

HRA COMPLAINTS POLICY AND PROCEDURE

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Owner: Head of Corporate Governance & Risk
Scope of Policy: HRA

Background

The HRA is committed to providing a service in a professional, fair and courteous manner. We recognise, however, that there may be times when things can go wrong and have established this complaints policy and procedure for dealing with such concerns when they happen. The HRA encourages people to let us know when our service does not meet their expectations and will continually strive to put things right and improve our service.

All HRA managers and staff have a responsibility for dealing with potential complaints, issues, queries, concerns or formal complaints (either in writing or verbally) when they are raised, reporting them in line with this policy and procedure in a timely manner and undertaking or assisting in the investigation of and action following investigation if and as requested by the HRA Complaints Lead.

The HRA supports and upholds the Principles of Good Complaint Handling which are:

- Getting it right;
- Being customer focused;
- Being open and accountable;
- Acting fairly and proportionately;
- Putting things right; and
- Seeking continuous improvement.

This document sets out the HRA's policy and procedure for complaints.

1.0 Policy

1.1 Scope

This policy and procedure applies to all directly employed staff, secondees, agency workers, contractors and volunteers including Research Ethics Committee (REC), Confidentiality Advisory Group (CAG) and National Research Ethics Advisory Panel (NREAP) Members.

This policy and procedure applies to complaints made about the standard or quality of services provided by the HRA, divergence from procedures and the behaviour of our directly employed staff, secondees, agency workers, contractors and volunteers including REC, CAG and NREAP Members. This policy and procedure excludes:

- matters which have already been fully investigated in accordance with this policy;
- matters where legal or police proceedings are about to commence or are already underway;
- complaints that are being dealt with by other responsible bodies i.e. complaints about the conduct of research projects;
- any complaint arising out of the alleged failure of another responsible body or third party;
- appeals made against the decision of a REC that are covered by their standard operating procedures (SOPs) appeal process but may include an associated complaint;
- A possible serious breach of the protocol or good clinical practice
- representations made against the advice of the CAG that are covered by CAG Standard Operating Procedures;
- internal complaints about HRA staff or contractors which will be addressed under the relevant HRA HR policies and procedures;
- complaints made by job applicants which may be addressed under the HRA recruitment and selection policies and procedures; and
- anonymous complaints.

For the avoidance of doubt, a complaint is defined as being a statement (either in writing or verbally) made by a complainant that:

- the standard and/or quality of service provided by the HRA;
- a divergence from HRA procedures: and
- the behaviour of HRA directly employed staff, secondees, agency workers, contractors and volunteers including Research Ethics Committee (REC), Confidentiality Advisory Group (CAG) and National Research Ethics Advisory Panel (NREAP) Members;

is unsatisfactory or unacceptable and requires an investigation with a written response. It is not a potential complaint, issue, query or concern that can be addressed by other less formal means.

The HRA may receive and agree to undertake an investigation of issues involving an alleged failure of another responsible body or a third party, for example a researcher, research team or Clinical Research Organisation (CRO). When this is the case the matter is not recorded as a complaint against the HRA and not included in the HRA complaints register though it may be recorded separately.

1.2 Purpose

The purpose of this policy and procedure is to ensure that the complaints process:

- is easy to follow;
- provides a speedy acknowledgement of concerns raised;
- ensures complaints are investigated thoroughly and fairly;
- keeps complainants informed if there are delays;
- is fair to complainants and staff;
- provides a full written response or other means of resolution where appropriate;
- ensures that where appropriate lessons are learned and changes made to prevent recurrence and services improved;
- sets out how complaints should be received, acknowledged and investigated, how action should be taken (both immediate corrective action and longer term preventative action) and how responses to complainants should be made;
- set out how complaints should be recorded; and
- provide guidance for managers and staff on how to manage complaints and to use the lessons learned to proactively improve services.

This policy and procedure is aimed at anyone who is directly affected by the:

- the standard and/or quality of service provided by the HRA;
 - a divergence from HRA procedures: and
 - the behaviour of HRA directly employed staff, secondees, agency workers, contractors and volunteers including REC, CAG and NREAP Members;
- and gives details on how the HRA will deal with a complaint.

Complaints can be raised directly, or by an authorised representative of the complainant.

1.3 Roles and responsibilities

The HRA Chief Executive has overall responsibility for ensuring that complaints are managed in line with this policy and procedure.

