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| **SUMMARY COMPLAINTS REGISTER 2016 - 17** |
| **Ref** | **Category** | **Nature of complaint** | **Date received** | **Working days to respond** | **Outcome** | **Action resulting from the complaint** |
| 16.C.01 | Ops/REC | Treatment at a REC | 03.06.16 | 11 | Partially Upheld | To maintain confidentiality of discussion, signage changed at meeting room venue to ensure applicants are not waiting directly outside the meeting room.  |
| 16.C.02 | Ops / Approval | Length of time taken to process an Amendment request | 03.06.16 | 2 | Upheld | We have had an unexpectedly high volume of amendments, including requests for HRA Approval to set up new sites for existing studies. We have put in a number of measures to address this and are in the process of implementing a range of other actions to resolve the backlog and improve the turnaround times. |
| 16.C.03 | Ops / Approval | Length of time taken to process an Amendment request | 09.06.16 | 1 | Upheld | We have had an unexpectedly high volume of amendments, including requests for HRA Approval to set up new sites for existing studies. We have put in a number of measures to address this and are in the process of implementing a range of other actions to resolve the backlog and improve the turnaround times. |
| 16.C.04 | Ops / Approval | HRA Approval governance / authorisations | 13.06.16 | 8 | Not Upheld | HRA Approval must accept all information provided as part of an application in good faith. In this case, the data sharing agreement was not reviewed internally. As part of an application HRA Approval cannot double-check a document to ensure that all the applicant’s internal authorisations for that document have taken place. |
| 16.C.05 | Ops / Approval | Handling and processing of an Amendment request | 14.06.16 | 4 | Upheld | We have had an unexpectedly high volume of amendments, including requests for HRA Approval to set up new sites for existing studies. We have put in a number of measures to address this and are in the process of implementing a range of other actions to resolve the backlog and improve the turnaround times. |
| 16.C.06 | Ops / Training | Conduct at internal training event | 06.04.16 | 57Kept fully informed | Partially Upheld | Feedback was provided to trainer. Broader lessons for the organisation in setting up and running this sort of training are to be adopted. |
| 16.C.07 | Ops/CAG | Conduct of staff member in CAG meetings | 01.07.16 | 64Kept fully informed | Partially Upheld | We have taken the opportunity taken to reflect and learn from incident to ensure work relations are maintained in the future. |

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| 16.C.08 | Ops / Approval | Length of time taken to process an Amendment request | 22.07.16 | 12 | Upheld | We have taken a number of actions that have already significantly improved the turnaround times for new amendments, as well as actions to clear the backlog. For more information about our actions in responding to the initial surge of applications and our overall performance please see our website.Also gave some feedback about our website. We recognise that there is a large volume of information and we constantly try to meet the varied needs of the audiences who use our guidance. |
| 16.C.09 | Ops / Approval | Delay in issuing HRA approval, following ethics approval | 09.08.16 | 20 | Upheld | In this case it would appear that the review of the study started early on but because of application volumes failed to complete the process. We are working hard to ensure that our tracking systems highlight such cases so that a similar situation does not occur again. |
| 16.C.10 | Ops / Approval | Poor communication following initial assessment  | 13.09.16 | 16 | Upheld | We have implemented a number of actions that have now cleared this backlog and the volumes have also returned to the anticipated levels. We are working on our tracking systems and oversight to ensure that applicants are kept appropriately informed about the review of their study. We are now publishing our performance on a regular basis and hope that this will help you in working with sponsors in future.  |
| 16.C.11 | Ops/REC | Concerns over panels conduct at interviews for REC Chairs | 25.09.16 | 11 | Not upheld | We should be clearer in our correspondence to those attending interviews that they are formal with all that that entails. We will revise our correspondence in this respect. |
| 16.C.12 | Ops / Approval | Delays in HRA approval application | 18.10.16 | 10 | Upheld | We have received an unexpectedly high volume of applications following the full roll out of HRA Approval and have uncovered a number of reasons for these volumes. Actions have been implemented to clear the backlog and volumes have returned to the anticipated levels. We are now working to return to planned processes and timelines. |
