**CTU ‘Fit to Submit’ internal quality check form - new clinical trials**

**GUIDANCE**

* The form must be completed for all new clinical trials run through either an Oxford Clinical Trials Units (CTU), or an approved external CTU, that requires sponsorship by the University of Oxford through the Research Governance, Ethics and Assurance Team (RGEA).
* The CTU must document, in full where required, the findings of the internal quality check that has taken place on the full submission package.
* The quality check provides valuable information for the sponsor reviewer, but does not replace the requirement for sponsorship review. Thus, the content and composition of the submission package is still subject to change following input and questions from the sponsor reviewer as part of the sponsorship review process.

**Internal quality check process:**

* Once a full submission package has been developed it must be quality checked by a colleague in the CTU who is independent of the trial1 before onward submission to RGEA for sponsorship review.
* Any revision of documents/addressing any quality check comments should take place between the independent colleague and the study team before it is submitted to RGEA.
* Complete this ‘fit to submit’ form detailing information that may require input from RGEA to resolve. Please do not just tick, type ‘yes’ or leave a box blank in Section C. If something is not applicable then write ‘N/A’ in the box.
* The completed form must then be sent to RGEA along with a ‘clean’, full document set ready for sponsorship review.

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| **Internal, independent ‘fit to submit’ CTU quality check review form** |
| **Section A – Details and declarations** |
| **Name of Clinical Trials Unit** |  |
| **Study Title (short)** |  |
| **Name of independent colleague(s)** |  |
| **Date(s) internal quality check completed** |  |
| **Declaration:** *By completing this form, the independent internal quality checker declares that the information contained in this form is true and accurate, and completed to the best of their knowledge (if any section is unclear then please refer to the accompanying guidance or email* *rgea.sponsor@admin.ox.ac.uk**)* |
| **Section B – Checklist of basic requirements** |
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| **Question** | **Tick**2 |
| All IRAS filter questions have been answered appropriately |  |
| The duration of the study - is it appropriate and achievable3 |  |
| There is a complete document set (as required by HRA/MHRA and all other possible review bodies e.g. CAG/ARSAC) ready for submission to RGEA. This includes any other submission documentation cited in the protocol/IRAS form (including the IMPD and IB)4  |  |
| There is consistency across all documents: titles, formatting, spelling, structure, and that the language used is appropriate for each document5 |  |
| There is consistency across the documents with regard to inclusion/exclusion criteria; study assessments; study outcomes; safety data collection; withdrawal procedures (including data management)6 |  |
| Correct version numbers, dates and identifiers are on all documents including University logo (if applicable)7 |  |
| Appropriate licences and copyright are clearly stated in the relevant documents (e.g. on any images/videos/other media/questionnaires) |  |
| A draft Risk Assessment has been included, that includes study classification and categorisation, and that any risks of concern have been mitigated8 |  |
| Copies of any relevant pre-approval correspondence with MHRA (or HRA/FDA etc.) are included in the sponsorship submission pack. |  |
| If the trial involves human tissue samples, the protocol and participant-facing documentation mentions plans for the samples at the end of the study and consideration for future use. If the samples are to be transferred to an Oxford Research Tissue Bank (RTB)– discussions have taken place between the study team and the RTB9 |  |

