

HRA REGISTER OF COMPLAINTS 2013-2014

Complaint #	HRA staff member managing the complaint	Category	Nature of complaint	Date complaint received	Date complaint acknowledged	Date investigation complete	# working days to respond	Outcome of the investigation	Any preventative action introduced as a result of the complaint
13/C/01	J Kirkbride	NRES Ops	The CI arranged to dial in to the REC meeting but at the last minute was informed that could not and too late to attend. Application received UFO and on second submission, further issues not raised the first time were picked up	05/04/2013	05/04/2013	10/04/2013	5	Upheld with regard to attendance. The Chair confirmed that there were ethical issues which he did not agree could have been addressed by speaking with the applicant due to the poor quality of the application. The study was resubmitted and received a provisional opinion and now has a FIFO	REC staff and Chairs reminded that SOPs state that facilities to 'attend' meetings by telephone and every attempt should be made to ensure this is available. CMs tasked with reviewing accommodation where signal problems exist.
13/C/02	S Oliver	NRES Ops	Delay in responding for request to review conditions made as part of the favourable opinion. Initial request for review of conditions sent to Centre Manager on 27.02.13, not communicated to REC. RM contacted on 15.04.13 and acted, SC set up to review 03.05.13. REC then requested external review. No response received from external reviewer. Complaint made 03.07.13, external review received 04.07.13 and decision letter sent out on 09.07.13	03/07/2013	03/07/2013	09/07/2013	6	Complaint up-held with regard to delay. Inaction of CM noted (now no longer in post). Delay in response from external reviewer investigated and found that correspondence sent to incorrect email address. Decision letter sent to CI 09.07.2013, minor change only and conditions remain. Note that this delay did not delay the commencement of the study which had already started taking account of the conditions placed upon recruitment and consent processes.	Need for external review queried by DD Ops and discussed with REC Chair. NREAP Guidance sent to REC Chair and REC meeting observation arranged for August meeting.
13/C/03	Debbie Corrigan / Janet Wisely	Unfair treatment	Linked to vexatious applicant	29/07/2013 07/08/2013		30/07/2013 08/08/2013	4 working days / 3 working days	Complaint not upheld	N/A
13/C/04	Joan Kirkbride	NRES Ops	Concerns raised with regard to access of the TOPs register by the previous owner.	26/07/2013	29/07/2013	14/08/2013	14	Complaint upheld Issue reviewed and response provided to complainant that we had not switched off the email system but it was switched off by 14 August	No
13/C/05	Sheila Oliver	NRES Ops	Issue relating to conduct of a member at the REC meeting July 2013. Further issues raised with regard to conditions of the FO requested by the REC regarding TOPs (08/10/13 acknowledged 08/10/13)	12/09/2013	13/09/2013	09/10/2013	20	Issue related to conduct of the member inconclusive, but partially up-held because of the complainant's perception of the conduct, investigated and actioned through formal meeting observation. Wording on TOPs web-site reviewed and could be improved but noted that no other concerns have been raised about this wording. Complaint related to the conduct of the member partially up-held, complaint related to wording on the TOPs website partially up-held	Wording on the TOPs web-site to be revised at the next up-date of the web-site. Chair to monitor conduct in the meeting. Further letter to the complainant sent on the 22/01/2014 outlining action planned and taken.

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13/C/06	Sheila Oliver	NRES Ops	Concerns raised with regard to the PIS and whether it contained sufficient information regarding the side effects of the MP to allow research participants to give informed consent. Part of a wider complaint about the study already being investigated by the MHRA. Decision made to work with the MHRA and provide a coordinated response	13/09/2013	18/09/2013	17/10/2013	25	Complaint not up-held with regard to the REC review of the PIS. Initial and formal response on the 17/10/2013 was a joint response from HRA and MHRA, complainant was not satisfied with the response and subsequently further investigation and subsequent responses were also made on the 6/11/2013, 20/11/2013, 29/11/2013 and 19/12/2013. The MHRA is responsible for the safety of the study and has given CTA for this study, HRA has consulted with the CI and provided detailed responses with regard to the PIS, the CI has undertaken to amend the wording of the PIS for clarity and this will be reviewed by the REC. The study has been on-going since 2004, the recruitment phase is completed and the final dosing period for participants will end in November 2014	No
13/C/07	Sheila Oliver	NRES Ops	Concern raised that the study is to include women who have not yet had any pregnancies or who have not yet completed their families.	30/09/2013	30/09/2013	19/05/2014	158	Outcome – Not a complaint, rather a query related to the recruitment of women into the study who may not have completed their families. Reviewed by the REC Chair and HRA Ethics advisor and response provided that recruitment was deemed satisfactory. Information provided to the CI.	None required
13/C/08	Sheila Oliver	NRES Ops	Behaviour of the chairperson.	27/11/2013	28/11/2013	19/12/2013	17	Complaint not upheld. Discussed concerns raised with the REC Chair and REC Manager who was in attendance at the meeting, also next meeting observed by the RM, also reviewed previous meeting observation reports, and no concerns evident with regard to the behaviour of the Chair at the meeting in question or previous or subsequent meetings.	None required
13/C/09	Sheila Oliver	NRES Ops	Complaint raised related to the initial review and on-going oversight of a study about the age extension of the NHS Breast Screening programme.	07/11/2013	07/11/2013	18/11/2013	8	Not up-held (no complaint to answer). Investigated the reason for the complaint, complainant requesting information about the initial review and on-going monitoring of the study. Information provided including changes to the information available to women in the study explaining the risks and benefits of screening. Information also provided related to the responsibilities of the REC and the CI.	None required
13/C/10	Alison McCallum	NRES Ops	The researcher considers that the committee did not have the relevant experience or expertise to understand the interests of the research participants or effectively reconcile the rationale, aims, objectives and design of the research proposal with the dignity, rights, safety and wellbeing of the people who are likely to take part, drawn from the locked ward of a psychiatric hospital	20/12/2013	21/12/2013	10/01/2014	13	Complaint not upheld as the committee was quorate, comprised the appropriate balance of lay and expert members, and is suitably accredited	None required

