Subject information for the representative of the incapacitated patient

Dear Sir/Madam,

You have been asked to give consent on behalf of your partner or relative for participation in the biobank mentioned above. Before you decide whether you want to give permission, we would like to explain what it involves. You have received this letter to provide you with this information. Please read this information carefully and ask the investigator any questions you may have. You may also discuss this letter with your friends or family. It is important that you read and fully understand the information, which applies to everyone who participates in this biobank.
Participation is voluntary and you may refuse or withdraw your consent at any time, without any consequences for the medical treatment of your partner or relative. If at any moment your partner or relative opposes an act to which he/she is subjected, participation will not be continued.
Please let us know if you want to give permission or not either before the performance of the lumbar puncture, or within two days if the lumbar puncture has already been performed.

1. Introduction

Your partner or relative is currently in the Emergency Room or admitted to hospital and a lumbar puncture will be (or has been) performed because meningitis is/was suspected. Meningitis may be caused by different bacteria or viruses, but also by a disruption of the immune system (auto-immune disease). Meningitis is a rare disease and a lot is yet unknown about some of the causes. Therefore, we would like to collect data of all the patients in whom the diagnosis was suspected and proven or excluded by a lumbar puncture. We will store these data in a so called biobank, so that in the future it may be used for scientific research.

2. Background and purpose of the biobank

A biobank is a place where bodily material of many patients is stored so that, in the future, it may be used for scientific research. The aim of this biobank is to systematically collect data of patients who are suspected of meningitis. Therefore, we first collect and store all the materials. Then, when we have collected enough samples in a few years, we can research meningitis.

3. What does participation involve?

We would like to ask your permission on behalf of your partner or relative to store their cerebrospinal fluid, which will be/has been collected during the routine lumbar puncture by the treating physician, in the biobank in order to study different causes of meningitis. If the lumbar puncture has not been performed yet we would like to ask you if we can collect some extra cerebrospinal fluid in addition to the regular amount. Furthermore, we wish to collect extra blood samples, and perform a rectal and throat swab. This will also be stored in the biobank. The blood withdrawal consists of one additional withdrawal (19 ml of blood), which, if possible, will be combined with a regular withdrawal. If you decide to enroll your partner/relative the investigators will fill in a questionnaire about his/her

symptoms before and during admission, findings on his/her physical examination and ancillary investigations like scans and blood tests. Because scans of patients with meningitis can show specific or subtle abnormalities we wish to save your scans so that we can evaluate them ourselves.
Collection of the extra tube of cerebrospinal fluid, blood and the rectal and throat swab are all extra tests for the biobank. All other investigations mentioned above are part of regular care.

4. Additional burden

If possible, we will withdraw an extra tube of cerebrospinal fluid during the lumbar puncture. This does not pose an extra risk. There will be one additional blood withdrawal during admission or stay at the Emergency Department. We will try to combine this with a regular withdrawal. Furthermore, we will collect one additional rectal and throat swab. The throat swab will be collected with a long cotton swab which will be brushed against the back of your throat. This can briefly induce a gag reflex. This is not dangerous, but it may be uncomfortable. The rectal swab will also be collected with a cotton swab. This needs to be inserted 1 cm into the anus and rotated a few times. This is not dangerous nor is it painful.

5. If you do not wish to participate or wish to stop participating

It is up to you to decide whether or not you give consent for your partner or relative to participate in the biobank. Participation is voluntary and you may refuse or withdraw your consent at any time without providing a ground for withdrawal. This does not have any consequences for the medical treatment. Even if you give your consent at first but later change your mind, your partner or relative will receive usual care. As soon as it is possible we will ask your partner or relative if he/she gives consent for participation in the biobank. Should you withdraw your consent, the bodily material and research data of your partner or relative will be destroyed. If however analyses with this data have already been performed, these results will be used.

6. Confidentiality

We will be very careful with your partner's/relative's data. Personal data are coded with a unique number and only the investigators of this biobank have access to this code, which falls under the authority of the biobank's administrator. If material or data is sent to other investigators they will only contain this unique code, never the personal data. In reports and publications regarding the research none of the data will be traceable to your partner or relative personally. The investigators will use your partner's/relative's medical chart to fill in the forms with clinical data, and all this information will be treated confidentially. Some people in the AMC may access the data which is necessary to store all the coded data in the biobank correctly and to check if all future research is performed well and reliably. The investigators in the AMC are the people who have access in order to store the coded data. Other people who have insight in the data are a research monitor of the AMC and the national supervisory authorities like the health-inspection (Inspectie voor de Gezondheidszorg- IGZ). If you participate in this biobank you consent to their and the investigators' access to your partner's/relative's medical chart for the purpose of this biobank.

Research data will be stored in the biobank for 20 years, so that in the future it may be used for other research in the field of meningitis. During this period you or your partner or relative may withdraw your consent at any moment in which case the data will be taken out of the database and the materials will be destroyed.
By signing this consent form you give permission to use your partner's/relative's bodily material for any future research with a comparable purpose. On the form you can state if we may approach you again for this research.
It is possible that in the future bodily material and (coded) data will be shared with foreign research institutes outside of the European Union. In those countries the level of protection of privacy can differ from within the European Union because different rules apply. On the consent form you can indicate whether or not you give permission to send the data to countries outside of the European Union.
This biobank is approved by the Biobank Review Committee (Biobank Toetsingscommissie) from the AMC. We adhere to international guidelines for medical-scientific research.

7. Unexpected findings

It is possible that in future scientific research certain things come to light that could be of interest for your partner's/relative's health and/or the health of his/her family members. By this we mean findings that could indicate a certain disease, or a higher risk for a certain disease, which is for example caused by a genetic variation that could also occur in family members. We will inform you or your partner or relative about these kind of findings if they indicate a serious health problem or risk for which a treatment is available. We will carefully weigh the decision whether or not to inform you or your partner or relative about such a finding and we will ask a committee in our hospital to advise us on if it would be necessary to inform you. If you object to this course of events your partner or relative cannot participate in this biobank.

8. Questions

If you have any further questions about this biobank, please contact one of the investigators:

- Drs. I.E. van Zeggeren, PhD student, +31 20 5661564
- Dr. M.C. Brouwer, neurologist AMC, +31 20 5664042
- Prof. Dr. D. van de Beek, neurologist AMC, +31 20 5663647

You may also consult an independent physician, who is not directly involved in the biobank but has substantial knowledge about it:

- Prof. Dr. R.M.A de Bie, neurologist AMC, +31 20 5663445
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9. Signing the consent form

With your signature you confirm the participation of your partner or relative in this biobank. You may still withdraw your consent at any given time. The treating physician or the investigator will also sign

the form saying that he or she has explained you everything about the biobank and future research and gave you this letter.

10. More information on your rights regarding the processing of data

For general information on your rights regarding the processing of data you can go to the website of the Autoriteit Persoonsgegevens: autoriteitpersoonsgegevens.nl/privacy/persoonsgegevens. If you have any questions about your rights in this biobank you can contact the administrator. In case of questions or complaints regarding the personal data of your partner or relative you can reach out to mrs. M. Inge, data protection official of the AMC (fg@amc.amc.nl) or the Autoriteit Persoonsgegevens.

Representative consent form I-PACE biobank CRF nr: ……..

I have read the subject information form for the repesentative (version 5.4). I was also able to ask questions. My questions have been answered to my satisfaction. I had enough time to decide whether to consent for the participation of my partner/relative.

I know that participation is voluntary. I also know that at any time I may decide to withdraw my consent. I do not need to provide an explanation for this.

I know that some people may have access to all the data in order to store it correctly and verify the future research. These people include the investigators in the AMC, the health-inspection (Inspectie voor Gezondheidszorg – IGZ), the medical ethical committee of the AMC and monitors. I consent to their inspection.

I give permission for the withdrawal, storage and future analysis of my partner's/relative's data in the field of meningitis research.

I give permission to store the coded bodily material for 20 years to use this for medical-scientific research in the future.

I give permission for storage and use of the data for possible follow-up research.

I give permission to use my partner's/relative's bodily material in the future in possible research with a comparable purpose. I **do/do not** give permission to approach me again in the future (please cross out what is not applicable).

I **do/do not** give permission to share my partner's/relative's data with research institutes outside of the EU (please cross out what is not applicable).

I am aware of the fact that it is possible that during the performance of future scientific research with my partner's/relative's bodily material findings may come to light that could be important to him/her or his/her family's health and that I will be informed about these findings by the treating physician.

I give permission for my partner's/relative's participation in the abovementioned biobank.

Name of study subject :

Name of legal representative:

Signature: Date:__ / __ / __

I declare that I have fully informed this/these person(s) about this biobank.

If information comes to light during the course of the biobank that could affect the legal representative's consent, I will inform him/her of this in a timely fashion.

Name of investigator (or his/her representative):
Signature: Date:__ / __ / __

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