Subject information for participation in medical research

Screening of patients at risk for liver problems due to fat buildup in the liver (GRIPonMASH)

"Global Research Initiative for Patients screening on MASH"

de Jong VD, *et al. BMJ Open* 2025; 15:e092731. doi: 10.1136/bmjopen-2024-092731

Introduction

Dear Sir/Madam,

With this letter, we would like to ask you to take part in a medical study. Participation is voluntary. You have received this letter because your health care provider found you are at risk of developing liver problems due to fat buildup in your liver and it is possible to be screened for this.

You can read about the medical study in this information sheet. We will explain what it means for you and what the pros and cons of participation are. It is a lot of information. Can you please read the information carefully and decide if you want to take part? If you want to take part, complete the form in Appendix E.

Feel free to ask your questions
You can take your decision based on the information in this information sheet. We also suggest that you do this:

- Ask questions to the health care provider who gave you this information.
- Talk to your partner, family or friends about this study.
- Read the information on: [refer to government information website, if applicable].

1. General information

Julius Clinical has set up this study together with commercial and non-commercial research partners in Europe. This is called a research consortium. Julius Clinical is a research institute located in Zeist, the Netherlands. Below, we always call Julius Clinical the 'sponsor'. Investigators, these can be doctors, research nurses or other hospital staff, carry out the research in different hospitals in collaboration with associated general practitioners. In [country] these are [names of hospitals]. A central Julius Clinical research team oversees the entire study.

This study needs 10.000 subjects from 10 different countries. In [specific county], it is expected that 1000 patients will take part. The Medical Ethics Review Committee [X] has approved this study.

You will have at least one week to decide if you want to take part in the study. After this week you will be approached by the investigator and you can let him/her know your decision.

2. What is the purpose of the study?

This study screens 10.000 patients in 10 countries with an increased risk of liver problems due to fat buildup in the y liver. This way we learn more about how often these liver problems occur and how they can be detected earlier. With the screening program we hope to improve the collaboration between general practitioners and specialized clinics/hospitals by introducing a so-called ‘patient care pathway’. This care path has been established by international scientific associations. The current study is investigating whether less invasive methods to detect liver problems (blood tests and ‘FibroScan’) work just as well as liver biopsy (where a small sample is taken form the liver). We are also trying to find other ways to detect and predict liver problems.

3. What is the background of the study?

More and more people suffer from overweight, obesity and associated diseases like type 2 diabetes mellitus. This is a growing healthcare concern, and it is for example related to an increased risk of cardiovascular diseases. It is also related to metabolic dysfunction-associated steatotic liver disease (MASLD). MASLD is a long-lasting liver condition caused by fat buildup in the liver. MASLD often interferes with the proper functioning of the liver. MASLD can lead to inflammation of the liver (called metabolic dysfunction-associated steatohepatitis; MASH) and scarring of the liver (called fibrosis). Severe MASLD can ultimately cause liver failure (cirrhosis) and can even lead to liver cancer (hepatocellular carcinoma), although the chance of having these severe complications is very small.

The risk of developing MASLD is higher if you have obesity, diabetes, arterial hypertension and 'metabolic syndrome'. It is not yet known exactly how many people in Europe have MASLD. In the early stages MASLD is reversible. That is why it is so important to detect patients with MASLD at an early stage and to start in time with available treatments , like adjusting your lifestyle and in some cases bariatric surgery. Lifestyle changes can for example be, what and how much you eat, and how much you exercise.

4. What happens during the study?

How long will the study take?
Are you taking part in the study? The screening program will be completed within 8 months after enrolling in the study in the hospital. In the third and fifth year after the start, you will be asked again for a short check in the hospital. So the total study duration is 5 years.

