Standard Operating Procedures (SOP) for:			
Review of Research Including Peer Review and Departmental Authorisation			
SOP Number:	**14**	Version Number:	**4.0**
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Date	**11th July 2017**

Purpose and Objective:

To ensure that only high quality research is undertaken within Queen Mary University of London (QMUL) and Barts Health NHS Trust (BH).

To ensure that projects are adequately resourced to deliver, that the sponsor, regulators and researchers working on the project at all sites have a high quality, clear project protocol to work from.

To identify and align the processes for scientific peer review, protocol review and resource capacity review for research projects within QMUL and BH.

To ensure the effectiveness of the review process that clearly demonstrates the responsibility and accountability of the Clinical Board (CB) Director of Research for the Trust and Institute Directors for QMUL to ensure the quality, need and ability to deliver a research project.

The objective is to improve organisational oversight of research studies, the quality of trial conduct and to demonstrate clear lines of accountability.

Please note that review described in this SOP is in addition to Sponsor review as described in *SOP 11a BH/QMUL Sponsorship CTIMPs – Process for Researchers*, *SOP 12 BH/QMUL Sponsorship of non-CTIMPs* and *SOP 13a Governance Review of QMUL and BH Sponsored Studies*.

Scope:

This applies to all researchers wishing to perform medical research at BH or QMUL (i.e. School of Medicine or Dentistry) and Joint Research Management Office (JRMO) staff where applicable.

Abbreviations:

BH	Barts Health NHS Trust
CB	Clinical Board
JRMO	Joint Research Management Office
QMUL	Queen Mary University of London
R&D	Research and Development
SOP	Standard Operating Procedure

Definitions (if needed)

Peer Review: Evaluation of scientific, academic, or professional work by others working in the same field [Oxford Dictionaries (online version)]

*Departmental Authorisation at grant application stage: for the purpose of this SOP this is defined as review of application and confirmation the department is content to allow the research to take place, the research question is valid, the

financing comprehensive and appropriate and that the project fits with the departmental strategy. This authorisation includes agreement to underwrite any undeclared costs.

Relevant SOP s

Queen Mary University of London and Barts Health NHS Trust Research Management Policies: Peer Review of Research

SOP 1: Research Project Applications

SOP 11a: BH/QMUL Sponsorship of CTIMPs, ATMPs and Clinical Trials of non-CE marked Medicinal Devices – Process for Researchers

SOP 12: BH/QMUL Sponsorship of Non-CTIMPs

SOP 17c: Research Amendments for Sponsored Studies

SOP Text

	Responsibility	Activity
1.	Institute, School or CB Directors or Directors of Research	**As per QMUL and BH Research Management Policies, prior to a research study being initiated the Institute, School or CB Directors, or Directors of Research (as appropriate) must ensure that research being undertaken under the auspices of their institute, school or CB is reviewed.**
2.	Institute Directors or CB Directors of Research	**Establish and maintain an appropriate formal research review system or committee**. All research must undergo a level of review. A review of the quality of the research, the quality of the 'protocol' and a review to establish the resource and financial implications of the research activity for the institution and department must be undertaken. Guidance on appropriate constitution of membership of review groups, timelines for review, principles of independence and conflict of interest can be found in *Associated Document 2 - Guidance for Peer Review Groups*. It is also good practice to assess how the research fits in with departmental research strategy and balance in research portfolios. Systems should have a five part review: 1. Review of grant applications (Departmental Authorisation including strategic fit) 2. Scientific peer review* 3. Review of project level protocols (Quality of protocol document)* 4. Review of resource and capacity * 5. Review of resource and capacity [as per HRA requirements] for instances where BH or QMUL is acting as a site only ** These review systems can be set up at Institute, CB or Centre level. It is for staff in each Institute and CB to establish the most appropriate model for themselves. However, accountability for the reviews will remain with the Institute Directors, or for the trust CB Directors of Research. It is envisaged that where CBs and Institutes are aligned they may wish to collaborate on this element. It should be noted that if this does occur the Director of the sponsoring organisation will retain responsibility. Once established, follow administrative procedures as per this SOP. * Review of project level protocols and review of resource and capacity may be performed simultaneously if appropriate. Peer Review of the scientific quality of research may include peer review and feedback from funders.
		Setting up the review system

