PARTICIPANT TRANSFERS

1. If a participant would like to transfer their care to another STAMPEDE site, the original site should contact the MRC CTU to locate suggested sites, and request details of the first point of contact(s) at the prospective receiving site. Please refer to the further information at the end of this document for additional guidance.
2. The original site should then contact the potential receiving site to confirm whether they would be able to accept this participant transfer. If they are not able to accept the participant, the original site should contact the MRC CTU to discuss it further.
3. If the receiving site are able to accept the transfer, the original site should then inform the MRC CTU accordingly. The responsible data manager at the MRC CTU will then send an updated Form Status Report (FSR) and Data Clarification Form (DCF), in order for the original site to resolve any outstanding data items or queries for that participant, prior to the transfer being completed.
4. Photocopies of the following documents **must be** securely sent to the receiving site, to ensure the participant's confidentiality is protected. Please note the original copies must be retained at the original site:
    - Consent form
    - Completed CRFs
    - Any documentation relating to the patient's participation in STAMPEDE (participant names must be removed from any documentation)

5. **Re-consent**:
    a) Upon transfer to the receiving site, the participant must be re-consented at the receiving site at the earliest opportunity. This should be performed using the correct version of the consent form in use at the time that informed consent was initially obtained at randomisation, and the corresponding Patient Information Sheet, unless there has been:
        - A safety update relevant to that participant's trial arm;
        - OR significant changes to the trial since their initial consent.

        If either of these are the case, the participant may need to re-consent using a more recent version than the one initially used at the time of randomisation. This may need to be assessed on a case-by-case basis, therefore if you are unsure, please contact the MRC CTU for clarification.

    b) As part of the re-consent process, the participant must also be made fully aware and informed of:
        - When and where they need to attend for trial treatments, follow-up visits and drug collection and return.
        - Any aspects of the study that may potentially differ between the sites, for example if your site is accredited for a particular sub-study that the original site was not, such as the metabolic sub-study introduced in Protocol V21.0.

    Until the MRC CTU has received a copy of the anonymised re-consent form, confirming that the participant has been appropriately re-consented at the receiving site, the original site are considered to be responsible for the care of the participant, therefore they should continue to complete CRFs until the participant has been re-consented.

6. In order to formally document the transfer process, the main contacts who are liaising the transfer, at both the original and receiving site, should complete and sign each of the corresponding sections of the attached **Patient Transfer Form (V2.0)**. By the receiving site signing this form, they are accepting responsibility of all data management and correspondence relating

to this participant, including any outstanding CRFs or existing queries raised prior to the transfer, therefore all relevant data queries for that participant will be sent to the receiving site going forward.

7. Once the Patient Transfer Form has been fully completed, a copy of the form must be sent to the MRC CTU (either via secure email to mrcctu.stampede@ucl.ac.uk, or fax on 0207 670 4818). Only once this form has been received, along with an anonymised copy of the re-consent form, will the transfer be marked as being completed.

Further information regarding means of data collection:

Participants still on trial treatment:

- If the participant is still on trial treatment, they should ideally be transferred to another STAMPEDE site in order to continue their treatment and scheduled follow-up visits.
- If the participant is still on trial treatment but cannot be transferred to an accredited site, early cessation of trial treatment prior to the transfer may be required, though where possible, they should still aim to continue on follow-up.

Participants no longer on trial treatment:

- If the participant is no longer on trial treatment, it is acceptable for them to have routine follow-up care at their GP, or a site that is not accredited to participate in STAMPEDE, provided that all CRF completion can be done effectively using data obtained from their routine care medical notes.
- However, if the participant is not transferred to another accredited STAMPEDE site, CRF completion can only be performed by members of staff at the original site, who have been authorised and delegated to do so according to the delegation log. The non-accredited site would therefore need to either send the data to the original site, or supply the information via phone.
- If the data is being supplied by phone, it must be recorded in the participant's clinic notes at the receiving site, to act as the source data. It should be documented:
    - That the data was received via a phone call
    - Who the person was that gave the data
    - Who made the notes

For any further information, please contact the STAMPEDE trial team at: mrcctu.stampede@ucl.ac.uk