Clinical Trial Sponsorship Review Checklist

CTS-FORM005

For Office Use: ***LU-CTRN***	

This Clinical Trial Sponsorship Review Checklist must be completed by Clinical Research Support Officer or their delegate for all clinical trials sponsored by Lancaster University. It should be completed in conjunction with the Clinical Trial Sponsorship Risk Assessment Form and supporting trial documentation.

Note: Where the answer to the sponsor review consideration is not 'Yes', 'No' or 'Not Applicable', a written response should be provided in the comments box. Please use the comments box to provide further information where needed for any responses.

No.	Sponsor Review Consideration	Yes	No	N/A	Comments
Section 1 – 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, page numbers and IRAS reference numbers where applicable? Check for cut and paste, grammar and spelling errors.	☐	☐	☐	
3.	Has the study been referred to or described consistently across all documentation? (e.g. study or trial, calorie deficit study or calorie restricted trial?)	☐	☐	☐	
Section 2 – Funding					
1.	Is there evidence of funding e.g letter?	☐	☐	☐	
2.	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, laboratory, radiology, tests etc.?	☐	☐	☐	
3.	Are any funds passing to third parties i.e. contractor /sites?	☐	☐	☐	
Section 3 – Participant Information Sheet(s) (PIS)					
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 and include the IRAS reference number?	☐	☐	☐	
3.	Are there appropriate information sheets for all cohorts e.g. children and young people, parents/guardians, carers, consultees?	☐	☐	☐	
4.	Does the PIS reflect the protocol and IRAS form giving adequate details to the potential participant?	☐	☐	☐	
5.	Is the indemnity clause worded appropriately?	☐	☐	☐	

For Office Use: ***LU-CTRN***	

No.	Sponsor Review Consideration	Yes	No	N/A	Comments
6.	Is the funding clause worded appropriately and accurately?	☐	☐	☐	
7.	Is it clear who to contact about the study the contact number for further information correct?	☐	☐	☐	
8.	Are all procedures involved in the study clear in the PIS?	☐	☐	☐	
9.	Are the risks / benefits clearly stated to the participants?	☐	☐	☐	
10.	Have any sensitive or difficult topics to be discussed been written clearly?	☐	☐	☐	
11.	If so, is there adequate provision for additional support and has this been included in the costing?	☐	☐	☐	
12.	Is it clear how long will each participant be involved in the study?	☐	☐	☐	
13.	Will there be any reimbursement of travel expenses or any other payment to participants and is this clear in PIS?	☐	☐	☐	
14.	Will any standard of care intervention(s) be withdrawn - if so is this clear in the PIS?	☐	☐	☐	
15.	Will the research intervention(s) be available post study – is this clear in the PIS?	☐	☐	☐	
16.	Is it clear what data will be collected from the participants, where it will be stored, how long it will be retained and how it will be destroyed?	☐	☐	☐	
17.	Is it clear that data will be transferred to a country or territory outside the European Economic Area (EEA)?	☐	☐	☐	
18.	Is it clear that regulatory authorities/sponsor etc. may look at research data for monitoring or auditing purposes?	☐	☐	☐	
19.	Is it clear how participants can withdraw from the study?	☐	☐	☐	
20.	Is it clear if there any study specific procedures required prior to consent e.g. fasting to attend clinic?	☐	☐	☐	
21.	Is it clear what procedures are in place should participants loose capacity once consented?	☐	☐	☐	
22.	If it is important that participants are not involved in other studies, is this included in PIS (and protocol in exclusion criteria)?	☐	☐	☐	
23.	Do any sub studies have separate sections in the PIS & appropriate consent forms?	☐	☐	☐	

No.	Sponsor Review Consideration	Yes	No	N/A	Comments
24.	Is it clear what tissue 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?	☐	☐	☐	
25.	Is it clear that GP will be notified about participation in study?	☐	☐	☐	
26.	Are research specific procedure results notified to the participant and/or GP, and is this clearly stated in the Protocol & PIS?	☐	☐	☐	
27.	Are the 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?	☐	☐	☐	
28.	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?	☐	☐	☐	
29.	Have any sensitive or difficult topics to be discussed been written clearly?	☐	☐	☐	
Section 4 – Informed Consent Process/Form(s) (ICF)					
1.	Has the HRA ICF template been used and is the ICF appropriately dated and version controlled and include the IRAS reference number?	☐	☐	☐	
2.	Will participants who lack capacity to consent be included in the study?	☐	☐	☐	
3.	Is there an appropriate process in place for nominated/appointed consultees to inform consent on the behalf of the participant?	☐	☐	☐	
4.	Will children (aged <16 y.o.) be included in the study?	☐	☐	☐	
5.	Is there an appropriate process in place for child assent?	☐	☐	☐	
6.	Are there appropriate assent/consent forms for all cohorts e.g. children and young people, parents/guardians, carers, consultees?	☐	☐	☐	
7.	Is consent sought for regulatory authorities/sponsor etc. to access medical records for monitoring and auditing purposes?	☐	☐	☐	