3.	Institute, Directors or CB Directors of Research	**Establish and maintain robust system(s) and processes to undertake review including peer review of research projects as described above** This must include (but is not limited to): a. Ensuring CB Directors of Research or Institute Director (as appropriate for sponsoring organisation) approval and oversight. b. Ensuring written processes and Terms of Reference are present and maintained. c. Ensuring committee independence from the research team. d. Managing conflicts of interest within the committee and between committee and applicants. e. Maintaining appropriate documentation and ensuring clarity for who will be responsible for this. f. Maintaining appropriate confidentiality. g. Conducting periodic reviews in compliance with this SOP and Committee terms of reference. h. Ensuring feedback and decisions are implemented. i. Disseminating local procedures to relevant staff. j. Reviewing substantial project amendments as appropriate.
4.	Institute Directors or CB Directors of Research	**a. Written processes and Terms of Reference.** Create terms of reference (using associated documents to this SOP) appropriate for the committee ensuring any delegated responsibilities provide a clear picture of the full system.
5.	Institute Directors or CB Directors of Research	**b. Independence from the research team.** Ensure Committee membership is broad enough to encompass all specialities within the School/institute/CB and/or that there is a mechanism to access additional expertise if required. Ensure that processes are in place to ensure independence from the submitting researcher (*e.g.* there is a deputy in case the chair submitted a project for review).
7.	Peer Review /Committee Chair or designee	**c. Maintain appropriate documentation.** Create and maintain a log containing details of review and outcome. All documentation pertaining to the committee should be retained as per Good Clinical Practice and QMUL and BH retention policies for 20 years.
8.	Reviewer /Committee Members	**d. All project outlines or protocols sent for review should be clearly marked as confidential.** Protocols and project outlines that are sent outside the Trust or QMUL for review should only be sent once agreement has been received that the reviewer is willing to carry out the review. If there are any concerns surrounding intellectual property or pending patents, advice regarding confidentiality agreements should be sought from the JRMO or Queen Mary Innovation Ltd **prior** to sending out any documentation.
9.	Reviewer /Committee Members	**e. Conduct reviews in compliance with this SOP and Committee terms of reference.** Compile a report of recommendations, and issue to researcher. Retain one copy for department as a reference. Ensure JRMO is made aware of the decision (note a copy of the review will be needed by the JRMO. Additionally if no scientific review has occurred as part of the study funding body review, as part of a funder's national open competition, then this review will be needed by the HRA and NIHR portfolio adoption teams). Should existing committees wish to modify the form by adding sections specific to their area, this can be requested formally and a waiver issued if changes are appropriate. The CB/Institute must have a robust mechanism in place to ensure compliance of this review process.

		If the researcher wishes to appeal any decision made by the committee, the Terms of Reference of the reviewers/committee should stipulate the process.
10.	Peer Review /Committee Chair or designee	**f. Process to ensure feedback and decisions are implemented, and the outcome of review should be sent in writing to submitting researcher and CI/PI (as applicable).** If a funding gap has been identified this should include evidence of whether the Institute/CB is willing to absorb any cost identified (if applicable), either by email or within the review form.
11.	QMUL Institute Directors/CB Directors of Research	**g. Institute Director / CB Directors of Research must ensure dissemination of local procedures.** Institute and CB staff should be made aware of: • How to send research for peer review, including a named contact person, telephone number and email address. • The frequency and dates of meetings. • The expected turnaround time for applications. • How researchers will be notified of the results. • Any special arrangements that may apply.
12.	CI/PI or delegate	**For substantial amendments to an existing study (that could have an impact on the original peer review approval), documentation should be submitted as for new studies.**
Review Process Review of grant applications (Departmental Authorisation)		
13.	Institute, school and CB Directors or Directors of Research	**Department authorisation should be given following appropriate review by Institute Directors/CB Directors of Research.** Departmental authorisation at grant application stage: for the purpose of this SOP this is defined as review of application and confirmation the department is content to allow the research to take place, the research question is valid, the financing comprehensive and appropriate and that the project fits with the departmental strategy. This authorisation includes agreement to underwrite any undeclared costs. See *SOP 1 Research Project Applications*.
Scientific peer review		
14.	Peer Review /Committee Chair or designee	**It is the responsibility of the departmental review committee or designee to ensure that suitable scientific review has occurred to assure the quality of the research.** If scientific review has occurred as part of the study funding body review, as part of a funder's national open competition this should normally be accepted and only in exceptional circumstances would there be justification for it to be repeated. In instances when a drug or device manufacturer is also the funder of the study, care should be taken to assess how impartial any review conducted is likely to be. It is advised that in many cases an independent scientific review should be undertaken. As per major funder policies, review of a programme grant does not constitute review of specific projects or studies within the programme. The individual studies in a programme should be reviewed separately, with the appropriate level of detail provided. See *Associated Document 2: Guidance for Peer Review Groups*, for full details.
15.	Reviewer /Committee Members AND CI/PI	**h. Manage Conflicts of interest** Any conflicts of interest of researchers in the study should be clearly declared, documented, assessed and managed according to organisational Policies. They should cover, but are not limited to, the following:

