**Appeals Report – 2016/17**

1. **Background**

RES Standard Operating Procedures give provision for any applicant who has received an unfavourable opinion on an application the right to appeal that decision.  Additionally, from 1 September 2011 applicants have the right to appeal an unfavourable opinion on a substantial amendment.

During the reporting period, 4600 non CTIMP and 905 CTIMP applications were reviewed by UK RECs and of these, 225 (4.9%) and 22 (2.4%) applications respectively received an unfavourable opinion.

Applicants are required to set out in writing their reasons for wishing to appeal the decision and the Appeal Manager will consider this request.  For full applications, the Appeal REC will consider the same documentation which was considered by the original reviewing REC together with a copy of the Appeal letter and any other representations the research team may wish to make.  In respect of substantial amendments the appeal requires a review by a subcommittee of a second REC which provides advice back to the original reviewing REC which may choose to accept the advice or uphold their decision.

RECs which are not based in England are not appointed by the HRA but do follow UK wide Standard Operating Procedures and appeals are dealt with by the appeals manager.

1. **Appeals Data 01.04.2016 - 31.03.2017 - New applications**

During the reporting period, a total of 11 (4.45% of the total number of unfavourable opinions) requests were received to appeal an unfavourable opinion for a new application, of which none were for a CTIMP.

Of the total 11 requests received, 5 were allowed, 4 did not proceed and 2 were re-submitted as a new application. On receipt of the appeal request, consideration is given to the various options available to proceed and the applicant is advised. Where it is clear that the applicant is able to make the changes requested as part of the unfavourable opinion, the applicant is advised that resubmission to the same REC after making the changes is advisable. Both applications which were resubmitted to the same REC instead of proceeding as an appeal received a favourable opinion from the REC after the second submission.

The reasons for the 4 appeal requests which did not proceed were as follows:

* Managed locally by Scientific Officer
* Applicant decided not to proceed with the appeal
* Managed as a complaint instead
* REC agreed to vary the unfavourable opinion to a favourable opinion[[1]](#footnote-1)

Of the 5 applications which went to appeal, 3 subsequently received a favourable opinion, 1 received an unfavourable opinion and 1 received a provisional opinion and was subsequently withdrawn.

Table 2.1

|  |  |
| --- | --- |
| Name of REC | Outcome |
| West of Scotland REC 5 | Allowed -Further information Favourable |
| North of Scotland REC | Allowed -Further information Favourable |
| Stanmore REC | Allowed -Further information Favourable |
| Camden and Kings Cross REC | Allowed - Unfavourable |
| Coventry & Warwick REC | Allowed - Withdrawn |
| Southeast Scotland REC 2 | Did not proceed |
| Brighton and Sussex REC | Did not proceed |
| Cornwall and Plymouth REC | Did not proceed |
| York REC | Did not proceed |
| Nottingham 2 | New application submitted  |
| Bloomsbury REC | New application submitted |

Table 2.1 sets out which RECs issued the unfavourable opinion which was appealed against and the outcome of the request to appeal.

For the studies which subsequently received a favourable opinion, further analysis has been undertaken to better understand the reason for the different opinion and to reflect on whether there were any key inconstancies which would require further consideration.

1. **West of Scotland REC 5**

**Reason for the UFO**

* + The UFO was issued because the REC was of the opinion that patients with post stroke dementia should be excluded, the researcher did not have sufficient experience to deal with such a vulnerable group with the study as proposed and also that the study was under powered for a study involving such a vulnerable group which was considered to be burdensome.

**Response in appeal letter**

* + The applicant challenged the exclusion of patients with post stroke dementia and the power calculation but agreed that the researcher should be more closely supervised with someone with more experience.

**Outcome of the second REC review**

* + The second REC stated that the issues raised by the first REC had now been addressed which it was satisfied with. The applicant had agreed to variations to the study in discussion with the REC. Additional issues were raised as a provisional opinion, all of which were also addressed by the applicant. There was no notable inconsistency between the two REC reviews.
1. **North of Scotland REC**

**Reason for the UFO**

* + The proposed study involved using software to scan emails which were written by early stage dementia patients to see whether themes in the language can identify and potentially predict the onset of dementia. The REC raised a significant number of issues, largely in relation to the practicality of the study.

 **Response in the appeal letter**

* + The applicant provided some further information and also stated that they were of the opinion that the REC had not understood what was being proposed.