For Office Use: ***LU-CTRN***	

No.	Sponsor Review Consideration	Yes	No	N/A	Comments
8.	Is consent sought for individuals outside of the participant's direct healthcare team to access their medical records for the purpose of the study?	☐	☐	☐	
9.	Has consent been sought to inform the GP about their patient's participation in the study?	☐	☐	☐	
10.	Has been consent been sought to make audio or video recordings of the participants as part of the study?	☐	☐	☐	
11.	Are personnel appropriately trained to obtain consent from participants or will study specific training be provided& by whom?	☐	☐	☐	
12.	If Multi-Centre – is it clear who will verify that appropriate personnel will be obtaining consent?	☐	☐	☐	
13.	Will interpreters been used to facilitate the informed consent process?	☐	☐	☐	
14.	Is there a process for confirming consent at subsequent clinic/study visits?	☐	☐	☐	
15.	Is consent sought for obtaining tissue samples?	☐	☐	☐	
16.	If tissue samples are collected, is consent sought to retain the tissue samples for use in future research?	☐	☐	☐	
17.	Is there adequate time in the IRAS form allocated for the consent process?	☐	☐	☐	
18.	Is it clear in the application that potential participants will be given a minimum of 24 hours to decide whether they would like to take part in the study?	☐	☐	☐	
19.	Is it clear how the consent process will be recorded?	☐	☐	☐	
Section 5 – Patient and Public Involvement					
1.	If applicable, have 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?	☐	☐	☐	

For Office Use: ***LU-CTRN***	

No.	Sponsor Review Consideration	Yes	No	N/A	Comments
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?	☐	☐	☐	
Section 6 – Research Data Management and Security					
1.	Has a Lancaster University Research Data Management Plan been created?	☐	☐	☐	
2.	If Multi-Centre – who will provide support to sites & manage data queries?	☐	☐	☐	
3.	How will data cleansing be carried out?	☐	☐	☐	
4.	What QC measures are in place?	☐	☐	☐	
5.	Has the CRF informed the database?	☐	☐	☐	
6.	Is identifiable data being transferred outside of the NHS?	☐	☐	☐	
7.	If yes, does the consent form give explicit consent for this?	☐	☐	☐	
8.	Is there a process for anonymisation / pseudonymisation?	☐	☐	☐	
9.	When will data lock occur?	☐	☐	☐	
10.	When is data release expected?	☐	☐	☐	
11.	Is the data team included in protocol amendment discussions and implementation?	☐	☐	☐	
12.	What will source data comprise of?	☐	☐	☐	
13.	Is the CRF Electronic or paper form?	☐	☐	☐	
14.	Who will complete the CRFs/e-CRF?	☐	☐	☐	
15.	Where will the enrolment log be held?	☐	☐	☐	
16.	Where will the master list of participant study numbers be held?	☐	☐	☐	
17.	Is the data custodian different to the CI / POC?	☐	☐	☐	
18.	Where will analysis of the data take place?	☐	☐	☐	
19.	How will the data be archived at the end of the study?	☐	☐	☐	
20.	Will any data be transferred to a country or territory outside the European Economic Area (EEA)?	☐	☐	☐	
21.	If yes to 22 will the data be anonymised?	☐	☐	☐	
Section 7 – Randomisation					
1.	Is it clear what type of randomisation is being used?	☐	☐	☐	
2.	Is there 24 / 7 cover	☐	☐	☐	
3.	Is a third party providing randomisation?	☐	☐	☐	

No.	Sponsor Review Consideration	Yes	No	N/A	Comments
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?	☐	☐	☐	
Section 8 – Statistics					
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 life cycle of 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 been referred to in the protocol?	☐	☐	☐	
7.	Who owns the licence?	☐	☐	☐	
Section 9 – Participant Recruitment					
1.	Has an overall recruitment target been set?	☐	☐	☐	
2.	Will participants be recruited from outside of the UK?	☐	☐	☐	
3.	Is the recruitment strategy relevant to the participant population?	☐	☐	☐	
4.	Will pregnant women be recruited to the study?	☐	☐	☐	
5.	Is the research team aware of recruitment timelines and targets?	☐	☐	☐	
6.	If Multi-Centre – is the recruitment target per site feasible?	☐	☐	☐	
7.	Will members of the research team be accessing the participant's medical records?	☐	☐	☐	
8.	Are there conflicting studies that will have an effect on ability to recruit targets?	☐	☐	☐	
9.	Recruitment of healthy volunteers – how will medical history be confirmed?	☐	☐	☐	
10.	Is the recruitment strategy relevant to the participant population?	☐	☐	☐	
Section 10 – Protocol					
1.	Has the Protocol been adequately peer reviewed?	☐	☐	☐	
2.	Are there any outstanding queries in relation to the Peer Review?	☐	☐	☐	

No.	Sponsor Review Consideration	Yes	No	N/A	Comments
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.	Is it clear how long each participant will be involved in the study?	☐	☐	☐	
13.	Has registration of the study protocol been agreed?	☐	☐	☐	
Section 11 – Questionnaires					
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?	☐	☐	☐	
Section 12 – Safety Reporting					
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.	☐	☐	☐	

