FORM008 IRAS Application Checklist for LJMU Sponsored Research

To be completed by the academic supervisor (for student research) or chief investigator (for non-student research)

Completing this checklist will help your application be considered as quickly as possible. This document will be used by LJMU to confirm sponsorship.

Once completed, please email to sponsor@ljmu.ac.uk

|  |
| --- |
| Checklist completed by: |
| Name: |  |
| Position: |  |
| Date: |  |
|  |  |
| Full title of Research: |  |
| IRAS ID: |  |

The information contained within this checklist outlines the minimum essential detail (marked with asterisk) required by the University to proceed with sponsorship.

Colour key: Item from Research Hazard Assessment and Risk Mitigation Checklist.

**Applicable across all study specific documents submitted for review**

| **Ref** | **Item** | **Studies/All** | **Also for Non-CTIMPS** | **Also for CTIMPs** | **YES** | **NO (or NA)** | **Comments** |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Full title\* | Full title of research project (cross-match on all documents including IRAS) and document version numbers and date. |  |  |  |
|  | Document version number and date\* | Should be on every page |  |  |  |
|  | IRAS ID\* | Matches across all documents including IRAS |  |  |  |
|  | Sponsor RG number and Sponsor details\* | The protocol clearly identifies LJMU as sponsor.All contact details where included on the protocol, IRAS and participant information sheet as applicable are correct. |  |  |  |
|  | Appropriate language, abbreviations explained and consistent terminology\* | Any abbreviations have been explained. Where images have been used in the participant information sheet, no copyright infringements have taken place. Participant facing documents use appropriate level of language. |  |  |  |

