HSCR-GD004 Sponsor Review Route Guide

The review and approval route each sponsorship application will take will be determine by the Clinical Research Governance Team, in collaboration with the Health and Social Care Research Sponsorship Committee. The decision will be based predominantly on the IRAS category as outlined in the table below; but will also be informed by the Project Risk Assessment Form (HSCR-FORM005) and the Clinical Research Governance Officer (CRGO) review.

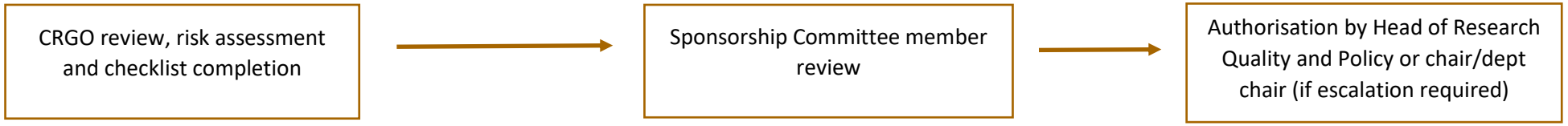
Review Levels

Category	Level 1 Review	Level 2 Review	Level 3 Review
Study Type (IRAS CAT)	• Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology* • Study involving qualitative methods only* • Study limited to working with secondary data (specific project only) • Research database • Other study*	• Lower risk basic science study involving procedures with human participants* • Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology* • Study involving qualitative methods only* • Study limited to working with human tissue samples (or other human biological samples) and data (specific project only) • Research tissue bank • Low risk clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice* • Other study*	• Basic science study involving procedures with human participants* • Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice*

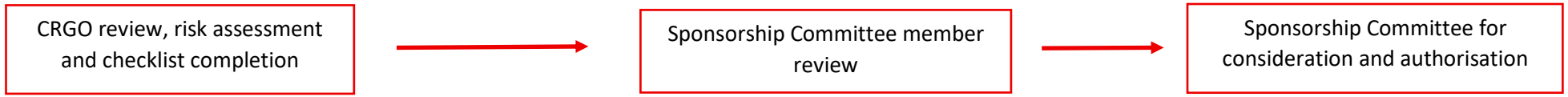
*These items are items that depending on topic, methodology and expertise of the research team may fall under either of the categories they are listed under. Level will be determined by CRGOs upon application validation.

Level 1 Review

Level 2 Review



Level 3 Review



All projects will undergo an initial assessment by the Clinical Research Governance Officer (CRGO), this includes an assessment of the research topic/methodology for potential adjustment to review route and an iterative process between CRGO and applicant to incorporate amendments to the IRAS form before being reviewed by the Clinical Research Sponsorship Committee or its delegate. Requested amendments from the CRGO are required to be addressed by applicants before review by the committee or committee member if required. The CRGO, committee, or member may also request an increased level of review, should they feel it is required. Where the project has been escalated to an increased level of review, the CRGO will inform the applicant as soon as possible. For clinical trials, or high-risk studies, this dialogue should start prior to the completion of an IRAS form and will involve discussions about the most appropriate site for sponsorship.

Where University Research Ethics Committee approval is required, this will happen following the CRGO review and once any revisions requested have been made.