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| National Research Ethics Service (NRES)Framework for raising a Concern |

**Author:** Janet Wisely and Sandra Holley

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### 1.0 Introduction

The National Research Ethics Service (NRES) is a complex, geographically diverse organisation providing UK wide services that are delivered by some 130 staff and over 1000 volunteers employed or appointed by a number of different NHS organisations. NRES Head Office is a Division of the Health Research Authority (HRA) and NRES undertakes some functions in agreement with or on behalf of the HRA which is the appointing authority for research ethics committees (RECs) in England. NRES works to deliver an important service to research applicants to protecting research participants while also facilitating research.

1. **Culture of Respect**

NRES encourages open on-going communication between staff and volunteers to ensure issues arising during the delivery of our service can be aired and wherever possible resolved quickly and to the satisfaction of all concerned. It is hoped wherever possible issues can be dealt with as near as possible to the source of the concern and not escalated unless it is felt this will help to deal with issues more appropriately e.g. where it is felt that there is shared learning that will help others or it is felt the issue has not been dealt with satisfactorily at a local level. The roles of volunteers and staff while largely well defined do impact on each other and are in some aspects shared. Where roles do have a shared element or an impact on each other it is important this is undertaken with a level of agreement based on respect and understanding of each other’s role. It is only then that an effective service can be achieved. NRES has put in place this mechanism to aid the resolution of concerns where a local solution cannot be found. When using this process care will be taken to seek and consider the views of all parties involved to find and fair and workable solution.

As part of the culture of respect NRES expects concerns involving NRES staff, REC Chairs and members, procedures, guidance and actions to be raised in the first instance with NRES directly and not to a third party. NRES is anxious to ensure that concerns are dealt with impartially and to the satisfaction of the person raising the concern. For this reason if there is dissatisfaction with the way a concern is handled by NRES this procedure puts in place parties external to NRES where the concern can be taken for further consideration.

1. **When Should this Process be used**

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| **This framework should be used by NRES staff ,REC Chairs and members to raise concerns relating to the actions, behaviours or decisions of NRES staff, REC Chairs and members, including concerns that arise from the delivery of NRES procedures and policies.**  ***Examples to illustrate when and who could use this process***   * ***A member could write to the Head of Operations expressing concern about how a REC meeting is chaired. The member may feel members are unable to express their views fully at a REC meeting and the chair does not take into account the views of members when stating the decision on an application. The member has raised the issue locally but still feels concerned is unresolved.*** * ***A Chair could write to the Head of Operations expressing a concern about a member who is unhelpful and potentially rude to applicants attending the REC meeting. The Chair has raised the issue locally but still feels concerned is unresolved.*** * ***A Coordinator could write to the Head of Operations when he/she has difficulties progressing work between REC meetings under delegated authority from the meeting because of the lack of availability of the Chair and other REC members. The Coordinator has raised the issue locally but still feels concerned is unresolved.*** * ***A member may raise a concern with the NRES Senior Finance Manager about how the NRES expenses policy is applied locally. The member has raised the issue locally but still feels concerned is unresolved.*** |

**4.0 Scope of the Process**

The following are excluded from this framework for raising a concern:

* Serious matters that should be dealt with through policies of the employer or appointing authority
* Concerns relevant to an ongoing matter being managed through local policy
* matters which have already been thoroughly and fully investigated in accordance with appropriate policies
* matters which have already been thoroughly and fully investigated in accordance with this framework
* matters where legal proceedings are underway
* anonymous concerns
* complaints that are being dealt with by other relevant complaints procedures
* a complaint arising out of the alleged failure by a responsible body to comply with a request for information under the Freedom of Information Act 2000.

### 5.0 How to Raise a Concern

* **Formal feedback for REC Chairs and Members**

REC Chairs and members are encouraged to raise concerns using the formal feedback mechanism on the NRES website by completing the electronic feedback form setting out the concern including any relevant background information. This will be reviewed by NRES and concerns will be considered by the appropriate NRES Manager depending on the nature of the issue. Concerns will always be dealt with sensitively and care will be taken to inform the respondent of the outcome.

* **Raising a concern directly to NRES**

Where concerns are of a more specific or potentially sensitive nature then a formal concern should be put in writing to the appropriate Head of Department.

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| ***Please note contact details for the Heads of Department and the NRES Director can be found on the NRES website*** ***http://www.nres.nhs.uk/contacts/office-addresses/*** |

**6.0 How Concerns will be managed by NRES**

* The appropriate Head of Department will inform you within 3 days of how your concern is being handled, who is going to handle it and the likely time it will take.
* The aim is to facilitate early highlighting of concerns which can be resolved through dialogue and learning. However where the nature of the complaint is such that it may fall into the scope of the policies of a local employing Trust or Appointing Authority the Head of Department will ensure the appropriate Trust or Appointing Authority is informed and the management of the concern is discussed and the most appropriate method of solution is agreed.
* This could lead to the concern being solely managed by the employing Trust or Appointing Authority. Should this occur the person raising the concern will be informed and given the name of the person who is taking forward the management of the concern.
* If it is agreed the management of the concern will be shared by NRES and the employing or appointing organisation how the concern is being managed will be explained giving the remit of the concern being dealt with by each organisation and the names of those taking forward the concern in both organisations.
* If the concern is dealt with solely by the NRES Head of Department:

A plan will be taken forward and held on file and responded to as follows

Each response will include the following;

- A summary of each element of the concern

- Details of the policy followed

- A summary of the investigation

- Details of key issues or facts identified by an investigation

- Conclusions of the investigation

- What needs to be done to put things right

- 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)

- Information of what the person with the concern should do it they are

still unhappy with how the concern has been dealt with so far.

### 7.0 What do you do if you are not satisfied with how a concern has been handled by NRES

* If you are dissatisfied with how a concern has been handled by NRES you should raise the matter initially with the NRES Director. The Director will establish an appropriate review of the concern. You will be advised of the method of dealing with this and the likely time to be taken.

**If you remain dissatisfied with how the matter has be handled you can:**

**Either**

* If you are not satisfied with how the NRES Director has dealt with the concern you can raise the matter with the Chair of the National Research Ethics Advisors (NREAs) who will consider the matter and undertake a review of the concern with the support of other NREAs if it is seen to be appropriate and depending on the nature of the concern. The Chair will then report back to you and NRES giving advice on how it is felt the matter should be taken forward.

**Or**

* If the concern involves an issue about your membership an appeal can be made to the HRA lead from which you received an appointment letter/indemnity.

### 8.0 Reviewing and Monitoring Concerns

When dealing with concerns NRES is anxious to learn from the investigating the issues and to ensure similar concerns are avoided in the future**.** Therefore as a result of the investigation of a concern, where necessary changes will be made to processes and staff training to prevent the reoccurrence of problems that could lead to future complaints. All concerns will be recorded along with the action taken so that the effectiveness of the corrective action can be reviewed. Anonymised details of concerns received, resolution and lessons learnt will be considered by the NRES DMG so that trends can be considered and lessons learned.

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| Acknowledgements *This policy is informed by the Listening, Responding, Improving – a guide to better customer Care (DoH) and the SI 2009 no 309 – The Local authority Social Services and National Health Service Complaints (England) Regulations 2009.* |

# Document Control

**Change Record**

| Version Status | Date of Change | Reason for Change |
| --- | --- | --- |
|  |  |  |
| 1.6 | 2011.10.10 | Minor changes to reflect annual review |
| 1.6 | 2011.10.21 | Updated to HRA version |
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**Reviewers**

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**Distribution of Approved Versions**

| Name of Person/Group | Position | Version Released |
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| Extranet |  | v1.5 |
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