International Agency for Research on Cancer

World Health Organization

IARC ETHICS QUESTIONNAIRE

This form should be completed by the IARC Principal Investigator for all applications.

The questionnaire is divided into 8 sections:

A. Description of project
B. Enrollment of participants
C. Interaction with participants
D. Informed consent
E. Confidentiality
F. Scientific management of project
G. Financial management of project
H. Ethical issues

Please answer all questions unless directed to move on to the next section. If you consider some of these are not relevant to your study, answer N/A.

Title of Research:

Acronym

IARC Principal Investigator

IARC Section/Group

Section A. Description of project

Please answer all questions in this section

A1. Type of project:

Select study type

If other, give details:

A2. Proposed study dates and duration:

Start date: End date:

Duration: Years: Months:

A3. What is the principal research question / objectives? (Must be in language comprehensible to a lay person – up to 250 words):

Section B. Enrollment of participants

Has the enrollment of participants in the study been previously approved by the IARC Ethics Committee (IEC)?

☐ **No** *If no, fill in section B*

☐ **Yes** *If yes, provide reference of previous approval and go to section C*

B1. How will potential research participants in the study be (i) identified, (ii) approached and (iii) recruited? What are the principal inclusion and exclusion criteria?

Give details for controls separately if appropriate.

B2. Will individual research participants receive any *payments* for taking part in this research?

☐ **No**

☐ **Yes** *If yes, indicate how much and on what basis this has been decided:*

B3. Will individual research participants receive *reimbursement of expenses* or any other *incentives or benefits* for taking part in this research?

☐ **No**

☐ **Yes** *If yes, indicate how much and on what basis this has been decided:*

B4. Will any research participants be recruited who are involved in existing research or have recently been involved in any research prior to recruitment?

☐ **Not known**

☐ **No**

☐ **Yes** *If yes, give details and justify their inclusion*

Section C. Interaction with participants

Has all interaction with study participants, including interviews, examinations and interventions, been previously approved by the IARC Ethics Committee (IEC)?

☐ **No** *If no, fill in section C*

☐ **Yes** *If yes, provide reference of previous approval and go to section D*

C1. Provide practical details of all interaction with study participants. It should be clear what happens to each research participant, how many times and in what order (up to 250 words):

C2. Will the research participants receive any clinical procedure including taking samples of human biological material different from routine clinical care?

☐ **No**

☐ **Yes** *If yes, provide details below, comparing research procedures with routine care*

Type of procedure	Average number per patient		Average time taken (mins/hrs/days)	Details of type of procedure and who will undertake it
	Routine care	Research		

C3. Will research participants be subject to any non-clinical research-related procedures (for example, administration of questionnaires)?

☐ **No**

☐ **Yes** *If yes, provide details below, comparing research procedures with routine care*

Type of procedure	Average number per patient	Average time taken (mins/hrs/days)	Details of type of procedure and who will undertake it

Add more details on a separate sheet if necessary.

C4. Will any interview with participants discuss any topics or issues that might be sensitive, embarrassing or upsetting?

☐ **No**

☐ **Yes** *If yes, give details of procedures in place to deal with these issues*

C5. What is the potential for pain, discomfort, distress, or inconvenience for research participants?

C6. What is the potential for adverse effects, risks, discomfort, distress or inconvenience to the researchers, technicians and nurses involved?

C7. Will the research participants receive any medical or lifestyle intervention, or randomized allocation of clinical care?

☐ **No** *If no, go to section D*

☐ **Yes** *If yes,answer questions C8 - C9*

C8. What arrangements have been made to provide indemnity and/or compensation in the event of a claim by, or on behalf of, participants for *non-negligent* harm?

C9. What are the potential adverse effects, risks or hazards for research participants either from giving or withholding medications, medical devices, ionizing radiation or from changes to lifestyle or any other interventions including non-clinical?

Section D. Participant consent

Informed and voluntary consent should generally be sought from the persons involved. They should be informed about the purpose and nature of the study, what participation requires them to do and to risk, and what benefits are intended to result from the study. The information to the participants should include a description of how you are going to handle such communication.

Please answer all the questions in this section.

D1. Will a signed record of informed consent be obtained from research participants?

☐ **Yes** *If yes, please provide copies. Give details of how it will be done and who will do it.*

☐ **No** *If no, please justify*

D2. How long will the participants have to decide whether to take part in the research?

D3. What arrangements have been made for participants who might not adequately understand verbal or written information in the local language? *(e.g. translation, use of interpreters, etc.)*

D4. Describe and justify the inclusion of vulnerable groups: children, the elderly, those unable to consent because of mental incapacity:

Section E. Data and specimen handling

Please answer all the questions in this section

E1. Will the research involve any of the following activities at any stage (including identification of potential research participants)? *Tick as appropriate:*

- ☐ Examination of medical records by those who would not normally have access
- ☐ Electronic transfer by magnetic or optical media, e-mail or computer
- ☐ Sharing of data with other organizations
- ☐ Export of data
- ☐ Use of personal addresses, postcodes, faxes, e-mails or telephone numbers
- ☐ Publication of direct quotations from respondents
- ☐ Publication of data that might allow identification of individuals
- ☐ Use of audio/visual recording devices

Storage of personal data which allows identification of any of the following:

- ☐ Manual files including X-rays
- ☐ Local study centre
- ☐ IARC computer

Further details:

E2. What measures will be put in place to ensure confidentiality of personal data? Give details of whether any encryption or other anonymisation procedures will be used, and at what stage:

E3. Who will store and have control of the data generated by the study?

