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| **COMMERCIAL GOVERNANCE REVIEW CHECKLIST** | | | | | | |
| **Short Title:** |  | | | | **R&D & IRAS Number:** |  |
| **Sponsor:** |  | **CI/PI:** |  | **Study-Wide Review Board:** | |  |
| **CRO/CRA:** |  | **Reviewer:** |  | **NHSL Target Recruitment:** | |  |

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|  |  |  | **Comment** |
| **Study Documents** | | | |
| Protocol | *Add date/version to comment box* | Yes N/A |  |
| PIS/CF | *Add date/version to comment box* | Yes N/A |  |
| Agreement | *Contract must be reviewed, accepted and fully signed before R&D Management Approval.* | Yes |  |
| Budget | *Reviewed and accepted.* | Yes |  |
| Insurance | *Add insurance policy number, period and insurance limit.* | Yes |  |
| **Approvals** | | | |
| REC Favourable Opinion | *Add date of favourable opinion for initial submission and any subsequent amendments* | Yes N/A |  |
| MHRA Approval | *Add date of notice of acceptance/letter of no objection for initial submission and any subsequent amendments* | Yes N/A |  |
| ARSAC | *The sponsor must provide a study specific ARSAC license for studies involving use of radioactive substances (see project study information form section F)* | Yes N/A |  |
| Phase I Committee Approval Letter (involving CRF) | *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 N/A |  |
| Advanced Therapy and Gene Modification Safety Committee (ATGMSC) Approval Letter | *For human trials involving advanced therapy medicinal products (ATMPs), ATGMSC approval must be in place (ACCORD SOP GS012). Approval letter must be in file.* | Yes N/A |  |
| **Local information** | | | |
| CV & GCP | *PI CV required (CI CV required if Lothian based)*  *GCP (within the last 2 years) required for CTIMP and CIMD studies.* | Yes N/A |  |
| Local Authorisations | *List support dept and clinical service sign offs required/obtained.* | Yes N/A |  |
| IRMER | *See IRAS Part B, Section 3: Exposure to ionising radiation / page 1 of Project Study Information document – complete the* [*IRMER request form*](https://forms.office.com/Pages/ResponsePage.aspx?id=veDvEDCgykuAnLXmdF5JmsvHTx6UXndNroeVlqOJUFlUOUZJSDVEWDAwSktBVTc2N1NBNkNINEExRCQlQCN0PWcu) | Yes N/A |  |
| Caldicott / PBPP Approval Required and Received? | *Caldicott approval required for unconsented use of data.*  *Multi-centre studies: Caldicott approval should be sought from the Public Benefit and Privacy Panel (PBPP).* | Yes N/A |  |
| Data Protection Compliance | ***Summarise in the comments section (or make reference to relevant section in IRAS/Study Information form, protocol or PIS/ICF where this information is detailed);***   1. *Does the study process personal data and/or special categories of data?*   No Yes N/A | No Yes |  |
| 1. *Does the study align with the relevant NHS Lothian R&D Generic DPIA (i.e. for hosted studies)?*   *(record this on SReDA – Local Information tab)*  No Yes N/A |
| 1. *Has a separate DPIA been provided e.g. Sponsor study specific DPIA?*   *(record this on SReDA – Local Information tab)*  No Yes N/A |
| 1. *Is the participant personal data (identifiable or pseudonymised) being transferred/stored out with NHSL and/or the UK? If yes, where is it going? (name the organisation(s) e.g. NHS Board/Trust, Sponsor, 3rd party organisation(s), country or countries). This includes collection of data in the Case Report Form (CRF) or database/portal.*   No Yes N/A |
| 1. *Where personal data (identifiable or pseudonymised) is leaving the UK, are there UK adequacy agreements in place with this country (if not, refer to IT Security for risk assessment).*   No Yes N/A |
| 1. *Is participant information/consent explicit for the data processing activities involved i.e. details provided in the PIS and/or CF?*   No Yes N/A |
| 1. *How is the participant personal data being transferred? Please provide details or reference to section(s) in relevant study documentation e.g. IRAS/Study Information form, protocol, PIS/ICF. This information will be required for the IT Security risk assessment.* |
| 1. *Is there a contract or data processing/sharing agreement in place with NHSL (e.g. UK-wide model agreement)? This needs to cover all activity and where data is being transferred to a 3rd party (clauses to be added to agreement regarding 3rd party contracting, where applicable).*   No Yes N/A |
| 1. *Where data is being shared with a 3rd party, does the Sponsor have a contract or data processing/sharing agreement in place between them and the 3rd party to cover the 3rd party processing activity?*   No Yes N/A  ***If unable to answer the questions detailed above, please contact the Sponsor and/or the local Principal Investigator to obtain the required information.*** ***Advice may be sought from the R&D Information Governance Lead, NHSL Information Governance and/or the NHSL Data Protection Officer where required.*** |
| Information Governance/IT Security Risk Assessment Complete and Recommendations Implemented? | *Where the study requires the use of non-NHSL devices/software or a new form of technology to hold patient data or be connected to NHSL network, provide details in the comments section and refer to IT Security* *New forms of technology include but are not limited to web portals, portable devices (including wearable devices) and Artificial Intelligence (AI).* | Yes N/A |  |
| **Additional Checks** | | | |
| SReDA Updated | *a) UKCRC Health Category (Project Information Tab)*  *b) Project Type (Project Information Tab)*  *c) Financial Reporting (Recruitment Tab); refer to financial reporting crib sheet.*  *d) DPIA status (Local Information tab)*  *e) ATMP/GMO/Vaccine Study (Project Information tab)* | Yes |  |
| **Date review complete and referred for Management Approval:** | | **Name of Reviewer:** | |