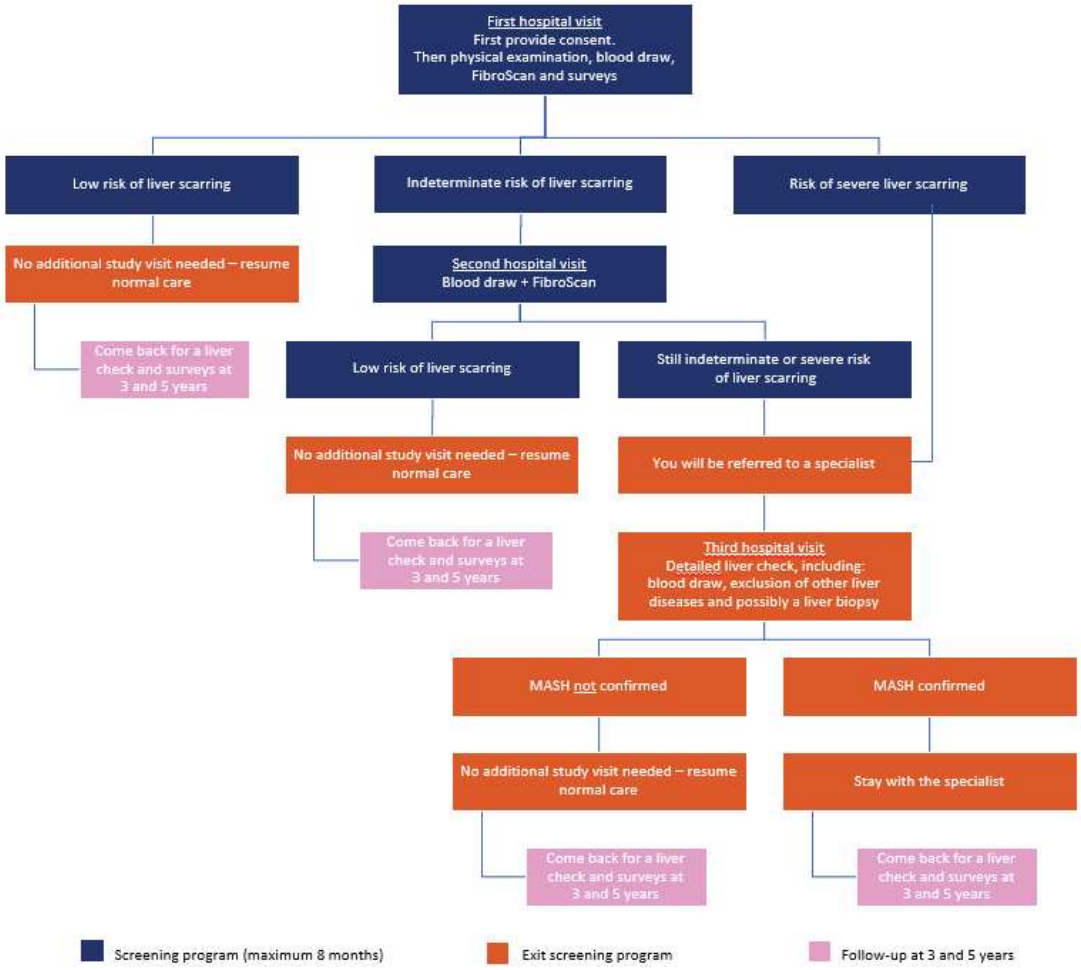
Step 1: are you eligible to take part? This step will take around 10 minutes
First, we want to know if you are eligible to take part. That is the reason that the investigator or general practitioner will do some checks:

- Your medical history.
    - You are only eligible for the screening if you have an increased risk of developing MASLD. In this study defined as: people with obesity, type 2 diabetes, high blood pressure and metabolic syndrome.
    - You cannot have any other liver diseases.
- Excessive alcohol consumption can also damage the liver, so the investigator will ask about your average alcohol consumption.
    - You cannot participate if you consume more than 2-3 units of alcohol per day.

Please note: it is possible that due to other reasons you are not eligible for this study. The investigator will tell you more about this.

Step 2: study and measurements
If you are eligible to participate in the study, you are invited to come to the [name hospital] for further investigation. In the hospital we will first confirm if you are eligible to take part in the study. Then we will check if you have fat buildup or scar tissue on your liver using a kind of ultrasound machine (FibroScan). The outcome of that test determines the further steps within the screening program.

An overview of the screening program (dark blue) and corresponding follow-up checks in the third and fifth year are shown in the figure below:



For the study, you need to visit the [name hospital] at least once. This hospital visit will take approximately one hour. It is important that **you come in fasted**, that means that you are not allowed to eat or drink anything (except water) for at least 8 hours before the hospital visit.
The results of the examinations done in the hospital will be sent to you and the doctor or general practitioner who referred you to the study.

We will carry out these checks during the first visit to the hospital:

- Short physical examination. For example, the examiner may measure your blood pressure, weight, length and waist circumference.
- Blood draw. For this, the investigator takes 8 tubes of blood. In total, we will collect approximately 47,5 ml of blood from you. This amount does not cause any problems in adults. For comparison: if you give blood at the blood bank, you will give 500 ml of blood at a time. With the blood test, we measure:
    - Your liver status values
    - Other values related to your health, such as cardiovascular risk factors.
    - If your genes in your DNA are related to a higher risk of MASLD.
    - If there are compounds (such as fats or proteins) in your blood that can predict if you have MASLD or not.
- FibroScan. This is a kind of liver ultrasound that can estimate the amount of fat buildup and scarring of the liver.

- Questionnaires about your diet and lifestyle.
- If the FibroScan provides an indeterminate result, lifestyle recommendations will be provided.
- You may be invited for an interview about your diet, this will extend the visit by 30 minutes. The interview will be conducted by a dietitian or a trained research assistant.

Depending on the results from the first visit, the next visits are scheduled or no additional visits are required:

- *Low risk of liver scarring*: no additional visit needed.
- *Indeterminate risk of liver scarring*: You will be asked to visit the hospital again after 12 weeks for a second FibroScan. We will collect 3 tubes of blood (total approximately 8,5 ml). This will take around 30 minutes.
    - If your liver status improved, no additional visit is needed.
    - If your liver status did not improve, you will be referred to a specialist who will check your liver in more detail. A liver biopsy is performed to be able to definitively diagnose if you have MASH or not. You will be asked to visit the hospital again, and again you need to be fasted. This visit will take around 4 hours as you will have to lay down for a while after the biopsy. We will collect 3 tubes of blood (total approximately 16,5 ml).
- *Severe liver scarring*: you will immediately be referred to a specialist who will check your liver in more detail, according to standard care. We will collect 3 tubes of blood (total approximately 16,5 ml).

Step 3: follow-up check
Three and five years after your first visit, you will be asked to visit the hospital again. At both visits a short physical examination is done. We will collect 3 tubes of blood (total approximately 16,5 ml) and you will be asked to complete the diet and lifestyle questionnaires. At the three year visit we will also do another FibroScan. The results of the FibroScan will again be shared with you and the doctor or general practitioner who referred you to the study.

Appendix C has a list of the measurements we carry out during each visit.

What is the difference with standard care?
This study is an addition to your regular care. The screening program and follow-up checks can be done next to your regular care.

5. What agreements do we make with you?

We want the study to go well. That is why we want to make the following agreements with you:

- You go to every appointment.
- You should contact the investigator in these situations:
    - You are hospitalised or get treatment in a hospital.
    - You suddenly have problems with your health.
    - You no longer want to take part in the study.
    - Your telephone number, address or email address changes.

The next two paragraphs are only applicable for female participants.

Is it OK for you to get pregnant during the study?
*T*his study cannot have any consequences for an unborn child, however we do not know if the

FibroScan does provide a reliable result during pregnancy. Therefore, women who are pregnant cannot participate in this study.

Pregnant after all?
If you do become pregnant during the study, then let investigator know. In the event of a pregnancy, where a FibroScan was still scheduled, you should postpone participation in the study until after the birth in consultation with the investigator.

6. What are the pros and cons if you take part in the study?

Taking part in the study can have pros and cons. We will list them below. Think about this carefully and talk to other people about it.

If you follow the screening program, it will become clear whether you have MASLD or not. If you participate in this research, it does not mean that MASLD will be cured or that you will suffer less from the disease, but your participation will help the investigators to gain more insight into the timely detection of MASLD. You will also help the investigator to gain more insight into the occurrence of MASLD in different countries.

Taking part in the study can have these cons:

- There may be some discomfort from the measurements during the study. For example: taking a blood sample can be a little painful. Or you could get a bruise as a result.
- Taking part in the study will cost you extra time.
- You have to comply with the study agreements.

What are the possible discomforts you may experience with checks or measurements during the study?
Blood sampling is a regular medical procedure with low risks, although in rare cases you may develop bruising after the blood sampling. The FibroScan is a kind of ultrasound and thus has no risks.

In a selected group of patients (see Figure 1) a liver biopsy will be performed. With the collection of liver tissue, there is a risk of bleeding. This bleeding will be cared for immediately.

When you are referred to a specialist to check your liver in more detail, , the specialist will ask for your permission again as these checks are part of standard care. If you participate in the study you give the investigator permission to collect the results of these checks. In case of a liver biopsyyou give permission to collect the results and a bit of your liver tissue.

Possibility of accidental discoveries
It is possible that an accidental discovery is made during the study (for example during the FibroScan, with the blood testing or genetic examination) that is not directly related to the research, but does concern your health. If this happens, your own doctor or specialist will discuss with you what needs to happen next.

You do not wish to participate in the study?
It is up to you to decide if you wish to participate in the study. Do you not wish to participate? You will not be screened for the presence of MASLD and you will continue your health care visits as usual.

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7. When does the study end?

The investigator will let you know if there is any new information about the study that is important to you. The investigator will then ask you if you want to continue to take part.

In these situations, the study will stop for you:

- All checks according to the schedule are finished.
- You have become pregnant (in this case the study will be postponed until after the birth).
- You want to stop participating in the study yourself. You can stop at any time. Report this to the investigator immediately. You do not have to explain why you want to stop. You will then exit the screening program and resume your usual health care visits. The investigator will no longer collect information from the moment you indicate that you want to stop participating in the study.
- The investigator thinks it is better for you to stop. The investigator will still invite you for a follow-up check.
- One of the following authorities decides that the study should stop:
    - Julius Clinical
    - the government, or
    - the Medical Ethics Review Committee assessing the study

What happens if you stop participating in the study?
The investigators use the data and body material (the blood samples, and in some cases liver samples) that have been collected up to the moment that you decide to stop participating in the study. If you wish, we will destroy the collected body material. Please let the investigator know. Investigators will always be able to use the data that was collected between the moment you started the study and the moment that you indicated that you want to stop participating in the study.

The entire study ends when all the participants have finished.

8. What happens after the study has ended?

The first analysis is planned within 3 years after the start of the study. You will then receive a report about the most important results of the study.

9. What will be done with your data and body material?

Are you taking part in the study? Then you also give your consent to collect, use and store your data and body material.

What data do we store?
We store these data:

- your gender
- your ethnicity
- your date of birth (month and year only)
- information about your health
- (medical) information that we collect during the study
- Your name
- Your e-mail address
- Your phone number

- Your address
- Results of tests done during the study

What body material do we store?
We store the tubes of blood, and in some case pieces of liver tissue (biopsies). Your DNA can be analysed from the blood and tissue, or other compounds (such as fat and proteins) can be measured. This is further explained in Appendix D.

Why do we collect, use and store your data and body material?
We collect, use and store your data and your body material to answer the questions of this studyand to be able to publish the results.

What do we do with your data?
In this study we work together with commercial and non-commercial partners, which form a research consortium together. The collected data and test results may be shared with these partners to answer the research questions. Also your data will be added to a healthcare platform.

How do we protect your privacy?
To protect your privacy, we give a code to your data and your body material. We only put this code on your data and body material. We keep the key to the code in a safe place in the hospital. When we process your data and body material, we always use only that code. Even in reports and publications about the study, nobody will be able to see that it was about you.

Who can see your data?
Some people can see your name and other personal information without a code. Your referring health care provider and the staff at the hospital will know who you are. The hospital staff executes all physical measurements and collects the data and body material.

The body material is sent to the central storage facility at UMC Utrecht in The Netherlands. The body material will only be referred to by the code, so employees of the central storage facility only know the code. The hospital staff enters the collected data into the central research database. Only coded information is entered, so the central research team at Julius Clinical or other consortium partners only know the code.

Other people who are allowed to see your information without a code, are people checking whether the investigators are carrying out the study properly and reliably. These persons can access your data:

- An auditor and/or monitor who works for the sponsor or is hired by the sponsor.
- National and international supervisory authorities.

These people will keep your information confidential. We ask you to give permission for this access.

For how long do we store your data and body material?
We store your data at the hospital for 15 years. And for 15 years with the sponsor. We store your body materials at the central storage facility at the Utrecht UMC (UMCU Biobank). They will be stored for a maximum of 15 years in order to be able to make new assessments related to this study or in the course of this study. If no longer needed, we will destroy your body material.

Can we use your data and body material for other research?
Your data and your remaining body material may also be important after this study for other medical research on MASLD and related liver problems, such as improving detection methods and developing possible treatment options. For this purpose, remaining body material will be stored at the central

storage facility at the UMC Utrecht for 15 years. Your data will be stored centrally for 15 years. Please indicate in the consent form whether you agree with this. Do you not want to give your consent for this? Then you can still take part in this study. You will enter the same screening program. When a request is made for the use of your data and/ or for the use of your remaining body material, the sponsor will first determine if the request is in line with your consent. If so, the sponsor will request the central storage facility to release the requested remaining body material and/ or will provide the requester with your data. If the other research is of a commercial nature, you as participant will not take share in any possible commercial gains and will not gain a right to the investigational product or medicine.

What will be done with your body material?
Blood samples will be divided in three groups. The first group will be analysed in the hospital. The second and third groups will be shipped to the central storage facility at the UMC Utrecht. The second group of samples will be shipped from the central storage facility to different laboratories and commercial and non-commercial partners in Europe to be analysed. The third group of samples will stay in the storage facility and will be used if additional measurements are needed to answer the research questions or, if you agreed, for other related research.

Liver tissue samples will be sent to the central storage facility at the UMC Utrecht or central analysis directly. Analyses are done at a central laboratory or at commercial and/or non-commercial partners in Europe.

Remaining body material will be stored in the central storage facility and will be used if further or other analysis is needed to answer the research questions or, if you agreed, will be used for other related research.

What happens if there are accidental discoveries?
It is possible that during the study we discover something that is important to your health. In that case, the investigator will contact your referring health care provider. You will then discuss what needs to be done with them.. By signing the form (Appendix E), you give consent to inform your referring health care provider.

Can you take back your consent for the use of your data?
You can withdraw your consent for the use of your data at any time. This applies both to the use in this study and to the use in other medical research. But please note: if you withdraw your consent, and the investigators have already collected data for research, they are still allowed to use this information. The investigators will destroy your body material after you withdraw your consent if you ask them to do so. But if assessments with your body material have been carried out, the investigator can continue to use the results.

Do you want to know more about your privacy?

- Do you want to know more about your rights when processing personal data? Visit [refer to government website if possible].
- Do you have questions about your rights? Or do you have a complaint about the processing of your personal data? Please contact the person who is responsible for processing your personal data. For the present, this is:
    - [name hospital]. See Appendix A for contact details and website.
- If you have any complaints about the processing of your personal data, we recommend that you first discuss them with the research team. You can also contact the Data Protection Officer of [the hospital]. Or you can submit a complaint to the [local Data Protection Authority].

Where can you find more information about the study?
You can find more information about the study on the following website: https://griponmash.eu/
After the study, the website may show a summary of the results of this study.

10. Will you receive compensation if you participate in the study?

Participating in the screening program will not cost you anything. For participating in this study, you will receive an [site-specific: i.e., expense allowance of a maximum of €10,- per visit to the hospital, as a contribution towards travel and parking costs]. If you stop before you have visited the hospital, you will not be reimbursed for expenses.

11. Are you insured during the study?

Insurance has been taken out for everyone who takes part in this study. The insurance pays for damage caused by the study. But not for all damage. You can find more information about this insurance and any exceptions in Appendix B. It also says who you can report damage to.

12. We will inform your general practitioner

The investigator will send your referring health care provider an email to let them know that you are taking part in the study.

As part of the screening program the referring health care provider and research staff of the hospital will exchange information. This following information will be exchanged:

- Results of tests and/or diagnosis or medication use related to the conditions required to join the study.
- The result of the FibroScan (including CAP, LSM, FIB-4 and FAST) will be sent from the hospital to your referring health care provider.
- Results of urine tests related to liver diseases of the past six months (if available) will be sent from your referring health care provider to the research staff at the hospital.

By signing the form (Appendix E), you give consent to the exchange of information as described above.

13. Do you have any questions?

You can ask questions about the study to the research staff at the hospital.

Do you have a complaint? Discuss it with the doctor who is treating you. If you prefer not to do so, please visit [complaints officer/complaints committee of your hospital]. Appendix A tells you where to find this.

14. How do you give consent for the study?

You can first think carefully about this study. Then you tell the investigator if you understand the information and if you want to take part or not. If you want to take part, fill in the consent form that you can find with this information sheet. You and the investigator will both get a signed version of this consent form.

Thank you for your attention.

15. Appendices to this information

A. Contact details <to be adjusted per participating centre>

B. Information about the insurance

C. Schedule of study measurements

D. More information about measurements

E. Consent form

F. Withdrawal from prior consent

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A. Contact details hospital and Julius Clinical

If you have any further questions about this study, please contact the research staff at your hospital.

Study centers [text below to be completed for each center]

Center X
Local investigator: [for principal investigator of centre: name, contact details (including phone number) and accessibility]

< if applicable>
[Study nurse/study doctor/nurse specialist]:

Complaints: [service or person with contact details and accessibility]

Data Protection Officer of the institution:

For more information about your rights: [Contact details [including website] of the person(s) responsible for processing personal data]:

<if applicable, to be supplemented with, for example, a coordinating investigator and/or an emergency number/24-hour availability>

Central investigation team at Julius Clinical
Coordinating principal investigators: Assoc. Prof. M. Castro Cabezas and Prof. D.E. Grobbee
Address: Julius Clinical, Broederplein 41-43, 3703 CD Zeist, The Netherlands
Website: https://www.juliusclinical.com/contact/
E: griponmash@juliusclinical.com

B. Information about the insurance

To be added

C. Overview of study measurements

Depending on the outcome of visit 1, either no extra visits are needed, or you will be invited for visit 2 and then possibly visit 3.

	Screening program					Long-term follow up	
Who needs to go to this visit?	All patients		Only if indeterminate risk at 1st FibroScan	Only if risk of severe liver scarring at 1st FibroScan	Only if risk of severe liver scarring at 2nd FibroScan	All patients	
Name of visit	Pre-screening	Visit 1	Visit 2	Visit 3	Visit 3	Follow-up 1	Follow-up 2
Time (from first hospital visit)	- 4 weeks	0	12 weeks	16 weeks	30 weeks	3 years	5 years
Location	GP or hospital	Hospital	Hospital	Hospital	Hospital	Hospital	Hospital
Inclusion/exclusion criteria	x	x					
Demographics (birth date, gender, ethnicity)		x					
Medical history		x					
Medication use		x				x	x
Blood pressure (mm Hg)		x	x			x	x
Height (m)		x					
Weight (kg)		x	x			x	x
Waist circumference (cm)		x	x			x	x
Request recent urine laboratory measurements from health care provider		x					
Questionnaires diet and lifestyle		x				x	x
FibroScan		x	x			x	x
Blood draw		x	x	x	x	x	x
Feedback on FibroScan results		x				x	x
Diet and lifestyle review and lifestyle recommendations (only if indeterminate risk		x					
Optional: interview about diet		x		x	x		

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D. More information about study measurements

Genetic and DNA research
We will analyse your genes in your DNA from the blood that will be collected. These genes may be related to the development and/or cure of MASLD. We expect that even more genes will be discovered that play a role in the coming years, so we would like to keep your blood sample for 15 years for further research.

Metabolomic, lipidomic, proteomic and fluxomic research
We will also look at different compounds (such as fats and proteins) that can be found in the blood. For example, we are interested to see if these compounds can predict if you have MASLD or not. Again, we expect that more will be possible in the coming years, and we would like to keep your blood for further research.

FibroScan
The FibroScan is a kind of ultrasound device that works on the basis of pressure waves. Please find a picture of the FibroScan device below. There is no need to take off your clothes for the measurement, only the abdomen must be exposed. The location of the liver is determined and some gel will be applied. For the measurement, the ultrasound probe will be held above the liver and will emit sound waves. The examination is not painful and takes around 10 minutes.

It is important that you arrive at the appointment fasted, meaning you are not allowed to eat or drink anything for some time before the appointment. You will receive more information about the precise rules from your local researchers.

Liver biopsy (optional)
First, the skin above your liver will be numbed. The doctor will then make a small incision in the skin and take a small piece of tissue from the liver through a hollow needle. A liver biopsy is a safe test. In a small number of cases, punctures in the liver may cause bleeding or post-bleeding. That is why you will be asked to lie down for at least 3 hours after the examination so that the doctors can monitor this. You must also arrive fasted at this appointment. We expect that for approximately 20% of the participants a liver biopsy will be advised to determine what liver disease you have and how severe it is.

E. Consent form(s)

Belonging to: *Screening of patients at risk for liver problems due to fat buildup in the liver (GRIPonMASH)*

- I have read the information sheet. I was able to ask questions. My questions have been answered well enough. I had enough time to decide if I wanted to take part.
- I know that taking part is voluntary. I also know that at any time I can decide not to take part in the study. Or to stop taking part. I do not have to explain why.
- I give the investigator consent to inform my referring health care provider that I am taking part in this study.
- I give consent to request information from my referring health care provider about the tests and/or diagnosis or medication use related to conditions to participate in this study and results of urine measurements of the past six months (if available).
- I give consent to give my referring health care provider information about accidental discoveries made during the study that are important for my health.
- I give consent to collect, store, ship and use the results and body material that were obtained during procedures, carried out under standard of care as mentioned in the information letter.
- I give consent to collect, store, ship and use my data and body material. The investigators only do this to answer the question of this study.
- I know that some people will be able to see all of my data to review the study. These people are mentioned in this information sheet. I give consent to let them see my data for this review.
- I know that if I become pregnant, the study appointments are postponed until after the birth.

- Please tick yes or no in the table below.

I give consent to store my data to use for other research, as stated in the information sheet. The data will be stored for this purpose for another 15 years.	Yes ☐	No☐
I give consent to have my (remaining) body material stored and shipped for use in other research, as stated in the information sheet. The body material is stored for this purpose for another 15 years.	Yes ☐	No☐
I give consent to have my DNA (from blood and tissue) stored for use in other research, as stated in the information letter. The DNA is then stored for another 15 years.	Yes ☐	No☐
I give consent to ask me after this study if I want to participate in a follow-up study or drug development research.	Yes ☐	No☐

- I want to take part in this study.

My name is (subject): ……..
Signature: …… Date : __/__/__

I declare that I have fully informed this subject about the study mentioned.

If any information becomes known during the study that could influence the subject's consent, I will let this subject know in good time.

Investigator name (or their representative): .....
Signature:…… Date: __/__/__

The study subject will receive a complete information sheet, together with a signed version of the consent form.

F. Withdrawal Form for Prior Consent

Belonging to: *Screening of patients at risk for liver problems due to fat buildup in the liver (GRIPon MASH)*

I hereby give notice that I withdraw my participation in GRIPonMASH. This means that no new body material may be taken from me and no more medical data may be collected for GRIPonMASH.

I understand that body material that has been collected from me and has already been processed in the investigation, cannot be recovered or destroyed. Furthermore, I am aware that the medical records used in the study are not recovered or destroyed. This body material and medical data remain encoded and available to the person conducting the investigation.

With regard to the my body materials still stored for GRIPonMASH, I declare that my body material:

O may still be used according to the consent form I previously signed,
O must be destroyed.

My name is (subject): ……..
Signature: …… Date : __/__/__

I declare that I have taken note of the withdrawal of consent by the aforementioned patient and as described above.
Institution: ……..

Investigator name (or their representative): .....
Signature:…… Date: __/__/__

The investigator will send the signed form to Julius Clinical within 1 week, attn. Study coordinator GRIPonMASH. Julius Clinical will confirm receipt of the form.