**Protocol**

| **Ref** | **Item** | **Studies/All** | **Also for Non-CTIMPS** | **Also for CTIMPs** | **YES** | **NO (or NA)** | **Comments** |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Full title\* | Full title of research project (cross-match with A1 on IRAS). |  |  |  |
|  | Protocol version and date\* | Should be on every page. |  |  |  |
|  | IRAS ID\* | Should match the one in IRAS, and that it is clearly marked in protocol (usually in footer). |  |  |  |
|  | CI details\* and signature page | There is space to add the date and wet signature of CI to signify approval of that version of the protocol.A statement should be present in the protocol outlining that a signature on the IRAS form by the Sponsor constitutes sponsorship agreement, and therefore not required on the protocol. |  |  |  |
|  | Sponsor RG number and Sponsor details\* | Clearly specifying that LJMU is the Sponsor and including the RG number. Info may be on introductory pages, on the footer or at end of protocol, together with insurance and funding details. |  |  |  |
|  | Key Study/Trial Contacts | * CI, Study/Trial Team, Study/Trial Committees (if applicable), statistician (if applicable), Medical Oversight (if applicable), pharmacist (if applicable).
* Where medical oversight is required, access and availability of the clinician to participants and the research team, if necessary has been explained.
* If a trial is being managed without a dedicated trial coordinator the CI has sought guidance from the Clinical Research Compliance Team.
* Study team be adequately trained, have GCP training etc.?
* All study members have access to the relevant SOPs, processes etc.?
* Explained - Who would provide medical oversight in case of CI absence on an interventional study?
 | * The CI needs to be an authorised health professional appropriately qualified for the study.
 |  |  |  |
|  | Research team Training / CPD | For example, * Good Clinical Practice ([GCP training](https://www.nihr.ac.uk/our-research-community/clinical-research-staff/learning-and-development/national-directory/good-clinical-practice/) is not compulsory for investigators undertaking non-CTIMPs, but may be appropriate for certain studies to demonstrate the research team are trained to ensure patients’ safety and wellbeing)
* Research Ethics training ([LJMU Research Ethics Training](https://www.ljmu.ac.uk/ris/research-ethics-and-governance/research-ethics/research-ethics-training) compulsory for students)
* Research Integrity training,
* [Human Tissue Training](https://teams.ljmu.ac.uk/7/SCS/HumanTissue/_layouts/15/start.aspx#/SitePages/Home.aspx)
* GDPR – [LJMU e-learning module](https://www.ljmu.ac.uk/staff/ldf/elearning-modules)
* Diversity in the workplace – [LJMU e-learning module](https://www.ljmu.ac.uk/staff/ldf/elearning-modules)
* Bribery Act – [LJMU e-learning module](https://www.ljmu.ac.uk/staff/ldf/elearning-modules)
* Understanding modern slavery - [LJMU e-learning module](https://www.ljmu.ac.uk/staff/ldf/elearning-modules)
* An introduction to the prevent duty - [LJMU e-learning module](https://www.ljmu.ac.uk/staff/ldf/elearning-modules)
* Consent training -
* Others…
 |  |  |  |
|  | Study summary | * Completed?
* Start date – realistic?
* Countries – insurance and risk?
* Study period – for student research, within their registered period?
 | Should be clear what phase trial it is. (Study arrangements should be appropriate to phase of the trial). |  |  |  |
|  | Funding | The funding arrangements have been listed. This could either be the name of the company/institute that is providing the funding or whether the study is self-funded/part of a bigger grant. |  |  |  |
|  | Roles & responsibilities | Being conducted in line with the principles of GCP (if applicable), UK Policy Framework for Health and Social Care Research and applicable LJMU policies, and HTA compliance if applicable. | Includes adherence to The Medicines for Human Use (Clinical Trials) Regulations 2004’ (SI 1031) and subsequent amendments, and any other applicable regulations. |  |  |  |
|  | 1&2. Background and Rationale\* | Is the research question explicitly justified, why it is worth asking explained, why this is worthwhile to patients explained, limitations of existing treatments etc. is provided? |  |  |  |
|  | 3. Research question | Clearly worded as a question and appropriately linked to the research objectives and outcomes. |  |  |  |
|  | 4. Primary and secondary objectives\* | Objectives have been clearly defined as primary and secondary where relevant and are in quantifiable terms  |  |  |  |
|  | 4. Outcomes\* | Outcomes are in relation to the objectives and have been formulated in quantifiable terms in order to measure any effects—if applicable given the nature of the study. |  |  |  |
|  | 5. Justification for participant population and study design\* | May refer to previous research (this may be included under another item, i.e. Background and Rationale or Study design, methodology, location). |  |  |  |
|  | 5. Interventions / study processes\* | * Explained – whether clinical care be altered by the protocol?
* Explained – the use of Ionising radiation (Magnetic Resonance Imaging or ultrasound investigations do not involve ionising radiation) be used:
* Diagnostic X-rays, CT scans or DXA scans;
* Radiotherapy (including brachytherapy and therapy using unsealed sources; or
* Radionuclide imaging (including diagnostic imaging and in vivo measurements)?
* Explained - administration of radioactive medicinal products to humans (Diagnostic X-rays, CT scans and DXA do not involve the administration of radioactive materials)?
* PET-CT
* Nuclear Medicine Bone Scans
* MUGA
* Are any devices CE marked, are they being used within that CE marking? Are devices being tested for the purposes of obtaining CE marking?
* Explained - Is the risk associated with the IMP/Intervention Comparable to risk of standard medical care (Type A), Somewhat Higher than the risk of standard medical care (Type B) or Markedly Higher than the risk of standard medical care (Type C)?
* Explained - Is there a risk to the safety and wellbeing of the researchers and other staff?
* Explained – whether an advanced Therapy Medicinal Product, gene therapy or cell therapy involved?
* Explained - Will intrusive interventions or data collection methods be used?
* Explained - Will the study involve investigating sensitive/difficult topics (i.e. participants sexual behaviour, illegal or political behaviour, experience of violence/abuse/exploitation, mental health, gender or ethnic status)?
* Explained - Are questionnaires/diagnostic tools being used? Have they been validated? Does LJMU hold a licence for the use of the questionnaire/diagnostic tool?
* Explained - Will justified deception be used to recruit participants or will participants be recruited without valid informed consent at the time the study is carried out?
* Explained - Does the research have potential to expose participants to issues that can make them vulnerable? (Especially in social research)
* Explained - Is the research ‘participatory’ research where research participants may themselves be involved in data collection? If so is this appropriately managed and have risks associated with this been properly considered?
 |  |  |  |
|  | 5. Number of expected participants\* | A clear justification on the recruitment target (e.g. power calculations, opportunity sampling, previous research). Note this may be broken down by cohorts if applicable. |  |  |  |
|  | 6. Statistical analysis methodology linked to outcome measures | Includes appropriate detail on sample size calculation\*, (if applicable), process, interim analyses if applicable, Statistical Analysis Plan (if applicable). Where statistical analyses are to be performed, there is a named individual listed under key study contacts who takes a lead on the statistical analyses. The level of expertise required will depend on the complexity of the project and is at the discretion of the chief investigator. Has appropriate statistical advice been provided? | A detailed statistical analysis plan should be available (e.g. in the protocol).  |  |  |  |
|  | 6.2/3. Inclusion and Exclusion criteria\* | Criteria should be selected in such a way that it is possible to evidence that the participant has fulfilled each criterion. The inclusion criteria will need to include a point stating that the participant has the ‘Ability to give Informed Consent’ unless stated otherwise (if incapacitate patients included, check that filter question on the IRAS form reflects this). The criteria should not include anything discriminatory, or unnecessary.* Can participants be below age 5 (if the study falls within the UMAL definition of clinical trial has it been referred?
* Can participants be pregnant women?
 |  |  |  |
|  | 6. Recruitment process\* | * Detailed account of the research setting, location and the recruitment process
* Includes the participant pathway to getting on the trial – screening, information given, consent as applicable
* researcher is not trying to get ‘cold’ access to participants, through screening notes etc. (GDPR)
* Explained - who is identifying participants, and how this is done (via appropriate access to personal information etc.?). If this is to be done via clinic appointments, participants must be introduced via the clinical care team and should not be approaching participants randomly.
* Eligibility (if any medical conditions included) is confirmed by a qualified clinician
 |  |  |  |
|  | 6. Consent process\*, roles, timelines and setting | * Consent will be gained before participants take part in any research activity (e.g. participants are not instructed to fast before consent is taken). Where this is not possible due to the type of research being carried out, appropriate justification has been given and appropriate approvals have been sought (e.g. Confidentiality Advisory Group).
* Will identifiable data be used without consent (e.g. to identify potential participants)? (Note: it is quite common for researchers to think they can access care records in order to identify participants – care records must only be accessed by members of the care team, and they will need to be the ones to approach participants)
* The minimum time allocated for the participants to consider taking part in the research should ideally be a minimum of 24 hours from receiving the participant information sheet. It can be less but clear justification needs to be provided in the protocol, and it needs to be clear how consent will be evidenced if this is not initially taken with a consent form.
* Consent should be obtained by PI or delegated to a member of the research team, trained in the project and GCP. This should be defined in the protocol. Are the people taking consent appropriately trained?
* Explain - translations are required or the use of interpreters, based on the proposed participant population group
* For vulnerable participants or participants without capacity, the protocol has to clearly describe what processes will be in place instead, which may include liaising with consultees (personal/nominated consultee), witnessed consent (if applicable), consent in emergency situations and obtaining consent from the participant at a later stage in the project.
* For children, the protocol has to clearly state how the research will be introduced to the child if relevant, and whether assent will be taken and how this will be documented.
* Under ‘Gillick competence’ a child has the right to consent if they have the capacity to understand the specific circumstances and details of the research being proposed. Young people 16-18 are usually assumed capable of consent.
* Check setting of where consent will be taking place and whether consent forms will be transferred across organisational boundaries.
* Where there are differing types of participant information sheets and consent forms it should be clear when different documents should be used.

