ETHICS ADVISORY GROUP

**2013**

**APPLICATION FORM FOR STUDIES ON HUMAN PARTICIPANTS**

**(Excluding studies on existing records or data For these studies please use the specific application form)**

**Studies that require review by The Union Ethics Advisory Group** are those in which The Union and its staff members are involved in any of the following capacities:

**Principal investigator Named collaborator**

**Sponsor or funder Intended co-author**

***Applications and accompanying documents should be sent to the Ethics Advisory Group at:* eag@theunion.org  *In cases of doubt, the Chairperson should be consulted at this address.***

**Documents required (in electronic format):**

* **Completed EAG Application form**
* **Study proposal**
* **Short summary of the CV of principal investigator**
* **Local Ethics approval certificate(s) See below\***
* **Questionnaires, interview forms, details of investigative procedures or laboratory tests to be used and all data sheets**
* **Participant information sheet\*\* In a separate file not attached to the proposal, together with the consent form**
* **Participant consent form \*\***

***\*\*Requirements for the information sheet and consent form are provided on theEAG website***

**\*Local ethics committee approval**

For **intervention** studies, the appropriate local ethics approval certificate must be obtained **before** application to the EAG and a copy sent with the EAG application. For all other studies, EAG approval may be sought before local ethics approval is obtained. Any EAG comments or requests for changes will be sent directly to the relevant local ethics committees. EAG approval is given conditional on a copy of the local ethics approval certificate once this is available. This must be forwarded to the EAG.

**Protocol modification**

Should the protocol be modified after ethical approval is given, the EAG must be advised of the modifications. Please see the requirements and the form on the Union website under EAG “Modifications or extensions to previously approved applications”.

**Progress report**

A Progress report must be provided for all studies on human participants that are not completed within 12 months of EAG approval. This does not apply to studies of existing records.

**Serious Adverse Events (SAEs) in studies previously approved by the EAG:**

 SAEs must be reported to the EAG if there is no DSMB. When a DSMB exists, their report must be sent to the EAG.

# **STUDY TITLE AND MANAGEMENT**

*Please type inside the boxes which expand with the text*

## **Study Title:**

## **Study Site(s):**

##  **Principal Investigator**

##  **Name:**

##

## **Position:**

##

##  **Institution where employed:**

##

## **Full address:**

##

##  **Email address:**

## **Union staff member** associated with the study (if not the P.I.)

##  **Name:**

##

## **Full Address:**

##  **Email address:**

## **Research partners (Institutions):**

##  **Source of Funds/Grants:**

**Funding conditions:** If there are any conditions attached to funding that may influence the protocol, conduct of the research or reporting of results, please explain here:

Is there any potential **CONFLICT OF INTEREST** between members of the research team or their employing institution and the funding agency? *(A potential conflict of interest might arise from various relationships, past or present, including employment, consultancy, investments and stock ownership, funding for research, family, relationship, etc.)* **Yes / No** *If yes, please explain:*

## **Insurance**

 Is indemnity insurance in place (insurance should a research subject make a financial claim
 for damages incurred from participating)?  **Yes / No** *If not, why not needed:*

##

## **SignaturesPrincipal Investigator: SIGNATURE ………………………………………….Date ………………….**

## **Head of Institution under which study will be done**

##

## **NAME……………………………………..:……. POSITION …………………………………………**

##

## **SIGNATURE …………………………………………………………….. Date ……………………………..**

## **Union staff member involved (if not the PI)**

##

##

## **SIGNATURE …………………………………………………………… Date …………………………………..**

# **DETAILS OF STUDY**

## **Research Plan**

 **Aims and objectives**

 **Study duration**

 **Expected benefits from results for participants and the local and general populations:**

1. **Summary**

Please write a short summary of the intended study **(not more than 8 lines)**

1. **Selection of Participants**

**Study population**

Please state who will be studied.

If children are to be studied, please state age range

If controls are to be used, please explain how they will be selected

**Sampling Method: (Brief outline)**

**Expected number of participants ……………………**

**Exclusion criteria:**

## **Vulnerable Groups**

The study may include vulnerable groups, but we need to know if any of those listed below are to be **SPECIFICALLY selected**. If so, please mark any of the listed groups with a X

**Children Economically disadvantaged**

**Educationally disadvantaged / illiterate Employees**

**Homeless Life-threatening /seriously debilitating conditions**

**Mentally disabled Non-native language speakers**

**Residents of nursing homes/chronic care facilities Physically impaired**

**Pregnant women Prisoners**

**Students Substance dependent**

**Wards of state Other – state …………………………….**

For any marked blocks, please explain what precautions will be taken to protect each of the identified vulnerable group(s):

## **Information for Study Participants**

Attach a copy of the participant Information document **Please consult recommended information form on The Union website**

**How will the information be given to the potential participant?**(e.g., verbally, in writing, or both, and in what language)

**Who will give it?** (category of person)

1. **Consent from Participants *Attach a copy of the participant consent form and an assent form if children are to be studied.***

