**R&I NBT HRA Study Checklist**

1. **PURPOSE AND SCOPE**

The aim of this checklist is to ensure that your project meets the relevant requirements prior to applying for regulatory approvals.

The sponsorship team will require a completed checklist from the researcher before Sponsorship in principle will be agreed.

1. **DEFINITONS/ABBREVIATIONS**

|  |  |
| --- | --- |
| CTIMP | Clinical trials of Investigational Medicinal Products |
| HRA | Health Research Authority |
| HRA Approval | The new single application process for the NHS in England that brings together the assessment of governance and legal compliance, undertaken by the HRA, with the independent Research Ethics Committee opinion provided through the UK research ethics service |
| ICF | Informed Consent Form |
| Ionising Radiation | Procedures involving ionising radiation include but are not limited to: general radiography, interventional imaging, CT scans, DXA scans, mammography and dental radiography, radiotherapy, administration of radioactive substances (e.g. nuclear medicine and PET/CT). |
| IRAS | Integrated Research Application System |
| NBT | North Bristol NHS Trust |
| OID | Organisation Information Document |
| PIS | Patient Information Sheet |
| R&I | NBT Research & Innovation Office |
| SoE/SoECAT | Schedule of Events/ Schedule of Events Cost Attribution Template |
| Sponsor | The individual, company, institution or organisation, which takes on ultimate responsibility for the initiation, management ( or arranging the initiation and management) of and/or financing (or arranging the financing) for that research |

1. **PROCEDURE**

Complete the checklist below and send to researchsponsor@nbt.nhs.uk.

Please note not all questions will be relevant to your study.