| 16.C.13 | Ops / Approval | Various issues raised: Amendments process is unclear; communication issues; position on GCP training is concerning; lack of oversight; anddelays in approvals. | 05.11.16 | 34Kept fully informed | Partially Upheld | We have already made significant improvements having eliminated the backlog of amendments and pre-Approval studies and have made considerable progress on responding proactively to new applications. Happy to discuss the general points arising from the letter and in particular to update on the progress of HRA Approval since your colleagues shared this feedback. |
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| 16.C.14 | Ops / Approval | Concern over the new system which requires all studies, including small observational non-CTIMPs to go through a lengthy set up process followed by the requirement of IRAS amendments every time a new centre would like to join. | 09.11.16 | 33Kept fully informed | Partially Upheld | We accept that there is considerably more we need to do in the UK to apply proportionate approaches to a range of study types and would like to use the study as an example to discuss with colleagues about how we can clarify guidance and improve the processes associated with different studies. |
| 16.C.15 | Ops / Approval | Complaint about the length of time taken to review and approve a non-substantial amendment to study | 21.11.16 | 25 | Upheld | We have implemented a number of actions that have now cleared this backlog and the volumes have also returned to the anticipated levels. We are now working to return to our planned processes and timelines. We continue to listen closely to feedback and review our processes in the light of experience. |
| 16.C.16 | Ops/REC | Concerns over process whereby a resubmitted small in house project was rejected by 2nd REC | 22.11.16 | 21 | Partially Upheld | Asked the REC Manager to ensure that agreed process for applicant attendance at REC is followed in future and we will monitor to make sure that this is the case. Pleased to note that a useful discussion with the Chair of the REC has occurred, that the application is booked for review at the REC meeting on the 17th January and arrangements have been made for attendance by telephone.  |
| 16.C.17 | Ops / Approval | The new system has created an unhelpful loop whereby a trial can be approved by one body but rejected by HRA until a series of additions have been made. Then then the whole process has to start again since NRES considers these additions major amendments.  | 24.11.16 | 48Kept fully informed. | Upheld | Lessons have been learned to prevent recurrence: Training for Assessors, age range assent forms and information sheets agreed to be the sole responsibility of the REC and not part of the assessment. We apologise for the delay caused between the two HRA Approval processes (REC review and HRA assessment). We have a Service Improvement Programme to streamline our processes so as to provide a better service for researchers. |
| 16.C.18 | Ops/CAG | An application was due to be reviewed end of September but still heard nothing. This has seriously delayed research and may have had a detrimental effect on the complainants PhD.  | 02.02.17 | 27 | Upheld | Due to staff shortages followed by sickness absence in the small team there were delays in processing your application. Unfortunately due to the specialised nature of the work we do not have the ability to cross cover from elsewhere within the HRA and there were other significant workload pressures. We have also identified that the processing of this amendment from the HRA approval perspective was lost. We have rectified this and identified necessary revisions to our internal processes. |
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| 16.C.19 | Ops/CAG | Complaint regarding an extremely long delay from CAG in receiving the outcome of an application which was discussed by the committee back in Sept 2016.  | 06.02.17 | 25 | Upheld | Due to staff shortages followed by sickness absence in the small team there were delays in processing your application. Unfortunately due to the specialised nature of the work we do not have the ability to cross cover from elsewhere within the HRA and there were other significant workload pressures.  |
| 16.C.20 | Ops/REC | Concerns that a study was inappropriately categorised and the error was 'covered up' which led to a challenging REC meeting | 17.03.17 | 25 | Upheld / Partially upheld | Proportionate review: It has been identified that the guidance in the No Material Ethical Issues Tool was not explicit with regard to the use of retrospective data by members of the clinical care team and this has now been revised to make it entirely clear that this type of research would fit criteria 1. We were already in the process of updating our guidance and training for staff in relation to PR and this aspect has been incorporated into this; it is due to be rolled out to RES staff by the end of May.Meeting: We would be very happy to offer you the opportunity to attend one or more meetings of other RECs as an observer to provide you with reassurance about the ethical review process and the approach to putting questions to researchers.  |