This sponsor review checklist must be completed by the Head of Research Operations (UHL) or their delegate when conducting Sponsor reviews on behalf of UHL.

**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)** | **Comments** |
| **General Points To Be Considered Across All Study Documentation** |  |
| 1 | Is the study title consistent across all documentation? |  |  | **Sponsor 13 WF** |
| 2 | Does the document footer contain the document title, version/date and pages numbers? Check for cut and paste, grammar and spelling errors. |  |  | **Sponsor 13 WF** |
| 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?) |  |  | **Sponsor 13 WF** |
| 4 | Is there a clear process for allocating participants a unique identifier? |  |  | **Sponsor 11 E** |
| **Funding** |  | **Yes** | **No**  | **Comments**  |
| 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,  |  |  | **Sponsor 9 E** |
| 2 | Are any funds passing to third parties? i.e. contractors/sites |  |  | **Finance Approval E** |
| **Patient Information Sheets** |  | **Yes** | **No** | **Comments** |
| 1 | Does the PIS share the same title as the other study documentation? |  |  | **Sponsor 15 WF** |
| 2 | Has the HRA template been used and is the PIS appropriately dated and version controlled, paginated, spelt correctly and grammar clear? |  |  | **Sponsor 15 WF** |
| 3 | Does the PIS reflect the protocol and IRAS form giving adequate details to the potential participant? |  |  | **Sponsor 15 WF** |
| 4 | Is the indemnity clause worded appropriately? |  |  | **Sponsor 15 WF** |
| 5 | Is the funding clause worded appropriately and accurately? |  |  | **Sponsor 15 WF** |
| 6 | Is if clear who to contact about the study & the contact number for further information correct? |  |  | **Sponsor 15 WF** |
| 7 | Are all procedures involved in the study clear in the PIS? |  |  | **Sponsor 15 WF** |
| 8 | Are the risks / benefits clearly stated to the participants? |  |  | **Sponsor 15 WF** |
| 9 | Have any sensitive or difficult topics to be discussed been written clearly? |  |  | **Sponsor 15 WF** |
| 10 | If so, is there adequate provision for additional support and has this been included in the costing? |  |  | **Sponsor 9 E** |
| 11 | Is it clear how long will each participant be involved in the study? |  |  | **Sponsor 15 WF** |
| 12 | Will there be any reimbursement of travel expenses or any other payment to participants and is this clear in PIS? |  |  | **Sponsor 15 WF** |
| 13 | Is it clear that regulatory authorities/sponsor etc. may look at notes? |  |  | **Sponsor 15 WF** |
| 14 | Is it clear how participants can withdraw from the study?  |  |  | **Sponsor 15 WF** |
| 15 | Is it clear if there any study specific procedures required prior to consent i.e. fasting to attend clinic? |  |  | **Sponsor 15 WF** |
| 16 | If relevant, is it clear what procedures are in place should participants loose capacity once consented? |  |  | **Sponsor 15 WF** |
| 17 | If it is important that participants are not involved in other studies, is this included in PIS (and protocol in exclusion criteria)? |  |  | **Sponsor 15 WF** |
| 18 | Do any sub studies have separate sections in the PIS & appropriate consent forms? |  |  | **Sponsor 15 WF** |
| 19 | 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? |  |  | **Sponsor 15 WF** |
| 20 | If applicable, is it clear that GP will be notified about participation in study? |  |  | **Sponsor 15 WF** |
| 21 |  Are research specific procedure results notified to the participant and / or GP, and is this clearly stated in the Protocol & PIS? |  |  | **Sponsor 15 WF** |
| **Consent Forms/ Process** |  | **Yes** | **No** | **Comments** |
| 1 | Has the HRA template been used and is the CF appropriately dated and version controlled, paginated, spelt correctly and grammar clear? |  |  | **Sponsor 15 WF** |
| 2 | Is it clear that regulatory authorities/sponsor etc. may look at notes? |  |  | **Sponsor 15 WF** |