Note: Participant’s willingness to continue should be reaffirmed periodically and they should be re-consented where new information becomes available (though this may not be described in the protocol). | As per studies but with the following differences:* For vulnerable participants or participants without capacity, a legal representative may be referred to as opposed to a nominated consultee.
* Children under the age of 16 will not be able to consent for a CTIMP. A guardian or legal representative will need to give consent on behalf of the child.
 |  |  |  |
|  | 6. Participant information / consent. | * The study/trial assessments, timelines and follow-up are clearly detailed.
* Explained - How long will participants be in the study?
* The timelines listed is feasible and practical. (Where fixed times/dates have been specified these can lead to protocol breaches, in how far time windows may be more appropriate. The use of words such +/- x days/hours is recommended)
* The processes and timelines match across all documents (IRAS and protocol).
* Use of Prescription only meds (prescription only medicine – check BNF) for non-IMP trials. Where prescription only medicines are to be used, these are going to be appropriately sourced, used and stored, and under guidance of a clinician (refer to A34 for further checks that may be required). Written prescriptions will need to be available.
 |  |  |  |
|  | 6. Withdrawal process, consent and data/sample storage\* | It is clear that participants can withdraw at any time without having to give a reason and that it will not impact on their standard of care. Needs to also detail what happens to data/samples if they do withdraw. Check this is compliant with Human Tissue Act/Data Protection Act/GDPR and matches info in participant information sheet/Information consent form. |  |  |  |
|  | 7. Data Management process (data management, storage and access)\* | * Contains link to Data Protection Act (or international equivalent), identifiable source documents, access, any transfers, processing and query resolution, archiving and the people responsible for the data management process.
* Confirm the data pathway, which is to include (where applicable):
* Explained - What will be considered source data?
* Explained - What data items are to be collected?
* Explained - Will the data used be identifiable; coded or anonymised format and if it is coded or anonymised is the process clearly described somewhere?
* Explained - What is the data verification process? Role of supervisor in the data verification process for student project
* Explained - Is anything being recorded and transcribed? Will transcription be done by a third party and is an appropriate agreement in place?
* Explained - Is the data analysed by a third party or delegated to a CRO? Otherwise disclosed to other parties? (Have appropriate agreements measures been put in place, will there be consent for this)
* Explained - Are data being sent to a country or territory in other jurisdictions or outside of the European Economic Area?
* Explained - The security of location and transfer of data
* Explained - Has particular consideration been given to situation where there is a risk of access to sensitive health information (i.e. mental health or sexual history) through access to full medical records?
* Explained - Who will be able to access data and what information will they be able to access?
* Explained - Is disclosure and use of information justified? (Is the minimum necessary identifiable information being used?).
* Explained - Data (including essential documents) to be archived for a minimum of 5 years as per LJMU code of practice (this may be covered elsewhere).
* Explained - Database lock procedures where applicable

Explained -: Are data security and transfer arrangements satisfactory and in line with LJMU policy, the Data Protection act and GDPR? | Archiving policy of 25 years (30 years for Advanced Therapy IMPs) instead of 10 years. |  |  |  |
|  | 7. Sample storage and access (if applicable\*) | * The location and transfer of samples have been clearly specified.
* Check the Information consent form – does consent cover what is happening to the samples?
* Explained - What are samples used for? Are they being analysed (other than in an NHS diagnostic lab)? Will analytic data be used to screen participants for eligibility, impact on safety, inform on the efficacy of the IMP, form a primary/secondary outcome, or is the analysis part of a translational research study? (May prompt query about what analytical standards are analyses are being conducted to, who by and where).
* Explained - The duration of sample storage and what is to happen to the samples after the study has been completed is clearly outlined (destroyed/stored in a licenced biobank/rendered acellular within x days of receipt) including labelling of the samples i.e. anonymising where required., transferred to another ethically approved research project (with patient consent e.g. future research)).If samples not being kept under ethics, are appropriate arrangements in place to keep relevant material in licenced facility?
* Acknowledge when the Human Tissue Act (2004) is applicable (i.e. if samples stored in England). Is the study compliant with the Human Tissue Act?
* Sample pathway has been outlined (from collection to processing, storage, use and destruction/transfer to another project or tissue bank).
* Explained - Will the research involve human embryos and/or gametes? (If so, identify Human Fertility and Embryology Authority licencing requirements are met).

