Quality Control Document:

Sponsor Review Tool

# Purpose:

The purpose of this tool is to be used as a guide to review clinical research projects that have been submitted to the University of Birmingham (UoB) for sponsorship. The information contained within this tool outlines the minimum essential detail (marked with asterisk) required by the Research Governance Team (RGT) to proceed with sponsorship. Colour key:

* Guidance notes for reviewers
* Items from the Research Hazard Assessment and Risk Mitigation Checklist. The reviewer should consider whether there are risks/hazards associated with the item and whether they have been appropriately managed, flagging any that have not.

Note: this tool was originally developed as a checklist to help reviewers identify key items that may be missing from study/trial documents. The tool has now been combined with the Hazard and Risk Mitigation Checklist, which was designed as a series of prompts for consideration. Therefore, this document has both items to check and prompts for consideration. This reflects the way that a project document set is used in a governance review, which is as the definitive source of information about a project that enables the sponsor to make decisions about it.

# Related documents:

* UoB-AES-SOP-001 Adverse Event Reporting
* UoB-CRG-POL-002 UoB Clinical Research Definitions
* UoB-CRG-SOP-001 Sponsor Oversight of Clinical Research
* UoB-DSB-SOP-001 Deviations and Serious Breach Reporting
* UoB-FNC-SOP-001 Food and Nutritional Components
* UoB-MED-SOP-001 Medicinal Product Management
* UoB-PRV-SOP-001 Peer Review
* UoB-SPO-QCD-001 Clinical Trials Task Delegation Log

Note the UoB quality management system (QMS) documents can be found on the [Clinical Research Compliance Team (CRCT) website](https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/index.aspx). Internal work instructions can be obtained from the CRCT ([crct@contacts.bham.ac.uk](mailto:crct@contacts.bham.ac.uk)) and/or from the RGT ([researchgovernance@contacts.bham.ac.uk](mailto:researchgovernance@contacts.bham.ac.uk)).

# Sponsor Review Tool

Applicable across all project-specific documents submitted for review

| Ref | Item | For all clinical research (including clinical trial of investigational medicinal products (CTIMPs)) | Also for CTIMPs |
| --- | --- | --- | --- |
|  | Full title\* | Full title of research project (crossmatch on all documents including IRAS) | |
|  | Document version number and date\* | Should be on every page. | |
|  | Integrated research application system (IRAS) ID\* | Check it matches across all documents. | |
|  | Sponsor RG number and sponsor details\* | The protocol clearly identifies the UoB as sponsor.  Check sponsor’s contact details correct and included on the protocol, IRAS and participant information sheet (PIS) as applicable. | |
|  | Appropriate language, abbreviations explained and consistent terminology\* | Any abbreviations have been explained. Where images have been used in the PIS, no copyright infringements have taken place. Participant facing documents use appropriate language for the target population. | |