The Head of Corporate Governance & Risk is the HRA Complaints Lead and is responsible for arranging the acknowledgment of the receipt of a complaint, assigning an Investigating Officer (where appropriate) to manage the complaint, reporting complaints to the HRA Board (including a

summary of their investigation, action and outcome) and the management of the hra.complaints@nhs.net email address and HRA Complaints Register, including the identification of any trends and monitoring. The Complaints Lead is responsible for notifying the relevant director of any complaints in their directorate. The Complaints Lead is also responsible for the raising of staff's awareness of this policy and procedure.

The Investigating Officer is delegated the task of investigating the complaint in accordance with the procedures set out below by either the Complaints Lead or the Director to whom the Complaints Lead has delegated the complaint.

Any member of staff receiving a complaint is responsible for reporting it in accordance with the procedure.

The HRA encourages all staff who receive potential complaints, issues, queries or concerns to attempt to resolve these matters locally and in a timely manner to prevent formal complaints (see 2.1 Local Resolution below).

2.0 Procedure

2.1 Local resolution

The HRA encourages all those who receive potential complaints, issues, queries or concerns to attempt to resolve these matters locally and in a timely manner to prevent formal complaints being made. This procedure therefore empowers all members of staff who receive potential complaints, issues, queries or concerns to resolve them to the complete satisfaction of the person raising the potential complaint, issue, query or concern. This will provide a far more satisfactory resolution for both parties.

Where the potential complaint, issue, query or concern is straightforward and local resolution can be achieved, the person raising the potential complaint, issue, query or concern will be advised by the receiving staff member of the plan of action, an outline of the concerns to be addressed, the proposed timescale and action(s) to be taken. The action(s) should then be undertaken in line with this plan and the person provided with an email or letter advising that this has been completed.

Wherever sensible or possible and taking into account the nature and severity of the potential complaint, issue, query or concern, the staff member should report the event to the Complaints Lead.

2.2 Receipt and acknowledgement of complaints

A complaint must be made within 12 months of an incident occurring, or on the date on which the complainant becomes aware of the matter if this is more than 12 months after the incident. The time limit may be waived if the HRA considers there are good reasons for the delay and it is still possible to investigate the matter fully and fairly.

Complaints may be made verbally or in writing. Where a verbal complaint is made the complainant may be asked to follow this up in writing. Alternatively notes may be taken by the person handling the complaint and these should be shared with and agreed by the complainant.

Complaints (verbal or written) may be received directly by the Complaints Lead or by any member of staff. Where a complaint is received by a member of staff it should be referred to the Complaints Lead as soon as it has been received.

The Complaints Lead will acknowledge written and verbal complaints within 3 working days using hra.complaints@nhs.net.

2.3 Recording and delegation for investigation

The Complaints Lead will ensure that the complaint is logged on the HRA Complaint Register.

Complaints are numbered sequentially, and a new register is commenced for each financial year.

The Complaints Lead should assess whether the complaint falls within the remit of this procedure. If the complaint falls outside the remit of this procedure the complainant should be contacted and the decision explained.

Where there is a significant risk to the reputation of the HRA the Chief Executive should be informed.

The Complaints Lead will review the complaint and may delegate it to an appropriate manager, henceforth known as the Investigating Officer, for investigation.

Alternatively, the Complaints Lead may choose to delegate the complaint to a Director who may in turn delegate it to an appropriate Investigating Officer in their Directorate for investigation.

For clarity, any manager can be designated by the Complaints Lead or Director as an Investigating Officer which is a temporary and time limited role for the purpose of drawing the complaint to a satisfactory conclusion.

2.4 Initial investigation

The Investigating Officer should establish a preferred method of communication with the complainant. An initial phone call is recommended to establish the reasons for the complaint, what the complainant would like to happen as a result of the complaint and whether this is feasible or realistic.

The seriousness of the complaint should be assessed to determine the extent of the investigation required and whether others need to be informed.

The complainant should then be advised of the expected timescale for the investigation.

At this stage, the Investigating Officer should again assess whether the complaint falls within the remit of this procedure. If the complaint falls outside the remit of this procedure the Complaints Lead should be informed who will ensure the complainant is contacted and the decision explained.

2.5 Investigation

It is recognised that when things go wrong and a formal complaint is instigated, it is important to establish the facts of what has happened in a systematic, timely way. Investigations need to collect and examine evidence in a variety of ways, which may include;

- carrying out interviews or seeking information from staff, and where appropriate committee officers and members;
- reviewing written and electronic records and copies of documents;
- carrying out site visits; and
- taking expert advice.