Consider: Whether an MTA needs to be put in place, researchers to be advised accordingly. Are arrangements for storage and transfer satisfactory and in line with LJMU policy? |  |  |  |
|  | 8. Safety reporting | * Refers to National Research Ethics Service SAE definition, and covers non-reportable events, pregnancy monitoring (if appropriate), reporting period and procedures – ensure section is fit for purpose. Should be consistent with LJMU AES SOP for reporting and escalation, to include assessment of potential SAEs by a clinician, and reporting SAEs to the Sponsor etc.
* For different studies, appropriate definitions have been included i.e. SSAR, USADE etc.
* Psychological/qualitative studies include how to deal with distress.
* It is understood that some projects may be very low risk and may not require such stringent procedures. This will need to be clearly outlined.
* Explained - Serious Breaches\* Is consistent with LJMU Serious Breach SOP for reporting to Sponsor and the REC.
 | Check it against the CTIMP definitions. Includes definition and reporting to MHRA |  |  |  |
|  | 9. Monitoring and Quality Management procedures\* | documentation outlining appropriate quality management procedures have been considered and will be implemented.  | Quality management procedures should be documented in protocol or other document (for CTU studies may be elsewhere in the QMS). Should be consistent with any requirements in the risk assessment. |  |  |  |
|  | 9. Oversight\*, TMG, TSC, DMC etc. | * Appropriate oversight is in place reviewing the safety and data aspects of the project. This can be done by the Trial Management Group. An example of this could be in the form of the Academic Supervisor having regular meetings with the CI.
* Annual Progress Reports (APR) will be sent to the REC and LJMU REG throughout.
 | * TSC and DMC as appropriate
* APRs will be sent to the REC and LJMU throughout.
 | * TSC and DMC as appropriate
* APRs and DSURs will be sent to the MHRA, REC and LJMU throughout.
 |  |  |  |
|  | 10. Ethical considerations and adherence to GCP principles\* | Text stating that the study/trial will adhere to the principles of GCP, the UK Policy Framework for Health and Social Care Research, and will have REC approval. | The research is being performed in line with GCP as defined in the EU Directive |  |  |  |
|  | 11. Scientific review | * According to LJMU policy
* Supported by reviewers
 |  |  |  |
|  | 14. Insurance | States that LJMU provides insurance and indemnity.Should be consistent with the text in the LJMU Protocol Template: | May require more specialist coverage. |  |  |  |
|  | 15. Financing | Costs are considered and approved |  |  |  |
|  | 16. Contracts / agreements | Details provided.NHS site agreements - No transfer of funds to NHS? Clinical trials, medical device studies, research using patient data only and research using human tissue? = Statement of Activities or a standard Non-Commercial Model Agreement (mNCA). NHS site agreements - No transfer of funds to NHS? Non-intervention = HRA statement of activityTransfer of funds? = populate the details on the mNCA or statement of activities including the Finance section. |  |  |  |
|  | 17. End of study defined\* | Defines the end of the study, when notification of End of Study/Trial will be sent to REC/LJMU. | End of Trial notification will also need to be sent to the MHRA. |  |  |  |
|  | 20. Dissemination process\* | States whether participants will be notified (consider how they will be notified, will personal details be needed? Is this covered in the data storage section and participant information sheet?), who has access to study/trial final dataset; sometimes will say who determines authorship etc. Are arrangements in line with HRA guidelines: <https://www.hra.nhs.uk/planning-and-improving-research/research-planning/publishing-your-research-findings/> |  |  |  |
|  | 22. References\* | Are included |  |  |  |
| **Depending on the project, the following may also need to be checked:** |  |
|  | When using a nutritional or medicinal product: | * Clear description of product being used.
* Review sourcing, make up and labelling, transfer and storage arrangements, dosage and schedules, any drug interactions (if applicable) and/or contraindications (including with concomitant medications), and references to IB/SmPC, safety data sheets or like.
 |  |  |  |
|  | Laboratory outcomes listed (\*if applicable) | It is clear which lab results rate to primary and secondary outcomes and which relate to exploratory outcomes. |  |  |  |
|  | Allocation ratio and randomisation process (\*if applicable) | Method of randomisation, allocation sequence and time point has been outlined, should be clear who is responsible for randomisation and what the site has to do. |  |  |  |
|  | Blinding process, roles and location(\*if applicable) | For blinded studies should include if single or double-blind, comparability of interventions, emergency un-blinding procedure (who and how). It should be clear what the blinding (and un-blinding) process is, and who is responsible for it. Might prompt further questions around risk mitigation (if applicable) does it make sense in terms of the randomisation process, is the process for emergency un-blinding robust. |  |  |  |
|  | If a Medical Device is being used specifically for the research, check whether it counts as a clinical investigation for MHRA purposes | Appropriate contracts/costings must be in place for any required servicing, use of disposals and appropriate insurance coverage. The owner of the device also needs to be clarified. |  |  |  |
|  | Is Human Tissue taken from healthy volunteers? | Reference to policy in protocol where relevant. Can be covered in general statement specifying that LJMU policies / LJMU HTA licence will be adhered to. Local Trust policies would also be acceptable for NHS sites. |  |  |  |
|  | Does lone working policy apply? | Reference may be made to LJMU policy in protocol where relevant. Can be covered in general statement specifying that LJMU policies will be adhered to, or actual practice can be described. Reference Lone Working Policy on the IRAS form, as forestalls questions from RECs. |  |  |  |
|  | Are community visits going to take place?  | Reference to this in protocol where relevant, or description of what will be done |  |  |  |
|  | Is the study taking place on LJMU premises. | If LJMU is a site or a location for study interventions then liability for those interventions may lie with the University. It will be important that i) appropriate processes have been identified for interventions, ii) insurance covers the interventions and iii) location for interventions has been risk assessed as appropriate.  |  |  |  |