		1. Personal or family involvement with any external sponsor or vendor/sub-contractor associated with the study *e.g.* Employment or consulting arrangements and/or a financial interest; 2. A financial interest in the product/medical device that is the subject of the study. Researchers must declare any conflicts of interest to reviewers/committee and must be noted within the final documentation. This should be updated if there is any change in circumstances.
Review of project level protocols (Quality review) *		
16.	Peer Review /Committee Chair or designee	**Conduct review of full protocol and ethical/MHRA applications forms to ensure quality of documentation.** The quality of the conduct of the study and, hence, the validity of outputs is increased by having a well written, clear, unambiguous and internally consistent protocol. This is especially important to ensure that endpoints and deliverables are clear and achievable. Considerations should include, but are not limited to: • Does the protocol clearly describe scientific justification, risks and benefits, for all procedures involved in the study? • Does the protocol match the study design? • Is the protocol internally consistent? • Has all template wording been removed? • Does the protocol give a clear description of the practical way in which the study will be conducted? • Is the research proposal/protocol clearly described, so that it can be easily understood and followed by research staff at all sites? See *Associated Document 2: Guidance for Peer Review Groups* for full details.
Review of resource and capacity *		
17.	Peer Review /Committee Chair or designee	**Review the departmental resource & capacity to successfully perform the project.** Considerations should include, but are not limited to: • 'Resource' to conduct the project within the Department (*e.g.* staff capacity –especially research nurse, clinical trial practitioner, trial coordinator, database manager, equipment, technology; capacity and funding streams for imaging, pharmacy, pathology elements above and beyond standard of care for the particular patient pathway)? This includes an understanding of the cost and funding arrangements for the Study. • 'Feasibility' (*e.g.* meets Departmental objectives, does not overexpose participants to research, and clearly identifies how potentially competing studies will be managed). See *Associated Document 2: Guidance for Peer Review Groups* for full details.
		Review of resource and capacity for BH or QMUL as a site. The process for this review varies if the project is: • NIHR portfolio studies: North Thames [NT] CRN procedures will be followed to obtain Pharmacy review, Imaging review, costing and contracting review and CB agreement. The NT procedures cover the requesting of such review but not the content or scope of the review. Therefore any individual or committee requested to perform this function for the NT network should consider *Associated Document 2: Guidance for Peer Review Groups*, - Resource and capacity review considerations. Non NIHR portfolio studies: Individual PIs will be responsible for obtaining Pharmacy review, Imaging review, costing and contracting review and CB agreement. These should be obtained in writing and sent to

		research.submissions@bartshealth.nhs.uk for the Research Governance Team leader Manager's review. Any individual or committee requested to perform this function for the NT network should consider points below labelled Resource and Capacity Review considerations.
Researcher responsibilities		
18.	CI/PI or delegate	**Submit all relevant final documentation to the chair/administrator of the committee/reviewer as per CB/Institute procedure.**
19.	CI/PI or delegate	**Submit signed review documentation to research.submissions@bartshealth.nhs.uk** **QMUL and BH sponsored Studies:** The outcome forms (encompassing evidence of Scientific peer review, review of project level protocols [Quality review] and Review of resource and capacity) are part of a valid submission for provisional approval. Please see *SOP 11a Sponsorship for CTIMPS* and *SOP 12 Sponsorship for Non-CTIMPs* for details. **Where BH or QMUL will act as a site:** Review of resource and capacity for BH or QMUL as a site is mandatory. Researchers must submit a copy of the review committee's approval and all relevant correspondence to the above email address marked clearly 'Peer review'. Review committee's approval must be submitted by or copying in the Authorised CB individual.
Institute and CB Directors		
20.	Institute Directors or CB Directors of Research	**Establish a process to ensure that they themselves are adequately informed to have responsibility and oversight of all clinical studies proposed and taking place within their area of responsibility.** Directors remain responsible for all studies conducted within their area and must confirm that the studies are of high quality (peer review), that the protocol is of high quality and that there are adequate resources and capacity in place to conduct the study well. They must ensure there are processes in place to ensure they have sufficient knowledge of all research within their department in order to fulfil this responsibility.
JRMO responsibilities		
21.	JRMO R&D Operations manager, Projects and Communications Manager or designated website manager	**The JRMO will review and advertise the procedures for each area on the JRMO website and, when there are changes, in the R&D News Bulletin.**

