**UHL Sponsor request Guidance**

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| Please send all documentation to be reviewed by the Sponsor to UHLSponsor@uhl-tr.nhs.uk. A review will not commence until a full minimum data set is received.Minimum dataset includes: * Full IRAS Dataset (.pdf)
* Latest version of Protocol (word format - on UHL Template – See SOP S-1021 UHL)
* Latest versions of all Patient documentation – include ICF, PIS, letters etc.
* Evidence of Peer Review – See SOP S-1002 UHL
* Evidence of Finance approval – See SOP S-1034 UHL
* Latest versions of GP Letters (where appropriate)
* Copy of All data collection forms – CRF etc.
* Copy of Completed DATA / CRF Questionnaire
* CV of Chief Investigator
* Evidence of relevant training of Chief Investigator
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| **List of Documentation submitted for Sponsor Review** |
| **Name of Document** | **Version Number** | **Date of Document** |
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Please add rows as necessary

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| **Quality Check of Documents prior to submission for Sponsor review** |
| The checks listed below should be made on the documentation lists on Page 4 (above). All QC issues should be addressed prior to submission to the Sponsor for review. |
| **Check conducted** | **Conducted by** |
| Is the study title consistent across all documentation? |  |
| Have standard answers been completed in IRAS as indicated below (Page 6)? |  |
| Does the document footer contain the document title, version / date and page number and is this consistent with the document content? Please check for any cut and paste errors, grammar and spelling errors. |  |
| Has the study been referred to or described consistently within all documentation? (E.g. is it a study or a trial, calorie deficit study or calorie restricted trial etc.) |  |
| Has every protocol procedure been included in the IRAS form and PIS? Is each visit or time point named consistently (e.g. baseline visit or preadmission visit, day 1 or visit 1 etc.?) |  |
| Are all the timings/length of study procedures consistent within all documentation? |  |
| Has the Sponsor protocol template been used? |  |
| Have you listed expected side effects of all drug/treatments in your protocol? |  |
| Have all the risks and side effects in the protocol been included in the IRAS form and PIS? |  |
| Is it clear what side effects in the protocol will be reported as SAEs? |  |
| Have all the inclusion/exclusion criteria been listed in the Protocol and IRAS in the same order? Are they consistent? |  |
| Have all the primary and secondary objectives in the protocol been listed in the IRAS form and in the same order? |  |
| Have you included a schedule of assessment table in your protocol and does it contain study visit windows? (e.g. 1 week +/- 3 days). Is it consistent with the protocol text? |  |
| Have you included a detailed patient recruitment strategy in the IRAS form and protocol? |  |
| Have the HRA PIS and consent templates been used? |  |
| Have you described all study procedures and side effects in the PIS? |  |
| Is it clear how participants can withdraw from the study? Have you included what would happen if the patient lost capacity during the trial (and to the data)? |  |
| Is it clear that regulatory authorities, sponsor/NHS trust etc. may look at notes in the PIS/Consent form |  |
| Is the indemnity and funding clause in the PIS worded accurately |  |
| If samples are taken during the study, and are to be retained for use in future research has consent been requested to allow this? Has the correct field in the IRAS form been ticked re sample destruction or retention at end of study? |  |
| Have all external vendors been included on the IRAS form? |  |
| Have all expenses been provided in your costing? (including pharmacy, MHRA, monitoring, archiving and external vendors where applicable) |  |
| Have you included appropriate scientific peer reviews in accordance with the SOP S-1002 UHL? |  |

**SPONSOR APPLICATION HINTS AND TIPS**

**GENERAL**

* Where UHL and local organisation logos are to be used, NHS guidelines must be followed.
* Include IRAS number on all documentation.
* Where possible the study should be registered on a publically accessible database, e.g. Clinicaltrials.gov
* Please take the time to check all documentation for **consistency**, grammar and full stops.
* The study should be referred to consistently throughout all documentation (e.g. study or trial, calorie deficit study or calorie restricted trial etc)
* Draft documentation should be marked as v0.1, v0.2 etc and only changed to FINAL v1 after Sponsor review and upon submission to HRA/MHRA.
* There should be details of any withdrawal timelines in the protocol, IRAS and the participant information sheets, (i.e., up to which point are they able to withdraw), ***for example***, is it up until the end of the focus group, up until transcripts are completed and anonymised? Also they should be told the process for withdrawal (i.e., who to contact and that their data collected to date, with consent, will be used but no further data will be collected), please amend all documents. Also include what will happen if the participant loses capacity in IRAS, protocol and PIS.
* **Take the time to conduct the QC check in section D of the Sponsor application form – we can tell if you just initial it without conducting the checks!**

