ETHICS ADVISORY GROUP

**2013**

**APPLICATION FORM FOR STUDIES OF EXISTING RECORDS OR ON DATA ALREADY COLLECTED**

**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:

* **Intended co-author**
* **Principal investigator**
* **Named collaborator**
* **Sponsor or funder**

**In cases of doubt, the Chairperson should be consulted.**

**Applications and accompanying documents should be sent to the Ethics Advisory Group at:** [**eag@theunion.org**](mailto:eag@theunion.org)

**Documents required for application for record or existing data review (all in electronic format):**

* **Completed EAG Application form**
* **Study proposal**
* **Study data sheet**
* **Short summary of the CV of principal investigator**
* **Local Ethics approval certificate** If not available at the time of application to the EAG, these must be forwarded when received, as final approval is provisional until proof of local ethics committee approval is sent to the EAG by investigators. Any EAG comments or requests for modification will be sent directly to the relevant local ethics committees. If the local approval certificate/letter is not received within 6 months , EAG approval will be cancelled.

**Protocol modification**

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

**Final study report:**

A final report, either as the abstract of a paper submitted for publication in a journal or as the executive summary of the final report must be sent (to [eag@theunion.org](mailto:eag@theunion.org)) within 90 days of the end of the study.

**STUDY TITLE AND MANAGEMENT**

Please type inside the blocks 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 (other organisations involved in the study)**

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

If there any any conditions attached to funding that may influence the protocol, conduct of the research or reporting of results, please explain these.

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:*

## **Signatures Principal 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 ………………………………**

**STUDY DETAILS**

## **Aims and objectives (Please list)**

## **Scientific justification**

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

1. **DATA COLLECTION**

4.1 Explain the source of the data to be studied

4.2 Who will collect the data? (categories and numbers of researchers)

4.3 Where will data be collected?

4.4 How will records or data be sampled? (brief outline)

4.5 What is the expected number of records that will be studied?

1. **LOCAL ETHICS COMMITTEE**

5.1 Please provide the name of the ethics committee, and the **name and email address** of the committee Chairperson or secretary

5.2 Give the results of the submission: (mark appropriate answer with **X**)

Local ethics approval certificate attached

Application made to local ethics committee, result pending

No application made (please explain)

**For record reviews**, 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. Any EAG approval is provisional until proof of the relevant local ethics committee approval is sent by the investigator.

If the study will use **data already collected in another study**, the **ethics approval certificate(s)**  of the original study must be sent to the EAG with this application.

1. **CONFIDENTIALITY OF DATA**

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

**Yes / No**

6.2 If names will be collected (Yes to 6.1), please explain how confidentiality will be maintained so that participants cannot be individually identified?

6.3 If names are not collected (No to 6.1), 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**

6.4 If yes to 6.3 (there are other identifying records), explain how confidentiality will be maintained:

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

6.6 Will researchers who collect data or who have access to data sign a confidentiality agreement? **Yes /No**

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

## **Communication of Study Results**

Describe how results will be made available and to whom. e.g. local communities, health care managers, government agencies, scientific publications and others

Please explain how communities whose data is studied will be informed about the study results

## **Co-Authorship**

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