Version 1.0 July 2004

CLL4
SERIOUS ADVERSE EVENT REPORT

A Serious Adverse Event is any adverse event that

- results in death,
- is life-threatening
- requires hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability or incapacity
- is a congenital anomaly or birth defect

PLEASE FAX THIS FORM TO CTSU ON 01865-743986 WITHIN 24 HOURS OF KNOWLEDGE OF EVENT,
AND POST HARD COPY TO:
FREEPOST RLUJ-UUUU-UUAC, CTSU, Richard Doll Building, Old Road, Headington, OXFORD, OX3 7LF

PATIENT NAME: _____ **DATE OF BIRTH:** _____/ _____/_____

TRIAL REFERENCE NUMBER: _____ **SEX: M** ☐ **F** ☐

TREATMENT GIVEN: Chorambucil ☐ **Fludara** ☐ **Fludara + Cyclo** ☐

CONSULTANT: _____ **HOSPITAL:** _____

Date of Event ___/___/___

Brief description:

Outcome at time of report:

Recovered ☐ **Date recovered:** ___/___/___ **Died** ☐ **Date died:** ___/___/___

Recovered with sequelae ☐ **Date recovered:** ___/___/___ **Ongoing** ☐

Was the event related to treatment:

DEFINITELY ☐ **PROBABLY** ☐ **POSSIBLY** ☐ **UNLIKELY** ☐ **NOT RELATED** ☐

Name of person completing this report (please PRINT): _____

Date: ____/_____/____ **Telephone number:** _____ **Signed** _____

CTSU: Date received: ___/___/___ Date faxed to Prof Catovsky ___/___/___

Prof Catovsky: Date received ___/___/___ Code: SUSAR ☐ SSAR ☐ Other serious adverse event ☐

If SUSAR: Date informed MHRA ___/___/___ Date informed lead REC ___/___/___
(If fatal/life-threatening, to report within 7 days, (+8 for further info), otherwise within 15 days)

Copy of report sent to investigator: ___/___/___ ***Copy of this form sent to CTSU on*** ___/___/___