Please outline how consent will be obtained from potential participants, with special attention to consent from vulnerable groups and minors, if these are to be studied. (Please consult recommended consent form on Union EAG website)

1. **Study Procedures
7.1 Mark research procedure(s) that will be used:**

**Record review [ ]**

**Observation [ ]**

**Interview (interview format must be attached) [ ]**

**Self-administered questionnaire (must be attached) [ ]**

**Focus group discussion guide (must be attached) [ ]**

**Physical Examination [ ]** (state below the nature and frequency of examinations)

 **Drug or other substance administration [ ]** (below state name, dose and frequency of administration)

 **Sputum sampling; [ ]** (state below the frequency of sampling)

 **Radiographs** **[ ]**

 **Blood sampling; [ ]** (state below the amount to be taken and the frequency of sampling)

 **Isotope administration [ ]**  (below state name, dose, and frequency)

 **Biopsy [ ]**

**Audio recordings or photographs or videos See below\* [ ]**

 **Other procedures (say what and explain in box below)** **[ ]**

 For other procedures marked here, elaborate as necessary here:

\* Please note that specific consent must be obtained for audio or video recordings or for photographs. This applies to interviews/discussions and any other procedures

7.2 Who will perform the procedures (categories and numbers of researcher). If researchers other than the PI, explain how they will be trained?

7.3 Where will the procedures be performed?

1. Referral for Health Care For Study Participants

How will health problems identified in study participants including controls be managed?

1. **Potential Risks for Study Participants** Place X in appropriate boxes (double click and mark “checked”)

**[ ]  Physical discomfort**

**[ ]** **Pain**

**[ ]  Side effects from agents used**

**[ ]  Possible complications** (Pls. Specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

**[ ]  Breach of confidentiality**

**[ ]  Stigmatisation**

**[ ]  Psychological stress**

**[ ]  Drug resistance**

**[ ]  Death**

**[ ]  Infection of third parties**

**[ ]  Other** (Pls. Specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

**[ ]  No risk**

If any boxes other than "No risk", have been checked, please provide details—including what is known about frequency and severity and the precautions to be taken to control risks:

##  **Payments**

State any payments that will be offered to participants including compensation for loss of earnings, re-imbursement of travelling, medical care and other expenses:

##  **Confidentiality**

11.1 Will names or any other identifying characteristics of study participants be collected?

 **Yes / No**

11.2 If names will be collected (Yes to 11.1), please explain how confidentiality will be maintained so that participants cannot be individually identified?

 11.3 If names are not collected (No to 11.1), are there other possible means of identifying study participants? For example, are study numbers small or are individuals’addresses recorded or facilities named? **Yes / No**

 11.4 If yes to 11.3 ( there are other identifying records), explain how confidentiality will be maintained:

11.5 State where data will be stored and who will have access to study data?

 11.6 Will researchers who collect data or who have access to data sign a confidentiality agreement?

 If no confidentiality agreement, please explain how confidentiality will be ensured

## **12. Communication of Study Results**

Describe how results will be made available and to whom. (Some examples: study participants, their communities, health care managers, government agencies, scientific publications)

 Please explain how study participants and their communities will be informed of results

## **13. National/Local Research Ethics Committees**

## 13.1 Does a country or regional or institutional ethics committee exist? **Yes/No**

13.2 If yes, please provide name of the committee, and name and email address of the committee Chairperson or secretary

11.3 Give the results of the submission: (mark appropriate square with X)

Approved (attach copy)

Submitted, awaiting result \*

Not submitted (give reason)

\* If the result is not available at the time of this application, the EAG requires the applicant to send this to the EAG when available. EAG approval is provisional until proof of national or local ethics committee approval is sent to the EAG by investigators.

## **14. Co-Authorship**

Who will be included as co-authors of papers reporting this study? Please name and list their affiliations:

 **15. Risks for Research Staff**

 15.1 Describe any procedures undertaken before field work begins to assess risks for staff involved with the project:

 15.2 Describe how risks for staff will be managed:

## **16. Healthcare for study participants**

 Are medically qualified person(s) and facilities available for care of study participants should this be needed?

 **Yes / No**

 If no, please explain how necessary health care is provided for study participants:

**17. Serious Adverse Events (**For Studies involving clinical studies on research participants**)**

 A serious adverse event related toa drug is defined as "any untoward medical occurrence that at any dose,results in death, or is life-threatening, or requires hospitalizationor prolongation of treatment

17.1 State any known possible SAEs that may result from study procedures:

17.2 Does a data safety and monitoring committee (DSMC) exist for this study?

 **Yes / No**

17.3 In the event of SAEs, these must be reported to the EAG if there is no DSMC

 If there is a DSMC, please send a copy of their report to the EAG

## **18. Storage of Specimens**

Is there is any intention to store any specimens for further testing?

 **Yes / No**

 If yes, how will informed consent for storage be obtained from study participants?

## **19. Regulatory Approval for clinical trials**

Please provide details of any national regulatory approval required for clinical trials and how this was obtained: