**Sponsor review Checklist (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. It should be completed in conjunction with the Risk Assessment Form if applicable. A flowchart of the procedures required are detailed in the Sponsor Risk Assessment & management of Research Sponsored by UOL – SOP S-1003.

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Sponsor oversight area | Sponsor Review Consideration | Yes | No(or mark N/A) | Sponsor Comments | Study Team Response |
| **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 Response |
| 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 Response |
| 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 & 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 | **CTIMPs only:** Will any treatment or medication be withdrawn – if so is this clear in the PIS? |  |  |  |  |
| 14 | **CTIMPs only:**-Will the treatment / medication be available post study – is this clear in the PIS? |  |  |  |  |
| 15 | Is it clear that regulatory authorities/sponsor etc. may look at notes? |  |  |  |  |
| 16 | Is it clear how participants can withdraw from the study?  |  |  |  |  |
| 17 | Is it clear if any study specific procedures are required prior to consent i.e. fasting to attend clinic? |  |  |  |  |
| 18 | If relevant, is it clear what procedures are in place should participants lose capacity once consented? |  |  |  |  |
| 19 | If it is important that participants are not involved in other studies, is this included in the PIS (and protocol in exclusion criteria)? |  |  |  |  |
| 20 | Do any sub studies have separate sections in the PIS & appropriate consent forms? |  |  |  |  |
| 21 | Is it clear what samples will be taken during the study and does it states that if samples to be retained for use in future research, consent will be sought to allow this? |  |  |  |  |
| 22 | If applicable, is it clear that GP will be notified about participation in study? |  |  |  |  |
| 23 |  Are research specific procedure results notified to the participant and / or GP, and is this clearly stated in the Protocol & PIS? |  |  |  |  |
| 24 | Are research specific procedure results written in the patient medical record as well as the CRF but not specifically notified directly to the participant and / or GP, and is this clearly stated in the Protocol & PIS? |  |  |  |  |
| 25 | Are research specific procedure results written only in the CRF, and only the fact that the test has been carried out noted in the participant medical record with contact details for further information and no notification to GP, and is this clearly stated in the Protocol & PIS? |  |  |  |  |
| Consent Forms/ Process |  | Yes | No | Sponsor Comments | Study Team Response |
| 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? |  |  |  |  |
| 5 | If Multi-Centre – is it clear who will verify that appropriate personnel will be obtaining consent? |  |  |  |  |
| 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 Multi-Centre – Is it clear where signed consent forms be stored during and at the end of the study? |  |  |  |  |
| 9 | Will participants who lack capacity be included in the study? |  |  |  |  |
| 10 | Is there a process for Assent prior to Consent? |  |  |  |  |
| 11 | Is there a process for confirming consent at subsequent clinic/study visits |  |  |  |  |
| 12 | If samples taken during study are to be retained for use in future research, has explicit consent been requested to allow this |  |  |  |  |
| 13 | Is there adequate time in the IRAS form allocated for the consent process? |  |  |  |  |
| 14 | Is it clear how the consent process will be recorded? |  |  |  |  |
| 15 | Will interpreters be used? |  |  |  |  |
| Patient/Public Involvement |  | Yes | No | Sponsor Comments | Study Team Response |
| 1 | If applicable, has there been adequate protocol development involving patients, service users, and / or their carers, or members of the public? |  |  |  |  |
| 2 | Will patients, service users, and / or their carers, or members of the public be used in the delivery of the research? |  |  |  |  |
| 3 | Will patients, service users, and / or their carers, or members of the public be used in the dissemination or publication of the research? |  |  |  |  |
| 4 | Will travel or out of pocket expenses to the patients, service users, and / or their carers, or members of the public be reimbursed - please consult INVOLVE website? |  |  |  |  |
| **DATA** |  | **Yes** | **No** | **Sponsor Comments** | **Study Team Response** |
| 1 | What type of database will be used? |  |  |  |  |
| 2 | Is the database bespoke or off the shelf? |  |  |  |  |
| 3 | Where is it held? |  |  |  |  |
| 4 | Who owns the user licence for the database? |  |  |  |  |
| 5 | Is access to the data restricted? |  |  |  |  |
| 6 | Are there validation processes in place? |  |  |  |  |
| 7 | How frequently will validation take place |  |  |  |  |
| 8 | Who will manage data queries? |  |  |  |  |
| 9 | If Multi-Centre – who will provide support to sites & manage data queries? |  |  |  |  |
| 10 | How will data cleansing be carried out? |  |  |  |  |
| 11 | What QC measures are in place? |  |  |  |  |
| 12 | Has the CRF informed the database? |  |  |  |  |
| 13 | Is identifiable data being stored outside of the NHS? |  |  |  |  |
| 14 | If yes, does the consent form give explicit consent for this? |  |  |  |  |
| 15 | Is there a process for anonymisation / pseudonymisation? |  |  |  |  |
| 16 | When will data lock occur? |  |  |  |  |
| 17 | When is data release expected? |  |  |  |  |
| 18 | Is the data team included in protocol amendment discussions and implementation? |  |  |  |  |
| 19 | What will source data comprise of? |  |  |  |  |
| 20 | Is the CRF Electronic or paper form? |  |  |  |  |
| 21 | Who will complete the CRFs/e-CRFs? |  |  |  |  |
| 22 | Is there a data management plan and who wrote it? |  |  |  |  |
| 23 | Where will the enrolment log be held? |  |  |  |  |
| 24 | Where will the master list of participant study numbers be held? |  |  |  |  |
| 25 | Is there a backup of the database or system restore protocol? |  |  |  |  |
| 26 | Is there a disaster recovery plan in place? |  |  |  |  |
| 27 | Is the data custodian different to the CI / POC? |  |  |  |  |
| 28 | Where will analysis of the data take place? |  |  |  |  |
| 29 | How will the data be archived at the end of the study? |  |  |  |  |
| 30 | Does length of storage of data comply with sponsor policies? |  |  |  |  |
| 31 | Will any data be transferred outside of the UK/EU? |  |  |  |  |
| 32 | In this case with the data be anonymised?? |  |  |  |  |
| Randomisation |  | Yes | No | Sponsor Comments | Study Team Response |
| 1 | Is it clear what type of randomisation is being used? |  |  |  |  |
| 2 | Is there 24 / 7 cover |  |  |  |  |
| 3 | Is a third party providing randomisation? |  |  |  |  |
| 4 | Is the point of contact for randomisation clear? |  |  |  |  |
| 5 | Is the un-blinding process of participants clear? |  |  |  |  |
| 6 | Is there a formal documented process for un-blinding? |  |  |  |  |
| **Statistics** |  | **Yes** | **No** | **Sponsor Comments** | **Study Team Response** |
| 1 | Is it clear who has provided Stats support during the development of the protocol? |  |  |  |  |
| 2 | Is it clear who will be providing Stats support during the life cycle of the trial? |  |  |  |  |
| 3 | Are the Stats support personnel employed by a third party?- If so, contracts will be required? |  |  |  |  |
| 4 | Has a Stats plan been written? |  |  |  |  |
| 5 | Is it clear how the analysis will take place?  |  |  |  |  |
| 6 | Has the analysis programme referred to in the protocol? |  |  |  |  |
| 7 | Does the university own the licence? |  |  |  |  |
| Recruitment Strategies  |  | Yes | No | Sponsor Comments | Study Team Response |
| 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 Response |
| 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? |  |  |  |  |
| 12 | **CTIMP only**: If proved successful will there be an option for the participant to continue with treatment post study? |  |  |  |  |
| 13 | **CTIMP only**: Is this clear 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 Response |
| 1 | Does the study require the use of Bespoke or validated Questionnaires? |  |  |  |  |
| 2 | If Validated – who holds the license and is it valid? |  |  |  |  |
| 3 | Are questionnaires provided by third parties? |  |  |  |  |
| Safety Reporting |  | Yes | No | Sponsor Comments | Study Team Response |
| 1 | Are the study team trained in the Sponsor process of safety reporting? |  |  |  |  |
| 2 | Is the Safety Reporting section in the protocol adequate? Is it clear which SAEs will be reported? |  |  |  |  |
| 3 | If Multi-Centre - Will the sponsor process for safety reporting be followed? |  |  |  |  |
| 4 | If Multi-Centre – Is it clear who will coordinate the safety reporting for all sites? Insert name in comments. |  |  |  |  |
| 5 | Will medical oversight be provided in the absence of the CI? If so, provide details of named individual. |  |  |  |  |
| 6 | Is it clear who is responsible for ensuring annual review of SmPC / IB /DSUR and annual reports? |  |  |  |  |
| 7 | Is a DSMC to be established (Sponsor must be copied into all minutes from meetings & DSMC reports)? |  |  |  |  |
| 8 | If so, is it utilising the sponsor Charter template? |  |  |  |  |
| 9 | **CTIMP only**: Is there a named individual responsible for completion of e-SUSAR |  |  |  |  |
| 10 | **CTIMP only**: Is it clear who will complete e-SUSAR if study team are blinded? |  |  |  |  |
| Personnel  |  | Yes | No | Sponsor Comments | Study Team Response |
| 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 | If multi-centre, how have trial personnel been identified and chosen at each site? |  |  |  |  |
| 5 | Do individuals have adequate experience or access to relevant training to undertake their individual role in the study? |  |  |  |  |
| 6 | Do personnel know how to access the sponsor SOPs on the RG webpages? |  |  |  |  |
| 7 | Will there be regular study progress updates to all study personnel? |  |  |  |  |
| 8 | Is there a named person and process as to how study specific updates, amendments, safety information etc. be disseminated to all study personnel? |  |  |  |  |
| Training |  | Yes | No | Sponsor Comments | Study Team Response |
| 1 | Are all study personnel up to date with GCP Training? |  |  |  |  |
| 2 | Or if full team unknown how will this be verified? |  |  |  |  |
| 3 | If Multi-Centre –will study personnel access GCP Training in accordance with sponsor requirements? |  |  |  |  |
| 4 | Do all study personnel require GCP Training? |  |  |  |  |
| 5 | Will the main site provide protocol & equipment training? Will it be adequate? |  |  |  |  |
| 6 | Will study personnel be adequately trained in the process of obtaining consent? |  |  |  |  |
| 7 | Will the study staff have training files and is it clear who will keep the training files up to date? |  |  |  |  |
| 8 | Is it clear how training throughout the trial will be managed including amended documents and revisions to trial processes? |  |  |  |  |
| 9 | Is it clear how study specific training will be recorded? |  |  |  |  |
| 10 | Do the study personnel require TMF / ISF training? |  |  |  |  |
| 11 | Is it clear how SOP training will be delivered to all study personnel? |  |  |  |  |
| Indemnity |  | Yes | No | Sponsor Comments | Study Team Response |
| 1 | Does the study design trigger any action required in respect of referral to insurers? |  |  |  |  |
| Equipment |  | Yes | No | Sponsor Comments | Study Team Response |
| 1 | Is there any equipment /device required specifically for the study? |  |  |  |  |
| 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 | 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 Response |
| 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? |  |  |  |  |
| Pharmacy | CTIMP only | Yes | No | Sponsor Comments | Study Team Response |
| 1 | Where Pharmacy is required, have the study team started discussions – are there any issues that need to be addressed early in study work up Refer to Risk assessment page 4 |  |  |  |  |
| Radiology |  | Yes | No | Sponsor Comments | Study Team Response |
| 1 | Has the Radiology expert been consulted during the protocol design and writing process? |  |  |  |  |
| External Vendors |  | Yes | No | Sponsor Comments | Study Team Response |
| 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 Response |
| 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 |  |  |  |  |
| 2 | Do any of the contract agreement require the services of RED or external companies? |  |  |  |  |
| 3 | Does this study have any IP issues and need to be sent to the relevant IP lead? |  |  |  |  |
| 4 | Will an equipment loan agreement be necessary? |  |  |  |  |
| Monitoring |  | Yes | No | Sponsor Comments | Study Team Response |
| 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 Response |
| 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?  |  |  |  |  |