B. Participant information sheet\* (participant information sheet)

| **Ref** | **Item** | **Studies/All** | **Also for Non-CTIMPS** | **Also for CTIMPs** | **YES** | **NO (or NA)** | **Comments** |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Planned to be printed on headed paper | For multiple sites, check that a message such as ‘Printed on local headed paper’ has been added to where the local header should be. |  |  |  |
|  | Study title | The full study title should be present on both the participant information sheet/s and informed consent form/s, except in circumstances where inclusion of the full study title would not be appropriate. This is in order that participants have a single reference for a study. |  |  |  |
|  | Funding described in participant information sheet | The participant information sheet mentions the funder. |  |  |  |
|  | Expectations of participant are clear (# of visits etc.) | Participant information sheet clearly specifies the commitments expected from the participants. This may include the number of visits, the approximate duration of the visit and (if known) the location, and should match the protocol and the IRAS form. |  |  |  |
|  | Risks and benefits clearly described | The risks and benefits of taking part in the research have been clearly identified. Where there are no benefits, this is also mentioned. |  |  |  |
|  | Participant reimbursement | Details of any reimbursement for taking part in the research has been mentioned. The participant information sheet will also need to specify where there is no reimbursement available. |  |  |  |
|  | Duration of study | The full duration of the participant’s involvement in the study is clarified. This includes any follow-ups. |  |  |  |
|  | Study Procedures and activities adequately described | Matches what has been outlined in the protocol and IRAS. |  |  |  |
|  | Time allocated for consent process, including minimum time | The minimum time allocated for the participants to consider taking part in the research should ideally be a minimum of 24 hours from receiving the participant information sheet. However it can be less if there is appropriate justification for it. The duration needs to be specified in the participant information sheet highlighting that participants can have more time if they wish. |  |  |  |
|  | Contact details for complaints – PALS for NHS and SJ as an independent LJMU representative for any other projects | Where research is involving NHS patients, PALS (or devolved nation equivalent) details are listed for any complaints. For investigator led studies it is also recommended for Dave Harriss’ details to be added as an independent LJMU representative for any complaints. Where no NHS patients are involved, Dave Harriss’ details should be listed as an independent LJMU representative for comment/complaint:Dr Dave HarrissResearch Governance ManagerResearch Innovation ServicesExchange StationTithebarn StreetLiverpoolL2 2QPEmail: Sponsor@ljmu.ac.uk Phone: 0151 231 2121 |  |  |  |
|  | Prohibited concomitant medications are clear | Listed as applicable. |  |  |  |
|  | Data Access statement | Should be included in line with guidance from the LJMU Data protection Officer.  |  |  |  |
|  | Location/storage of any personal data collected | The participant information sheet should indicate how long personal data are likely to be kept for who data will be shared with if being shared. It should give details of data security and data access arrangements. It should also clarify what personal identifiers will be collected and shared and what medical data collected. It should specify who the data controller is for the purposes of the study (usually the Sponsor), and the legal basis on which we will hold the data under GDPR (usually public interest). |  |  |  |
|  | Details of any data transfers | Clearly specifies whether identifiable/non-identifiable data will be transferred and what identifiers will go with them. The level of detail may depend upon the amount of personal data transferred and the number of organisations involved.If data will be transferred outside of the UK this should be clear. |  |  |  |
|  | Withdrawal process clear as per protocol | The withdrawal process has been clearly defined, including what happens to any data/samples that have been already collected prior to the participant withdrawing. |  |  |  |
|  | For a child’s participant information sheet the terminology is appropriate | * The language used is appropriate for the child’s age.
* Use of different versions for different ages - generally not expected for under 8s, guidance is taken from PPI groups and REC, potential to split it into 8-12 and 12-15
 |  |  |  |
|  | Confidentiality and insurance / indemnity assured in line with protocol | Check that wording correctly describes the indemnity arrangements for the study. |  |  |  |
|  | Sponsor and regulatory bodies have access to data | The participant information sheet mentions that sponsor representatives and regulatory bodies will access the data where relevant. |  |  |  |
|  | Contact details of researcher for further information |  |  |  |  |
| **Depending on the project, the following may also need to be checked:** |  |
|  | Any change to standard care | The participants are clearly informed where there will be any changes to standard care. |  |  |  |
|  | Links to more information on the disease | Recognised/reputable links |  |  |  |
|  | Participants informed of outcomes | It should be clearly outlined in the participant information sheet how patients are to receive information on outcomes. This is to match the IRAS. |  |  |  |
|  | Whether or not GPs will be contacted | Participants are informed that their GP will be notified of their participation where applicable. |  |  |  |
|  | Sample location, storage, transfer, what happens to all samples | Where samples are to be collected, the participant information sheet clearly outlines what samples will be taken and what will happen to the samples (e.g. storage for future research and the duration of storage/ samples destroyed). If there are plans to share the samples with other institutions, the participant information sheet will need to clearly specify this and also outline the types of institutions (e.g. national, international, academic/commercial). It needs to be particularly clear: * Where samples are being exported.
* Where samples are to be used on animal models.
 |  |  |  |
|  | Who will contact participants | If participants will be contacted by someone other than their care team then that should be clear who will be contacting them. |  |  |  |

