**Sponsor review Checklist (Non-Risk Assessed Studies)**

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| --- | --- |
| **Study Title:** |  |
| **Sponsor Number:** |  |
| **Chief Investigator:** |  |

This sponsor review checklist must be completed by the Research Governance Manger (UoL) or their delegate when conducting Sponsor reviews on behalf of UoL.

**Note: Where the answer to the sponsor review consideration is not a Y/N answer, text should be provided in the comments box.**

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| --- | --- | --- | --- | --- | --- |
| Sponsoroversightarea | Sponsor Review Consideration | Yes | No(or mark N/A) | Sponsor Comments | Study Team Responses |
| **General Points To Be Considered Across All Study Documentation** | | | |  |  |
| 1 | Is the study title consistent across all documentation? |  |  |  |  |
| 2 | Does the document footer contain the document title, version/date and pages numbers? Check for cut and paste, grammar and spelling errors. |  |  |  |  |
| 3 | Has the study been referred to or described consistently within all documentation? (e.g. study or trial, calorie deficit study or calorie restricted trial?) |  |  |  |  |
| Funding |  | Yes | No | Sponsor Comments | Study Team Responses |
| 1 | Are there adequate funds for the duration of the study for:  Travel expenses, staff, all study procedures, study payments, translation services, archiving costs, courier costs, counselling costs, pharmacy, laboratory, radiology, tests, |  |  |  |  |
| 2 | Will funding cover storage of samples for future use? |  |  |  |  |
| 3 | Are any funds passing to third parties? i.e. contractors / sites |  |  |  |  |
| Patient Information Sheets |  | Yes | No | Sponsor Comments | Study Team Responses |
| 1 | Does the PIS share the same title as the other study documentation? |  |  |  |  |
| 2 | Has the HRA template been used and is the PIS appropriately dated and version controlled, paginated, spelt correctly and grammatically clear? |  |  |  |  |
| 3 | Does the PIS reflect the protocol and IRAS form giving adequate details to the potential participant? |  |  |  |  |
| 4 | Is the indemnity clause worded appropriately? |  |  |  |  |
| 5 | Is the funding clause worded appropriately and accurately? |  |  |  |  |
| 6 | Is it clear who to contact about the study & is the contact number for further information correct? |  |  |  |  |
| 7 | Are all procedures involved in the study clear in the PIS? |  |  |  |  |
| 8 | Are the risks / benefits clearly stated to the participants? |  |  |  |  |
| 9 | Have any sensitive or difficult topics to be discussed been written clearly? |  |  |  |  |
| 10 | If so, is there adequate provision for additional support and has this been included in the costing? |  |  |  |  |
| 11 | Is it clear how long each participant will be involved in the study? |  |  |  |  |
| 12 | Will there be any reimbursement of travel expenses or any other payment to participants and is this clear in the PIS? |  |  |  |  |
| 13 | Is it clear that regulatory authorities/sponsor etc. may look at notes? |  |  |  |  |
| 14 | Is it clear how participants can withdraw from the study? |  |  |  |  |
| 15 | Is it clear if there any study specific procedures required prior to consent i.e. fasting to attend clinic? |  |  |  |  |
| 16 | If relevant, is it clear what procedures are in place should participants lose capacity once consented? |  |  |  |  |
| 17 | If it is important that participants are not involved in other studies, is this included in PIS (and protocol in exclusion criteria)? |  |  |  |  |
| 18 | Do any sub studies have separate sections in the PIS & appropriate consent forms? |  |  |  |  |
| 19 | Is it clear what samples will be taken during the study and does it state that if samples are to be retained for use in future research, consent will be sought to allow this? |  |  |  |  |
| 20 | If applicable, is it clear that the GP will be notified about participation in the study? |  |  |  |  |
| 21 | Are research specific procedure results notified to the participant and / or GP, and is this clearly stated in the Protocol & PIS? |  |  |  |  |
| Consent Forms/ Process |  | Yes | No | Sponsor Comments | Study Team Responses |
| 1 | Has the HRA template been used and is the CF appropriately dated and version controlled, paginated, spelt correctly and grammatically clear? |  |  |  |  |
| 2 | Is it clear that regulatory authorities/sponsor etc. may look at notes? |  |  |  |  |
| 3 | Has express permission been obtained to inform the participant’s GP about participation in the study? |  |  |  |  |
| 4 | Are personnel appropriately trained to obtain consent from participants or will study specific training be provided& by whom? |  |  |  |  |
| 6 | Will participant identifiable data leave the NHS Organisation? |  |  |  |  |
| 7 | If participant identifiable data is to leave the NHS Organisation, has express permission been sought on the consent form? |  |  |  |  |
| 8 | If samples taken during study are to be retained for use in future research, has explicit consent been requested to allow this? |  |  |  |  |
