



Guidance on Resubmissions and Amendments of ISAC Research Protocols

This guidance document has been produced to help applicants resubmit an ISAC Protocol Application or submit proposed amendments to approved ISAC Research Protocols. Resubmissions and Amendments not completed in accordance with the guidance will be returned as invalid.

Protocol Resubmissions

ISAC may request resubmission of a Protocol Application where further information is required before approval can be granted. Feedback will be provided by ISAC on the points to be addressed in any resubmission.

The format of resubmissions should be as follows:

- The ISAC Feedback Form, with applicant's responses to each of the questions or issues raised by the reviewers;
- An updated ISAC Protocol Application Form, with all changes from the originally submitted protocol highlighted in yellow using the highlight feature. Track changes are not permitted.

Resubmissions of ISAC Protocol Applications should be received by the ISAC Secretariat within 6 months of the date of ISAC feedback. **Protocols that do not receive a resubmission within 6 months of the feedback date will be recorded as withdrawn, and applicants will be required to submit a new ISAC Protocol Application.** The ISAC Secretariat should be contacted if there are circumstances which may result in the resubmission exceeding the 6-month deadline.

In cases where the applicant(s) do not intend to resubmit a Protocol Application to the ISAC, the Secretariat should be contacted, and the application withdrawn. Please email isac@cprd.com for advice.

Protocol Amendments

During the course of some studies, it may become necessary to deviate from an ISAC approved protocol. Applicants should follow the guidelines below to ensure that the correct process is followed for requesting amendment(s). Any amendment requests that do not follow the correct process will be returned as invalid.

In cases of uncertainty, the applicant should contact the ISAC Secretariat at isac@cprd.com for advice, quoting the ISAC Protocol Number and providing a brief explanation of the nature of the amendment(s) and justification.

To submit an amendment request, please provide the following documents to the ISAC Secretariat (isac@cprd.com):

1. An email, listing the proposed amendment(s), providing justification, addressed to the ISAC, sent by the Chief Investigator or Corresponding Applicant;
2. A completed and updated ISAC Protocol Application form with:
 - a. All changes to Part 1 of the form highlighted in yellow using the text highlight feature;
 - b. There should be **no changes to Part 2 of the approved application form**. Instead, applicants should create a new section with the heading 'Amendment - DATE' at the end of Part 2. Please include all proposed amendments to Part 2 under this heading, referring to the relevant sub-headings in Part 2 of the application.

Please note that applicants should receive approval for all amendments. Amendments that do not receive approval are not valid, and any studies published with unapproved deviations will be in breach of the licencing agreement.



Examples

Amendments to Part 1 of the Protocol Application Form

Example 1: Adding a new collaborator

Title:	Dr
Full name:	John
Job title:	Smith
Affiliation/organisation:	MHRA
Email address:	j.smith@mhra.gov.uk
CV Number (if applicable):	001_19
Will this person be analysing the data? (Y/N)	Y

Example 2: Adding a new linkage

ONS Death Registration Data	X	CPRD Mother Baby Link	
HES Admitted Patient Care	X	Pregnancy Register	
HES Outpatient	X	NCRAS (National Cancer Registration and Analysis Service) Cancer Registration Data	
HES Accident and Emergency	X	NCRAS Cancer Patient Experience Survey (CPES) data	

Amendments to Part 2 of the Protocol Application Form

Example: Amendments to text in Section E

<p>List of Appendices Appendix 1: Code Lists Appendix 2: Research Paper 1 Appendix 3: Research Paper 2</p>
<p>Amendment – 01/03/2019</p> <p>E. Objectives, Specific Aims and Rationale</p> <p><i>Objectives:</i> Lorem ipsum dolor sit amet, consectetur adipiscing elit. Suspendisse pretium, odio vitae rhoncus mollis, felis ante sollicitudin lectus, at ornare nibh nisi porttitor urna. Vivamus sed turpis et ipsum malesuada pellentesque. Integer ac nisi tincidunt est cursus lacinia quis quis velit. In at tellus malesuada, tincidunt sapien eu, tempus lectus. Integer mauris mi, facilisis id ligula mollis, mattis venenatis nisi. In rutrum turpis nec suscipit eleifend. Proin nec risus aliquet, facilisis ante a, sodales augue. Mauris ornare non lacus et pulvinar. Mauris eleifend purus pellentesque est dignissim gravida. Cras imperdiet leo at elit congue accumsan</p>