal history file of NHP.

5.1.3. Are they genetically modified?

Choose YES/NO

I: Details of the phenotype and any inherent suffering expected. What scientific justification is there for producing such animals? Give details. What measures will you take to minimise suffering in breeding, maintaining the colony and using the GM animals? Give details.

D: Copies of GMO authorisations.

5.1.4. Are they cloned farm animals?

Choose YES/NO

I: Details of the phenotype and any inherent suffering expected. What scientific justification is there for producing such animals? Give details. What measures will you take to minimise suffering in breeding, maintaining the colony and using of the GM animals? Give details.

D: Copies of authorisations for cloning (if required).

5.1.5. Are they endangered species?

Choose YES/NO

I: Why is there no alternative to using this species? Give details. What is the purpose of the research? Give details.

D: Copies of authorisations for supply of endangered animal species (including CITES).

6. THIRD COUNTRIES

- 6.1. In case non-EU countries are involved, do the research related activities undertaken Choose YES/NO in these countries raise potential ethics issues?
- I: Specify the countries involved. Provide risk-benefit analysis. What activities are carried out in non-EU countries? Give details.
- D: Copies of ethics approvals and other authorisations or notifications (if required). Confirmation that the activity could have been legally carried out in an EU country (for instance, by submitting an opinion from an appropriate ethics structure in an EU country).
- **6.2.** Do you plan to use local resources (e.g. animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples, etc.)?

Choose YES/NO

- **I:** What type of local resources will be used and how exactly? Give details.
- D: For human resources: copies of ethics approvals. For animals, plants, micro-organisms and associated traditional knowledge: documentation demonstrating compliance with the UN Convention on Biological Diversity (e.g. access permit and benefit sharing agreement)
- **6.3.** Do you plan to import any material including personal data from non-EU countries Choose YES/NO into the EU? (for data import see section 4, for imports of human cells or tissues see section 3)
- I: What type of materials will you import? Give details. Specify material and countries involved.
- D: Copies of import licences.
- Choose YES/NO 6.4. Do you plan to export any material - including personal data - from the EU to non-EU countries? (For data exports, see section 4)
- I: Details of type of materials to be exported. Specify material and countries involved.
- D: Copies of export licences.
- **6.5.** In case your research involves low and/or lower middle income countries, are any Choose YES/NO benefits-sharing actions planned?
- I: Details of benefit sharing measures. Details of responsiveness to local research needs. Details of procedures to facilitate effective capacity building.

- **6.6.** Could the situation in the country put the individuals taking part in the research at Choose YES/NO risk?
- I: Details of safety measures you intend to take, including training for staff and insurance cover.

7. ENVIRONMENT & HEALTH and SAFETY

- **7.1.** Does your research involve the use of elements that may cause harm to the environment, to animals or plants? (For research involving animal experiments, see section **5**)
- **I:** Risk-benefit analysis. Show how you apply the precautionary principle (if relevant). What safety measures will you take? Give details.
- **D**: Safety classification of laboratory. Copy of GMO and other authorisations (if required).
- **7.2.** Does your research deal with endangered fauna and/or flora and/or protected areas? Choose YES/NO **D:** Specific authorisations (if required).
- **7.3**. Does your research involve the use of elements that may cause harm to humans, Choose YES/NO including research staff?
- I: Details of health and safety procedures you intend to apply.
- D: Safety classification of laboratory.

8. DUAL USE Page

- **8.1.** Does this research involve dual-use items in the sense of Regulation **428/2009**, or Choose YES/NO other items for which an authorisation is required?
- **I:** What goods and information used and produced in your research will need export licences? How exactly will you ensure compliance? How exactly will you avoid negative implications?
- **D**: Copies of export licences.

If you answered YES to any of the questions in this section, your application is not eligible.

9. EXCLUSIVE FOCUS ON CIVIL APPLICATIONS

- **9.1.** Could your research raise concerns regarding the exclusive focus on civil Choose YES/NO applications?
- *I:* Explain the exclusive civilian focus of your research. Justify inclusion of military partners or military technologies (i.e. explain how they relate to civilian applications, e.g. in the context of law enforcement activities).

If you answered YES to any of the questions in this section, your application is not eligible.

10. MISUSE Page

10.1. Does your research have a potential for misuse of research results?

Choose YES/NO

- *I:* Risk-assessment. plus: Details of the applicable legal requirements. Details of the measures you plan to take to prevent misuse.
- **D**: Copies of authorisations (if required). Copies of security clearances (if applicable). Copies of ethics approvals (if applicable).

If you answered YES to any of the questions in this section, your application is not eligible.

11. OTHER ETHICS ISSUES

11.1. Are there any other ethics issues that should be taken into consideration?

Choose YES/NO

I: Please specify and provide any additional information

D: Any relevant document.