E4. Where will the analysis of the data from the study take place and by whom will it be undertaken?

E5. Who will have access to the data generated by the study?

E6. For how long will the data be stored?

☐ **Permanently**

☐ **For a fixed duration of**

Give details of where they will be stored, who will have access, and of the custodial arrangements for the data:

E7. Explain measures for specimen storage, transport and processing:

Include details of (i) where will the specimens be stored and for how long, (ii) who will have access to these samples, (iii) will identification of individuals be feasible:

Section F Scientific management of project

Please answer all of the questions in this section

F1. Please list all partner institutions where the research will take place and indicate their tasks. Give contact details of the main investigator in each centre. For new partners, please provide their website address (continue on separate sheet if necessary):

Name and address of institution	Main investigator and role

F2. Has any responsibility for the research been delegated to a subcontractor?

☐ **No**

☐ **Yes**

If yes, give details including name of research contract organization/site management organization and summary of delegated responsibility

F3. How has the scientific quality of the research been assessed? *(Tick as appropriate):*

☐ During grant application submission

☐ Independent external review

☐ Review within a multi-centre research group

☐ Internal review (e.g. involving colleagues, academic supervisor)

☐ None external to the investigator

☐ Other

If other, give details

If you are not in possession of any referees' or other scientific critique reports relevant to your proposed study, justify and describe the review process and outcome. If review has been undertaken but not seen by the researcher, give the details of the body which has undertaken the review:

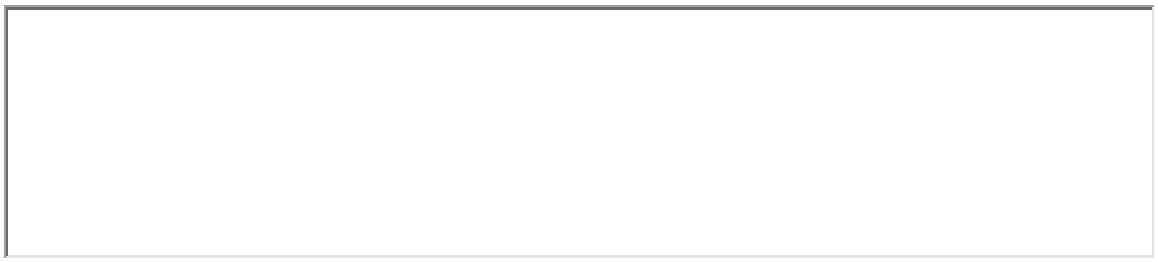
A copy of any referees' comments or other scientific critique reports relevant to the proposed research must be enclosed with the application form.

F4. What arrangements are in place for monitoring and auditing the conduct of the research?

F5. How will the results of the study be reported and disseminated?

- ☐ Peer reviewed scientific journals
- ☐ Internal report
- ☐ Conference presentation
- ☐ Other publication
- ☐ Submission to regulatory authorities
- ☐ Written feedback to research participants
- ☐ Presentation to participants or relevant community groups
- ☐ Access to raw data and right to publish freely by all investigators in study or by independent Steering Committee on behalf of all investigators

If other/none of the above, give details and justify:



Section G. Financial management of project

Please answer all the questions in this section

G1. How will the project be funded?

☐ **By IARC**

☐ **External funding**

If external funding, please give details of funding organization(s), amount and duration of funding below:

Organization	
Address	
Postcode	
IARC contact	
Telephone	
e-mail	
Fax	
Amount €	
Duration (months)	

Organization	
Address	
Postcode	
IARC contact	
Telephone	
e-mail	
Fax	
Amount €	
Duration (months)	

G2. Will external researchers, receive any personal payment over and above normal salary for undertaking this research?

☐ **No**

☐ **Yes** *If yes, indicate how much and on what basis this has been decided*

G3. Will the host organisation or the researcher's department(s) or institution(s) receive any payment or benefits in excess of the costs of undertaking the research?

☐ **No**

☐ **Yes** *If yes, give details*

Section H. Ethical issues

Please answer all the questions in this section

H1. Has local ethics approval been requested from all the partner institutions listed in question F1? If yes, what was the outcome? (Attach copies) If no, please indicate if it will be requested and if not, explain why:

H2. What is the potential for benefit for research participants and the community as a whole?

H3. What do you consider to be the main ethical issues or problems which may arise with the proposed study, and what steps will be taken to address these?

Please attach, as appropriate:

- ☐ **The participant information sheet**
- ☐ **The consent form**
- ☐ **The questionnaire**
- ☐ **The protocol**
- ☐ **Any advertising material**
- ☐ **Any other relevant documents**

Date ……

Signature of Principal Investigator ……

Signature of Group Head ……

Signature of Section Head ……

Responsible Unit IEC/DIR
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