



RAMBAM
Health Care Campus

Rambam Helsinki Committee

Attn:
Audience engaged in research
Dear Sirs!

Re: Procedure for payment of handling fees at the Rambam Helsinki Committee

Entry into force: : 1 January 2022

This procedure is relevant to any study that receives funding or financial support from a source other than Rambam Hospital

The procedure is as following:

- 1- Any application to the Helsinki Committee for examination and review of study application documents must be accompanied by a reference confirming payment of the handling fee and a form detailing the deposit in the Committee Fund - **Fund 1029** (please see Appendix 2 to this procedure).
- 2- Since the submission is electronic only (except for new studies), the confirmation of payment must be **attached** to the **study documents** in Matarot (payment reference), as part of the submission.
- 3- The list of documents that require the payment of a handling fee and the amount to be paid are listed in Appendix 1 to this procedure (the price list).
- 4- Payment can be made by bank transfer, check or special voucher as follows:

A. Payment by bank transfer:

Name of the bank: Bank 20 Mizrahi Tefahot Ltd.

Branch number: 479, Shaare Zedek Jerusalem branch.

Bank address: Shmuel Bate 12, Jerusalem 9372212.

Account number: 456456

Name of the account holder: Rambam Health Corporation.

IBAN: IL80 0204 7900 0000 0456 456

SWIFT CODE: MIZBILIT

Please indicate in the transfer details the Helsinki number of the study for which the payment is made and the details of the actions for which the payment is made. The automatic email confirming the transfer of the payment should be sent to Mrs. Meital Siso

m_siso@rambam.health.gov.il

As stated above, the transfer confirmation as well as the receipt, if any, should be attached to the study documents in Matarot. Inquiries regarding the transfer can be directed to Ms. Meirav Ibn Suissa at the same email address.



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B. Payment by check:

The check will be payable to the **Rambam Health Corporation** at the cash register of the Health Corporation in the hospital treasury (at the entrance to the old building) by the sponsor/sponsor's representative/investigator/study coordinator. **The receipt must bear the number of the study for which the payment is made.** The receipt and deposit details form shall be attached to the study documents in Matarot, as specified above.

C. Payment by voucher:

There are special vouchers intended for the payment of Helsinki fees obtainable from the committee coordinator, Mrs. Dolly Haddad, or in the Research Promotion Unit from Mrs. Limor Bernstein or at the Health Corporation from Mrs. Lilach Landau. The payment with this voucher may be made at any of the commercial banks, including the Post Office Bank. **The number of the study for which payment is made must be recorded on each of the sections of the voucher. The voucher bearing the bank stamp shall be attached to the study documents in Matarot, along with the deposit details form.**

D. Procedure for payment of treatment fees in the Helsinki Committee in studies sponsored by the investigator (investigator-sponsor), but which receive full or partial funding from an external source:

- The investigator or study coordinator will send an email to Mrs. Lilach Landau of the Rambam Health Corporation, with a copy addressed to:
 - Owner of the fund
 - And the principal investigator (when the sender is not the principal investigator).
- The wording of the payment request sent by email will be as following: "*Please confirm the transfer of payment to Fund No. 1029 in the amount of _____ NIS for submission / extension / change in Helsinki Study No. _____. The payment will be transferred from Fund No. _____ for Helsinki study No. _____*"
- If there is budget approval, Mrs. Lilach Landau will approve the request in a return email to the investigator and the coordinator, and will inform Mrs. Dolly Haddad, Mrs. Bruria Moreno, and the fund owner.
- The e-mail with the approval should be printed by the investigator or coordinator and will be attached to the study documents in Matarot. This email will serve as



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a payment reference instead of Appendix 2 of this procedure in studies in which the investigator is the sponsor.

- If there is no budget approval, Mrs. Lilach Landau will respond to the investigator and the coordinator and will look for another source of funding.

Best regards,

Dolly Haddad

Rambam Helsinki Committee Coordinator

Attached:

Appendix No. 1 - Price List

Appendix No. 2 - Form detailing the deposit of funds in the Helsinki Committee Fund - Fund 1029

Appendix No. 1 - Helsinki Committee Price List

Part A - Relevant to studies sponsored by an external party (not hospital staff)

Type of application/document	Treatment fee in NIS
- New study of any type	7500 NIS
- Request to add documents to the study after the initial submission (such as consent forms, questionnaires, explanation sheet, etc.) - *Please see additional explanation at the end of the document	1000 NIS *Please see explanation at the end of the document
- Changes in submission documents after the first submission (changes in the protocol, in the investigator's brochure, in the consent forms, in the questionnaires, in the diaries, etc.) - **Please see additional explanation at the end of the document	1000 NIS ** Please see additional explanation at the end of the document
- Application for an extension of validity	1000 NIS

Part B - Relevant to studies sponsored by an investigator from Rambam Hospital staff ("investigator-sponsor" study) funded by an external grant



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Type of application/document	Treatment fee/rate in NIS
New application	2000
Application for change in the submission documents	500
Application for extension of the study validity	350

*The payment for addition of documents after first submission will be payment for document type and not payment per document. For example, submission of several types of questionnaires will be charged only once. If the submission includes more than one type of document (informed consent, questionnaires, diaries...), the payment will be for each type of document separately.

**Changes in the submission documents:

- A. The payment is for the type of document (for example, a change in the protocol + a change in the investigator's brochure submitted together, will be charged a fee of 2000 NIS).
- B. Insignificant changes or administrative changes that will not be charged a handling fee:

1- A change in the study team (change of principal investigator, sub-investigators) at the site, or such changes abroad and amendment/updating of the study documents accordingly (including consent) without any content change.
2- Correction of a registration error (footer/header) or notification of such an error, without changing the content of the document.
3- Change of sponsor/sponsor's representative and updating the relevant documents accordingly.
4- <u>Administrative letters</u> from the sponsor 5- On the other hand, when submitting administrative changes to the protocol, a handling fee must be paid.
6- Submission of changes for documents <u>translated into languages after</u> these changes have been approved in Hebrew documents.
7- Any type of safety reports: Periodic safety reports (line listing), reporting SUSAR that occurred at the institution, reports of death,



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updates from regulatory authorities regarding the study product
8- Submission of an insurance certificate update, submission of an interim report without requesting an extension, submission of end of study report, submission of a final clinical report, submission of notifications from monitoring committees (DMC/DSMB)
9- Update of Form 11

For inquiries regarding requests or documents that are included in the above, you can see extended details in the clarification table for payment procedure or contact the committee secretariat.

Appendix No. 2 - Form detailing the deposit of funds in the Helsinki Committee Fund - Fund 1029

On A payment was transferred of NIS

for study number For:

(please check the relevant option)

☐ New application

☐ Change in the submission documents (please specify the type of document/s)

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☐ Addition of documents to the application file (please specify the type of document/s)

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☐ Application for validity extension

Name of the principal investigator:

Name of the sponsor/sponsor's representative:

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**Rambam - Health Care
Campus**

**Dolly Haddad - Helsinki
Committee Coordinator**

P.O.B. 9602, Haifa
3109601

Tel: 04-7773501,
Fax: 04-7772520

State of Israel - Ministry of Health

E-mail: d_haddad@rambam.health.gov.il





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Details of contact person for inquiries (name, telephone number, and e-mail address):

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Committee Coordinator**

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