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| **NON-COMMERCIAL GOVERNANCE REVIEW CHECKLIST** | | | | |
| **Short Title:** |  | | | |
| **R&D Number:** |  | **Sponsor:** |  | |
| **Reviewer:** |  | **CI/PI:** |  | |
| **Study-Wide Review Board:** |  | **Funder:** | | Eligible  Adopted  NEF  Pilot |

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|  |  |  | **Comment** |
| **Study Documents** | | | |
| IRAS Form / Project Study Information Document | *Signed & Valid* | No Yes |  |
| Protocol | *Add date/version of current approved document to comment box*  *This will be listed in the MA letter* | No Yes |  |
| PIS/CF | *Add date/version of current approved documents to comment box*  *These will be listed in the MA letter* | No Yes |  |
| Funding Award | *Add funder, funding reference and funding amount.*  *If no funding ‘No external funding.’* | No Yes |  |
| Extended Review? | *Where the funder of a non-commercial study is not present on the NRS List of Eligible Funders* [*(Annex 2)*](https://www.nhsresearchscotland.org.uk/education-and-funding/funding-for-nhs-research-infrastructure)*, then the reviewer must make the following check:*  *If the funding for the study is in part or in whole from:*  *• Overseas Government*  *• Overseas charity*  *• Funded by a commercial company as collaborative research (or Investigator initiated trial) \**  ***AND*** *is identified as:*  *• Having high quality peer review*  *• Been awarded in open competition*  *• Meeting the definition of research*  *and regardless of whether sites exist in other UK nations or not, will meet the criteria for Extended Review.*  *The study should be categorised as Extended Review within the “project type” within SReDA.*  *\* Extended Review studies are defined as non-commercial studies. Occasionally the classification may not be clear. The contracting arrangements between the Sponsor/Funder and study sites can be used to determine classification in the first instance,*  *Please refer to the NRS ‘Extended Review Process for Scotland’ guidance for further information and the NRS Funding Guidance (Annex 3, applicable from 1st December 2024).* | No Yes  **SReDA updated to Extended Review?**  No Yes |  |
| Agreement | *For UoE/NHS Lothian sponsored CTIMP/CIMD studies, contact the Clinical Research Facilitators to query the status of necessary agreements.*  *Studies which are in the first 4 categories on the IRAS form require a separate site agreement. All other studies may use the OID as the agreement, this is a sponsor decision.*  *For hosted CTIMP/CIMD studies the fully signed agreement must be in place before R&D approval is issued. Non-CTIMP hosted studies may be approved while the signed agreement is pending.*  *When a medical device is being provided to NHSL, advise the Contracts Team as this requires a change to wording in the agreement around indemnity.* | No Yes |  |
| Organisation Information Document (OID) used as the agreement | *Any queries around the use of the OID as the agreement should be directed to the Principal R&D Manager/NRS Generic Review Manager.* | No Yes |  |
| Insurance | *Add insurance policy number; valid/expiry dates; ensure appropriate for the study.*  *Minimum cover for CTIMP studies is £5m.*  *For NHS sponsors, NHS indemnity will apply.*  *For non-interventional studies, can accept public liability insurance/professional indemnity.* | No Yes |  |
| **Local Information** | | | |
| Valid Local Information Pack | *The UK Local Information Pack is made up of:*  *Localised Organisation Information Documents (LOID) (using correct template).*  *SoE/SoECAT. Are there excess treatment costs (ETCs)? If yes, send to the Finance Team for review. The service authoriser should be made aware of ETCs in the e-mail request for authorisation (attach Finance Teams review of ETCs). Additional budget holder sign-off will also be required for ETCs. If ETCs apply, advise the Contracts Team not to proceed to execution of agreement until the ETCs have been approved. SoE not required if UoE/NHSL sponsored single centre study.*  *Delegation Log (CTIMP only). This can be the template or completed log.*  *In addition, the pack includes:*  *Covering email using standard template format.*  *Relevant supporting documents - these will include some of the documents that have been submitted/approved with the IRAS Form submission and other documents to support study set up at the participating NHS/HSC organisation(s).* | LOID  No Yes  SoE/SoECAT  No Yes  Delegation Log  No Yes  Supporting Documents  No Yes |  |
| Local Authorisations | *Support departments can include Pharmacy, Medical Photography, NHS Labs, Radiology, CRF, Edinburgh Imaging.*  *For studies including use of a non-CE marked device or device being supplied by the sponsor, Medical Physics sign off must be obtained certifying that the device is safe for use in humans.* | No Yes |  |