C. Informed Consent Form\*(Information consent form)

| **Ref** | **Item** | **Studies/All** | **Also for Non-CTIMPS** | **Also for CTIMPs** | **YES** | **NO (or NA)** | **Comments** |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Planned to be printed on headed paper | For multiple sites, a message such as ‘Printed on local headed paper’ and includes space for Sponsor and participating organisation logo has been added to where the local header should be. |  |  |  |
|  | Study title\* | The full study title is present on both the participant information sheet/s and informed consent form/s, except in circumstances where inclusion of the full study title would not be appropriate. In either case the title on the Information consent form should be the same as on the participant information sheet |  |  |  |
|  | Quotes the relevant participant information sheet specific document title, date and version number | The full participant information sheet document title, version number and date have been inserted.Where there are multiple information sheets and only one Information consent form, a space may be left on the Information consent form for the person taking consent to manually add the title, version and date of the participant information sheet that the participant has read.  |  |  |  |
|  | Appropriate language, abbreviations explained and consistent terminology | The language used in the Information consent form is not too complicated for the audience and that each point clearly outlines what the participant is consenting for. Any abbreviations should be explained. |  |  |  |
|  | Data storage location, access and transfer (if applicable) | This information has been summarised in the Information consent form where applicable.If data may be transferred to other organisations this os clear and consented for. For CTU studies Information consent forms may be sent to the CTU, in which case there should be specific consent for this on the form. |  |  |  |
|  | Withdrawal process offered | Participants are informed that they can withdraw at any time without having to give a reason and that this will not impact on the care they receive in any way. The Information consent form should also summarise the withdrawal criteria for any samples/data already collected (withdraw all samples/data or any collected samples/data will be kept). |  |  |  |
|  | Sponsor and regulatory bodies have access to data\* | Participants will need to consent to allow sponsor representatives and regulatory bodies to have access to the data. |  |  |  |
|  | Agreement to take part in research | This should be the last point of the consent form and on its own. |  |  |  |
|  | Sufficient space to collect signatures (including person taking consent) | There is likely to be sufficient space to add the participant’s name, the date and signature for both the participant and the person taking consent. |  |  |  |
|  | Participants are instructed to initial boxes and that these align with relevant statements. | There is sufficient space in the boxes for the participant to add their initials and that the box can be easily traced to the corresponding item. There should also be clear instructions that participants are to initial the boxes. |  |  |  |
| **Depending on the project, the following may also need to be checked:** |  |
|  | Is child assent being requested? Is the terminology appropriate? | Where child assent is being requested, the information portrayed is accurate and appropriate for the age range and any requests for completion are feasible (e.g. gaining initials from younger children may not be practical). |  |  |  |
|  | Samples being taken | The Information consent form clearly specifies that samples are to be taken. |  |  |  |
|  | Sample storage and transfer | The Information consent form clearly summarises what will happen to the samples once the research project has ended (e.g. destroyed/stored acellular/stored in licenced biobank/used in other ethically approved projects).  |  |  |  |
|  | Are samples to be used for future ethically-approved projects? | Where samples are planned to be used for future research projects, this needs to be specified in the Information consent form, emphasising that they will be used only after ethical approval has been gained. Explicit consent will also need to be gained for when samples are going to be:* Sent abroad
* Shared with other institutions (especially commercial entities)
* Used in animal models
 |  |  |  |
|  | Storage of contact details etc. if required | Participants should be informed of the likely duration of time their details will be stored for (this can be covered in the participant information sheet). Where researchers have identified that they would like to store participant’s details to contact them for future projects, the duration should be clearly specified and this should be listed as a separate optional point in the Information consent form. The researcher would also need to specify that they may contact the participants at intervals to ensure the details they have on their records are up to date. |  |  |  |
|  | If consultee is being used, does it identify the participant and match the participant information sheet? | Where consultee declaration is being gained, there is space to capture the participant’s name, consultee’s name, date and signature, and type of consultee (personal or nominated). If consent is witnessed need signature space for witness. Consent in emergency situations? Are there forms for each scenario described in the protocol? |  |  |  |
|  | Clarification if any sections are optional, and a statement about the requirements within the form for consent to count | The optional components are clearly identified and are separately listed to any core items. |  |  |  |
|  | Consent to notify GP. | Present in the Information consent form whereby the participant will provide consent for their GP to be notified. |  |  |  |
|  | Space to add Participant ID | It is recommended for the participants unique study identifier to be added to the Information consent form. |  |  |  |
|  | Phrase at bottom of Information consent form clarifying what will happen to the original and copies of the Information consent form (e.g. original to be kept in study files and copy to be given to participant) | It is recommended for the Information consent form to have a phrase at the bottom clearly outlining what should be done with the original and copies of the Information consent form. |  |  |  |