| 3 | Has express permission been obtained to inform the participant GP about participation in the study? |  |  | **Sponsor 15 WF** |
| 4 | Are personnel appropriately trained to obtain consent from participants or will study specific training be provided& by whom? |  |  | **Sponsor 15 WF & Sponsor 09 WF** |
| 6 | Will participant identifiable data leave the NHS Organisation? |  |  | **Sponsor 15 WF & Sponsor 11 E** |
| 7 | If participant identifiable data is to leave the NHS Organisation, has express permission been sought on the consent form? |  |  | **Sponsor 15 WF & Sponsor 11 E** |
| 8 | If samples taken during study are to be retained for use in future research, has explicit consent been requested to allow this |  |  | **Sponsor 15 WF** |
| 9 | Is there adequate time in the IRAS form allocated for the consent process? |  |  | **Sponsor 11 E** |
| 10 | Is it clear how the consent process will be recorded? |  |  | **Sponsor 11 E** |
| 11 | Will interpreters be used? |  |  | **Sponsor 11 E** |
| **Patient/****Public Involvement** |  | **Yes** | **No** | **Comments** |
| 1 | If applicable, has there been adequate protocol development involving patients, service users, and / or their carers, or members of the public? |  |  | **Mandatory Category 1 E** |
| **DATA** |  | **Yes** | **No** | **Comments** |
| 1 | Does this study require advice from information governance or the data security team? |  |  | **Mandatory Category 4 E** |
| **Recruitment Strategies**  |  | **Yes** | **No** | **Comments** |
| 1 | Is the recruitment strategy relevant to the participant population? |  |  | **SPONSOR 13 WF** |
| 2 | Are individuals with capacity issues to be approached to participate? |  |  | **MANDATORY CATEGORY 1 E** |
| 3 | Are pregnant women to be approached to participate? |  |  | **MANDATORY CATEGORY 1 E** |
| 4 | Are children to be approached to participate? |  |  | **MANDATORY CATEGORY 1 E** |
| 5 | Is the research team aware of recruitment timelines and targets? |  |  | **SPONSOR 13 WF** |
| 6 | If Multi-Centre – is the recruitment target per site feasible? |  |  | **SPONSOR 2 WF** |
| 8 | Who will be accessing participant medical records to collect data? |  |  | **STUDY STAFF ADDED WF** |
| 9 | Do the study personnel accessing data have legitimate permission? |  |  | **STUDY STAFF ADDED WF** |
| 10 | Do personnel accessing identifiable data possess appropriate contracts with the NHS Organisation? |  |  | **STUDY STAFF ADDED WF** |
| 11 | Are there conflicting studies that will have an effect on ability to recruit targets? |  |  | **SPONSOR 5 E** |
| 12 | Recruitment of healthy volunteers – how will medical history be confirmed? |  |  | **SPONSOR 13 E** |
| **Protocol** |  | **Yes** | **No** | **Comments** |
| 1 | Has the Protocol been adequately peer reviewed?  |  |  | **SPONSOR 13 WF** |
| 2 | Are there any outstanding queries in relation to the Peer Review? |  |  | **SPONSOR 13 WF** |
| 3 | Is there a process for ensuring all study personnel, at all sites are trained in the protocol? |  |  | **SPONSOR 13 WF** |
| 4 | Is it clear who will do protocol training? |  |  | **SPONSOR 13 WF / SPONSOR 10 OR 11 WF** |
| 5 | Is the Chief Investigator listed as an author on the Protocol |  |  | **SPONSOR 13 WF** |
| 6 | Has the sponsor template been used?- If not, are all relevant sections of the Protocol included i.e. Safety reporting / inclusion / exclusion etc. |  |  | **SPONSOR 13 WF** |
| 7 | Have all aspects of the protocol been included in the IRAS application? |  |  | **SPONSOR 13 WF** |
| 8 | Do the IRAS application and the protocol correlate with each other? |  |  | **SPONSOR 13 WF** |
| 9 | Have all clinical and non- clinical procedures within the protocol been listed in IRAS? |  |  | **SPONSOR 13 WF** |
| 10 | Will any standard or routine treatments or medication be withheld prior to or during the study? |  |  | **SPONSOR 15 WF** |
| 11 | If so, is this clearly stated in the PIS? |  |  | **SPONSOR 15 WF** |
| 12 | Is it clear how long each participant will be involved in the study? |  |  | **SPONSOR 15 WF** |
