Site Guidance on Participant Withdrawal and Long Term Follow Up

We recognise there are instances when patients are unable to continue to comply with all, or some of their STAMPEDE trial assessments, either by choice or due to extenuating circumstances.

Long-term follow up information, even just limited to whether the patient is still known to be alive, is very important in ensuring that the efforts on the part of the patient and research team translate into meaningful results.

We therefore request that in such instances, you consider the following questions:

- Is the patient still being seen at your centre?
- Is the patient still being followed-up at the hospital e.g. in another department?
- Is the patient still registered with a GP?
- Has the patient transferred to another site participating in STAMPEDE?
- Can the patient be followed-up via telephone consultation?

If the answer to any of the above is 'yes' the patient does not need to completely end their trial participation as it may still be possible to obtain follow-up data using the options outlined below:

- Follow-up via telephone consultation.

The telephone consultation checklist (v2.0 Mar-2020) is available on the STAMPEDE website (www.stampedetrial.org) and should be used to document the follow-up assessment.

- Follow-up data collected from routine clinical/doctor's records and national registries (see level 1 withdrawal below).

In both of the above instances, when completing the FU (follow-up) CRF please provide the date the patient was last known to be alive and provide all other available data, clearly identifying those items for which the information was unavailable. Extensive CRF completion guidelines are available on the STAMPEDE website.

In the event of a **patient losing mental capacity** or being **placed in palliative care** during the course of the trial, it may be possible to collect minimal data through their routine care or GP as outlined above. However, if the patient is discharged from the care of the urologist or oncologist due to illness, it may be more appropriate for the patient to be withdrawn at level 2.

Should a **patient wish to terminate protocol specified follow-up schedule** (via telephone consultation or via clinical notes, GP or national registries), the site is required to outline the patient's wishes in writing and if possible give a detailed description of the discussion with the patient (see level 2 withdrawal below). A template letter is available on request. This should be emailed to the STAMPEDE Trial Team (mrcctu.stampede@ucl.ac.uk), and will be filed with the patient's CRFs and all documentation relevant to their participation in the trial.

If a patient wishes to **withdraw their consent from all trial participation, including biological samples already obtained** (see level 3 withdrawal), please provide similar written confirmation outlined above including their wishes and your discussions with the patient. Provided samples have

not already been analysed/processed, the STAMPEDE Trial Team will work with the central laboratory to destroy or return any remaining specimens (as applicable) to the randomising site.

The five withdrawal categories are as follows:

Level 0: Withdrawal from taking trial treatment (study IMP) or providing biological (blood, saliva, tissue) samples

- Follow-up continues as scheduled
- Complete an end of research treatment form and withdrawal letter, and send both to mrcctu.stampede@ucl.ac.uk

Level 1: Withdrawal from routine scheduled follow-up (other types of follow-up accepted)

- Patient no longer wishes to attend scheduled follow-up visits
- Follow-up data is collected via hospital records/GP notes or national registries
- Complete withdrawal letter and send to mrcctu.stampede@ucl.ac.uk

Level 2: Withdrawal from all types of protocol scheduled follow-up

- Patient no longer wishes to attend scheduled follow-up visits and does not consent to further information or biological samples to be collected
- Complete end of research treatment form and withdrawal letter, and send to mrcctu.stampede@ucl.ac.uk

Level 3: Withdrawal of all data and biological samples (retrospectively and prospectively)

- The patient no longer wishes for any type of follow-up to be conducted and does not want their data and samples already collected to be used for analysis, if possible.
- The patient's wishes must be clearly documented in the withdrawal letter and a copy sent to mrcctu.stampede@ucl.ac.uk with an end of research treatment form

Level 4: Lost to follow-up

- If a patient cannot be contacted or located for at least 3 years, despite repeated efforts, they are considered 'lost to follow-up'
- Complete an end of research treatment form and withdrawal letter with the date of last known contact, and send a copy to mrcctu.stampede@ucl.ac.uk