## Protocol \*

| Ref | Item | For all clinical research (including CTIMPs) | Also for CTIMPs |
| --- | --- | --- | --- |
|  | Full title\* | Full title of research project (crossmatch 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). | |
|  | Sponsor research governance (RG) number and sponsor details\* | Clearly specifying that the UoB is the sponsor and including the RG number. Sponsor details may be on introductory pages, on the footer or at end of protocol, together with insurance and funding details.  Where UoB is not acting as a sponsor but is a National Coordinating Centre (NCC) on an international trial with an external sponsor, the sponsorship and management arrangements should be made clear. The RG number should still be included. | |
|  | 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. | |
|  | Chief investigator (CI) details\* and signature page | Check for the CI name and that 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. | |
|  | Key project contacts | * CI, project team, project oversight committees (if applicable), statistician (if applicable), medical oversight (if applicable), pharmacist (if applicable). * Where medical oversight is required, check access and availability of the clinician to participants and the research team, if necessary. * Is the project being led by an independent CI outside of a United Kingdom clinical research collaboration (UKCRC) registered clinical trials unit (CTU)? * Is the project being managed without a dedicated project coordinator? – If so, has the CI sought guidance from the CRCT. * Will the project team be adequately trained, have good clinical practice (GCP), human tissue training etc.? * Do all project members have access to the relevant standard operating procedures (SOPs), processes etc.? * Who would provide medical oversight in case of CI absence on an interventional project? | The CI needs to be an authorised health professional appropriately qualified for the project. |
|  | Study summary | Brief summary that covers the key details of the research project. This can include but is not limited to the following: research objectives, recruitment target and process, duration of project etc. This can be in the format of a table or schema. | Should be clear what phase project it is. Project arrangements should be appropriate to phase of the project. |
|  | Reference to applicable regulations, GCP etc\* | As appropriate, reference to being conducted in line with the UoB principles of GCP for clinical research, UK Policy Framework for Health and Social Care Research, Human Tissue Act, and any other application regulations and standards. | Includes adherence to The Medicines for Human Use (Clinical Trials) Regulations 2004’ (SI 1031) and subsequent amendments, and any other applicable regulations. |
|  | Background and rationale\* | Perform common sense check on this section. Check for references and that justification of research question, why it is worth asking, why this is worthwhile to patients, limitations of existing treatments etc. is provided. | |
|  | 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. | |
|  | Research question/aim/hypothesis\* | Clearly worded as a question and appropriately linked to the research objectives and outcomes. | |
|  | Primary, secondary and exploratory objectives\* | Objectives have been clearly defined as primary, secondary and exploratory where relevant and are in quantifiable terms. | |
|  | 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 project. | |
|  | Justification for participant population and project design\* | May refer to previous research (this may be included under another item, i.e. background and rationale or project design, methodology, location). | |
|  | Assessment of risk\* | Researchers must perform and document a project-specific risk assessment (either within the protocol or within a separate document) for all clinical research.  Consider: for low-risk projects the researcher may include a statement within the protocol to include an explanation that the study was assessed as being low risk or of comparable risk to standard of care.  Consider: where the risk assessment is a separate document, this should be referenced in the protocol. RGT may request a copy of the risk assessment at sponsor review. | A standalone risk assessment must be developed for all CTIMPs. |
|  | Public involvement\* | Is there evidence of public involvement in the design of the trial? Details of which aspects of the research process have actively involved or will involve patients, service users, and/or their carers, or members of the public. | |
|  | Interventions/project processes\* | * Will clinical care be altered by the protocol? * Will Ionising radiation (magnetic resonance imaging (MRI) or ultrasound investigations do not involve ionising radiation) be used: * Diagnostic X-rays, computerised tomography (CT) scans or bone density (DEXA) scans; * Radiotherapy (including brachytherapy and therapy using unsealed sources; or * Radionuclide imaging (including diagnostic imaging and in vivo measurements)? * Will the research involve administration of radioactive medicinal products to humans (Diagnostic X-rays, CT scans and DXA do not involve the administration of radioactive materials)? * Positron emission tomography (PET)-CT * Nuclear Medicine Bone Scans * Multigated acquisition scan (MUGA) * Are any devices CE/UKCA marked, are they being used within that CE/UKCA marking? Are devices being tested for the purposes of obtaining CE/UKCA marking? * Is the risk associated with the investigational medicinal product (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)? * Is there a risk to the safety and wellbeing of the researchers and other staff? * Is an advanced therapy medicinal product (ATMP), gene therapy or cell therapy involved? * Will intrusive interventions or data collection methods be used? * Will the project 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)? * Are questionnaires/diagnostic tools being used? Have they been validated? Does UoB hold a licence for the use of the questionnaire/diagnostic tool? * 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? * Does the research have potential to expose participants to issues that can make them vulnerable? (Especially in social research) * 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? | |
|  | 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 so, the project will need an insurance referral. * Can participants be pregnant women? If so, the project will need an insurance referral. | |