**HELPFUL HINTS AND TIPS TO COMPLETE IRAS Form (Full dataset)**

**Project Filters pages**

Please ensure that the correct filter questions are ticked, otherwise the correct pages to complete in IRAS will not be populated.

When cutting and pasting from the protocol, please ensure full stops and grammar have been checked and that the random scripts that sometimes appear are removed.

Please ensure that you enter the following information for the appropriate sections of the application form. Additional help can be found in the IRAS Help menu:

|  |  |
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| **SECTION** | **ADVICE** |
| IRAS FORM project information | Please ensure Short title matches that on protocol and PIS/ICF. Please do not put version and date after the short title. |
| A1 | Full title should match that on protocol, PIS/CF and other patient facing documentation. |
| A3-2 | Please ensure that correct details for CI or PI are entered to this section. |
| A4 & A64-1 | The main contact for the University as Sponsor is:Mrs Carolyn MaloneyHead of Research OperationsResearch Office. Trust Headquarters. Level 3 Balmoral Building. Leicester Royal Infirmary. Infirmary Square. Leicester LE1 5WW Tel: 0116 258 4109Email: uhlsponsor@uhl-tr.nhs.uk |
| A5-1 | * Sponsor reference number given when application is validated for Sponsor review should be added here. This will be the EDGE ID.
* Protocol version and date (matching that on the protocol) should be entered. Care should be taken to update this section once all the documents are finalised to v1.
* Where possible every trial should be registered on a publically accessible database (e.g., clinicaltrials.gov).
 |
| A6-1 | Brief summary of the research no more than 300 words. Please check grammar if cutting and pasting from the protocol. Take care to remove any reference to literature/references (i.e., (1)). |
| A6-2 | ALL main ethical, legal and management issues summarised here. |
| A10 & A11 | This should match the protocol primary and secondary objectives (i.e., what is written in the Protocol Synopsis table). |
| A13 | ALL assessments discussed in the protocol should be summarised in this section. Please be consistent in the way visits and the study are described (e.g., Day 1, visit 1 or baseline visit, trial or study).If indicated that posters / leaflets will be used for recruitment purposes, please forward copies of these for review by the Sponsor, they will need to be included as part of your HRA submission. |
| A15 | ***EXAMPLE:*** You have included an upper age limit of 75 years but this isn’t indicated in the inclusion / exclusion criteria, please amend. |
| A17-1 & 17-2 | This should match the inclusion and exclusion criteria in the protocol. Please note that if you have stated in A33-1 that only patients who can understand written and verbal English this must be included in your inclusion/exclusion criteria. If you have stated that, *‘participants must not have been involved in any other study within the last X months’*, that this is also in the inclusion and exclusion criteria.  |
| A18  | Only non-clinical interventions or procedures listed here. Include ALL from the protocol. Ensure that you include here adequate time for Consent. We recommend a minimum of 30 minutes. |
| A19  | Only clinical interventions or procedures listed here. Include ALL from the protocol.  |
| A22 | Include ALL drug side effects as listed in the SmPC, and all side effects listed in protocol. All should be discussed in the PIS. |
| A27 | Any contact prior to consent should only be from the clinical care team and not the research team, (e.g., searches via MIQUEST in GP surgeries should only be carried out by the practice staff). |
