Seropositivity and Adverse Birth Events in Migrants From Bilharzia-endemic Areas

NCT03158298

Study: **Impact of Schistosomiasis in pregnancy on Newborn Birth Weight (Bilharzia study)**

Fax number: + 49 3641 9 324652 (Primary study center in Jena, Germany)

Study Center: .....

Investigator: .....

Informed consent form

.....
Full Name of pregnant woman in block letters

Date of Birth ..... Patient identification number.....

I have, in a personal interview by the investigator

.....
(Doctor's Name/Investigator)

been explained in detail and understand the objectives and the course of the study, opportunities and risks of investigations, my rights and responsibilities, and the voluntary nature of participation. I also have read and understood the text of the Information Sheet for the pregnant woman and the Data Protection Statement printed below. I have had the opportunity to speak with the investigator on the implementation of the study, and all my questions were answered satisfactorily.

Please document additional questions from pregnant women or other aspects of the consent conversation below:

Data Protection

I declare that I consent to the collection, processing, storage and transmission of personal data, in particular information about my health, in the context of the Schistosomiasis study. My data may be encrypted through the Center for Clinical Studies at the Jena University Hospital, Germany, where it will be stored electronically.

I am aware that I can stop participating in the study at any time, for any reason. In case of revocation of my Consent I hereby agree that the data stored up to that point may continue to be used.

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I agree to participate in the Bilharzia study.

I have had ample time to decide.

I have been advised that my participation in the above study is voluntary and that I have the right to terminate it at any time and without giving reasons, without incurring disadvantages to me.

I have received a copy of the Information Sheet for the pregnant woman and Consent form. A copy will stay in the maternity hospital notes.

....
Full Name of **pregnant woman** in block letters

....
Date Signature of **pregnant woman**

I have conducted the informed consent discussion and obtained the consent of the pregnant woman above.

....
Name of **consenting doctor** in block letters

....
Date Signature of consenting **doctor**

additional consent for further use of my study data and surplus samples for research purposes

....
Full Name of **Pregnant women** in block letters

Date of birth ..... Patient identification number.....

In addition to the aforementioned study, I can decide on the possibility of further use of my data collected in the study and materials (blood and afterbirth/placenta). With my signature I transfer ownership of the materials to the investigator or the primary study center at the Jena University Hospital, Germany. In this regard, I have no personal or financial claims. I renounce the confirmation of results obtained with the carrying out further research based on the data and materials.

I agree as follows, that the **data** collected in the study and **materials** for **more research into infectious diseases** may be **used, and thus passed on to other researchers.**

☐ YES, consent for further scientific use and dissemination of the residual sample (Blood), also to external partners
☐ YES, consent to the scientific use and dissemination of the afterbirth (Placenta), also to external partners
☐ YES, consent for further scientific use and dissemination of data, also to external partners

☐ NO, no further use and no dissemination of residual sample (blood) and afterbirth (placenta)

☐ NO, no further use and no dissemination of data

....
Date Signature of **pregnant woman**