|  | Recruitment process\* | * Detailed account of the research setting, location and the recruitment process * Check it includes the participant pathway to getting on the project – screening, information given, consent as applicable * Check that the researcher is not trying to get ‘cold’ access to participants, through screening notes etc. (General Data Protection Regulation - GDPR) * Check 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. * Check that eligibility (if any medical conditions included) is confirmed by a qualified clinician. | |
|  | Consent process\*, roles, timelines and setting | * Consent will be gained after agreement to participate in the project has been established and 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 (CAG) where applicable). * In situations where verbal consent is the most appropriate means of consent, this is clearly documented here and also in the PIS and informed consent form (ICF). * Will identifiable data be used without consent (e.g. to identify potential participants)? Note: researchers should not access care records in order to identify participants – care records must only be accessed by members of the care team who will then need to be the ones to approach the participants. * Timelines for project consideration are referenced. The participant should be given adequate time to consider their decision to participate in the clinical research. 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. * Details present as to who will be taking consent. Consent should be obtained by the PI or delegated to a member of the project team, trained in the project and GCP (where applicable). This should be defined in the protocol. Are the people taking consent appropriately trained? * Check if 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 ‘for all clinical research’ but with the following differences:   * Must be in writing (also see [Joint statement on seeking consent by electronic methods (PDF - 209 KB)](https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/hra-mhra-econsent-statement-sept-18.pdf)). * 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. |
|  | Treatment/project process\*, outcome measures and planned timelines | * The project assessments, timelines and follow-up are clearly detailed. * How long will participants be in the project? * The timelines listed appear feasible and practical. Where fixed times/dates have been specified, flag up with the researcher that these can lead to protocol breaches, and discuss in how far time windows may be more appropriate. The use of words such +/- x days/hours is recommended. * Check that the processes and timelines match across all documents (IRAS and protocol). | * Define IMP * Check treatment and dosing schedule is detailed, including route of administration and treatment period * Check details regarding storage * Ensure clarity where IMP is coming from and which sites it is going to * Check section detailing drug interactions and/or contraindications is present * Check reference to investigator brochure (IB) or summary of product characteristic (SmPC), as applicable, does this cover the reference safety information (RSI)? * Check accountability procedures |
|  | Use of prescription only meds (POM – check British National Formulary (BNF)) for non-IMP trials. | Where POMs are to be used, check that 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. | |
|  | 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 authority (HTA)/ data protection act (DPA)/GDPR and matches information in the PIS/ICF. | |
|  | Data management process (data management, storage and access)\* | * Contains link to DPA (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): * What will be considered source data? * What data items are to be collected? * Will the data used be identifiable; coded or anonymised format and if it is coded or anonymised is the process clearly described somewhere? * What is the data verification process? Role of supervisor in the data verification process for student project * Is anything being recorded and transcribed? Will transcription be done by a third party and is an appropriate agreement in place? * Is the data analysed by a third party or delegated to a contract research organisation (CRO)? Otherwise disclosed to other parties? (Have appropriate agreements measures been put in place, will there be consent for this) * Are data being sent to a country or territory in other jurisdictions or outside of the European Economic Area (EEA)? * The security of location and transfer of data (Note: it’s common for researchers to write that servers are encrypted, this is not usually the case for UoB servers and would need to be corrected). * 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? * Who will be able to access data and what information will they be able to access? * Is disclosure and use of information justified? Is the minimum necessary identifiable information being used? * Data (including essential documents, such as informed consent forms) to be archived in accordance with applicable regulatory requirements and the [UoB Data Management Policy](https://intranet.birmingham.ac.uk/as/libraryservices/library/research/rdm/Policies/Research-Data-Management-Policy.aspx). * Database lock procedures where applicable   Consider: Are data security and transfer arrangements satisfactory and in line with UoB policy, the DPA and GDPR? | |
|  | Sample storage and access (if applicable\*) | * The location and transfer of samples have been clearly specified. * Check the ICF – does consent cover what is happening to the samples? * What are samples used for? Are they being analysed (other than in a 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. * 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 are not being kept under ethics, are appropriate arrangements in place to keep relevant material in a licenced facility? * Researchers acknowledge when the Human Tissue Act (2004) is applicable (i.e. if samples stored in England, Wales or Northern Ireland). Is the project 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). * Will the research involve human embryos and/or gametes? If so, identify Human Fertility and Embryology Authority licencing requirements and check they are met.   Consider: Does a material transfer agreement (MTA) need to be put in place, or is this covered by an OID? If the OID is the main agreement, have the researchers to be advised accordingly? Are arrangements for storage and transfer satisfactory and in line with UoB policy? | |