| Devices | *Are there any devices to be used in this study, including the use of fitness trackers, movement monitors etc? If the device is not UKCA/CE marked approval is required from Medical Physics.*  *If the device is UKCA/CE marked and being used per its intended purpose, advise Medical Physics so they are aware of the study.* | No Yes |  |
| Tissue Governance | *See IRAS project filter question 2. If the study includes the collection/use/transfer of tissue and no local labs are involved, email Tissue Governance for their information.* | No Yes |  |
| ARSAC | *See IRAS project filter question 4. Where a study involves administration of radioactive substances, a study specific ARSAC license is required to be provided by the Sponsor.*  *If a study identifies that ARSAC is required but not IRMER (see below), send to Medical Physics for them to assess.*  *See Guidance GL006 for further information.* | No Yes |  |
| IRMER | *See IRAS Part B, Section 3: Exposure to ionising radiation / page 1 of Project Study Information document.*  *Medical Physics Expert review is required for all studies involving ionising radiation whether this is applicable for research scans or included in the protocol as standard care. A Medical Physics online form must be completed and submitted to request Medical Physics Expert IRMER approval. There is no requirement to wait for this to be approved before issue of R&D MA.*  *Add the IRMER insert into the R&D MA letter.* | No Yes |  |
| Caldicott / PBPP Approval required and received? | *If identifiable data is leaving NHSL and consent for this does not feature in the PIS/CF, forward R&D specific Caldicott approval form (GS008-F01) to the investigator for completion and return to* [*loth.accord@nhs.scot*](mailto:loth.accord@nhs.scot)*.*  *Where the local clinical care team are accessing patient data without consent for research purposes, Caldicott approval is required.*  *This* ***does not*** *include where the clinical team are screening for suitable participants to be approached, e.g. PIC activities.*  *Multi-centre studies: Caldicott approval should be sought from the Public Benefit and Privacy Panel (PBPP).*  *Use of portable media requires local Caldicott approval e.g. voice recorder, USB devices.*  *Where Caldicott/PBPP approval is required but is not yet received, and a decision has been made to issue R&D MA, this must be justified in the comments section and detailed in the R&D MA letter e.g. where PBPP approval for data linkage is needed for later in the study.* | No Yes |  |
| 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 (e.g. co-sponsored, NHSL singly sponsored, hosted)?*   *(record this on SReDA – Local Information tab)*  No Yes N/A |
| 1. *Has a separate DPIA be 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 person 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).*   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?* ***Only where this contract does not include details of data use is an additional Data Privacy Impact Assessment/Data Sharing Agreement required.***   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 non-NHSL devices/software or a new form of technology to hold patient data or be connected to NHSL network, the Researcher is responsible for liaising with NHSL IT Security regarding review of these processes. New forms of technology include but are not limited to web portals, portable devices (including wearable devices) and Artificial Intelligence (AI).**Where the study requires the use non-NHSL devices or a new form of technology, provide details in the comments section and refer to IT Security.****Include name(s) of systems/software if provided in study documents i.e. add systems in the comments section of this checklist to aid IT Security risk assessment.*** | No Yes |  |
| CV – CI/PI | *Signed CI CV only required for Edinburgh-led CTIMPs/CIMDs.*  *No CV is required for studies where NHS Lothian will be acting as a Participant Identification Centre (PIC) or if a 'Musketeer' study, although it is best practice to request.*  *If CV is sent directly via email by the NHS Lothian PI/CI, this can be taken as evidence of signed/dated CV. Must be dated within 2 years to be valid.* | No Yes |  |
| Research Passport (HRC / LoA) | *Check NHS contract status for all researchers.*  *For university contract holders, ensure researchers have contacted their HR to initiate research passport process.*  *Refer to Research Passport SOP GS006.* | No Yes |  |
