RAMPART (MRC RE06)

SELF-EVIDENT CORRECTIONS

Please complete this form, keep the original in your site file and email a copy to:
RAMPART Trial Management Team mrcctu.rampart@ucl.ac.uk

Institution: _____

I, the undersigned, agree to the use of the following abbreviations and self-evident corrections:

Abbreviations

Within free text questions the following abbreviations and symbols will be written out in full in the database as follows:

lt or L – left
rt or R – right
pt – participant/patient
↑ - increase
↓ - decrease
≥ - >=
≤ - <=
Tx – treatment
Rx – prescription
PMH – past medical history

Self-Evident Corrections

#1 Incorrect date format	If a CRF is returned with dates given in the dd/mm/yyyy format rather than the dd/mmm/yyyy format, the date will be entered into the database as dd/mmm/yyyy.
#2 Digit missing from centre number section of Trial ID	If the centre number section of a trial ID is missing a '0' at the beginning on one page of a multipage CRF and it is written correctly on the remaining pages of the CRF, it will be corrected on the database.
#3 Other	If an '*Other*' box is not ticked but information is provided in the follow on question, the '*Other*' box will be ticked on the database.
#4 Leading question not ticked	If a leading question is not answered but the follow on question(s) are answered, the appropriate box will be ticked on the database for the leading question.
#5 Year in date of birth given as current year	If the year in the participant's date of birth is given as the current year on one page, but is correct on other pages of CRF, it will be

	corrected on the database.
#6 Greater number of decimal places than required	If a numeric value is given to a greater number of decimal places than specified on the CRF, the value will be rounded to the required number of decimal places. However, if the value provided seems much lower or higher than expected, a query will still be raised to confirm the correct units have been used and the value is correct.
#7 Partial Dates	If a partial date is given, the date will be written in full in the database. If the day is missing it will be entered as the 15th. If the month is missing, it will be entered as July (only where deemed appropriate). The year will be required at all times. The following dates will not be subject to this SEC and will be queried if partial dates are provided: • All Forms - Dates in the form header (DOB and form date) • Form 01 - Date of informed consent • Form 01 - Date of electrocardiogram • Form 01 - Date of nephrectomy • Form 01 - Planned start date of treatment • Form 05 - Date of infusion Note: If after adherence to the SEC, a stop date is entered as being before the start date or a date is in the future, the partial date will be queried with site.
#8 Incorrect page used for Concomitant Medications Log	Instead of continuing onto the next page, the site continues onto the wrong page (eg. using 2 page 1's instead of going from a page 1 to a page 2), the concomitant medications will be written under the correct page and therefore row number on the database.
#9 Missing lab units	If a lab unit is not provided alongside the lab value in Treament CRFs/Additional Lab CRFs, the lab unit detailed in the lab transcript will be used and entered onto the database.
#10 Inpatient and outpatient visits	If the number of visits to a hospital department is left blank in section G of the Eligibility Criteria CRF, section G of the Treatment CRF and section C of the Post-Treatment CRF, it will be assumed that the

	patient did not have any visits and 0 will be entered into the database.

Name of Principal Investigator:
(Print name in capitals)

                            _____

Signature:

                            _____

Date:

                            _____