|  | Statistical analysis methodology linked to outcome measures | Includes appropriate detail on sample size calculation\*, (if applicable), process, interim analyses if applicable, Statistical Analysis Plan (SAP) (if applicable).  Where statistical analyses are to be performed, check that 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 reviewer. Has appropriate statistical advice been provided? | A detailed statistical analysis plan should be available (this may be as a separate document to the protocol). |
|  | Definition of adverse events (AEs) & serious adverse events (SAEs)\* | * Check that it refers to UK 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 Adverse Event Reporting SOP (UoB-AES-SOP-001) for reporting and escalation, to include assessment of potential SAEs by a clinician, and reporting SAEs to the sponsor etc. * Ensure reporting requirements are detailed, including timelines * Check that for different studies, appropriate definitions have been included i.e. suspected serious adverse reaction (SSAR), unexpected serious adverse device effect (USADE) etc. * Check that 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. | Check it against the CTIMP definitions. |
|  | Serious breaches\* | Is consistent with the Deviation & Serious Breach Reporting SOP (UoB-DSB-SOP-001) for reporting to sponsor and the research ethics committee (REC). | Includes definition and reporting to the Medicines and Healthcare products Regulatory Agency (MHRA) |
|  | Monitoring and quality management procedures\* | Some documentation from the researcher 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-managed projects, this may be document elsewhere in the QMS). Should be consistent with any requirements in the risk assessment. |
|  | Oversight\*, trial management group (TMG) , trial steering group (TSC), data monitoring committee (DMC) etc. | Appropriate oversight is in place reviewing the safety and data aspects of the project. This can be done by the TMG (TSC and DMC as appropriate). 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 RGT throughout. | APRs and development safety update report (DSURs) will be sent to the MHRA, REC and UoB throughout. |
|  | Ethical considerations and adherence to GCP principles\* | Text stating that the study/trial will adhere to the UoB 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 principles of GCP as per the UK clinical trial regulations. |
|  | Insurance and indemnity\* | States that UoB provides insurance and indemnity (to include further details where more specialist coverage is required). | |
|  | 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 PIS?), who has access to study/trial final dataset; sometimes will say who determines authorship etc. Are arrangements in line with HRA guidelines on [publishing your research findings](file:///\\MDS\Resources\College%20Hub%20Shared\Research%20&%20Knowledge%20Transfer%20Office\CRCT\1.%20QMS\Sponsor%20Oversight\Drafts\Sponsor%20Review%20Tool\%20https\www.hra.nhs.uk\planning-and-improving-research\research-planning\publishing-your-research-findings\).  The summary of the results of the clinical research project and a summary in lay language should be made available on a project registry (e.g. ISRCTN), see [UoB position paper on clinical research registration](https://www.birmingham.ac.uk/documents/college-mds/crct/uob-position-papers/uob-position-paper-clinical-research-registration-v1.0-vd-14-jan-2021.pdf).  Consider: Use of a study webpage to disseminate research findings and signpost participants to this to avoid retaining personal contact information. | |
|  | End of project defined\* | Defines the end of the project, when notification of end of project will be sent to REC/UoB. | End of project notification will also need to be sent to the MHRA. |
|  | 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) | Check that it is clear which lab results relate to which outcome (primary, secondary or exploratory). | |
|  | 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 projects 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.  Consider: Where will the code breaks be located? If sealed code break envelopes are used, how will the integrity be maintained? Who will have access? What are the out of hours arrangements? Will anyone need to be contacted to give permission for code break? Should a participant attend A&E, will it be evident to the clinician they are taking part in research? | |
|  | If a medical device is being used specifically for the research, check whether it counts as a clinical investigation for MHRA purposes | Remind researchers that they need to have appropriate contracts/costings in place for any required servicing, use of disposals and appropriate insurance coverage. The owner of the device also needs to be clarified.  Consider: Is the device CE/UKCA marked or not? Is it being used within its intended purpose? Has it been modified for the purpose of this project? Is there need for CTU support? | |
|  | Is blood taken from healthy volunteers? If so, refer to [UoB policy on taking blood from volunteers for research (PDF – 58 KB)](https://intranet.birmingham.ac.uk/hr/documents/public/hsu/hsupolicy/blood-taking-from-volunteers-policy.pdf). | Reference to policy in protocol where relevant. Can be covered in general statement specifying that UoB policies will be adhered to. Local Trust policies would also be acceptable for NHS sites. | |
|  | Does lone working policy apply? If so, refer to [UoB Lone Working Policy](https://intranet.birmingham.ac.uk/hr/wellbeing/worksafe/lone-working/loneworking.aspx). | Reference may be made to this in protocol where relevant. Can be covered in general statement specifying that UoB policies will be adhered to, or actual practice can be described. Check that Lone Working Policy is referenced on the IRAS form, as forestalls questions from RECs. | |
|  | Are community visits going to take place? If so, refer to [UoB Community Visits Guidance (PDF – 59 KB)](https://intranet.birmingham.ac.uk/hr/documents/public/hsu/hsuguidance/20cv.pdf). | Reference to this in protocol where relevant, or description of what will be done that is consistent with the policy. | |
|  | Is the UoB a Site (not applicable for CTIMPs) or are project interventions taking place on UoB premises. | If the UoB is a site or a location for project 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.  Consider flagging as risk on the database under the risk tab. | The UoB would not normally act as a ‘site’ for regulated clinical trials or surgery trials (i.e.  CTIMPs or of medical devices).  While exceptions to this may occasionally be made, where an exception is made this will be documented in writing in a letter from the University’s Head of Research Governance and Integrity. |