|  |  |  |  |
| --- | --- | --- | --- |
| **HRA Checklist** | **Yes** | **N/A** | **Document where details are required** |
| **IRAS** |
| Does the IRAS project filter category accurately reflect the study as described in the application form, protocol and PIS? For more information please select the green "i" icon in IRAS? |  |  | IRAS Form |
| Is it clear in IRAS form section 2b that ionising radiation will be used? |  |  | IRAS Form |
| Is it stated section 2b of the IRAS form that samples (new or existing) will be taken? |  |  | IRAS Form |
| Does part C reflect that the study will take place in Scotland or Northern Ireland? |  |  | IRAS Form |
| Has the appropriate filter been selected if participants aged under 16 years of age might be involved (question 6), or adults unable to consent (question 7) for themselves? |  |  | IRAS Form |
| Has the R&I Clinical Trials Manager, Clinical Trials Officer, or Research Operations Manager been listed as the contact on behalf of the Sponsor, and the contact email address given as researchsponsor@nbt.nhs.uk? |  |  | IRAS Form |
| Has researchsponsor@nbt.nhs.uk been provided as the email address for sponsor representative in section A4 and A64 of IRAS? |  |  | IRAS Form |
| Does the inclusion criteria outlined in the IRAS form match the Protocol? |  |  | IRAS Form /Protocol |
| Has HRA approval been selected within the project filter questions in IRAS? This is selected by choosing “IRAS FORM”. |  |  | IRAS Form |
| **General Study** |
| Have potential communications barriers to informed consent or the ability to withdrawal been considered? |  |  | IRAS Form /Protocol |
| Do all the study documents have the NBT logo? |  |  | All Documents |
| If the study involves intrusive research(that which would be unlawful if carried out on or in relation to a person who had consent, but without this consent) involving adults unable to consent for themselves, advice on the assumed will of the adult must be obtained from a nominated consultee. In these cases, has a consultee information sheet/declaration form been included in the application? Or Legal Representative if a CTIMP with Adults who Lack Capacity. Please note: Intrusive research is not limited to trials of clinical interventions. It includes non- interventional research where consent is legally required, for example involving the processing of personal data or the administration of questionnaires, interviews or observations. |  |  | PIS and Consent Form |
| Some studies may require a single technical pharmacy review, rather than site-level technical review at each individual site. The single radiation review is a component of HRA approval and therefore have you considered whether you need to submit for this single review? |  |  | IRAS Form |
| Some studies may require radiation assurance, rather than site-level radiation review at each individual site. The single technical pharmacy review is a component of HRA approval and therefore have you considered whether you need to submit for radiation assurance? |  |  | IRAS Form |
| Does the application clearly outline the insurance and indemnity arrangements for the management, design and conduct of the study? |  |  | IRAS Form |
| If your research involves the administration of radioactive substances have you completed the Section 2b of the IRAS form and populated the ARSAC Preliminary Research Assessment form? |  |  | IRAS Form |
| If the project indicates that post-study therapies will be afforded to participants, have you included evidence in your application to confirm how this access will be funded and managed? |  |  | Protocol /SoECAT |
| Has the protocol has undergone independent scientific and statistical review, and is this outlined in the application? |  |  | Protocol /Evidence of Review |
| Does the study documentation consistently describe how personal data will be used? |  |  | IRAS Form /Protocol/PIS |
| Is data being accessed without consent by members not part of the direct care team? |  |  | Protocol |
| Is clear and adequate justification provided as to why any identifiable data is being accessed without consent, or personal data is to be transferred outside of the European Economic Area (EEA)? |  |  | IRAS Form /Consent Form |
| Does the application describe how the data will be stored and what security measures are in place to keep it secure? |  |  | IRAS Form |
| Does the application describe whether the data is to be coded or anonymised, the methods for doing so, and why? If identifiable data is to be used, a minimum necessary amount of identifiable information should be used. |  |  | IRAS Form |
| **Patient Documentation** |
| Has the Research Ethics Committee Participant Information Sheet and Consent Form guidance and templates been used? R&I require the use of these templates for all projects. |  |  | PIS/Consent Form |
| Is the patient documentation appropriately version controlled? |  |  | PIS/Consent Form |
| Is the full title and IRAS reference present on the information/consent forms? |  |  | PIS/Consent Form |
| Does the patient documentation clearly outline how participant data (and tissue if relevant) will be used and who it will be shared with, and what will happen to it including after the end of the study? |  |  | PIS/Consent Form |
| If there are multiple PISs/ICFs is it clear which should be used in which circumstances/with which patient group? |  |  | PIS/Consent Form |
| If tissue is to be taken, is it clearly and consistently stated (including to the participant in the PIS) what will be done to it where and what will happen to it after the study?  |  |  | PIS |
| Does the PIS clearly state the study aims and participant arrangements for involvement? |  |  | PIS |
| Is a statement regarding indemnity/insurance and compensation arrangements present within the information sheet? (A statement must be included). |  |  | PIS |
| Does the information sheet give a point of contact for queries/complaints including an independent contact such as Patient advice and liaison service (PALS)? |  |  | PIS |
| Does the information sheet state what the arrangements are post-study? |  |  | PIS |
| Is it clear what will happen to personal data after the end of the study? |  |  | PIS |
| If the study is a CTIMP, does the patient documentation clearly describe the intervention/drug, its stage of development, and any potential side effects? |  |  | PIS |
| The following statement should be included in the consent form: "I understand that relevant sections of my medical notes, and data collected duringthe study, may be looked at by individuals from the research team, the regulatory authorities or the XXX Hospital Trust overseeing the research. I give permission for these individuals to haveaccess to the relevant parts of my medical records." |  |  | Consent Form |
| Is the most up to date HRA wording included regarding the protection of personal data? |  |  | PIS/Consent Form |
| **Protocol** |
| Does the information in the protocol match with the study documentation? |  |  | Protocol |
| Does the protocol include details of indemnity? |  |  | Protocol |
| If data is being transported from the site where it is collected, is this discussed (in the protocol for example)? |  |  | Protocol |
| Does the protocol adequately describe the activities to be conducted at site (including where and how these may alter between different sites)?  |  |  | Protocol/SoE /SoECAT |
| Is it clear in the documentation who will be allowed to identify participants and make the first approach, and who will access identifiable information in order to identify potential participants? |  |  | Protocol |
| Is it clear how participants who become pregnant during the study will be managed? |  |  | Protocol/PIS |
| Has the HRA protocol template been used? |  |  | Protocol |
| Does the protocol provide a clear description of the study including the objectives, design, methodology, statistical considerations (or other methods of data analysis) and the organisation of the study? |  |  | Protocol |
| If the tissue is to be retained post study, have you liaised with R&I to ensure are appropriate arrangements in place (e.g. licensed tissue bank)? |  |  | Protocol |
| Are digital channels i.e. social media/internet and or posters/flyers going to be used as a recruitment strategy? Has this been made clear in the protocol? |  |  | Protocol |
| **Data Protection** |
| Are arrangements outlined for what will happen to a participant and their data/material should they withdraw consent or lose capacity to consent clear and consistent? |  |  | PIS |
| Does the protocol describe the monitoring arrangements for the study and dissemination of the study findings? |  |  | Protocol |
| Do CRFs reflect data collection in the protocol? |  |  | Protocol/CRFs |
| If equipment is being loaned or gifted, has it been discussed with the Sponsor what the indemnity arrangements are?  |  |  | OID |
| **Financial Arrangements** |
| Does the application demonstrate an understanding of the costs associated with supporting the study? |  |  | Protocol/SoE |
| If your study has Excess Treatment Costs and is suitable to be adopted onto the CRN Portfolio, you should complete a SoECAT form. |  |  | SoECAT |
| Where the study is funded through a programme grant, does the IRAS application reflect the amount (or %) of funding to be used for this particular study? |  |  | IRAS Form |
| **Site Agreements** |
| If the study is multi-centre or is a single centre study undertaken at a non-NBT site, have Organisation Information Document (OID) and Schedule of Events (SoE) documents been prepared (or, where excess treatment costs are identified, SoECATs instead of SoEs). |  |  | SoE/OID |
| Is the study a Clinical Trial (first 4 categories on IRAS)? If so discuss with Sponsor about the need for an alternative contract to the OID, such as the mNCA |  |  | OID/mNCA |
| Does the OID/SoE/SoECAT describe the costs associated with the study, and what (if any) funding is to be provided to each site type? |  |  | SoE/OID |
| Does the OID state whether or not a PI / Local Collaborator is required for each site, as and whether these have already been identified? |  |  | OID |
| Has R&I reviewed and approved the OID/SoE/SoECAT documents? |  |  | SoA/SoE |
| Have letters from funders been obtained? |  |  | Funder Letter |
| **HR Review** |
| Have you ensured that all members of the research team are clearly listed in the application, and that the protocol clearly describes who will be responsible for undertaking each element of the project? |  |  | IRAS Form /Protocol |