| 13 | Has registration of the study protocol been agreed? |  |  | **SPONSOR 13 WF** |
| **Questionnaires** |  | **Yes** | **No** | **Comments** |
| 1 | Does the study require the use of Bespoke or validated Questionnaires? *If yes complete this section, if no move to next section.* |  |  | **SPONSOR 6 E** |
| 2 | If Validated – who holds the license and is it valid? |  |  | **SPONSOR 6 E** |
| **Safety Reporting** |  | **Yes** | **No** | **Comments** |
| 1 | Is the Safety Reporting section in the protocol adequate?  |  |  | **SPONSOR 8 WF** |
| 2 | Is it clear which SAEs will be reported? |  |  | **SPONSOR 8 WF** |
| **Personnel**  |  | **Yes** | **No** | **Comments** |
| 1 | Does the CI have previous experience of running this type of study? |  |  | **SPONSOR 13 WF** |
| 2 | Does the proposed research team have experience of running this type of study? |  |  | **SPONSOR 13 WF** |
| 3 | Are there adequate personnel to deliver the study at all sites? |  |  | **SPONSOR 13 WF** |
| 4 | Do individuals have adequate experience or access to relevant training to undertake their individual role in the study? |  |  | **SPONSOR 13 WF** |
| 5 | Do personnel know how to access the sponsor SOPs on the RG webpages? |  |  | **SPONSOR 13 WF / SPONSOR 2 WF** |
| **Training** |  | **Yes** | **No** | **Comments** |
| 1 | Are all study personnel up to date with GCP Training? |  |  | **SPONSOR 9/10 WF** |
| 2 | Will study personnel be adequately trained in the process of obtaining consent? |  |  | **SPONSOR 9/10 WF** |
| 3 | Do the study personnel require TMF / ISF training? |  |  | **SPONSOR 9/10 WF** |
| **Indemnity** |  | **Yes** | **No** | **Comments** |
| 1 | Does the study design trigger any action required in respect of referral to insurers? |  |  | N/A  |
| **Equipment** |  | **Yes** | **No** | **Comments** |
| 1 | Is there any equipment /device required specifically for the study? *If yes complete this section, if no move to next section.* |  |  | **Medical Devices/Equipment E** |
| 2 | Is this already in place at NHS Organisations? |  |  | **Medical Devices/Equipment E** |
| 3 | Has the equipment been reviewed and approved by appropriate Medical Physics departments? |  |  | **Medical Devices/Equipment E** |
| 4 | Is the equipment CE Marked? |  |  | **Medical Devices/Equipment E** |
| 5 | If not is MHRA Approval required? |  |  | **Medical Devices/Equipment E** |
| 6 | Is the equipment on loan?(if no state who owner is) |  |  | **Medical Devices/Equipment E** |
| 7 | Is it clear what will happen to the equipment at the end of the trial? |  |  | **Medical Devices/Equipment E** |
| 8 | What happens to equipment that is lost / damaged during the trials? |  |  | **Medical Devices/Equipment E** |
| 9 | Is there a calibration log? |  |  | **Medical Devices/Equipment E** |
| 10 | Who is responsible for calibration? |  |  | **Medical Devices/Equipment E** |
| 11 | Is there a maintenance log? |  |  | **Medical Devices/Equipment E** |
| 12 | Who is responsible for maintenance? |  |  | **Medical Devices/Equipment E** |
| 13 | Does a version controlled manual exist? |  |  | **Medical Devices/Equipment E** |
| 14 | Have all personnel using the equipment been appropriately trained? |  |  | **Medical Devices/Equipment E** |
| 15 | Is a temperature logging system required? |  |  | **Laboratory Services E / Managed Fridge/Freezer requirements** |
| 16 | Who is responsible for recording temperature? |  |  | **Laboratory Services E / Managed Fridge/Freezer requirements** |
| 17 | Are there clear instructions on action to be taken when temperature deviations are recorded? |  |  | **Laboratory Services E / Managed Fridge/Freezer requirements** |
| 19 | Who will be responsible for coordinating the equipment at other sites? |  |  | **Laboratory Services E / Managed Fridge/Freezer requirements** |
| 20 | Is a proforma to be signed by the patient required to ensure safe return of equipment? |  |  | **Medical Devices/Equipment E** |