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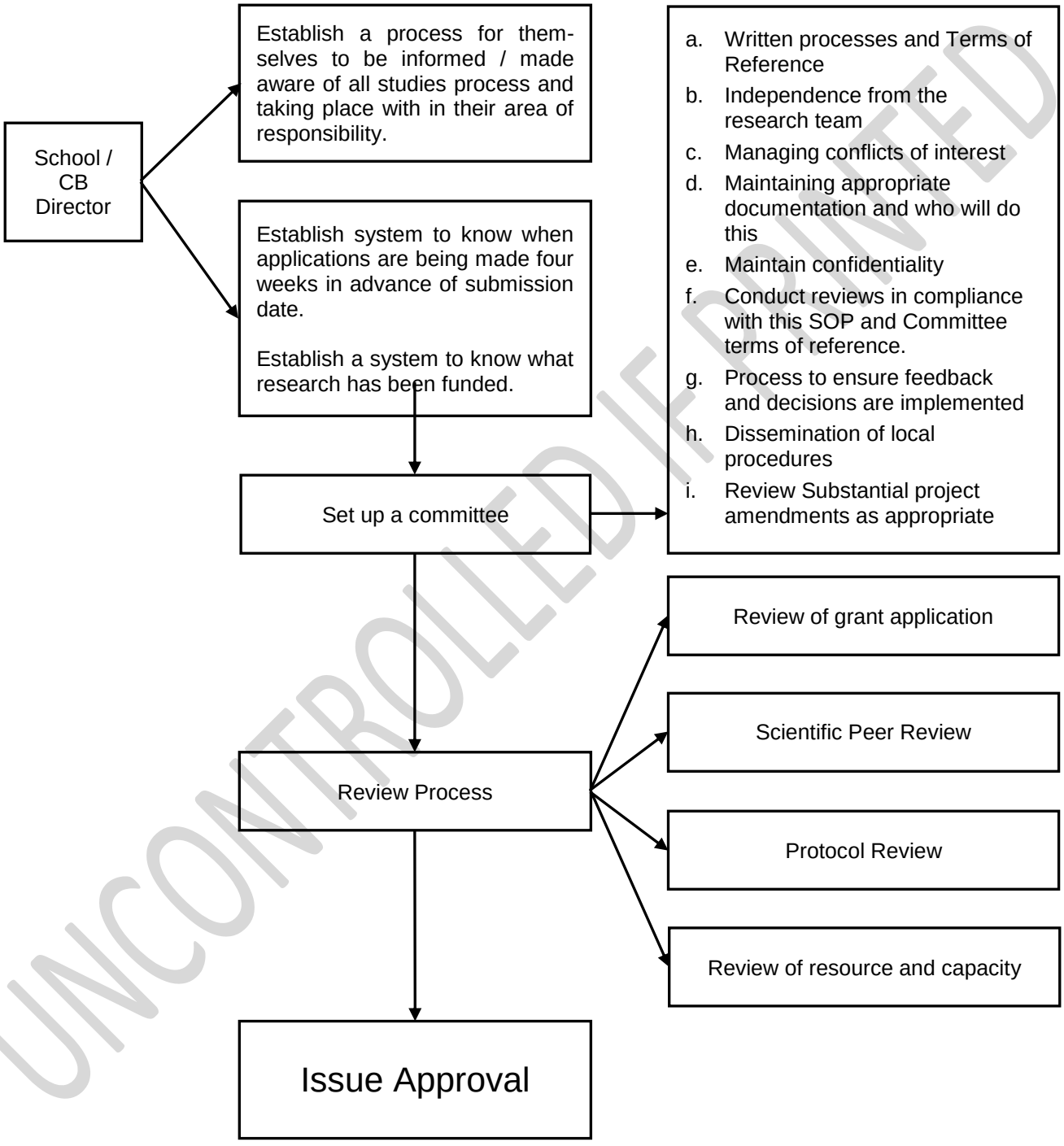
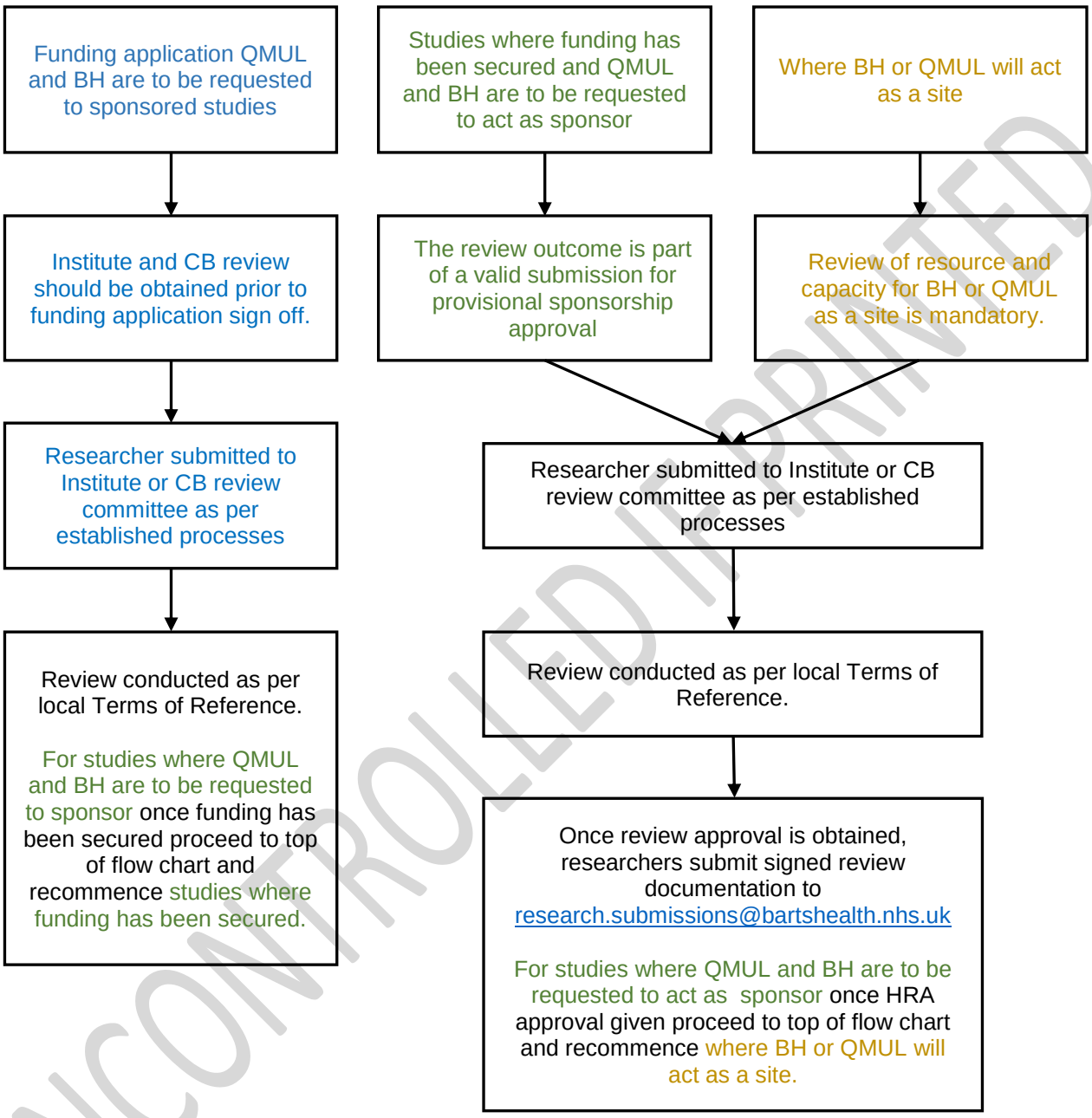
CB/Institute Director Review system set-up



Review process



Change Control

This section outlines changes from version 3.0 to version 4.0

Section Changed	Summary and description of change
All	Minor grammar, spelling and formatting corrections.
All	References to “Clinical Academic Group (CAG)” updated to “Clinical Board (CB)”

List of Associated Documents *(these are standalone documents)*

	Document name
Associated Document 1	Template Terms of Reference
Associated Document 2	Guidance for Peer Review Groups