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| **Section C – questions where a narrative response is required** |
| 1. **Provide details that the latest versions of appropriate (either RGEA or CTU approved) templates have been used for the document set and that the sections and information within the protocol are appropriate to the type of study. Comment on any relevant changes or modifications discussed with the study team.**
* *The latest document templates outlining the expected areas to be covered are on RGEA’s website:* [*https://researchsupport.admin.ox.ac.uk/clinical-trial-research-governance/preparation/documents*](https://researchsupport.admin.ox.ac.uk/clinical-trial-research-governance/preparation/documents)
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| 1. **Provide details that the study has been peer reviewed (e.g. as part of the grant application process or further along in the development stage).**
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| 1. **Confirm if appropriate licence or approval arrangements are in place for the use of any images/videos/other media/questionnaires**
* *Comment below on whether (and how) these have been arranged.*
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| 1. **Provide details that the study team has engaged with RS Funding and Contracts in relation to any contractual requirements.**
* *i.e. types of agreements in place/progress. Information on research contracts are on RF&C’s website:* [*https://researchsupport.admin.ox.ac.uk/contracts*](https://researchsupport.admin.ox.ac.uk/contracts)
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| 1. **Provide details that funder requirements have been considered, that evidence of funding is included in the sponsorship submission pack, and that the department’s Head of Administration and Finance (HAF) is aware of the study.**
* *RGEA sends a formal HAF approval request to the HAF (or their delegate) as part of the sponsorship review process. The expectation for the departmental approval quality check here, is to make sure that the HAF (or their delegate) is aware of the study in advance of submission in the hope that will speed up RGEA obtaining the HAF Approval confirmation. It also provides the HAF with an earlier opportunity to ask questions and do their own due diligence.*
* *Document details of the funder and the approach taken to inform the HAF of the study. You may also comment on CTU capacity to support this study here, if applicable.*
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| 1. **Confirm that at the point of submission to RGEA, no stakeholder groups (e.g. TSC, funder) still need to consider/review the study, such that the documents may be subject to significant change after RGEA review has started.**
* *Comment below on any further information.*
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| 1. **If third party processors are proposed (e.g. couriers, software providers, text/email service provider), has a Third-Party Security Assessment (TPSA) been considered and, where appropriate, conducted?**
* *See the University TPSA service* [*here*](https://www.infosec.ox.ac.uk/third-party-security-assessment)*.*
* *Please comments on whether these have been arranged and provide a list of who these are and their role.*
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| **Key points of note for RGEA that are not captured elsewhere.*** *Use this box to detail any key points of note/risk/areas of escalation for RGEA (e.g. study classification, scope committee review, any difficulties in answering the IRAS filter questions, first in human/multi-site platform trial/the nature of the drug being used/complex DoR).*
* *List any specific issues that you would like RGEA to comment or advise on.*
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1. *Independent colleague: is a senior member of the CTU or department, as determined by the CTU Director. Where possible, they should not be part of the main study team. The aim is to bring ‘fresh eyes’ to the document set to identify any basic issues to be resolved before it is submitted for sponsorship review.*
2. *By ticking that means: this item has been checked and any issues resolved. If not applicable then add ‘N/A’. If it requires input or discussion with RGEA then add in ‘RGEA’ and discuss the matter with the sponsor reviewer in conjunction with the study team.*
3. *For example - does the start date take account of setup time? Does the end date accommodate for analysis of the data or samples?*
4. *Information on the documents required for sponsorship and ethics review are on the RGEA’s website:* [*https://researchsupport.admin.ox.ac.uk/files/guidanceforresearchersseekingsponsorshipdocx*](https://researchsupport.admin.ox.ac.uk/files/guidanceforresearchersseekingsponsorshipdocx)*. If any NHS involvement (e.g. patients/data/premises) ensure HRA docs completed:* [*https://www.myresearchproject.org.uk/help/hlphraapproval.aspx*](https://www.myresearchproject.org.uk/help/hlphraapproval.aspx)*.*
5. *For example - lay language for PIS - including titles of the relevant study forms, that the level or nature of compensation matches between the protocol and PIS. Use this online tool:* [*https://readabilityformulas.com/free-readability-formula-tests.php*](https://readabilityformulas.com/free-readability-formula-tests.php) *if you would like to assess the reading level of the PIS and other participant-facing documents.*
6. *Essentially: where information appears in more than one document, it should be consistent in each presentation.*
7. *See University Core SOP 14: Version Control for additional guidance:* [*https://researchsupport.admin.ox.ac.uk/clinical-trials-research-governance/resources*](https://researchsupport.admin.ox.ac.uk/clinical-trials-research-governance/resources)
8. *This is risk assessment for the overall project. It is not necessarily within RGEA’s remit to review and comment on RAs, but it is extremely useful for RGEA to receive this early on in the process for their review of the protocol. This will inform the sponsor reviewer that specific risks have been considered and mitigated. Moreover, it is an important planning tool for the study team and is a key area of focus for MHRA inspections.*
9. *Contact the Human Tissue Group in RGEA on* *hta\_help@admin.ox.ac.uk* *if you are not sure or require specific advice.*