| **Laboratories** |  | **Yes** | **No** | **Comments** |
| 1 | Are labs required for any part of the study? *If yes complete this section, if no move to next section.* |  |  | **Laboratory Services E** |
| 2 | Is it clear where samples will be sent for analysis? |  |  | **Laboratory Services E** |
| 3 | Is there an appropriate quality control system in place? |  |  | **Laboratory Services E** |
| 4 | Is an MTA required? |  |  | **Contracts E** |
| 5 | Will any samples leave the UK? |  |  | **Laboratory Services E** |
| 6 | Will samples be stored for further research - If yes, is this expressed in the Consent Form? |  |  | **Laboratory Services E** |
| 7 | Will samples be anonymised, link anonymised or identifiable to the researcher? |  |  | **Laboratory Services E** |
| 8 | Who will maintain the coding lists for the samples and where will they be stored? |  |  | **Laboratory Services E** |
| 9 | Is it likely that the study will identify information significant to the participant or their family? |  |  | **SPONSOR 11 E** |
| 10 | How will this be managed? |  |  | **SPONSOR 11 E** |
| **Radiology** |  | **Yes** | **No** | **Comments** |
| 1 | Has the Radiology expert been consulted during the protocol design and writing process? |  |  | **Mandatory Category 1 E** |
| **External Vendors** |  | **Yes** | **No** | **Comments** |
| 1 | Are external vendors being used in the study? *If yes complete this section, if no move to next section.* |  |  | **SPONSOR 24 WF** |
| 2 | Have the external vendor /s been selected? |  |  | **SPONSOR 24 WF** |
| 3 | Is the vendor aware of the Sponsor processes and requirements? |  |  | **SPONSOR 24 WF** |
| 4 | Have the vendor personnel been trained appropriately in accordance with the Protocol and Sponsor SOPs? |  |  | **SPONSOR 24 WF** |
| 5 | Has the vendor been added to the Audit list for the study? |  |  | **SPONSOR 24 WF** |
| 6 | Is appropriate indemnity provided by the Vendor? |  |  | **SPONSOR 24 WF** |
| **Contracts & IP** |  | **Yes** | **No** | **Comments** |
| 1 | Are any contracts and agreement required? *If yes complete this section, if no move to next section.* |  |  | **Contracts E / SPONSOR 25 WF** |
| 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 |  |  | **Contracts E / SPONSOR 25 WF** |
| 2 | Do any of the contract agreement require the services of Contracts Manager? |  |  | **Contracts E / SPONSOR 25 WF** |
| **Monitoring** |  | **Yes** | **No** | **Comments** |
| 1 | Have adequate monitoring costs and resources been identified? *If yes complete this section, if no move to next section.* |  |  | **Monitoring Arrangements E** |
| **IT** |  | **Yes** | **No** | **Comments** |
| 1 | Do you plan to use desktop PCs to store or process data? *If yes complete this section, if no move to next section.* |  |  | **DATA / CRF E** |
| 3 | Are all the PCs you intend to use owned by the UHL – if not who owns them? |  |  | **SPONSOR 5 E** |
| 4 | Do you plan to use laptops or mobile computers to store or process data? |  |  | **SPONSOR 5 E** |
| 5 | Are all the laptops or mobile computers you intend to use owned by the UHL – if not who owns them |  |  | **SPONSOR 5 E** |
| 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?  |  |  | **SPONSOR 5 E** |
| 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 |  |  | **SPONSOR 5 E** |
| 8 | Do you plan to store data on any UHL storage or servers – if so, which drives, storage or servers do you plan to use  |  |  | **SPONSOR 5 E** |
| 9 | Do you plan to transfer data between different organisations e.g. UHL& Non-NHS? |  |  | **DATA / CRF E** |
| 10 | Which organisations do you intend to transfer data between? |  |  | **DATA / CRF E** |
| 11 | Which data transfer methods do you intend to use? |  |  | **DATA / CRF E** |
| 12 | If you plan to use email, will the email account be accessed on a mobile device e.g. smartphone or iPad? |  |  | **DATA / CRF E** |
| 13 | Is further advice required from IT services?  |  |  | **DATA / CRF E** |