| A28 | If *’yes’*, you should enclose a copy of the text that you intend to use on the website for recruitment, this should be versioned and dated. |
| A31 | It is recommended that patients have at least up to 24h to consider CTIMP studies but provided that the participant have ‘adequate’ time to consider taking part this will be acceptable. Date of approach and date of consent must be recorded in patient’s notes in all interventional studies, but importantly, the detail of the initial approach described here must be followed.  |
| A33-1 | If you have stated in A33-1 that only patients who can understand written and verbal English this must be included in your inclusion/exclusion criteria. |
| A40 | Add text to this section to state that *‘data may be accessed by authorised individuals from the Sponsor, regulatory authorities or host site (e.g. UHL) for monitoring and audit purposes’*. This must also be stated in your PIS and ICF. |
| A41 | If personal data leaving the host NHS organisation then this needs to be stated here and in the PIS/ICF. |
| A42 | It is not usual for the data custodian to be the student it is usually the CI, please check this with the CI. |
| A44 | This is currently 15 years for a CTIMP study and 5 years for a non-CTIMP study. (Please note that this may rise to 25 years for CTIMPs studies from 2018). |
| A46 | Please clarify amount per patient per visit and whether payment will only be given on production of a valid receipt. This also needs to be stated in the PIS. Patient travel costs should also be listed in your costings submitted as part of your Sponsor review application.  |
| A49-1 and A49-2 | If this is *‘yes’,* then a GP letter should be submitted for Sponsor review as part of your application for HRA approval. Notification to GP should also be included your PIS and ICF. |
| A57 & 58 | Primary and secondary outcome measures should match the protocol (i.e., what is written in the Protocol Synopsis table and in the body of the document).  |
| A63 | Please ensure full address, email address and phone number (where known) are inserted.  |
| A66 | Please ensure this is answered correctly. ***EXAMPLE:*** If employing the services of CTU for randomisation or databases then this should be ticked yes. |
| A68-1 | The lead UHL NHS R&D contact is:Ms Carolyn MaloneyUniversity Hospitals of Leicester Research and Innovation OfficeLeicester General HospitalLeicesterLE5 4PWTelephone: 0116 258 4109Please use the RIAdmin@uhl-tr.nhs.uk e-mail address in this section. |
| A69-1 and A69-2 | Be realistic with start and end dates. Do not submit with dates already past.  |
| A71 and 72 | Ensure number of sites match each other and match what you have inserted in section C. |
| A74 | Please include the following text, “*The University Hospitals of Leicester NHS Trust, as Sponsor, operates a risk based monitoring and audit programme, to which this study will be subject.*”  |
| A76-1 and A76-2 | Tick *'NHS Indemnity'*. |
| A76-3 | Tick *'NHS Indemnity'*. |
| A78 | Please note that if you tick *‘yes*’ here, the study will be referred to the IP manager for comment.  |
| Part B Section 1 IMPs | * 14-1: ALL information should be completed.
* 14-3: Please include a copy of the SmPC with your application if this is ticked *‘yes’*. Please state full title of the SmPC.
* 15-3: One option should be ticked *‘yes’*.
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| Part B Section 5 samples | * 4. If you have ticked *‘yes’* for future research then this needs included on your PIS/ICF.
* 8. Samples usually stored in link anonymised form.
* 14. Make sure that this is consistent with what you have stated in Section 4.
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| Section C | Number of sites should match Section A71 and A72. |

