

# QUERIES & COMPLAINTS TO NHREC

*Form for directing queries or complaints to the National Health Research Ethics Council (NHREC)*

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The NHREC requests that this form be used for all formal queries and complaints to facilitate tracking and responses. Users are invited to provide feedback, comments or recommendations (e-mail to [nhrec@health.gov.za](mailto:nhrec@health.gov.za)) regarding this form to improve it.

There are seven sections of this template to guide you:

1. Type of query or complaint
2. Details of the enquirer or complainant
3. Additional details in case of a complaint
4. Executive summary of the query or complaint
5. Nature and history of the query or complaint
6. How would you like the NHREC to help?
7. Supporting documentation (optional)

**Office Use Only**

Date received:  Click to enter date.

## 1. Type of Query or Complaint

Is this a query or complaint?		- select -		Date of query or complaint		Click to enter date.		
Have you consulted the institutional Standard Operating Procedures (SOPs) for queries / complaints / whistle blowing?				N/A <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>		
In the case of a query or complaint related to an approved study, have you communicated with the research ethics committee (REC) to resolve the matter?				N/A <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>		
Have you exhausted all available internal processes to resolve the matter?						Yes <input type="checkbox"/>	No <input type="checkbox"/>	
If "No", please comment.		<input type="text"/> Click to enter text.						
Which of the following would best describe your query / complaint? (select one or more)	About conduct in an approved study	<input type="checkbox"/>	Conduct of a researcher	<input type="checkbox"/>	Discrimination	<input type="checkbox"/>		
	Informed consent process	<input type="checkbox"/>	Conflict of interest	<input type="checkbox"/>	Data security	<input type="checkbox"/>		
	Inappropriate communication, etc.	<input type="checkbox"/>	General REC processes	<input type="checkbox"/>	About the REC in general	<input type="checkbox"/>		
	Human participant wellbeing / monitoring	<input type="checkbox"/>	Animal wellbeing / monitoring	<input type="checkbox"/>	Guidance or clarification	<input type="checkbox"/>		
	From a principal investigator (PI) about the outcome of ethics approval							<input type="checkbox"/>
	Other (please specify)	<input type="checkbox"/>	<input type="text"/> Click to enter text.					

**Note!** REC = Research Ethics Committee, which could be a Human Research Ethics Committee (HREC) or an Animal Research Ethics Committee (AREC).

2. Details of the enquirer or complainant (i.e. person or entity lodging the <b>query</b> or <b>complaint</b> )			
2.1.	Name	Click to enter name.	2.2. Do you prefer confidentiality (i.e. protection of your identity)? <input type="checkbox"/> Yes <input type="checkbox"/> No
2.3.	Capacity / role	- select -	
2.4.	Institution / entity affiliated to, or private	Click to enter text.	
2.5.	Email address	Click to enter address.	2.6. Telephone no. Click to enter text.
3. In case of a <b>query</b> or <b>complaint</b> about a <b>particular study</b> , provide the following details (of the study, person and/or entity pertaining to the query or against whom/which the complaint is lodged). Leave empty if not applicable.			
3.1.	Title of the research study or clinical trial	Click to enter text.	
3.2.	Name of Principal Investigator	Click to enter text.	
3.3.	Name of any sponsor	Click to enter text.	
3.4.	Institution or site where research project is being conducted	Click to enter text.	
3.5.	Name of the research ethics committee that reviewed and approved the study	Click to enter text.	
4. Executive summary of the query or complaint			
4.1.	Provide a short description of the essence of your query or complaint (500 words max)	Click to enter text.	
5. Nature and history of the query or complaint			
5.1.	What is the issue or problem? (e.g. question about law, ethical guidelines, authority question, practical problem, ethics review processes, REC policy, administrative matter.)	Click to enter text.	
5.2.	What are the implications if the problem is not resolved?	Click to enter text.	
5.3.	Describe how the REC or other entity of the organisation/institution has tried to address the problem.	Click to enter text.	
5.4.	What was the outcome?	Click to enter text.	
5.5.	If possible, indicate the guideline, regulation or policy provision considered when addressing the problem.	Click to enter text.	
5.6.	Other information?	Click to enter text.	

6. How would you like the NHREC to help?		
6.1.	<b>Guidance</b> on how the problem may be solved.	Click to enter text.
6.2.	<b>Ethical guidance</b> on how to manage dilemmas of this type.	Click to enter text.
6.3.	<b>Legal guidance</b> on the implications of this problem.	Click to enter text.
6.4.	Guidance on how to <b>interpret</b> the guideline/statutory provision concerned.	Click to enter text.
6.5.	Guidance on where to <b>find</b> appropriate <b>information</b> .	Click to enter text.
6.6.	Other information?	Click to enter text.
7. Supporting documentation		
7.1.	Please provide here a <b>list</b> of any supporting documents that you may have attached ( <i>if and as applicable</i> ).	1. Click to enter text.

## Submission

Please e-mail this completed form to the NHREC, with “**QUERY**” or “**COMPLAINT**” in the subject line. Receipt of your query or complaint will be acknowledged.

[nhrec@health.gov.za](mailto:nhrec@health.gov.za)