## Participant Information Sheet (PIS) \*

| Ref | Item | For all clinical research (including CTIMPs) | Also for CTIMPs |
| --- | --- | --- | --- |
|  | 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. | |
|  | Project title | The full project title should be present on both the PIS and ICF, except in circumstances where inclusion of the full project title would not be appropriate, in this case a participant friendly acronym can be used as long as it is referenced in the protocol. This is in order that participants have a single reference for a project. Appropriate logos have been included (e.g. sponsor logo, collaborator logo, trial logo) and is consistent across the participant-facing documents. | |
|  | Project identifiers | Appropriate project identifiers have been added, including the IRAS number (if applicable). | Consider: ISRCTN registry number or EudraCT number |
|  | Appropriate language, abbreviations explained and consistent terminology | The PIS is easy to read and has been written in a language appropriate to the audience. Terminology is consistent throughout the document. Abbreviations are infrequent and, where used, are appropriately defined when first mentioned. Terminology used is appropriate for the project. Repetition is avoided as much as possible, and where this is unavoidable, the text is consistent. | |
|  | Funding described | Check that the PIS mentions the funder. | |
|  | Expectations of participant are clear (# of visits etc.) | Check that the PIS 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.  Consider: including the approximate number of participants involved in the project. | |
|  | 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.  Consider the foreseeable circumstances and/or reasons under which the participants participation in the project may be terminated. | |
|  | Participant reimbursement | Check that details of any reimbursement for taking part in the research has been mentioned. The PIS will also need to specify where there is no reimbursement available. | |
|  | Duration of project | The full duration of the participant’s involvement in the project needs to be clarified. This includes any follow-ups. | |
|  | Discontinuation/ Interruption of treatment | Circumstances where the patient may discontinue treatment early are clearly defined and consistent with the protocol. There may also be circumstances where treatment is paused, consider what this would mean for the participant. | |
|  | Project procedures and activities adequately described | Check that this matches what has been outlined in the protocol and IRAS. | |
|  | Time allocated for consent process, | The recommended time allocated for the participants to consider taking part in the research is adequate from receiving the PIS. However, it can be less if there is appropriate justification for it. The duration needs to be specified in the PIS highlighting that participants can have more time if they wish.  Consider: If a minimum time is allocated for the consent process, whether the time could be less if there is appropriate justification for it. | |
|  | Contact details for complaints – patient advice and liaison service (PALS) for NHS and Head of Research Governance and Integrity as an independent UoB representative for any other projects using RG email address. | Where research is involving NHS patients, check that PALS (or devolved nation equivalent) details are listed for any complaints. For investigator led projects it is also recommended for Birgit Whitman’s details to be added as an independent UoB representative for any complaints.  Where no NHS patients are involved, Birgit Whitman’s details should be listed as an independent UoB representative for comment/complaint:  Dr Birgit Whitman  Head of Research Governance & Integrity  Research Strategy and Services Division  Research Park  University of Birmingham  Edgbaston  Birmingham, B15 2TT  Email: researchgovernance@contacts.bham.ac.uk  Telephone: +44 (0) 7814 650003 | |
|  | Prohibited concomitant medications are clear | Check these have been listed as applicable. | |
|  | Health Research Authority (HRA) GDPR transparency wording | See HRA guidance on [research transparency](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-transparency/) regarding GDPR as applicable.  In particular the following sections must be included:   * How will we use information about you? * What are your choices about how your information is used? * Where can you find out more about how your information is used? – one of the contacts listed here must be the Sponsor’s Data Protection Officer ([dataprotection@contacts.bham.ac.uk](mailto:dataprotection@contacts.bham.ac.uk)). | |
|  | Location/storage of any personal data collected | The PIS should indicate how long personal data, including ICFs 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 project (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.   * Methods of transfer should be clear (e.g. electronic, paper, email, phone). * It is clear whether third parties will be receiving patient data and for what purpose. * If patient data will be flagged via NHS digital or NHS data centres this will need to be made clear in the PIS.   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. | |
|  | How the research results will be disseminated and participants informed of outcomes | How will the participants access the results? Will they be notified and will personal details be needed?  Are arrangements in line with HRA guidelines – see [publishing your research findings](https://www.hra.nhs.uk/planning-and-improving-research/research-planning/publishing-your-research-findings/).  It should be clearly outlined in the PIS how patients are to receive information on outcomes. This is to match the IRAS. The use of a study webpage is recommended to disseminate research findings and signpost participants to this to avoid retaining personal contact information.  The summary of the results of the clinical project and a summary in lay language should be made available on a project registry (e.g. ISRCTN)  Consider: Use of a project webpage to disseminate research findings and signpost participants to this to avoid retaining personal contact information. | |
|  | For a child’s PIS 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 * For younger participants use images or diagrams where appropriate to explain the project. * Do not include the research team contact details as this will be included in the parent or guardian PIS. | |
|  | For a parent/guardian PIS the terminology is appropriate | The participant has been referred to as “Your child”. | |
|  | Confidentiality and insurance/indemnity assured in line with protocol | Check that wording correctly describes the indemnity arrangements for the project | |
|  | Sponsor and regulatory bodies have access to data | The PIS mentions that sponsor representatives and regulatory bodies will access the data where relevant. | |