**HELPFUL HINTS AND TIPS TO COMPLETE THE PROTOCOL**

* Please paginate this document using the ‘Page X of Y’ format.
* Please insert the Sponsor reference on the front page.
* Please remove all highlighted text from the template.
* Please ensure the date on the front page is consistent with information in section A5-1 of IRAS.
* Include all abbreviations.
* Synopsis, please ensure you complete any blank sections.
* Please note: If you have indicated that you may use an external transcribing service, a contract will be required between the Sponsor and the company.
* Please ensure the inclusion and exclusion criteria match those in IRAS.
* Please ensure all the primary /secondary objectives and outcomes match those in IRAS.
* Clearly state what the end of study definition is.
* Please ensure that you list all side effects in the SmPC for CTIMP studies.
* Please state what the Reference Safety Information (RSI) will be for CTIMP studies (e.g. SmPC).
* Please state clearly what adverse events will and will not be reported.
* For qualitative studies please delete sections of the non-CTIMP protocol template as appropriate or use the draft Qualitative HRA protocol template available from the HRA website.

**HELPFUL HINTS AND TIPS TO COMPLETE THE PATIENT INFORMATION SHEETS**

* Please paginate this document using the ‘Page X of Y’ format.
* Please add the short study title and the IRAS number to either the header or the footer.
* Please ensure short study title is the same in the footer and consistent with other documentation.
* In the section entitled ’Will it cost me anything to take part‘, please clarify the remuneration to read (***e.g.,*** *’up to £10 per participant per visit’*), so that it’s clear, you should also state whether you require a receipt to be able to give the refund.
* In the confidentiality section you should add some wording to inform that, ‘***data may be accessed by authorised individuals from the Sponsor, regulatory authorities or host NHS organisation (e.g. UHL) for monitoring and audit purposes’.***
* Also in this section you should inform them that you will be storing identifiable data on computers outside of the NHS. Consent must be sought for this.
* You should add a section on harm, suggested text is:

***What if I am harmed by the study?***

***It is very unlikely that you would be harmed by taking part in this type of research study. However, if you wish to complain or have any concerns about the way you have been approached or treated in connection with the study, you should ask to speak to [insert study team /phone] who will do their best to answer your questions. If you remain unhappy and wish to address your concerns or complaints on a formal basis, you should contact Patient Information & Liaison Service at*** ***pils.complaints.compliments@uhl-tr.nhs.uk******. The Firs, c/o Glenfield Hospital, Groby Road, Leicester. LE3 9QP Freephone: 0808 1788337***

***In the event that something does go wrong and you are harmed during the research and this is due to someone‘s negligence then you may have grounds for a legal action for compensation against University of Leicester but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).***

* You should include a section on potential benefits or disadvantages.
* ALL side effects should be listed (e.g., from all listed in the SmPC or any safety updates received for CTIMP studies).
* ALL study procedures should be listed.
* A separate PIS and consent form is recommended for sub studies.
* If you intend to keep samples for future use, this must be mentioned in your PIS and consent form.

**HELPFUL HINTS AND TIPS TO COMPLETE CONSENT FORMS**

* Please paginate this document using the ‘Page X of Y’ format.
* The short study title in the header should be consistent with other documentation.
* Please ensure you have added the IRAS reference to the header or footer.
* If you have two Statements that are optional they should have both a yes and a no box for them to initial one or the other.
* Please add a further statement if applicable to your study saying, ***‘I understand that relevant sections of my medical notes and/or study data may be looked at by responsible individuals from the study team, the Sponsor, NHS Trust or regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records’.***
* Please add a further statement if applicable to your study saying, ***‘I understand that my personal details and study data will be stored on secure computers, in secure cabinets or in archiving rooms at the XXXXX’.***
* Please add a further statement if applicable to your study saying, ’***I agree to my samples being stored for future research’.***

**COSTINGS**

 Costings are incomplete or confusing in the majority of applications. Please ensure you list:

* All staff costs.
* All non-staff costs.
* Confirmation of pathology and pharmacy costs will be required.
* Include randomisation, database support costs.
* Monitoring costs will be required for CTIMP studies and high risk interventional non-CTIMP studies.
* Include archiving costs.
* Include patient travel costs.
* Include MHRA costs and amendment costs.
* Payments to all external vendors.
* If it is documented that a department is funding the research to the cost of ***EXAMPLE*** £1,112, please send confirmation from the CI or their delegate (an e-mail will suffice) to confirm that they agree to fund this and that the amount has been ring-fenced for this purpose. A cost code will be required.
* Please provide proof of funding (e.g. grant funding letters).

**CONTRACTS**

* If there are costs to be paid to an external organisation then a suitable contract will be required.
* A contract will be required for all third party vendors (e.g., commercial funder or external CTU). Any commercial contracts will be drafted by the Contracts team
* A SLA will be required between UHL and Leicester CTU if their services are being used.

**SOECAT / OIL**

* Please complete and return to Sponsor for review. This should match A18 and A19 of the IRAS form.
* There needs to be a SOECAT and template OID for each organisation – please see guidance on HRA website. <https://www.hra.nhs.uk/planning-and-improving-research/research-planning/prepare-study-documentation/> (e.g. one for GP PIC site and one for secondary care sites).