No.	Sponsor Review Consideration	Yes	No	N/A	Comments
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?	☐	☐	☐	
Section 13 – Study Team					
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?	☐	☐	☐	
9.	Do relevant members of the research team have Research Passports?	☐	☐	☐	
10.	Will relevant members of the research team need appropriate contracts with the participating NHS site(s) i.e. Honorary Research Contract, Letter of Access etc.?	☐	☐	☐	
Section 14 – Training					
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?	☐	☐	☐	

No.	Sponsor Review Consideration	Yes	No	N/A	Comments
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?	☐	☐	☐	
Section 15 – Equipment					
1.	Is 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?	☐	☐	☐	
18.	Who will be responsible for coordinating the equipment at other sites?	☐	☐	☐	

For Office Use: ***LU-CTRN***	

No.	Sponsor Review Consideration	Yes	No	N/A	Comments
19.	Is a proforma to be signed by the patient required to ensure safe return of equipment?	☐	☐	☐	
20.	Are there any equipment /device required specifically for the study?	☐	☐	☐	
Section 16 – Laboratories					
1.	Will human tissue samples be taken as part of the study? *If yes complete this section, if no move to next section.*	☐	☐	☐	
2.	Will the study involve taking new tissue samples?	☐	☐	☐	
3.	Will the study involve the use of existing tissue samples?	☐	☐	☐	
4.	Are external labs required for any part of the study?	☐	☐	☐	
5.	Is it clear where samples will be sent for analysis?	☐	☐	☐	
6.	Is there an appropriate quality control system in place?	☐	☐	☐	
7.	Is an Material Transfer Agreement (MTA) required if the HRA Statement of Activities is not being used as a site agreement?	☐	☐	☐	
8.	Will any samples leave the UK?	☐	☐	☐	
9.	Will samples be stored for further research - If yes, is this expressed in the Consent Form?	☐	☐	☐	
10.	Does the study involve the use of a research tissue bank?	☐	☐	☐	
11.	Will samples be anonymised, link anonymised or identifiable to the researcher?	☐	☐	☐	
12.	Is there a named person who will maintain the coding lists for the samples and where will they be stored?	☐	☐	☐	
13.	Is it likely that the study will identify information significant to the participant or their family?	☐	☐	☐	
Section 17 – Radiology					
1.	Has the Radiology expert been consulted during the protocol design and writing process?	☐	☐	☐	
2.	Will the study involve exposure to ionising radiation?	☐	☐	☐	
3.	Will the study involve the administration of radioactive substances?	☐	☐	☐	
4.	Is an external provider required to provide a radiology service?	☐	☐	☐	
5.	Has the cost of the radiology service been included within the research grant?	☐	☐	☐	

For Office Use: ***LU-CTRN***	

No.	Sponsor Review Consideration	Yes	No	N/A	Comments
Section 18 – External Vendors					
1.	Are external vendors being used in the study? *If yes complete this section, if no move to next section.*	☐	☐	☐	
2.	Have the external vendor/s been selected?	☐	☐	☐	
3.	Is the vendor aware of the Sponsor processes and requirements?	☐	☐	☐	
4.	Have the vendor personnel been trained appropriately in accordance with the Protocol and Sponsor SOPs?	☐	☐	☐	
5.	Has the vendor been added to the Audit list for the study?	☐	☐	☐	
Section 19 – Contracts and Intellectual Property					
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 the Contracts Team?	☐	☐	☐	
4.	Does this study have any IP issues that need to be sent to the IP Manager?	☐	☐	☐	
Section 20 – Monitoring					
1.	Have adequate monitoring costs and resources been identified? *If yes complete this section, if no move to next section.*	☐	☐	☐	
Section 21 – IT					
1.	Do you plan to use desktop PCs to store or process data? *If yes complete this section, if no move to next section.*	☐	☐	☐	
2.	Are all the PCs you intend to use owned by Lancaster University – if not who owns them?	☐	☐	☐	
3.	If the machine is owned by the University, are they built using the Cyber Essentials Build (ISS Administered)?	☐	☐	☐	
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 Lancaster University? – if not who owns them	☒	☐	☐	

For Office Use: ***LU-CTRN***	

No.	Sponsor Review Consideration	Yes	No	N/A	Comments
6.	If the laptop or mobile computer is owned by the University, are they built using the Cyber Essentials Build (ISS Administered)?	☐	☐	☐	
7.	For any non-Lancaster University PC, lap top or mobile computer or removable media, are there any issues with virus protection or encryption or backup?	☐	☐	☐	
8.	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 Lancaster University.	☐	☐	☐	
9.	Do you plan to store data on any University of Lancaster storage or servers – if so, which drives, storage or servers do you plan to use?	☐	☐	☐	
10.	Do you plan to transfer data between different organisations e.g. Lancaster University & non- NHS?	☐	☐	☐	
11.	Which organisations do you intend to transfer data between?	☐	☐	☐	
12.	Which data transfer methods do you intend to use?	☐	☐	☐	