| 9 | Is there adequate time in the IRAS form allocated for the consent process? |  |  |  |  |
| 10 | Is it clear how the consent process will be recorded? |  |  |  |  |
| 11 | Will interpreters be used? |  |  |  |  |
| Patient/Public Involvement |  | Yes | No | Sponsor Comments | Study Team Responses |
| 1 | If applicable, has there been adequate protocol development involving patients, service users, and / or their carers, or members of the public? |  |  |  |  |
| DATA |  | Yes | No | Sponsor Comments | Study Team Responses |
| 1 | Does this study require advice from information governance or the data security team? |  |  |  |  |
| Recruitment Strategies |  | Yes | No | Sponsor Comments | Study Team Responses |
| 1 | Is the recruitment strategy relevant to the participant population? |  |  |  |  |
| 2 | Are individuals with capacity issues to be approached to participate? |  |  |  |  |
| 3 | Are pregnant women to be approached to participate? |  |  |  |  |
| 4 | Are children to be approached to participate? |  |  |  |  |
| 5 | Is the research team aware of recruitment timelines and targets? |  |  |  |  |
| 6 | If Multi-Centre – is the recruitment target per site feasible? |  |  |  |  |
| 8 | Who will be accessing participant medical records to collect data? |  |  |  |  |
| 9 | Do the study personnel accessing data have legitimate permission? |  |  |  |  |
| 10 | Do personnel accessing identifiable data possess appropriate contracts with the NHS Organisation? |  |  |  |  |
| 11 | Are there conflicting studies that will have an effect on ability to recruit targets? |  |  |  |  |
| 12 | Recruitment of healthy volunteers – how will medical history be confirmed? |  |  |  |  |
| Protocol |  | Yes | No | Sponsor Comments | Study Team Responses |
| 1 | Has the Protocol been adequately peer reviewed? |  |  |  |  |
| 2 | Are there any outstanding queries in relation to the Peer Review? |  |  |  |  |
| 3 | Is there a process for ensuring all study personnel, at all sites are trained in the protocol? |  |  |  |  |
| 4 | Is it clear who will do protocol training? |  |  |  |  |
| 5 | Is the Chief Investigator listed as an author on the Protocol |  |  |  |  |
| 6 | Has the sponsor template been used?- If not, are all relevant sections of the Protocol included i.e. Safety reporting / inclusion / exclusion etc. |  |  |  |  |
| 7 | Have all aspects of the protocol been included in the IRAS application? |  |  |  |  |
| 8 | Do the IRAS application and the protocol correlate with each other? |  |  |  |  |
| 9 | Have all clinical and non- clinical procedures within the protocol been listed in IRAS? |  |  |  |  |
| 10 | Will any standard or routine treatments or medication be withheld prior to or during the study? |  |  |  |  |
| 11 | If so, is this clearly stated in the PIS? |  |  |  |  |
| 14 | Is it clear how long each participant will be involved in the study? |  |  |  |  |
| 15 | Has registration of the study protocol been agreed? |  |  |  |  |
| Questionnaires |  | Yes | No | Sponsor Comments | Study Team Responses |
| 1 | Does the study require the use of Bespoke or Validated Questionnaires? *If yes complete this section, if no move to next section.* |  |  |  |  |
| 2 | If Validated – who holds the license and is it valid? |  |  |  |  |
| Safety Reporting |  | Yes | No | Sponsor Comments | Study Team Responses |
| 1 | Is the Safety Reporting section in the protocol adequate? |  |  |  |  |
| 2 | Is it clear which SAEs will be reported? |  |  |  |  |
| Personnel |  | Yes | No | Sponsor Comments | Study Team Responses |
| 1 | Does the CI have previous experience of running this type of study? |  |  |  |  |
| 2 | Does the proposed research team have experience of running this type of study? |  |  |  |  |
| 3 | Are there adequate personnel to deliver the study at all sites? |  |  |  |  |
| 4 | Do individuals have adequate experience or access to relevant training to undertake their individual role in the study? |  |  |  |  |
| 5 | Do personnel know how to access the sponsor SOPs on the RG webpages? |  |  |  |  |
| Training |  | Yes | No | Sponsor Comments | Study Team Responses |
| 1 | Are all study personnel up to date with GCP Training? |  |  |  |  |
| 2 | Will study personnel be adequately trained in the process of obtaining consent? |  |  |  |  |
| 3 | Do the study personnel require TMF / ISF training? |  |  |  |  |
| Indemnity |  | Yes | No | Sponsor Comments | Study Team Responses |
| 1 | Does the study design trigger any action required in respect of referral to insurers? |  |  |  |  |
| Equipment |  | Yes | No | Sponsor Comments | Study Team Responses |
| 1 | Is there any equipment /device required specifically for the study? *If yes complete this section, if no move to next section.* |  |  |  |  |
| 2 | Is this already in place at NHS Organisations? |  |  |  |  |
| 3 | Has the equipment been reviewed and approved by appropriate Medical Physics departments? |  |  |  |  |
| 4 | Is the equipment CE Marked? |  |  |  |  |
| 5 | If not is MHRA Approval required? |  |  |  |  |