|  | Contact details of researcher for further information | The contact details of the researcher are provided should the participant require further information or clarification. Ensure work contact details for researchers are provided as opposed to a personal mobile number. | |
| **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 | Check that these are recognised/reputable links | |
|  | Whether or not general practitioner (GPs) will be contacted | Participants are informed / consent to their GP being notified of their participation where applicable. If GP is to be notified, this will also be reflected in the PIS and ICF. | |
|  | Where radiation assessments are mandated in the protocol | Radiation procedures and risks involved are made clear. | |
|  | Sample collection, storage location, transfer, what happens to all samples | Where samples are to be collected, the PIS clearly outlines what samples will be taken. Ensure the amount of sample is described in a way that is relatable to the participant, e.g. with a blood sample referred to in teaspoons/tablespoons as well as ml.  It should be clearly outlined where the samples will be stored for the duration of the project and if they will be shared/transferred elsewhere 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 PIS 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.   If there is any possibility that genetic tests and/or deoxyribonucleic acid (DNA) extraction may be done, this has been clearly defined.   * If samples are going to be shared with a commercial collaborators, with no financial benefit to the participant. | |
|  | 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. | |
|  | Where skeletal muscle biopsies are performed | All procedures and risks involved are made clear. Where possible, this should include the frequency/likelihood of complications occurring. | |

## Informed Consent Form (ICF) \*

| Ref | Item | For all clinical research (including CTIMPs) | Also for CTIMPs |
| --- | --- | --- | --- |
|  | Planned to be printed on headed paper | For multiple sites, check that 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. | |
|  | Project title\* | The full project title should be present on both the PIS and ICF, except in circumstances where inclusion of the full project title would not be appropriate. In either case the title on the ICF should be the same as on the PIS.  Where an abbreviated title is to be used (e.g. for child participants or where a title is deemed to be complex) that this matches the abbreviated titles included in the project protocol. | |
|  | Quotes the relevant PIS specific document title, date and version number | Check that the full PIS document title, has been inserted, that there is a space to include the PIS version and date (Consider leaving a dotted line as it is better if the PIS version and date is not printed on the ICF as when the PIS is amended the ICF won’t have to be if all that is changing on the ICF is the PIS version). Where there are multiple PIS documents and a single ICF, it is clear which PIS version the participant is consenting to. | |
|  | Appropriate language, abbreviations explained and consistent terminology | Check that the language used in the ICF is written in lay language and is appropriate to the audience and that each point clearly outlines what the participant is consenting for. Any abbreviations should be explained. | |
|  | Mandatory sections | All applicable mandatory sections are included, and below this a section for optional consent where appropriate. Optional consent must be clearly defined and include a `Yes/No’ in addition to the initials box. | |
|  | Data access | Where follow-up data is being sought from GPs, a specific statement about this has been included in the ICF. | |
|  | Data/sample storage location, access and transfer (if applicable) | Check that this information has been summarised in the ICF where applicable, including the storage and retention of consent forms.  If data/samples may be transferred to other organisations this should be clear and consented for.  If data/samples are being sent outside of the UK, this should be covered as a specific point on the ICF.  For CTU projects, ICFs and other identifiable data may be sent to the CTU, in which case there should be specific consent for this on the form.  If third parties (e.g. pathologists) are being sent ICFs this is clear. | |
|  | 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) | Check that 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. | Check that 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, check that 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 ICF clearly specifies that samples are to be taken.  Where participation in sub-projects or donation of tissue is optional, the statements are included to record the patient’s participation. | |
|  | Sample storage and transfer | The ICF 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).  Where tissue samples are planned to be used for future research projects or other purposes (where there may be no ethical approval, e.g. in the educational setting or validation purposes), this needs to be specified in the ICF, emphasising that they will be used. Explicit consent will also need to be gained for when samples are going to be:   * sent abroad * shared with other institutions/third parties (especially commercial entities) * used in animal models. | |
|  | Sample analysis | Where DNA or genetic analysis is being performed, a specific statement about this has been included. | |
|  | 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 PIS). 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 ICF. 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.  Consider: where participant contact details are added to the ICF that it’s at the end/in a place that can easily be redacted if/when needed. It is recommended to have a separate sheet. | |
|  | If consultee is being used, does it identify the participant and match the PIS? | Where consultee declaration is being gained, check 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. It is recommended that a Yes/No response is included for optional items with space for the participant’s initials. | |
|  | Consent to notify GP. | This would need to be present in the ICF whereby the participant will provide consent for their GP to be notified. | |
|  | Space to add participants unique identifier | It is recommended for the participants unique identifier to be added to the ICF. | |
|  | Phrase at bottom of ICF clarifying what will happen to the original and copies of the ICF (e.g. original to be kept in project files and copy to be given to participant) | It is recommended for the ICF to have a phrase at the bottom clearly outlining what should be done with the original and copies of the ICF. | |

