

International Agency for Research on Cancer



IARC Ethics Committee

Annual Report for IARC studies

This form is to be completed for those studies where the IEC explicitly requested the filing of Annual Reports when the study was approved. The form should be completed and signed by the IARC Principal Investigator and returned to the IEC Secretary within one month of the anniversary date of IEC approval.

Annual Reports need only be submitted whilst the investigators are in active contact with research participants. When this phase is finished and all samples have been anonymized/ completely de-identified, the IEC considers a study 'closed' for the purposes of annual reporting, even if analysis and report writing are still on-going.

Review period – From _____ to _____

1. Details of the study

Study Title _____

IEC reference number _____

Date of IEC Approval _____

IARC Principal Investigator _____

IARC Section/Group _____

2. Update on the progress of the study

Study Start Date _____

Were there any changes from the date originally planned?

Yes No If **Yes** please give the reason for the changes (if not done so previously)

Were there any changes from the planned study as approved by the IEC?

Yes No If **Yes** please give details and reasons

3. Update on the recruitment of study participants

Number of eligible subjects recruited

Last 12 months

Total

Number of subjects that declined to participate

Last 12 months

Total

Was there any deviation from the scheduled inclusion of subjects versus the actual inclusion?

Yes No If **Yes** please give details and reasons

4. Update on the safety of study participants

Provide information on any adverse events recorded over the last year

Give details of the follow-up of any serious adverse events reported during this period

Or, for studies that must also submit an annual report to a **Data and Safety Monitoring Board**, please provide a copy of the document.

5. Other issues

Are there any ethical issues you wish to report to the IEC on which further advice is required?

Is the study still in a period of "active contact" (see above)?

Yes No If **YES** a new Annual Report will need to be submitted in 12 months time

6. Declaration

I confirm that the above study complied with ethical issues raised through the ethics review

Signature of Principal Investigator

Print full name

Date