| 6 | Is the equipment on loan?(if no state who owner is) |  |  |  |  |
| 7 | Is it clear what will happen to the equipment at the end of the trial? |  |  |  |  |
| 8 | What happens to equipment that is lost / damaged during the trials? |  |  |  |  |
| 9 | Is there a calibration log? |  |  |  |  |
| 10 | Who is responsible for calibration? |  |  |  |  |
| 11 | Is there a maintenance log? |  |  |  |  |
| 12 | Who is responsible for maintenance? |  |  |  |  |
| 13 | Does a version controlled manual exist? |  |  |  |  |
| 14 | Have all personnel using the equipment been appropriately trained? |  |  |  |  |
| 15 | Is a temperature logging system required? |  |  |  |  |
| 16 | Who is responsible for recording temperature? |  |  |  |  |
| 17 | Are there clear instructions on action to be taken when temperature deviations are recorded? |  |  |  |  |
| 19 | Who will be responsible for coordinating the equipment at other sites? |  |  |  |  |
| 20 | Is a proforma to be signed by the patient required to ensure safe return of equipment? |  |  |  |  |
| Laboratories |  | Yes | No | Sponsor Comments | Study Team Responses |
| 1 | Are labs required for any part of the study? *If yes complete this section, if no move to next section.* |  |  |  |  |
| 2 | Is it clear where samples will be sent for analysis? |  |  |  |  |
| 3 | Is there an appropriate quality control system in place? |  |  |  |  |
| 4 | Is an MTA required? |  |  |  |  |
| 5 | Will any samples leave the UK? |  |  |  |  |
| 6 | Will samples be stored for further research - If yes, is this expressed in the Consent Form? |  |  |  |  |
| 7 | Will samples be anonymised, link anonymised or identifiable to the researcher? |  |  |  |  |
| 8 | Who will maintain the coding lists for the samples and where will they be stored? |  |  |  |  |
| 9 | Is it likely that the study will identify information significant to the participant or their family? |  |  |  |  |
| 10 | How will this be managed? |  |  |  |  |
| Radiology |  | Yes | No | Sponsor Comments | Study Team Responses |
| 1 | Has the Radiology expert been consulted during the protocol design and writing process? |  |  |  |  |
| External Vendors |  | Yes | No | Sponsor Comments | Study Team Responses |
| 1 | Are external vendors being used in the study? *If yes complete this section, if no move to next section.* |  |  |  |  |
| 1 | Have the external vendor /s been selected? |  |  |  |  |
| 2 | Is the vendor aware of the Sponsor processes and requirements? |  |  |  |  |
| 3 | Have the vendor personnel been trained appropriately in accordance with the Protocol and Sponsor SOPs? |  |  |  |  |
| 4 | Has the vendor been added to the Audit list for the study? |  |  |  |  |
| 5 | Is appropriate indemnity provided by the Vendor? |  |  |  |  |
| Contracts & IP |  | Yes | No | Sponsor Comments | Study Team Responses |
| 1 | Are any contracts and agreement required? *If yes complete this section, if no move to next section.* |  |  |  |  |
| 2 | List all third parties involved in providing services for the study in the comments box. Note contracts detailing liabilities etc. for supply of equipment will be required between sponsor & third party |  |  |  |  |
| 3 | Do any of the contract agreement require the services of RED or external companies? |  |  |  |  |
| 4 | Will an equipment loan agreement be necessary? |  |  |  |  |
| Monitoring |  | Yes | No | Sponsor Comments | Study Team Responses |
| 1 | Have adequate monitoring costs and resources been identified? *If yes complete this section, if no move to next section.* |  |  |  |  |
| IT | IT section included in Sponsor application form | Yes | No | Sponsor Comments | Study Team Responses |
| 1 | Do you plan to use desktop PCs to store or process data? *If yes complete this section, if no move to next section.* |  |  |  |  |
| 3 | Are all the PCs you intend to use owned by the University of Leicester – if not who owns them? |  |  |  |  |
| 4 | Do you plan to use laptops or mobile computers to store or process data? |  |  |  |  |
| 5 | Are all the laptops or mobile computers you intend to use owned by the University of Leicester – if not who owns them |  |  |  |  |
| 6 | For any non-university PC, lap top or mobile computer or removable media, are there any issues with virus protection or encryption or backup? |  |  |  |  |
| 7 | Do you plan to use any other mobile device to store or process data e.g. smart phone? – if so, if this device (s) owned by the University |  |  |  |  |
| 8 | Do you plan to store data on any University of Leicester storage or servers – if so, which drives, storage or servers do you plan to use e.g. Z:Drive, X:drive, R:drive |  |  |  |  |
| 9 | Do you plan to transfer data between different organisations e.g. UoL&& NHS? |  |  |  |  |
| 10 | Which organisations do you intend to transfer data between? |  |  |  |  |
| 11 | Which data transfer methods do you intend to use? |  |  |  |  |
| 12 | If you plan to use email, will the email account be accessed on a mobile device e.g. smartphone or iPad? |  |  |  |  |
| 13 | Is further advice required from IT services? |  |  |  |  |