## IRAS Form

Refer to IRAS help section for further guidance on any checks that may be required.

At present the IRAS form will only apply to non-CTIMPs as CTIMPs will be processed via the Combined Review System (CRS) as of Jan 2022. However, the guidance below should also be used by those applying for CTIMPs via the CRS. Some checks and considerations will continue to be relevant for CTIMPs but will not correspond to the IRAS form section mentioned here.

| IRAS Ref | Item | For all clinical research (including CTIMPs) | Also for CTIMPs |
| --- | --- | --- | --- |
| 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 ['what approvals do I need'](https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/hra-approval/), as well as the UoB Clinical Research Definitions (UoB-CRG-POL-002). Where there is uncertainty on whether the project is a CTIMP, the query will first be discussed within the Research Governance Team and advice will be sought from the Clinical Research Compliance Team (if required). Where uncertainty remains, a final decision will be made in collaboration with (the chair of) the Clinical Trial Oversight Committee.  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.  Check the project falls within the UK Policy Framework for Health and Social Care Research.  Check that 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 whether they have taken place).  Note that responses to the filter questions will generate relevant sections for the applicant to complete, these will need to be checked and include but are not limited to:   * Application forms for the Confidentiality Advisory Group (CAG) if access is needed for: * Identifiable patient or service user information relating to people living in, or receiving care in, England and Wales without consent, prior to the disclosure of confidential information; or * Human Fertilisation and Embryology Authority (HFEA) Research Register Data. * Forms for research exposure involving ionising radiation that is being administered in addition of standard of care * Part B: Section 3 to create an Administration of Radioactive Substances Advisory Committee (ARSAC) for a new site * Part B: Section 5 for the use of newly obtained human tissue for research | Note:CTIMPs submitted via CRS will still require completion of IRAS forms for administration of radioactive substances advisory committee (ARSAC) and use of newly obtained human tissue for research, these forms will be generated and completed via the CRS system. |
| IRAS Project Filter: 5b | Portfolio adoption | If the researcher has specified that they would like the research to be portfolio adopted, check that it is eligible for adoption. If it is eligible and a non-CTU project, remind the researcher that a PAF will need to be submitted.  Also, check that the peer review that has been conducted on the project 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 Birgit Whitman’s details | The contact details listed here should be Birgit Whitman’s details as listed below.  Dr Birgit Whitman  Head of Research Governance & Integrity  Research Strategy and Services Division  Research Park  University of Birmingham  Edgbaston  Birmingham, B15 2TT  Email: researchgovernance@contacts.bham.ac.uk  Telephone: +44 (0) 7814 650003  Note: for CTIMPs submitted via the CRS, these details need to be included in section C1. Also, for CTU-managed projects, the CTUs may request for one of their staff member’s details (e.g., a trial coordinator) to be inserted. | |
| 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 project: should be in lay language (match against protocol) | Confirm summary included and written using lay terms  The HRA guidance on [research transparency](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-transparency/) should be referred to as applicable. | |
| A10 & A11 | Check the primary and secondary aims and objectives | Ensure that this matches the protocol and lay terminology is used. Where possible if secondary objectives have not been given in IRAS check if these are mentioned in the protocol and ensure the IRAS form is updated accordingly. | |
| A17-1 & A17-2 | Check the inclusion and exclusion criteria against those mentioned in protocol | If the inclusion and exclusion criteria do not match those given in the protocol the IRAS form will need to be updated. | |
| 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 nonsensical. | |
| A29 | Check the method of first approach to potential participants, please also check that this matches the protocol. | First approach to gauge a potential participants interest in taking part in the project (prior to informed consent) must be made by someone who is not a member of the research team to minimise the risk of coercion. This can be done by;   * a member of the potential participant’s healthcare team if they are a patient (i.e. during a clinic visit or appointment) * a department lead or manager if the project involves members of staff * or an advertisement poster to encourage potential participants to come forward to contact the research team | |
| 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 | Where it is not clear if personal data may be stored on other devices, discuss with the researcher. Researchers should also be advised that any 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 be in accordance with applicable regulatory requirements for research data. | Data generated for any clinical research sponsored by the University needs to kept in accordance with applicable regulatory requirements and the [UoB’s Data Management Policy](https://intranet.birmingham.ac.uk/as/libraryservices/library/research/rdm/policies/policies.aspx) , the end of archive at the CI’s discretion can be extended where necessary. Any personal data collected that is not fundamental to the research can be destroyed earlier; however, ICFs may need to be kept for the whole archiving period. | CTIMPs submitted via CRS, the archiving requirements for CTIMPs will remain in accordance with the regulatory requirements for clinical trials and the [UoB Data Management Policy](https://intranet.birmingham.ac.uk/as/libraryservices/library/research/rdm/policies/policies.aspx). |
| A50 | Registered research: needs to be on a public database or needs a reason why not. | All HRA-approved clinical research will need to be registered on a public database, with all clinical research now encouraged to be registered on a public database as per the HRA `make it public’ initiative. Please refer to the [UoB position paper on clinical research registration (PDF – 218 KB)](https://www.birmingham.ac.uk/documents/college-mds/crct/uob-position-papers/uob-position-paper-clinical-research-registration-v1.0-vd-14-jan-2021.pdf?_ga=2.220011673.1676715748.1668433925-1507232160.1663759573).  Projects funded by the US will need to be registered via the ClinicalTrials.gov database.  Free automatic registration is available via ISRCTN for projects that are CTIMPs or are NIHR portfolio adopted projects. Non-CTIMP projects that are not National Institute for Health and Social Care Research (NIHR) portfolio adopted will be charged a fee for ISRCTN registration. | |
| A64 | Sponsor details | Select `Non-Commercial’ from the drop-down list and check details are correct – should be Birgit Whitman (see A4 above). | |
| 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 project it is?  Is funding from the United States (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, European Union (EU), EEA)? (Do investigators know what to do with other nations? Check whether there are contracts appropriate to the type of project 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. For example, a project run by researchers from SportExR at University Hospitals Birmingham (UHB), UHB will be considered as the host of the research therefore requiring ‘NHS organisations in England’ to be ticked. Also check that the ‘total UK sites in study’ has been completed.  Consider whether the types of organisations involved raise any special issues (e.g. non-NHS sites may need alternative arrangements for R&D approval). See HRA guidance on [NHS site set-up in England](https://www.hra.nhs.uk/planning-and-improving-research/best-practice/nhs-site-set-up-in-england/).  Are NHS organisations involved? | |
| A74 | Monitoring and auditing | It should be noted that the sponsor may perform checks as part of their quality programme.  Is the planned level of monitoring appropriate? | This should be determined in line with the CTU QMS. The level of monitoring will be determined on a risk adapted basis. |
| A75 | Data monitoring committee | There should be a DMC or equivalent for most interventional projects, or an acceptable explanation of why one isn’t necessary.  Are charters/contracts required? (May need to prompt non-CTU teams) | |
| A76 | Set UoB text re insurance | A76-1 and A76-2, for any research sponsored by the University with there being no involvement with the NHS, generally ‘Other insurance or indemnity arrangements will apply (give details below)’ will need to be ticked and the following text added:  ‘The University has in force a Public Liability Policy and/or Clinical Trials policy which provides cover for claims for "negligent harm" and the activities here are included within that coverage.’  Where the NHS participants are involved and NHS organisations are acting as sites, the NHS indemnity will apply and should be reflected in the answer for A76-3 by ‘NHS indemnity scheme or professional indemnity will apply’ being ticked. | CTIMPs may require more specialist coverage. |
| A78 | Intellectual property (IP): if ‘yes’, is it planned? What are they developing? Via University of Birmingham Enterprise etc.? | Where researchers believe that IP may be generated, they should be made aware of UoB Enterprise who will be able to provide them with any IP related support. However, this is not to hinder sponsor authorisation as is not mandatory.  This will also need to be reflected in the Organisation Information Document (OID) and any model site agreements. See the HRA guidance on how to [prepare study documentation](https://www.hra.nhs.uk/planning-and-improving-research/research-planning/prepare-study-documentation/). | |
| 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 need to be e-mailed to the reviewer. This should include as a minimum the:   * protocol, PIS, ICF and any other participant-facing documents * CV for the CI * GP letter (if applicable) * OID\* and HRA Schedule of Events (if applicable) * model non-commercial agreement (mNCAs)\* (if the project falls under the first four categories in the IRAS filter questions)   \* the site agreements do not need to be finalised at the time of submission, but the HRA may request them. The site agreement will need to be finalised prior to project start up. | |

