|  |
| --- |
| **SUMMARY COMPLAINTS REGISTER 2017 - 18** |
| **Ref** | **Category** | **Nature of complaint** | **Date received** | **Working days to respond** | **Outcome** | **Action resulting from the complaint** |
| 17.C.01 | Ops/HRA Approval | Time taken for the HRA to respond to their IRAS application  | 19.05.17 | 12 | Partially Upheld | Making some changes to our tracking arrangements to make it easier to have visibility of the progress of applications and help them to support applicants. |
| 17.C.02 | Ops/REC | Hostility and lack of professionalism shown by REC Chair | 03.08.17 | 17 | Partially Upheld | The combination of the absence of the Chief Investigator, the quality of the application, and the misunderstanding over the questions led to an uncomfortable review. The regional manager has taken the opportunity to remind the REC Manager of the option to prompt the Chair to intervene and take a different approach should a similar impasse arise in future reviews. He will also speak directly to the REC Chair, reminding that where the Chief Investigator is absent and matters cannot be easily resolved in the meeting, the concerns should be raised in correspondence directly to the Chief Investigator. |
| 17.C.03 | Ops/IRAS | Several issues with the submissions process that reinforce an impression of a system that is unwieldy, unresponsive and which encourages error.  | 04.09.17 | 24 | Partially Upheld | Reminder for staff to re-enable e-submission when a provisional or favourable opinion with conditions is given. Improvements to research systems in train. |
| 17.C.04 | Ops/HRA Approval | Due process not followed by the HRA resulting in direct contact by the MHRA and the HRA appears to have no limit on the time allowed to reach a decision once it approaches the MHRA for advice. | 01.09.17 | 36(Kept informed) | Partially Upheld | Understand that there may have been confusion about the body responsible for liaison with MHRA. Have written to confirm to them that MHRA would expect to liaise directly with the applicant and not the HRA. |
| 17.C.05 | Ops/HRA Approval | Complaint about application handling which raises concerns in regards to transparency in the way administrators operate. | 02.11.17 | 27(Kept informed) | Partially Upheld | The guidance used to communicate to sponsors could be clearer. Will ensure that changes are considered as part of the current Service Improvement Programme and in particular ‘Get it Right First Time’ to help reduce number of applications with documents missing or incorrect signatures. |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Ref** | **Category** | **Nature of complaint** | **Date received** | **Working days to respond** | **Outcome** | **Action resulting from the complaint** |
| 17.C.06 | SCREC | Cannot be considered for the National social care REC due to living away from London. | 01.12.17 | 123  | Partially upheld  | Website updated to remove misleading reference to the ‘National’ Social Care REC. The HRA now hosts several committees with responsibility for reviewing social care studies However as REC is based in London, members are recruited from relevant geographical area in line with all RECs.Apologies given for considerable delay in responding to complaint due to management oversight. |
| 17.C.07 | Ops/HRA Approval | Chief Investigator was most disappointed as to how she was spoken to by a member of the HRA team. | 12.12.17 | 20 | Partially Upheld | Fed back importance of being more patient with applicants who may not be familiar with the application process and of remaining calm to be more helpful. |
| 17.C.08 | Ops/HRA Approval / Guidance & Advice | Several issues: HRA giving perceived wrong advice on interpreting IRMER guidelines on radiation exposure, communication from researcher diluted, expert opinion is ignored, and nobody advises on questions needed to be asked of MPE or RPO. | 31.01.18 | 47(Kept informed) | Partially Upheld | Broad description given in the application which did not make clear that the focus of the research is not the radiation itself but the comparison of images resulting from radiation which resulted in the wrong advice being given. Reviewed and revised our internal guidance, and will take forward wider revision of external guidance with input from radiation professionals. Staring to roll out new radiation technical assurance process which should assist in getting clear guidance for individual studies without the delays described. |
| 17.C.09 | Ops/REC | Treatment in a REC. The general attitude and unprofessional manner of the committee members left us feeling very dejected. | 21.02.18 | 64(Kept informed)  | Upheld | Requested the Chair to ensure this behaviour does not reoccur and to ensure members conduct themselves in a professional manner.  |