| Service Support Costs (SSC) identified | *SSC spreadsheet to be completed when:*   * *Study is single centre or NHS Lothian is lead Scottish health board.*   ***AND***   * *Study is eligibly funded, adopted OR may be sent for portfolio consideration by the lead nation.*   *SSC Spreadsheet is saved to R&D shared drive for finance to pick up when MA is issued.*  *If a study is deemed SWR ONLY and is eligibly funded, complete the SSC, save to R&D shared drive and email The R&D Finance Team to advise that it is complete and available.* | No Yes |  |
| **CTIMP & Regulated CIMD Studies (Experimental “other” studies)** | | | |
| Contraceptive advice | *Confirm exclusion criteria do not preclude the need for contraceptive advice to be given (e.g. male only / post-menopausal / pre-pubescent recruitment).*  *If contraceptive advice is not included, ask for clarification from Investigator or confirmation of local standard practice.* | No Yes |  |
| PI GCP Cert/Signed & Dated CV (CI also required if Lothian based) | *Evidence of PI GCP training required within the last 2 years.* | No Yes |  |
| **Approvals** | | | |
| REC Favourable Opinion | *Ensure version number and dates of study documents are consistent with the REC favourable opinion letter and that all conditions have been addressed/accepted.*  *Tissue studies that come under the REC Bioresource Umbrella will be issued a generic REC ref and do not require further review.* | No Yes |  |
| MHRA approval | *For device studies, a letter of no objection from the MHRA is required only in the case of studies:*  *involving a non-CE marked device and where there is an intention to commercialise the device based on the study research (seek a CE mark),*  *or*  *where a CE marked device is being used outside its labelled indication and where there is an intention to use the study data to modify the CE mark.*  *MHRA acceptance is always required for CTIMP studies.* | No Yes |  |
| 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.* | No Yes |  |
| Advanced Therapy and Gene Modification Safety Committee (ATGMSC) Approval Letter | *See Project Study Information form D3-11-3.*  *For human trials involving advanced therapy medicinal products (ATMPs), ATGMSC approval must be in place (ACCORD SOP GS012). Approval letter must be in file*.  *ATMPs are medicines for human use that are based on genes, tissues or cells.* | No Yes |  |
| UK Study-Wide Governance Report | *Add Scottish Study-Wide Review- (SWR) board and date Scottish SWR completed.* | No Yes |  |
| **Additional Checks** | | | |
| Adults with Incapacity | *For any* ***non-CTIMP*** *study involving Adults with Incapacity, REC approval must be provided by the Ethics Committee constituted by Scottish Ministers under the Adults with Incapacity (Scotland) Act 2000. (Scotland A REC).*  *If not, ask Investigator to submit application to Scotland A REC and await REC approved doc.* | No Yes |  |
| PIS Consistent | *Information consistent with IRAS and protocol?*  *Evidence of compliance with data protection regulation. Use of data clearly detailed. Transparency information for GDPR provided?*  *ACCORD template can be used to check minimum required information.* | No Yes |  |
| Informed Consent | *If identifiable data is being stored/transferred is this consented? Is CHI explicitly consented (if applicable)?* | No Yes |  |
| Child Consent | *Applies only to non-CTIMP studies.*  *\*\*IF ANY DOUBTS WITH SUITABILITY PLEASE CONTACT PAMELA DICKS AT SCOTCRN FOR ADVICE\*\** | No Yes |  |
| Genetic testing detailed to participants? | *See IRAS Form Part B QU 10. If the information is not sufficient, ask the Investigator to change accordingly and put in an Ethics amendment if necessary.* | No Yes |  |
| SReDA Updated | *Update "HB Comments" and the following fields of SReDA;*   * *UKCRC Health Category (Project Information Tab)* * *Project Type (Project Information Tab)* * *R&D Officer (Local Information Tab)* * *Service support costs (“Legacy SSC value” field in ‘Recruitment Totals’ tab)* * *DPIA status (Local Information tab)* * *ATMP/GMO/Vaccine Study (Project Information tab)* | No Yes |  |
| **NHSL/UoE Co-Sponsored Studies Only** | | | |
| Validated questionnaires | *If validated questionnaires, or questionnaires that are suspected to be validated, will be used in the study, send an email to the researcher stating:*  *"We note that you are using questionnaires on this study and would ask that you note your responsibility to obtain authorisation to use any validated questionnaires and pay any associated fees."* | No Yes |  |
| Incidental findings | *Is it clear that participant must agree to GP being informed of incidental findings?*  *Is information in PIS sufficient? Doesn’t have to be on the CF so long as it is stated on the PIS??* | No Yes |  |
| Signed Protocol (CTIMPs/CIMDs only) | *Separate signature pages are acceptable.* | No Yes |  |
| Co-enrolment (Interventional studies only) | *Is co-enrolment addressed in protocol and PIS?* | No Yes |  |
| **Date review complete and referred for Management Approval:** | | **Name of Reviewer:** | |