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| **R&D AMENDMENT CHECKLIST** | | | | | |
| **Study Title:** |  | | | | |
| **REC Number:** |  | **R&D Number:** | |  | |
| **Principal investigator:** |  | | | | |
| **Amendment Number and Date:** |  | | **Reviewer:** | |  |
| **Amendment Type** | **Substantial  Non-Substantial** | | | | |
| **Required approvals** | **REC  MHRA  ARSAC  Other** | | | | |
| **Location:** | **Multicentre  Single Centre** | | | | |

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| **Documents** |
| **Name/Version/Date** |
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| **Submissions** | | |
| Has R&D been informed of the amendment by NRS PCC? | | **Yes  No  N/A** |
| Date Amendment received |  | |
| Full Document Set (FDS) Date |  | |
| Date Amendment approved |  | |

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| **Approvals** | | |
|  |  | **Comments** |
| Do the documents submitted correspond to the REC Approval? | **Yes  No  N/A** |  |
| For CTIMPs and regulated CIMDs, has the MHRA been notified? | **Yes  No  N/A** |  |
| Will identifiable data or CHI now be leaving NHS Lothian or EU?  *If this is not stipulated in the PIS/CF approval will need to be sought from the Caldicott Guardian or PBPP and NHSL Information Governance regarding the secure transfer and storage of identifiable information.* | **Yes  No  N/A** |  |
| Will there be new tissue collection?  *If so inform labs / tissue governance* | **Yes  No  N/A** |  |
| Does this amendment have any impact on departments?  *i.e. WTCRF, labs, imaging, pharmacy (please note all protocol amendments are to be sent to support departments even if N/A and stated as FYI only).* | **Yes  No  N/A** |  |
| Is there evidence that a sponsor’s representative has authorised the submission? | **Yes  No  N/A** |  |
| Is this a Phase I study?  *For Phase I/First in Human trials involving the CRF, Phase I committee approval must be in place. Approval letter must be in file.* | **Yes  No  N/A** |  |
| Does the amendment require approval from the ATGMSC?  *For human trials involving advanced therapy medicinal products (ATMPs), Any amendments to the trial protocol or documents pertaining to the IMP, investigator notifications of important safety information or new Investigators conducting the study must be reviewed by the ATGMSC.*   * ATGMSC approval must be in place (ACCORD SOP GS012). Approval letter must be in file. * R&D must receive impact assessment from PI | **Yes  No  N/A** |  |
| **Agreements** | | |
| Does the amendment impact an existing clinical trial agreement? *i.e. change of PI, recruitment, financial implications* | **Yes  No  N/A** |  |