Participant Information Sheet

We are inviting you to participate in a research study exploring food choice across the menstrual cycle in a heavy menstrual bleeding population. Before you decide whether you would like to participate, please take the time to read the following information thoroughly and let us know if you have any queries (jody.salton@bristol.ac.uk).

What does this research involve?

This is a multi-part online study. Whilst the total study length will vary depending on your menstrual cycle, we predict that your participation will total around 2 hours in duration. Below is a step-by-step breakdown of what you will be doing.

Step 1 - After reading this information sheet and completing the consent form, you will be sent an email containing:

- Your participant number that you will use throughout the study
- Information on the finger-prick kits and instructions on how to use them
- A link that you can use to book a brief Teams call with the researcher
- A form to fill in that will ask you about your most recent menstrual cycle, as well as information required for the health kits to be sent to your home (first and last name, date of birth, email address, home address)
- Directions for downloading the Samply app. We ask that you try to download and set up the app before you have the call with the researcher (so that if you are having difficulties with the setup, the researcher can help you in the call)

Step 2 – You will have a 15-minute Microsoft Teams call with the researcher. Part of this call will involve:

- Checking that the Samply app is downloaded and working
- Running through examples of the food choice tasks that you will be doing in the study
- Showing what the finger-prick kits will look like
- The opportunity for you to ask any questions you have about your participation

Step 3 – Once fully signed up to the study, you will receive daily notifications via the Samply app (at a time you decide). When you click on the notification, it will take you to a Microsoft Forms that will ask you if you are currently menstruating. Engaging with

these daily notifications helps the researcher to understand when to complete the main tasks.

Step 4 – The evening before you should complete the finger-prick test, you will receive a Samply notification that takes you to brief instructions about what you will be doing the following day.

Step 5 - In the morning, you will receive a reminder notification to complete the finger-prick test. This should preferably be done before you have had anything to eat that morning. The kits should be mailed back to the provider on the day that they were completed, either via postbox (before collection time for that day) or post office (before mid-day).

Step 6 – In the evening, at a time you determine to be before your evening meal, you will receive a link to a short (15-minute) food choice task.

Step 7 – The following evening, at a time you determine to be before your evening meal, you will receive a link to a second short (15-minute) food choice task.

(You will complete steps 4 – 7 at two points during this study: once when you are menstruating, and once when you are not.)

Note: The food choice tasks will also include questions about your current mental and physical wellbeing. These questions are taken from established questionnaires commonly used for scientific research. If you have any questions or concerns about what you will be asked during the study, please contact the researcher (jody – jody.salton@bristol.ac.uk), who will be happy to share these questions with you at any point. Further to this, you are free to withdraw at any point within the study (up until you provide final consent) without explanation or penalty. More information on this is available in the "What will happen if I don't want to carry on with the study?" section.

Step 8 – At the end of the study, you will be asked to complete some questions about yourself (e.g., age, gender identity, ethnicity), your menstruation (e.g., symptoms, age of menarche, cycle duration), and your eating behaviour (e.g., how often you eat the test foods, how pleasant you'd find the foods, whether you take any supplements). Many of these questions have a prefer not to say option, should you not wish to disclose this information.

Step 9 – Following completion of the full study, you will receive a full debrief about the aims, provide final consent, and you will have the option to receive your health reports from the finger-prick kits.

Who can take part in this study?

To take part in this study, you should:

- Be aged 18-45

- Be a UK resident
- Be familiar with, and willing to consume, all of the test foods (steak, lamb, chicken, beef burger, macaroni cheese, pizza, roast beef, battered cod, beef bolognese, pork sausages, gammon steaks, halloumi)
- Be an omnivore (e.g., consume meat within your current diet)
- Not have a diagnosis of endometriosis or PCOS
- Experience heavy menstrual bleeding (meeting a minimum of two of the following criteria over the past 12 months):
    - Flooding through clothes or onto bedding
    - A need for frequent changes of sanitary towels or tampons (every 2 hours or less, or 12 sanitary items per day)
    - Need for double sanitary protection (e.g., a tampon and sanitary towel)
    - Passing large blood clots
- Have a menstrual cycle that meets the following:
    - Experienced at least 8 menstrual bleeds (periods) in the past 12 months
    - Duration of at least 12 days between menstrual bleeds
    - Not experienced bleeding in between menstrual bleeds
    - Experience a menstrual bleed of at least 3 days in duration
- Not currently pregnant or trying to conceive
- Not currently experiencing an eating disorder or disordered eating
- Own a smartphone with an internet connection and either Google play or the App store and be willing to download the Samply research app, which can be found here:
    - Google play: Samply Research - Samply Research on Google Play
    - App store: Samply Research - Samply Research on the App Store
- Furthermore, because of the finger-prick kits, you should not have:
    - A bleeding disorder or the use of a medication that increases the risk of bleeding.
    - A skin disorder or other conditions that may result in slower healing.
    - Impaired circulation, particularly in relation to the upper limbs.
    - A known condition (e.g., diabetes, cancer) or taking medication (e.g., immunosuppressants), which elevates the risk of infection
    - A known blood-borne disease (e.g., hepatitis B/C, Human Immunodeficiency Virus).
    - A fear of blood
    - A history of fainting, an arrhythmia, or any other applicable symptoms

Do I have to take part?