**Outcome of the second REC review**

* + The second Committee accepted the further information provided by the applicant and requested just minor clarifications from the applicant and changes to the information sheets. There was no notable inconsistency between the two REC reviews.
1. **Stanmore REC**

**Reason for the UFO**

* + The Committee was of the opinion that the student who was proposing to undertake the research had become upset at the meeting and because the student also had the condition which was being researched, was concerned about her ability to be objective.

**Response in the appeal letter**

* + The student and her academic supervisors all responded to say that this was not their perception of the meeting. She had become slightly upset at the beginning of the meeting but this had been all and that there were no concerns from the perspective of the supervisors in regards to her ability to undertake the research.

**Outcome of the second REC review**

* + The second REC requested a number of clarifications and revisions when issuing a provisional opinion but was assured that the student was able to undertake the research. There was no overall inconsistency between the two REC reviews based on the experience of the second Committee being different to the first and also further assurances having been provided to the second REC.
1. **Appeals data 01/04/2016 - 31/03/2017 - Substantial amendments**

During the reporting period, 12 (3% of all unfavourable opinions issued) requests (4 CTIMP and 8 non CTIMP) were received to appeal an unfavourable opinion issued for a substantial amendment.

During the reporting period, 8485 substantial amendments were reviewed by UK RECs, of these 383 (3.3%) received an unfavourable opinion

When receiving a request to appeal an unfavourable opinion for a substantial amendment, consideration is given in the first instance to whether the matter can be resolved with the REC in the first instance. Where this is considered possible after liaison with the REC Chair, the applicant is asked to submit a modified amendment. The reason for this is that when an appeal is allowed and review by a second REC is requested, the final opinion ultimately remains with the first REC and the outcome of the review by the second REC is for information and reference only. It is therefore preferable to work with the main REC in the first instance to resolve the issue when this is possible.

Of the 12 requests to appeal received in the reporting period, 1 was advised to submit a new application as advised by the REC, 8 resubmitted as a modified amendment and 3 proceeded as an appeal. Of the 8 appeal requests which resulted in an agreement to submit a modified amendment, all went on to receive a favourable opinion. Of the 3 amendments which went through the appeal process, 2 received a further unfavourable opinion and 1 received a favourable opinion.

Table 3.1

|  |  |  |
| --- | --- | --- |
| Name of REC | Outcome | CTIMP/Non CTIMP |
| Fulham | New application submitted | Non CTIMP |
| Cambridge Central (CTIMP) | Modified - Favourable | CTIMP |
| Greater Manchester Central | Modified - Favourable | Non CTIMP |
| Central Bristol | Modified - Favourable | Non CTIMP |
| Surrey Borders  | Modified - Favourable | CTIMP |
| Bloomsbury | Modified - Favourable | CTIMP |
| Camberwell St Giles | Modified - Favourable | Non CTIMP |
| Oxford B | Modified - Favourable | Non CTIMP |
| London Central | Modified - Favourable | Non CTIMP |
| Scotland A REC | Appeal - Favourable | CTIMP |
| Southeast Scotland REC 2 | Appeal - Unfavourable | Non CTIMP |
| Tyne and Wear South | Appeal - Unfavourable | Non CTIMP |

For the studies which subsequently received a favourable opinion, further analysis has been undertaken to better understand the reason for the different opinion.

1. **Scotland A REC**

 **Reason for the UFO**

* + The Committee was of the opinion that the changes to the inclusion and exclusion criteria and the addition of a participant group proposed in the substantial amendment would make the study scientifically invalid.

**Response in the appeal letter**

* + The study had not yet recruited any participants so there would be no issues with comparison of new data to previously collected data and the exclusion and inclusion criteria have been clarified but are not significantly different to the original protocol.

**Outcome of the second review**

* + The second REC was satisfied that the proposed changes would not compromise the scientific validity of the study as no recruitment had yet taken place. The main REC subsequently issued a favourable opinion.
1. **Comparison with previous years**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **2013/14** | **2014/15** | **2015/16** | **2016/17** |
| **Full** | 14 | 9 | 8 | 11 |
| **Substantial amendments** | 10 | 7 | 7 | 12 |

1. **Observations and Conclusions.**
* The number of requests to appeal unfavourable opinions continues to be very low in comparison to the number of unfavourable opinions issued (which in turn is relatively low compared to the overall number of applications reviewed - 5%).
* There were no notable issues identified during this reporting period which were deemed to warrant further consideration.
1. The REC had initially been of the opinion that inclusion of the control group was not justified and issued an unfavourable opinion on this basis. In the appeal letter, the sponsor highlighted a letter from the FDA which had been submitted with the application which provided this justification. The REC had overlooked this during this initial review. [↑](#footnote-ref-1)