IRAS Form

| **IRAS Ref** | **Item** | **Studies/All** | **Also for Non-CTIMPs** | **Also for CTIMPs** | **YES** | **NO (or NA)** | **Comments** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Project filter | Check that the right category has been selected for question 2 in the project filter section, based on the information provided in the protocol, participant information sheet and the IRAS form itself. Where in doubt, discuss further with the researcher. | The HRA provides guidance on the different study categories which can be found here: <http://www.hra.nhs.uk/resources/before-you-apply/types-of-study/study-types/>. Where the research is not considered a CTIMP but there is still uncertainty on what category the research fits in to, the ‘other’ option can be ticked as this will open all possible questions within the IRAS form. Where there is uncertainty on whether the project is a CTIMP, a query should be submitted to the MHRA clinical trial helpline, including a copy of the protocol and with ‘Scope - protocol review’ followed by the study title (shortened)’ as the subject line.The study falls within the Policy Framework for Health and Social Care Research. All referral groups and approvals have been properly identified, e.g. properly identifies if tissue or ionising radiation are in use. Are there any other approvals/consultations needed (e.g. Gene Therapy Advisory Committee)? (May need to query team whether they have taken place).  |  |  |  |
| IRAS Project Filter: 5b | Portfolio adoption | If the researcher has specified that they would like the research to be portfolio adopted, that it is eligible for adoption. If it is eligible and a non-CTU study, a Portfolio Application Form in IRAS will need to be submitted. The Peer review that has been conducted on the study will enable it to be submitted for portfolio adoption. If not, further Peer Review should be initiated. |  |  |  |
| IRAS Project Filter: 9 | ‘Educational project’ is the one for student projects | If the project is being undertaken as part of a qualification, this would need to be ticked ‘yes’ and the involvement of the student in the project will need to be briefly described. |  |  |  |
| A4 | Contact details: should be Dave Harriss’ details | The contact details listed here should be Dave Harriss’ details as listed below. However a CTU may request for one of their staff members details to be inserted here. This will need to be confirmed with Dave Harriss.Dr Dave HarrissResearch Governance ManagerResearch Innovation ServicesExchange StationTithebarn StreetLiverpoolL2 2QPEmail: Sponsor@ljmu.ac.uk Phone: 0151 231 2121 |  |  |  |
| A5 | Research reference numbers: needs to be completed (ensure protocol version number and date match) | Before providing sponsorship authorisation, ensure that the protocol version number and date recorded in the IRAS form matches the actual documents. If this is not the case and the IRAS form requires updating, inform the researcher that the updates will invalidate the signatures therefore requiring the IRAS form to be re-signed. |  |  |  |
| A6 | Summary of study: should be in lay language (match against protocol) | Confirm included and written using lay terms |  |  |  |
| A18 & A19 | Check if all interventions have been listed as per the protocol and that they are in the correct section (clinical/non-clinical). | Ensure that all the clinical/non-clinical interventions performed as part of the research project has been listed - this should include the process of taking consent. Check that the number of times listed for each intervention and the duration included isn’t obviously non-sensical. |  |  |  |
| A33 | Is any translation required? | Where there are plans to translate documents, these have been done or are to be done by someone who is fluent in the language. The REC are not required to see translated documents but just need to be informed that this approach will be taken. |  |  |  |
| A36 | Data storage: check if using personal or home computers  | Abides by LJMU policiesAny data stored should be securely and regularly backed up, with the most preferential storage format being the University’s network drive. |  |  |  |
| A43 | Length of data storage: Needs to always be over 3 years as research data needs to be for 10 years as per LJMU CoP | Data generated for any clinical research sponsored by the University needs to kept for a minimum of 10 years. Any personal data collected that is not fundamental to the research can be destroyed earlier; however Information consent forms may need to be kept for the whole archiving period. | Archiving policy of 25 years (30 years for Advanced Therapy IMPs) instead of 10 years. |  |  |  |
| A50 | Registered research: could be on a public database. Clinical Trials must be registered | All clinical trials will need to be registered on a public database. ISRCTN and Clinicaltrials.gov are free public database where clinical trials can be registered. It is recommended for clinical studies to be registered on a public database but this is not a requirement unless portfolio adoption is being sought which will require registration (in which case ISRCTN is recommended). |  |  |  |
| A64 | Sponsor details | Check details are correct – should be Dave Harriss. |  |  |  |
| A65 | External funding | For projects with external funding, details of where the payments are coming from will need to be outlined and appropriate evidence available where this is applicable. Where the funding is part of a programme grant, the amount attributed to the project will need to be outlined (and further peer review may be required). Does the funding amount look sensible for the type of study it is?Is funding from the US Federal Government? (In which case check conflict of interest forms completed and correct box ticked in the Filter Question 10)Is there industry funding? (In which case check appropriate contracting is in place) |  |  |  |
| A71 (and question 3 on Filter Questions) | Sites | Is it a multi-centre project?Are any other nations involved (Devolved nations, EU, EEA)? (Do investigators know what to do with other nations? Check whether there are contracts appropriate to the type of study and sites) If so, you check whether data or Tissue are being sent to those countries and that consent is being collected for that given. |  |  |  |
| A72 | Organisations hosting the research: how many and where? | The organisation hosting the research is generally considered to be where the research tasks will take place. Also check that the ‘total UK sites in study’ has been completed.Consider whether types of organisation involved raise any special issues (e.g. non-NHS sites may need alternative arrangements for R&D approval). Are NHS organisations involved? |  |  |  |
| A74 | Monitoring and auditing | It should be noted that the sponsor may perform checks as part of their quality programme. The planned level of monitoring is appropriate? | This will be determined in line with the CTU QM SOP. The level of monitoring will be determined on a risk adapted basis. |  |  |  |
| A75 | Data Monitoring Committee | There is a Data Monitoring Committee or equivalent for interventional trials, or an acceptable explanation of why one isn’t necessary. Charters/contracts included if required? |  |  |  |
| A76 | Set LJMU text re Insurance | A76-1 – check the second box. LJMU has arranged Public Liability insurance and/or Clinical Trials insurance (delete as required) to cover the legal liability of the University as Research Sponsor in the eventuality of harm to a research participant arising from management of the research by the University and the activities here are included within that coverage.This does not in any way affect an NHS Trust’s responsibility for any clinical negligence on the part of its staff (including the Trust’s responsibility for LJMU employees/students acting in connection with their NHS honorary appointments). (Delete this 2nd paragraph if not applicable e.g. if your research takes place on University premises and/or involves no clinical intervention by the NHS).A76-2 – check the second box if LJMU designed the research.LJMU holds Professional Indemnity insurance and/or Clinical Trials insurance (delete as required) to cover the legal liability of the University as Research Sponsor and/or as the employer of staff/students engaged in the research, for harm to participants arising from the design of the research, where the research protocol was designed by the University.A76-3 – If any of the research participants are NHS patients (or you are using patient tissue or data) then the NHS indemnity scheme will apply. If you check the second box:LJMU’s Public Liability and Professional Indemnity insurance policies and/or Clinical Trials insurance (delete as required) provide an indemnity to our employees and students for their potential liability for harm to participants during the conduct of the research and the activities here are included within that coverage.Again, this does not in any way affect an NHS Trust’s responsibility for any clinical negligence on the part of its staff (including the Trust’s responsibility for LJMU employees/students acting in connection with their NHS honorary appointments). (Delete this 2nd paragraph if not applicable e.g. if your research takes place on University premises and/or involves no clinical intervention by the NHS).• Option a) Use for clinical research within NHS Hospital Trusts. Add:Professor X/Doctor Y/Nurse Z/Student A also holds an honorary appointment with # NHS Hospital Trust giving him/her the protection of the NHS indemnity scheme.• Option b) Use for clinical research outside an NHS Hospital Trust (including Primary Care). Add:Professor X/Doctor Y has the protection of medical malpractice indemnity with MDU/MPS (delete as applicable).• Option c) Use where there is a collaborating institutionLJMU’s insurance policies do not provide an indemnity to collaborators or Site Management Organisations (delete as applicable). As Research Sponsor we will ensure as far as reasonably practicable at the outset of the study that collaborators/SMOs (delete as applicable) hold appropriate legal liability insurance.Evidence of insurance cover is available to download [here](https://www.ljmu.ac.uk/staff/finance/departments/insurance) | CTIMPs may require more specialist coverage which should be included here. |  |  |  |
| A78 | IP: if ‘yes’, is it planned? What are they developing? Via Alta Innovations etc.? | Where IP may be generated, please contact Jane Townend in Research Innovation Services |  |  |  |
| Documents | As part of the IRAS submission, researchers will need to upload the items on the IRAS checklist. | A copy of all the finalised documents submitted on to the IRAS system has been e-mailed to sponsor@ljmu.ac.uk. This could include:* + Summary CV for Chief Investigator (CI)
	+ Study protocol (based on TEM003 Research protocol Template for IRAS Application)
	+ Validated questionnaires / Non-validated questionnaires / Interview schedules (as applicable)
	+ Participant documentation (information sheets (e.g. TEM003 LJMU Participant Information Sheet Template for HRA Approved Research), consent forms, recruitment material etc. (as applicable)
	+ Evidence of peer review - copy of Independent peer review (TEM002 Peer Review Assessment Form for LJMU Sponsored Research) or grant award letter with confirmation of peer review and statistical review. (If required)
	+ Organisation Information Document (OID) for non-commercially sponsored projects – [template](https://myresearchproject.org.uk/help/help%20documents/Organisation_Information_Document__Non-Commercial_v1-2.docx) and [guidance](https://myresearchproject.org.uk/help/help%20documents/Guidance_Organisation_Information_Document__Non-Commercial_v1-2.pdf) (unless the participating R&D office confirms in writing that they are happy to conduct their review without an OID). Only required if the IRAS form is submitted for HRA approval.
	+ Evidence of Sponsor insurance or indemnity
	+ Confirmation of funding (if applicable/available)
	+ Evidence of costing and confirmation of adequate funding available for the duration of the study
	+ Letter confirming co-sponsorship from the Trust (if applicable/available)
* Agreements / contracts that have or will been agreed/negotiated. (If applicable)
 |  |  |  |

