**Annex D to the MREC Regulations**

MREC Complaints Procedure

The Medical Research Ethics Committee of University Medical Center Utrecht, considering that it is desirable to have a procedure that assures proper handling of complaints, having regard to Chapter 9 of the Dutch General Administrative Law Act (Awb), has decided to adopt the following Complaints Procedure:

I. General provisions

**Article 1 Right of complaint**

1. Anyone has the right to file a complaint with the MREC about the way in which the MREC has acted towards him/her or another party while exercising its powers.
2. An action performed by a person working under the responsibility of the MREC will be deemed to be an action of the MREC.

**Article 2 Proper handling**

The MREC ensures that any verbal and written complaints about its actions are handled properly.

**Article 3 Scope**

This Complaints Procedure applies to the handling of written complaints which relate to actions towards the complainant and which meet the requirements stated in Article 6(1), under a to d, of this Procedure.

**Article 4 Verbal/other complaints**

1. In the handling of verbal complaints or complaints filed via e-mail, or of complaints relating to actions towards another party than the complainant, the MREC will at least exercise due care.
2. If a complainant has filed a complaint verbally or via e-mail, the MREC will draw their attention to the option to file a complaint in writing.

**Article 5 Appeal**

A decision by the MREC concerning the handling of a complaint about an action as referred to in Article 1 cannot be appealed against.

ll. The handling of written complaints

**Article 6 Filing a complaint**

1. The written complaint must be signed before it is sent and must at least include the following information:
2. name and address of the party filing the complaint;
3. date;
4. a description of the action which the complaint relates to;
5. the written complaint must be addressed to:

MREC secretariat

University Medical Centre Utrecht
Internal mail no. D.01.343

Postbus 85500, 3508 GA Utrecht
The Netherlands

1. If the complaint is written in another language than Dutch and a translation is needed for proper handling of the complaint, the complainant must take care of this translation.

**Article 7 Discontinuation of complaint handling**

1. During every phase of the complaint handling process, the MREC may check whether it is possible to satisfy the complainant by handling the complaint in an informal manner.
2. As soon as the MREC has responded to the complaint in a way that satisfies the complainant, the obligation to further follow this Procedure will cease to apply.

**Article 8 Confirmation of receipt**

The MREC will confirm receipt of the written complaint in writing within one week’s time.

**Article 9 Complaint handling**

1. The MREC’s secretary is charged with handling of the complaint.
2. If the complaint relates to an action of the secretary, the complaint will be handled by the general chairperson of the MREC.

**Article 10 When complaint handling is not mandatory**

1. The MREC will not be obliged to handle the complaint if it concerns an action:
2. about which a complaint was filed previously, which was handled in accordance with this Complaints Procedure;
3. which occurred more than one year before the complaint was filed;
4. which the complainant was or is able to appeal against (via an administrative appeal or otherwise);
5. which has been submitted to the judgment of a judicial authority other than an administrative court via the institution of proceedings;
6. with regard to which an investigation ordered by the public prosecutor or prosecution is ongoing, or which is part of the investigation or prosecution of an offence, and an investigation ordered by the public prosecutor or prosecution is ongoing regarding that offence.
7. The MREC is not obliged to handle a complaint if the interest of the complainant or the significance of the action is manifestly insufficient.
8. If the complaint will not be handled, the MREC will inform the complainant about this in writing as soon as possible but at least within four weeks after the written complaint was received, stating the reasons for the decision.

**Article 11 Copy for the party complained about**

A copy of the written complaint, as well as copies of the accompanying documents, will be sent to the person whose action the complaint relates to.

**Article 12 Right to be heard**

1. The complaint handler will offer the complainant and the person whose action the complaint relates to the opportunity to be heard.
2. The complaint handler may decide not to hear the complainant if the complaint is manifestly unfounded or if the complainant has stated that they do not wish to make use of their right to be heard.
3. A report will be drawn up whenever a party has been heard.

**Article 13 Timelines**

1. The complaint will be handled in full within six weeks after it has been received.
2. Handling of the complaint may be postponed by up to four weeks. Both the complainant and the person whose action the complaint relates to will be notified of this postponement in writing.

**Article 14 Settlement of the complaint**

1. The MREC will notify the complainant in writing and with a substantiation about the findings of the investigation in connection with the complaint, as well as about any conclusions drawn.
2. In this notification the complainant’s option to file a complaint with the Dutch National Ombudsman will be mentioned.
3. The first paragraph also applies to the person whose action the complaint relates to.

**Article 15 Recording and publication of complaints**

1. The MREC records all written complaints filed with it.
2. The complaints recorded are published in the MREC’s annual report.

**Article 16 Short title, announcement and entry into force**

1. This Procedure may be referred to as the Complaints Procedure of the MREC of University Medical Center Utrecht.
2. The MREC secretary will take care of the announcement of this Complaints Procedure.
3. This Complaints Procedure will enter into force on the day after its announcement and will apply to complaints filed after the date of entry into force of this Procedure, even if the action which is being complained about occurred before that date.

Adopted by the MREC and the Executive Board of University Medical Center Utrecht during their meeting of 29 May 2018.

[signature]

Prof. E. Schneider

Chairperson of the Executive Board of UMC Utrecht

[signature]

Prof. L.J. Bont

General chairperson

of the Medical Research Ethics Committee of UMC Utrecht

General explanation

On 1 July 1999 the uniform complaints mechanism (Chapter 9) of the Dutch General Administrative Law Act (Awb) entered into force, which provides a procedure for complaint handling by administrative authorities.

Chapter 9 must be read in close relation to the effectiveness and manageability of the institution of the Dutch National Ombudsman and has two main consequences for the National Ombudsman’s duties. Firstly, this statutory mechanism further formalises the requirement that the administrative authority must be complained to first (which in Dutch is referred to as the *kenbaarheidsvereiste*). Secondly, the mechanism acts like a filter for the duties of the National Ombudsman. As a result of the requirement to complain to the administrative authority first, the Dutch National Ombudsman will only grant a request to handle a complaint after the complainant has filed their complaint with the administrative authority and the administrative authority has had the opportunity to respond to it.

The Awb complaints mechanism does not prejudice the fact that the internal organisational set-up must be laid down by the administrative authority. This Complaints Procedure regulates how complaints are to be handled and settled, as well as how they are to be recorded and published.

When this Complaints Procedure was drawn up, the Awb’s complaints mechanism was followed closely. As a result, this Complaints Procedure sufficiently provides for the proper handling of complaints, so that additional rules will not be necessary. However, the MREC reserves the right to include additional requirements in its own procedure, particularly if these offer extra guarantees for the complainant.

**Article by article explanation**

**Article 1**

The Complaints Procedure offers the complainant a means to take steps against behaviour, actions or a failure to act by the MREC or its members, or by employees of the MREC or its secretariat working under its responsibility. Complaints may concern the way in which the MREC and/or one or more of its members/employees have acted in a certain matter towards the complainant. Think of unfair treatment, slowness, a breach of privacy which is not open to legal action, ineffective information provision or communication, etc. This may also include the operation of the MREC’s organisation, even if the action which the complaint relates to cannot be definitely traced back to a concrete action of a certain person.

**Article 2**

This article sets out the general obligation of an administrative authority to ensure that complaints are handled properly. For written complaints the Procedure further specifies the principle of proper complaint handling in Articles 6 to 15 inclusive. For verbal complaints the general duty of care is sufficient for proper complaint handling - to avoid the risk of formalisation and of causing excessive bureaucracy.

**Article 3**

The Complaints Procedure regulates the handling of complaints filed in writing. The Awb requires that administrative authorities handle these complaints in a certain way. The Awb does not oblige complainants to file their complaint in written form, however.

If a complaint is filed in writing and meets the applicable formal requirements, the administrative authority will be obliged to handle this complaint in accordance with the relevant part of its complaints procedure.

**Article 4**

Complaints may also be filed verbally or via e-mail. In addition, it is possible to complain about an action towards another party than the complainant. These complaints, too, must be handled properly. As regards the latter complaints, the Awb leaves it up to the administrative authority to define proper handling, which means that this Complaints Procedure does not have to be adhered to in those cases. When these kinds of complaints are handled, the principles of sound administration must at least be adhered to. If the complainant files a verbal complaint and wishes to have it handled according to this Complaints Procedure, they will have to file the complaint in writing. In case of verbal complaints or complaints filed via e-mail, the complainant’s attention must be drawn to the option of filing their complaint in writing.

**Article 5**

Decisions on the handling of a complaint cannot be appealed against or objected to. As a rule, decisions in the context of complaint handling are not intended to have legal consequences. Therefore, they are not deemed to be decisions within the meaning of the Awb and they cannot be appealed against.

**Article 6**

This article describes the requirements which a written complaint must meet. If the complaint does not meet the requirements imposed, the MREC will not be obliged to further follow the complaint handling procedure. It will, however, still have a duty to handle the complaint properly. This may lead to a situation where the complainant is given the opportunity to supplement their written complaint, after which Articles 6 to 15 inclusive of this procedure must be applied after all.

**Article 7**

At every stage of the Complaints Procedure, the handling of the complaint according to the Procedure can be discontinued if a solution is found which satisfies the complainant. This allows quick and informal complaint settlement.

Settlement by telephone. A complaint may be settled verbally in an informal manner. This is only possible, however, if immediate verbal contact with the complainant has led to a settlement that is satisfactory in the complainant’s opinion.

Together, the MREC and the complainant will agree when a complaint has been handled to the complainant’s satisfaction. If the complainant confirms in writing that the complaint has been handled to their satisfaction, the handling of the complaint can be discontinued. The complaint handler will document their verbal response to the complaint and any arrangements agreed on with the complainant.

**Article 8**

In its confirmation of receipt, the MREC will also provide information on the further procedure, including the hearing of parties involved.

**Article 9**

Proper complaint handling means that the complaint handler cannot have had any involvement in the action which the complaint relates to. This does not apply, however, if the complaint relates to the MREC itself or to the chairperson or one of the members or replacement members.

The complaint handler chosen here is the secretary, who has been authorised to handle the complaints. The Awb uses a broad interpretation of the concept of ‘complaint handling’. Complaint handling means investigating the complaint, including hearing of the complainant and the person whose action the complaint relates to, and drawing conclusions from the investigation. However, the MREC still has final responsibility for the complaint’s settlement.

In view of the scope and structure of the MREC’s organisation, the use of an advisory procedure for handling complaints as referred to in Part 9:3 of the Awb has not been opted for.

**Article 10**

This article contains an exhaustive list of the grounds on which the MREC can decide not to handle a complaint. The obligation to handle the complaint will in these cases cease to apply but the authority to handle it will continue to exist.

The written notification of non-handling of the complaint is a decision within the meaning of the Awb and must therefore be substantiated. The decision not to handle the complaint cannot be objected to or appealed against, however.

**Article 11**

For the person whose action the complaint relates to it is important that they know that a complaint about them has been filed and that they can take note of the substance of the complaint. If a complaint leads to a hearing, the person whose action the complaint relates to must be able to prepare for it. All documents relating to the complaint will therefore be sent to this person.

**Article 12**

This article sets out the right to a fair hearing. This right forms an essential part of the Complaints Procedure. Hearings are intended to obtain information to ensure that the complaint can be handled properly. Under the Complaints Procedure it is entirely up to the MREC to decide whether or not the complainant and the person whose action the complaint relates to will be heard in each other’s presence.

Hearing people by telephone is not absolutely excluded; it may be possible after consultation with the complainant. As regards reporting on the hearing, a separate report is not required. In the settlement letter it can also be stated what was discussed during the hearing. A separate report is still preferable, however.

**Article 13**

The second paragraph of Article 11 provides for the option of postponing the handling of the complaint by four weeks. This may be necessary in a situation where insufficient information is available for proper handling of the complaint, for example. The absence of the person whose action the complaint relates to may also be a reason for postponement.

**Article 14**

The first paragraph requires the MREC to inform the complainant of its findings and any conclusions in writing after the investigation has been completed. For this purpose the decision will contain a representation of the facts established during the investigation into the complaint. The first paragraph refers to ‘any’ conclusions because the findings do not necessarily always lead to conclusions. Particularly if a complaint is deemed to be unfounded, it is possible that no conclusions are drawn.

In general, the result of the handling of a complaint will be an opinion that the complaint was either well-founded or unfounded.

The findings and conclusions are not intended to have any legal consequences. This means that the notification is not a decision within the meaning of the Awb. Even if the lawfulness of a decision is addressed in the complaint procedure, the result will not lead to a legally binding decision. Any conclusions may ultimately result in the MREC changing or withdrawing a decision, or making a new decision, however.

The intention of the second paragraph is that the complainant’s attention must be drawn to the existence of an external complaints body, which in this case is the Dutch National Ombudsman. In other words, the reference does not relate to any internal complaint options that are available.

**Article 15**

Only written complaints received have to be recorded.

The first paragraph does not require recording of the findings of the investigation into the complaint or of the conclusions drawn by the administrative authority.

As regards publication, too, only written complaints received have to be published. Likewise, there is no obligation to publish the findings of the investigation into the complaint or of the conclusions drawn by the administrative authority.

In the publication the MREC will at least state the following:

- how many complaints were filed during the year in question;

- how many of the complaints filed were handled, and within what time frame;

- the nature of the complaints;

- how many complaints were deemed to be well-founded and how many were deemed to be unfounded.

These data will be disclosed in a way that ensures that they cannot be traced back to the persons involved.