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13/C/11	Catherine Blewett	NRES Ops	The complainant was contacted after being discharged from hospital to invite her to take part in the research. She was concerned regarding whether her data had been accessed inappropriately to identify and contact her and also the letter which she received stated that she had not been diagnosed with meningitis when in fact she had been diagnosed.	24/11/2013	27/11/2013	15/01/2014	35	Complaint in fact relates to Third Party therefore not upheld. An out of date letter was sent to the complainant by the Research team. The letter the complainant received was version 1 and dated 5.10.2011. An amendment had been submitted to the REC in March 2013 to use a revised version which better reflects the fact that the letters are sent out by the local hospital and also do not specify the diagnosis. Unfortunately it appears that the superseded version of the letter was sent on this occasion. This has been noted by the REC. Principal investigator contacted researcher directly to offer apology.	The HRA recognises that there is considerable variation in perspective and practice about the ways in which patients and the public are offered opportunities to take part in research. We want to explore the potential for providing clarity for the research community by identifying ethical, practical and efficient models for identification of potential participants. In accordance with our remit to protect and promote the interests of patients and the public in health research, such approaches should be transparent, maintain patient and public confidence in research, and protect the privacy of personal medical information. They should also enable appropriate access to information that will give more patients the opportunity to take part in research.
13/C/12	Joan Kirkbride	NRES Ops	Complaint that in December despite numerous attempts to contact CAS via phone and sending 3 emails, there was no response and no availability to leave a voice mail.	02/01/2014	02/01/2014	02/01/2014	1	Complaint partially upheld. Regional Manager informed, and complainant contacted immediately and meeting slot booked. Voicemail facility is available, this was checked and no messages were left on the day in question though acknowledged that the line was very busy, apology given.	No
13/C/13	Tom Smith	NRES Training	Complaint that Welsh committee members were made to feel unwelcome at HRA NRES training events.	19/03/2014	20/03/2014	24/04/2014	25	Partially Upheld. Training event intended as an internal only HRA event however this was not made clear on training booking site.	Position confirmed for HRA staff training courses on training booking site.
13/C/14	Sheila Oliver	NRES Ops	Complaint regarding the way the REC meeting was conducted, in particular the manner of the questioning conducted by the REC Chair.	21/10/2014	21/03/2014	14/05/2014	42 (complainant kept updated)	Upheld. Apology from the Chair. Meeting observation brought forward.	Meeting observation brought forward. REC Manager advised about consequences of changing meeting attendance time at short notice
13/C/15	Sheila Oliver	NRES Ops	• Complaint regarding the Central Allocation System. Complaint regarding length of time to get through to speak to someone and lack of email confirming where the papers should be sent. Unable to contact anyone in the Central Allocation Office or HRA offices or Complaints telephone line. Complainant subsequently advised the meeting the application had been booked to had been cancelled.	31/03/2014	07/04/2014	08/05/2014	28	Upheld	Action taken Regional Manager to ensure in the short term (until CBS goes live) that inexperienced staff are supported when manning the booking line and that calls are diverted when the line is busy. Telephone SOP for BU staff revised to include complaint handling.
13/C/16	Sheila Oliver	NRES Ops	• 12/LO/1737 - A novel self-paced VO2max protocol for assessing maximal oxygen uptake. Complainant expressed concern that this study was given REC approval as they have consulted with clinical colleagues and others who are expert and familiar with the nature of perceptually-regulated exercise testing, and agree unanimously that this test exposes the patient to an unacceptable and unnecessary risk.	19/03/2014	07/04/2014			06/05/14 - SO updated complainant as over deadline. Investigation in progress	