Other Checks, Document and Requirements

| **Ref** | **Item** | **Studies/All** | **Also for Non-CTIMPS** | **Also for CTIMPs** | **Task/Standard defined:** | **Responsibility for verification?** |
| --- | --- | --- | --- | --- | --- | --- |
|  | Organisation Information Document | * This will need to be submitted for any research involving NHS sites.
* participant numbers from protocol match Organisation Information Document, for costings
 |  |  |
|  | CI CV | The CI is appropriately qualified to undertake activities as assigned to them through the project protocol etc., Explain what support they have in place. |  |  |
|  | Risk Assessment (mandatory requirement for CTIMPs, may be requested for other interventional studies) | Not normally required but may be requested for interventional studies. | Review and compare as a plan vs protocol |  |  |
|  | Monitoring Plan (may be submitted for CTIMPs) | Not required. | Review the appropriateness of the Monitoring Plan, comparing the Monitoring Plan against the RA and protocol. This may be developed after sponsorship approval has been issued. |  |  |
|  | Peer review; this is required for any studies under Policy Framework for Health and Social Care and when wishing for portfolio adoption. | Confirmation that it has been appropriately peer reviewed, and matches A54-1 in IRAS. Please refer to the LJMU SOP on peer review of clinical research. |  |  |
|  | Investigational Products | * Explained - Are there any study substances manufactured by the University?
* Explained - Are substances suitable for administration to humans?

Explained - Are the processes for handling the study drugs and the process for storage, preparation and dispensing okay? | Investigational Products |  |  |
|  | Collaborators and contracts | * Explained - Are any services contracted out to a third party (e.g. central laboratory services, centralised diagnostics, study monitoring or data collection)? Are appropriate contracts going to be put in place?
* Explained - Are there other Sponsors? (If so, check i) insurance and indemnity arrangements, ii) division of responsibilities. Be aware that Sponsor responsibilities cannot be shifted amongst co-sponsors).
* Explained - Are there any activities delegated to third parties? Are there expectations from the third party as to study conduct?
 |  |  |
|  | Study organisation | * Explained - Are there any particular organisational challenges in relation to the study?
* Explained - who will train sites on the protocol? (Note: CTUs will have a process for site set up in the QMS)
* Explained - Is there any equipment purchased as part of the study? If so, who is responsible for maintenance/calibration? Who own it past the end of the study? Who is liable if it goes wrong? Does it need to be separately insured?
 |  |  |
|  | Review substantiality of amendments | * appropriateness of the categorisation of substantiality?
 |  |  |