May 2024, Amsterdam, The Netherlands

Dear Madam,

This letter is to inform you about a medical study in which you can participate. You are receiving this letter because you have a diagnosed bleeding disorder and experienced heavy menstrual bleeding. We understand the concerns that you might have or have had.

Often, the perception of heavy menstrual bleeding results from harmless causes, such as an altered hormonal status or due to myomas (about 90-95%). But, in a small number (about 5-10%) the coagulation is not functioning properly, and problems may arise.

This medical study assesses how we can best take care of women e.g people who menstruate, with bleeding disorders. We would like to invite you to participate in this study. Participation is voluntary. To participate, your signed informed consent is required.

Before you decide whether you want to take part in this study, you will be given a short explanation about what the study involves. Please take your time to read this information and ask the principal investigator Heleen Eising (gynecologist) if you have any questions. You can also discuss it with your partner, friends, or family.

Participation in a medical study *(Summary)*: 'Study of the route to diagnosis in women with bleeding disorders in Europe; semi-structured interviews using a specific artwork (poetry/music)'

European Haemophilia Consortium (EHC) (www.ehc.eu) , Gelre Hospitals (www.gelreziekenhuizen.nl) and non-profit organization "Vertelkracht" (www.vertelkracht.com) are participating in this study that assesses how we can take best care of women with bleeding disorders and the route to diagnosis. We would like to inform you about this study which will be carried out in various European countries. For this study, a total of at least 30 participants are required. The Local Ethics Review Committee of Gelre Hospitals, The Netherlands has approved this study (study number: 2024-16).

Why participate?

With this study, we hope to find out which experiences of women's symptom recognition, appraisal and management of bleeding disorders would benefit from personal medical or socioeconomical pathways and which experiences can await the regular pathway. Your participation will help us to improve current care.

Background and purpose of the study

A bleeding disorder can contribute to excessive or prolonged bleeding during childbirth, trauma or surgery and a higher chance that these women need blood transfusions compared to those without a bleeding disorder. Heavy menstrual bleeding (HMB) can be the first symptom of **a** bleeding disorder. However, women with a bleeding disorder may experience various bleeding symptoms in addition to HMB, with which women may present at the outpatient clinic. An overall bleeding history besides careful listing and an obstetrical-gynecological history is an important factor in reducing diagnostic delay in bleeding disorders and could be crucial in optimizing management. Also, diverse samples in

bleeding disorders research in women are lacking with minimal data on socioeconomic status (SES). Until we are able to examine the patients' diagnostic journey in a culturally sensitive manner, accounting for the potential variation in the pattern of seeking medical attention, we will be unable to make relevant social conclusions based on the diagnosis of bleeding disorders alone. In this study we investigate if personal pathways to diagnosis of bleeding disorders in women across Europe might be useful. Women with laboratory confirmed bleeding disorders are invited to participate.

What will participation mean for me?

- One online zoom meeting (45-60 minutes):
- **Interviews questions** based on recent literature will be asked (30 minutes)
- **a site-specific artwork** (poetry/music) will be used to reveal different perspectives in addition to the interview questions (20 minutes)
- In order to assess how you are doing (Demographics and SES) and have experienced the study, we will ask you to fill out two online questionnaires: initially and then six weeks after the online meeting.

The data collected is always processed confidentially.

Do you have any questions?

If you have any questions, please contact the investigator. If you would like independent advice about participation in this study, please get in touch with the independent gynaecologist Karien Hack (k.hack@gelre.nl). She will be well familiarised with the study but has no affiliations with it.

Signing the informed consent form

When you are ready you will be asked to decide about participation in this study. If you consent, you will be asked to confirm this in writing on the corresponding consent form. With your written consent, you indicate that you have understood the information and agree to participate in the study. Both you and the investigator will receive a signed copy of this consent form.

Yours sincerely,

On behalf of the study team,

Heleen Eising, Gynecologist and principal investigator Gelre Hospitals,Apeldoorn, The Netherlands

Email: h.eising@gelre.nl Phone: (031)558446503

Consent form 'Study of the route to diagnosis in women with bleeding disorders in Europe; semi-structured interviews using a specific artwork (poetry/music)'

- ○ I have read the information letter. I was also able to ask questions. My questions have been answered sufficiently. I have had enough time to decide whether or not to participate.
- ○ I understand that participation is voluntary. I also know that I may decide at any time to not participate or to stop participating in the study, without having to provide any reason.
- ○ I know that some individuals could have access to my data. Those people are listed in this information letter.
- ○ I give consent to collect and use my data for answering the research question in this study.
- ○ I give consent to send my contact details to the coordinating investigator in the Gelre Hospitals in order to send the digital questionnaires.
- ○ I give consent to use the recorder Zoom online meeting in a professional documentary/module to stimulate meaningful discussions of the route to diagnosis and treatment in women with bleeding disorders in Europe for the study purposes such as stated in this letter.

I consent to participation in this study

Name

Phone

Email

Signature:

The undersigned investigator declares that the person mentioned above has been fully informed about the above mentioned study. If during the course of the study information becomes available that could influence the decision of the patient, I will inform her of this.

Name

Signature: