



Left-over material used for medical-research



It is sometimes needed for your treatment or examination in Erasmus MC to collect blood, body fluids or tissue as well as data and or images. Sometimes after the examination is done not all is there is still materials left-over. These materials are not directly destroyed until it is certain the examination results are complete and of sufficient quality. After that materials like blood or tissues are no longer necessary for your treatment or examination. In addition, data and perhaps images were collected during your treatment or examination for archival purposes. Such left-over materials can be very important for medical scientific research and might be used for medical scientific research. What this means for you and what you can do in case you do not want this, to prevent this is described in this folder.

Left-over material is body tissue or fluids like blood, medical images and medical data, which are no longer used for your treatment or examinations.

Medical-scientific research

Almost everything we nowadays know about disease and health originates from medical scientific research. Its main goal is to improve treatment of future patients. Left-over materials can be an easy accessible resource for that. This form of research has brought many new insights in the cause of diseases and their progression. It already resulted in discovery of new markers that are used in medical examinations as well as new insights to use drugs in disease management. Many more of these successes are expected in the future. It can be your treating physician is involved in the research. It can also be the medical scientific research is performed in cooperation with other hospitals and health care institutes within the Netherlands or abroad. It is of course very important that your privacy is protected and if data or images are going to be used the characteristics that could reveal your identity are removed. Recognizable parts of images are removed and data is coded. It is coded not anonymized, because if facts are discovered that could influence your current treatment in a positive way, they can be brought back to you through your treating physician. All materials must be kept in high quality for long periods of time in which they need to be tracked and traced also when in use. Such costs are not covered by your health insurance. The scientists using the materials can be asked to reimburse the costs for properly preserving the materials. Such reimbursement is only used to make available other left-over materials. For the left-over materials itself no payment will be asked. In addition, the left over materials can be used for educational purposes or to test or verify medical equipment or analytical methods.

How are left-over materials used

The materials used for medical scientific research are mostly used in the context of the disease for which they were collected to examine. The newest techniques are used to identify new molecular, data or image characteristics in relation to the medical history on disease progression, which can predict disease progression. This way we can in advance determine which patients will respond to treatment from patients who will not respond or distinguish patients that will respond with adverse effects. This can improve the choice of treatment and especially the direct benefits. For generating results that can reliably reveal such correlations large numbers of samples, data or images are needed with corresponding data that are collected over the years. Then if such markers are revealed it must be proven in another large dataset before they can be used in the real everyday situation. Such research is performed in together with medical research centers in Europe or even outside Europe to try and confirm the right characteristics or targets in different settings and different groups of people.



Conditions under which medical scientific research on left-over material is allowed

The most important rules medical scientist have to follow for working with left over materials are:

1. The medical research must first be evaluated by an ethical committee if the research is to comply with the Dutch law of medical research on people (Dutch abbreviation: WMO) or not. This objection procedure is only valid for research that is not to comply with the WMO.
2. Medical-scientific research not to comply with the WMO must follow:
 - The General Data Protection Regulation (GDPR) with the Dutch supplement (uAVG)
 - The Code of Conduct for the Use of Data in Health Research
 - Code of conduct for responsible use (2011)
 - This Erasmus MC information on left-over tissue used for medical research
 - Erasmus MC Research code

Consequences from these rules for you:

1. The data coming from you as a patient must be protected. Your name, address, social security number and hospital number will be replaced by a code. The date of birth replaced by the age the materials were collected. Identity revealing parts of images are removed before they are used for medical research.
2. Only your treating physician or those involved in your care are allowed to make the connection between the left over material and your identity.
3. You can object to using your left-over material for medical research purposes.
4. You can file a complaint in case you feel that your left-over material was not treated according to the rules

What does this mean for you?

You determine if your left-over material can be used in medical research, education of medical students or optimizing medical examinations. You are completely free to choose. In case you object, there will be no consequences at all in the relation with your treating physician or any other person involved in your care. You will receive the same treatment.

You can choose the following options

In case you do nothing Erasmus MC assumes you do not object against the use of your left-over material for medical scientific research. So, no objection means no action. In case you do object, please fill out the form that is attached to this flyer. If you object your left-over material will not be issued for medical scientific research or educational purposes.



Summarizing the two:

1. You do not object against the use of your left-over materials (Tissue, blood, body fluids, medical images and data) in medical research, education and calibration or optimizing medical equipment or analysis methods. In this case do nothing.
2. You object against the use of your left-over materials (Tissue, blood, body fluids, medical images and data) in medical research, education and calibration or optimizing medical examination methods. In this case fill out the form on the bottom of this flyer and send it to for free to the given address or hand it to the nearest reception.

Patients who cannot decide on their own

It may be you read this folder as custodian or representative of a patient. For example you are the parent of a child younger than 16 years of age or mentor of a mentally incapacitated patient. In that case you are the one that can object against using the left over materials for medical research.

Medical Research Results

Important scientific findings will be published on the Erasmus MC website. (www.erasmusmc.nl) amongst all other studies. You will not be personally informed about the medical scientific research results performed on your left-over materials. The results may contribute to products for a better treatment and which become commercially available. You cannot claim a share of any profits. On the other hand future patients can benefit from the newly developed treatment options.

Final remark

For questions, please contact your treating physician. In case you are not satisfied with our services please let us know. You can file your complaint to our complaint officer. You can do this by filling out a complaint form which you can obtain from Erasmus MC receptions, where you can also ask for the complaints officer. You can also obtain the digital form online, which you can return to klachtenopvang@erasmusmc.nl, or download the form and send it to the secretariat of complaints with the following address free of charge:

Postal address secretariat Klachtenopvang (No stamp needed)

Erasmus MC
t.a.v. secretariaat Klachtenopvang
Antwoordnummer 55
3000 WB Rotterdam



FORM: Object against use of left-over material

Important

In case you **DO NOT** object against the use of your left-over material (tissue, blood, body fluids, medical images without recognizable parts and coded data) for medical scientific research and educational purposes you **DO NOT** have to **fill out this form**.

Objecting patient:

Last name and initials: _____

Date of birth: ____ / ____ / ____

Gender: ☐ male ☐ female

Patient number: _____

(The patient number is the 7-digit number in the right hand corner on top of all your personally send communication from Erasmus MC. Without this number we can unfortunately not register your objection. It is the proof you are really the person behind the objection and not taking the right to participate in medical research away from someone else.)

☐ Objects against the use of left-over materials for medical research, education of medical students and optimizing medical examinations.

In case you declare the objection for a patient who is not capable in doing so, please print your name and initials as well as you relation to the patient (e.g. parent, partner, representative).

Name and relation: _____

Signature

Place: _____ Date: ____ / ____ / ____

Signature of patient or representative (if applicable):

Please return this form at the receptions called Inschrijvingen or mail this filled out form to:
Erasmus MC
Afdeling Pathologie / Weefselbank
Antwoordnummer 55
3070 WB Rotterdam
(No stamp needed)