Where the investigation cannot be completed within 25 working days the complainant should be kept informed about the reasons for the delay and the expected timescale for completion.

Once all the evidence has been collected and assessed the Investigating Officer will decide whether or not there has been a deviation from established policies and / or procedures, the expected and intended level of service and / or the expected level of behaviour and therefore conclude whether the complaint is upheld, partially upheld or not upheld. The complainant is then informed of the decision (see 2.6).

If necessary, this decision may be made in conjunction with the Complaints Lead.

It is good practice for the response to a complaint about a REC or other HRA Committee to be agreed in advance with the Chair.

The Investigating Officer in conjunction with other managers and staff as required will take any immediate action required to resolve the complaint. Consideration will also be given to any further action or preventative action required to prevent recurrence. This may include, but is not restricted to, staff training, changes to practice, policies and procedures and a review of current and established ways of working with a view to improving services provided.

2.6 Responding to the complainant

Every complainant has a right to a response to a complaint which explains how their concerns have been resolved, what action has been taken to deal with the complaint and if appropriate, to prevent reoccurrence. Should they remain dissatisfied with the outcome of the complaint, they should know how to take the matter further.

Each response to a complainant should include the following;

- a summary of each element of the complaint;
- details of the complaints policy followed;
- a summary of the investigation;
- details of key issues or facts identified by an investigation;
- conclusions of the investigation(whether the complaint is upheld, partially upheld or not upheld);
- what needs to be done to put things right (if appropriate);
- things done to prevent a reoccurrence (if appropriate);
- an apology, if needed;
- an explanation of what happens next (e.g. what will be done, who will do it and when); and
- information on what to do if the complainant is still dissatisfied.

The complaint response may be in the form a letter or an email and should be copied to the Complaints Lead.

The response email or letter will normally be signed and sent by the Investigating Officer.

The complaint response will be provided within 25 working days unless the complainant has been informed of any delays (See 2.5).

If the complaint involves an HRA committee the Committee Chair should also be copied.

2.7 Concluding Action

Once concluded, full details of the investigation, any action taken and the outcome, including any planned preventative action, should be provided to the Complaints Lead together with any related correspondence. These details may include investigation notes and/or the complaint response

letter. Where the complaint response letter is sufficiently detailed separate investigation notes may not be required.

2.8 Appealing the outcome or handling of a complaint

If the complainant is dissatisfied with the outcome or how a complaint has been handled, they have the right to appeal, in writing, to the HRA Chief Executive within 28 days of receipt of the response providing reasons for the dissatisfaction. The HRA Chief Executive will establish an appropriate review of the appeal depending on the nature of the complaint. This will include details on how the appeal is to be reviewed, documented and communicated. The Chief Executive will usually prepare a response within 25 working days.

2.8 Complaining to the Ombudsman

Complainants who remain dissatisfied at the conclusion of the HRA complaint procedure may put their complaint to the Health Service Ombudsman.

Contact details:

The Parliamentary and Health Service Ombudsman
Millbank Tower
Millbank
London
SW1P 4QP

Tel: 0345 015 4033

Website: www.ombudsman.org.uk

2.9 Confidentiality

All material associated with a complaint will be regarded as confidential. As such it will be retained securely with access being controlled and limited to nominated persons. The complainant should be made aware in the acknowledgement letter that potentially confidential information may be collected in the course of the investigation and that it will be retained confidentially.

2.10 Recording, reporting and monitoring

All complaints about the HRA will be recorded on the complaints register together with the timelines and action taken so that trends can be identified (see appendix A). The complaints register will be maintained by the Complaints Lead.

An annual complaints report together with the complaints register will be reviewed at the Leadership Team (LT) and HRA Board. They will be available on the HRA website as part of the publication of the HRA Board agenda, minutes and reports.

Where the complaint relates to Clinical Trials, the United Kingdom Research Ethics Committee Authority (UKECA) will be advised of the complaint and its outcome.

2.11 Monitoring and review

This policy and procedure will be subject to internal audit.

The management and use of this procedure is reviewed every two years.

Changes to improve it can be requested at any time and will be considered by the Complaints Lead and LT as necessary.

