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| **REGULATORY CHECKS COMPLETE AND AUTHORISATION TO START THE TRIAL** | |
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| **SPONSOR AUTHORISATION** | |
| **Trial Title:** |  |
| **REC Reference:** |  |
| **Date of REC Favourable Opinion:** |  |
|  |  |
| **Date of Competent Authority Approval:** |  |
| **Sponsor Reference:** |  |
| **Chief Investigator:** |  |

Dear [Chief Investigator],

The following documentation has been received in association with the above trial: [Delete as applicable]

1. Clinical Trial Authorisation (all conditions of that authorisation have been met)
2. A favourable research ethics committee opinion has been granted (including verification that any conditions stipulated have been met)
3. Confirmation of Technical/QP release of the IMP(s) or medical device release process [Delete as applicable]
4. Administration of Radioactive Substances Advisory Committee (ARSAC) approval [Delete as applicable]
5. WTCRF Phase I Committee Approval [Delete as applicable]
6. Advanced Therapy and Gene Modification Safety Committee Approval [Delete as applicable]
7. [Other relevant approvals]

As a representative of the Co-Sponsors (University of Edinburgh and NHS Lothian), **I hereby authorise the commencement of the aforementioned trial.**

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| Please note the following terms of this authorisation:   1. Local approvals (e.g. NHS R&D approvals or local hospital approvals) must be obtained for each participating site and a copy forwarded to (and acknowledged by) the Sponsor prior to shipping IMP/device to site. [Delete if not applicable] 2. Written Sponsor’s Authorisation to Open (SATO) must be provided by the Clinical Trials Monitor prior to recruitment commencing at any given trial site. 3. [Any additional trial specific conditions] |

Please contact me if you have any further questions.

Wishing you every success with your research,

[Lead Sponsor Representative]