## Other Checks, Documents and Requirements

| Ref | Item | For all clinical research (including CTIMPs) | Also for CTIMPs |
| --- | --- | --- | --- |
|  | Organisation Information Document/Schedule of Events | * This will need to be submitted for any research involving NHS sites. * An OID and Schedule of Events or SoECAT (where excess treatment costs or NIHR funding are involved) needs to be submitted for sites where different activities are to occur (e.g. if some sites will only act as a PIC site and others where the intervention, 2 sets each of Organisation Information Document and Schedule of Events will need to be submitted. They will not need to be submitted for each site, just by the activity being performed at the site if different). * Check participant numbers from protocol match OID/Schedule of Events, for costings. * The clinical research network (CRN) can help researchers in completing these documents. | |
|  | CI CV | Check that CI is appropriately qualified to undertake activities as assigned to them through the project protocol etc., may need to check what support they have in place. | The CI must be medically qualified or a dentist. |
|  | Risk Assessment (mandatory requirement for CTIMPs, may be requested for other projects e.g. international) | Researchers must perform and document a project-specific risk assessment (either within the protocol or within a separate document) for all clinical research.  Consider: for low-risk projects the researcher may include a statement within the protocol to include an explanation that the project was assessed as being low risk or of comparable risk to standard of care.  Consider: where the risk assessment is a separate document, this should be referenced in the protocol. RGT may request a copy of the risk assessment at sponsor review. | A standalone risk assessment must be developed for all CTIMPs. |
|  | Monitoring plan (may be submitted for CTIMPs) | Not generally required for low-risk projects but might be required for higher risk non-CTIMP projects (e.g. non-CE/UKCA marked device studies, surgical intervention projects) in line with UoB procedures. | 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 | Confirmation that it has been appropriately peer reviewed, and matches A54-1 in IRAS.  For the UoB procedures on peer review of clinical research projects, refer to the Peer Review SOP (UoB-PRV-SOP-001). | |
|  | Investigational products | * Are there any project substances manufactured by the University? * Are substances suitable for administration to humans? * Are the processes for handling the project drugs and the process for storage, preparation and dispensing okay?   See also the Food and Nutritional Components SOP (UoB-FNC-SOP-001) for further information and theMedicinal Product Management SOP (UoB-MED-SOP-001). | |
|  | Collaborators and contracts | * Are any services contracted out to a third party (e.g. central laboratory services, centralised diagnostics, project monitoring or data collection)? Are appropriate contracts going to be put in place? * Are there other sponsors? (If so, check i) insurance and indemnity arrangements, ii) division of responsibilities. Be aware that you can’t really shift sponsor responsibilities even amongst co-sponsors). * Are there any activities we are delegating as sponsor to third parties? Are there expectations from the third party as to project conduct? | |
|  | Project organisation | * Are there any particular organisational challenges in relation to the project? * May need to discuss who will train sites on the protocol? (Note: CTUs will have a process for site set up in the QMS)   Is there any equipment purchased as part of the project? If so, who is responsible for maintenance/calibration? Who owns it past the end of the project? Who is liable if it goes wrong? Does it need to be separately insured (likely if it is to be located off-site, we retain ownership of it and its value is more than £10,000) | |
|  | Review substantiality of amendments | * Review amendments in terms of the appropriateness of the categorisation of substantiality.   Note: as detailed in the Sponsor Oversight of Clinical Research SOP (UoB-SPO-SOP-001) should the RGT disagree with the assessment then evidence will be provided in writing, and for substantial amendments evidence of agreement is provided through the electronic signing off the IRAS form by RGT | |

# References

* HRA guidance:
* NHS site set-up in England: <https://www.hra.nhs.uk/planning-and-improving-research/best-practice/nhs-site-set-up-in-england/>
* Prepare study documentation: <https://www.hra.nhs.uk/planning-and-improving-research/research-planning/prepare-study-documentation/>
* Publishing your research findings: <https://www.hra.nhs.uk/planning-and-improving-research/research-planning/publishing-your-research-findings/>
* Research transparency: <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-transparency/>
* What approvals do I need: <https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/>
* MHRA and HRA Joint statement on seeking consent by electronic methods: <https://www.hra.nhs.uk/documents/1588/hra-mhra-econsent-statement-sept-18.pdf>
* The Human Tissue Act (2004): <http://www.legislation.gov.uk/ukpga/2004/30/contents>
* The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031): <http://www.legislation.gov.uk/uksi/2004/1031/contents/made>
* UK policy framework for health and social care research: <https://www.hra.nhs.uk/documents/1068/uk-policy-framework-health-social-care-research.pdf>
* UoB policies/guidance/documents:
* Community visits: <https://intranet.birmingham.ac.uk/hr/documents/public/hsu/hsuguidance/20cv.pdf>
* Lone working: <https://intranet.birmingham.ac.uk/hr/wellbeing/worksafe/lone-working/loneworking.aspx>
* Position paper on clinical research registration: <https://www.birmingham.ac.uk/documents/college-mds/crct/uob-position-papers/uob-position-paper-clinical-research-registration-v1.0-vd-14-jan-2021.pdf>
* Research data management: <https://intranet.birmingham.ac.uk/as/libraryservices/library/research/rdm/Policies/Research-Data-Management-Policy.aspx>
* Taking blood from volunteers for research: <https://intranet.birmingham.ac.uk/hr/documents/public/hsu/hsupolicy/blood-taking-from-volunteers-policy.pdf>