Related Documents

Supporting Documents	Publication	Confidentiality Issues
HRA Complaints Register	Redacted version to Board. Internal for nominated personnel only.	May contain personal information: names
Third Party concern register	Internal for nominated personnel only.	May contain personal information: names
Potential complaints / concerns register	Internal for nominated personnel only.	May contain personal information: names
Associated letters, investigation notes and correspondence. (Retained confidentially on the G: Drive in a restricted access folder).	Internal for nominated personnel only. Retained on secure drive for 8 years in accordance with the Records Management - NHS Code of Practice.	May contain personal information: names, addresses and sensitive investigatory material
Principles of Good Complaints Handling	Parliamentary & Health Service Ombudsman 10/02/2009	None
Guide to support staff in identifying and handling certain communications, complaints and requests for information	HRA Hub	None

Dissemination and publication of the policy and procedure

This policy and procedure will be released on the HRA Hub Central Library and its release will be communicated via HRA News.

The policy will also be published on the HRA website.

EQUALITY AND PRIVACY SCREENING QUESTIONS			
FOR EVERY HRA POLICY (<i>defined by the Equality and Human Rights Commission (EHRC) as a function, strategy, procedure, practice, project, or decision</i>) PLEASE ANSWER THE QUESTIONS BELOW TO DETERMINE WHETHER FURTHER ANALYSIS IS REQUIRED.		YES / NO	If yes, please copy and complete either the HRA Initial Equality Analysis and / or Initial Privacy Impact Assessment Template below. This one document can be found on the Intranet.
Equality	With due regard to our Equality Duty, could this policy have the potential to have a detrimental impact on anyone with a protected characteristic?	NO	
Privacy	With due regard to the Data Protection Act / GDPR, does this policy involve the use of Personal Information?	YES	

Author to type in name and date to verify analysis. (If further analysis is required, the Corporate Secretary must be informed).	NAME: Stephen Tebbutt DATE: 22/02/2019
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INITIAL PRIVACY IMPACT ASSESSMENT

What is Privacy?

Privacy refers to freedom from intrusion and relates to all information that is personal or sensitive in nature to an individual

	YES	NO
Does the policy or procedure have any impact on privacy?	YES	
If Yes please give details below of the impact and the actions being taken to address any adverse impact. The receipt and investigation of complaints is very likely to involve the collection of personal information and possibly personally sensitive information as defined by the Data Protection Act. It is also likely to involve the collection of confidential information. As such all complaints information should be treated as confidential. To accomplish this the HRA applies access controls that restricts the disclosure of the information to nominated individuals and retains all information in a secure folder on the shared drive.		

If you have answered YES to the questions above and the answers do not mitigate and adequately address the adverse impact, you may need to complete a full PIA. Please consult the Corporate Secretary.

Full Privacy Impact Assessment required? **NO**

Document Control

Change Record

Version	Date of Change	Reason for Change
V 1.0Draft	18/10/2011	Updated to HRA version to reflect the move to the HRA
V 1.1Draft	2011.11.25	JW comments added
V 1.0	2011.12.01	Approved by HRA SMG & HRA Board
V 2.0 Draft	2013.02.28	To up-date the policy in line with changes in the organisation, to combine the HRA and NRES Complaints Policy and Procedure.
V 2.1 Draft	2013.09.18	Addition of statement regarding local resolution
V 3.0	2013.10.16	Final amends after CMG approval
V 4.0 Final	20/11/2013	Harmonisation of appeals process in policy & procedure. Additional changes requested by EMT.
V 4.1	27/07/15	Combine Policy and Procedure in one document + minor amends
V 4.2 Final	17/08/2015	Minor amends after submitting Action Plan
V 4.3 Final	11/07/2016	Minor changes to scope
V 4.4 FINAL	22/02/2019	Minor changes to reflect change to personnel and supporting documentation
V 4.5 FINAL	02/08/2019	Inclusion of hra.complaints email address and notification of complaints to relevant director as standard

Reviewers

Name	Position	Version Reviewed
Janet Wisely	NRES Director	Version 1
Janet Wisely	NRES Director	Version 1.1
Joan Kirkbride	Operations Director	V2.0 Draft
Stephen Robinson	Complaints Lead	Version 3.0 & 4.0 Final, 4.2, 4.3
Sheila Oliver	Head of NRES	Version 3.0 & 4.0 Final
OMG, CMG, EMT	Committees	Version 3.0 & 4.0 Final
EMT	Directors and CEO	Version 4.1
LT	Senior HRA Management	Version 4.4

Distribution of Approved Versions

Platform (e.g.HRA intranet or website)	Date of Publication	Version Released
HRA Intranet and Website	09/09/2015	V4.2 Final
HRA Intranet and Website	11/07/2016	V4.3 Final
HRA Hub	04/04/2019	V4.4 Final
HRA Hub	02/08/2019	V4.5 FINAL