Your participation in this study is entirely voluntary. This also means that you are free to withdraw at any time during the study without giving a reason. Should you wish to withdraw your participation from the study at any point, the procedure to do so is outlined below in “What will happen if I don’t want to carry on with the study?”. Once

you have finished the study, you will be given full details of the aims and objectives of the research and asked whether you are happy for us to use your data in our analyses. Once you have given this "final consent", we are unable to withdraw your data since it will be anonymous, and there will be no way to identify the data you have contributed.

What are the benefits of taking part?

You will receive a £25 Amazon voucher in exchange for completing the full study! Should you only complete part of the study, you will still receive payment that is proportionate to the amount of the study you completed. In addition to this, you will have the opportunity to receive two health reports (from your finger-prick tests) that detail 4 biomarkers of your health at two time points. Finally, as a thank you for completing all parts of the study, you will have the opportunity to be entered into a prize draw for one of two additional £50 Amazon vouchers.

You may also find the research area interesting, and learn more about eating behaviour by taking part!

What are the possible risks of taking part?

Although we endeavour to minimise all risks, there is always a chance that you may feel uncomfortable answering some questions. For many of these questions, there is the option for you to respond with “prefer not to say”.

Additionally, in most psychology experiments, to preserve the scientific validity of research questions, it is not ideal to disclose all the factors and issues under study. This is because extensive prior knowledge of all the research questions may influence/bias the way you think, behave and react during the survey. As with all studies, we will provide you with a complete account of what we are interested in and give you the opportunity to ask questions when you complete the study.

There is also a small risk associated with the finger-prick kits, such as bruising, prolonged bleeding, and, in rare cases, infection. Whilst the risk is low, upon signing up to the study, we will provide you with thorough instructions about how to use the kits to minimise any risks. In addition to this, from the finger-prick kits, you may find out new information about your health. Whilst we do not expect these results to cause distress, it is important to highlight that receiving your health reports is entirely optional upon finishing the study. Furthermore, the tests you are completing as part of this study are not diagnostic tools. They are intended for research purposes only. If you have any concerns about your health as a result of this study or your personalised reports, we strongly encourage you to contact your health provider for professional advice.

Should you feel uncomfortable and wish to withdraw your participation from the study at any point, the procedure to do so is outlined below in “What will happen if I don’t want to carry on with the study?”.

What if there is a problem?

If you have a question or concern about any aspect of this study, you should speak to the researcher, who will do their best to answer your questions. You can contact the researcher via email (jody.salton@bristol.ac.uk). At any point, if you are unhappy and wish to speak to the research supervisor, please contact Professor Jeff Brunstrom (Jeff.Brunstrom@bristol.ac.uk). If you have any further concerns related to your participation in this study, please direct them to the School of Psychological Science Research Ethics Committee via the Research Governance Team (research-governance@bristol.ac.uk)

What will happen if I don't want to carry on with the study?

You are free to withdraw from the study without an explanation or penalty at any time up to the point at which you provide final consent at the end of the study. To withdraw your participation, just let the researcher know that you would no longer like to take part in the study. You will be asked whether you wish for your data to be deleted (you may need to provide your participant number), or whether you are happy to sign final consent and have your data kept for analyses where possible. If you wish for your data to be deleted, any information you have provided that is stored by the University of Bristol will be discarded before analysis. Information on how your data is stored by Samply and the finger-prick kit providers, and how to request it to be deleted, is detailed below ('What will happen to data collected from this study'). After you have finished the study, your data will be anonymised so it will no longer be possible to withdraw it.

What will happen to the data collected from this study?

As part of this study, you will be asked to use the Samply Research App. This app will not store any of your study data (this will be stored securely on the University of Bristol server). However, when you sign up to the Samply Research App, you will need to provide some personal information (name and email address). This information will be stored by Samply Research. Please read Samply's privacy policy to check you are happy with this (https://samply.unikonstanz.de/docs/policy). Once the study has finished, you can delete your Samply Research account, which will remove your personal information.

The finger-prick kits are provided by One Day Tests, which is owned and operated by Sussex Pathology Limited. Sussex Pathology requires the following information from you to send your finger-prick kits and analyse your blood sample: first and last name, biological sex, date of birth, email address, and home address. Information on how Sussex Pathology will treat this data, as well as the data from your finger-prick tests, can be found via this link: https://onedaytests.com/policies/privacy-policy. Importantly, should you wish to request that Sussex Pathology delete your data following your participation in this study, you should contact the data protection officer at

hello@onedaytests.com. This can be done at any point, even after your data held by the University of Bristol has been deleted.

Your involvement in the study, outside of what is highlighted above, will remain confidential. This information will only be available to research staff and national bodies which monitor whether research studies are conducted properly. Your study data will be anonymised following completion of the study. This means that it will be given an identification number, and any identifying information about you will be removed. Therefore, it will not be possible to identify you by name from any aspect of documentation or reporting for this research study. At the end of the study, your anonymous data will be made "Open Data". This means that it will be stored in an online database so that it is publicly available. Open data means that data are made available, free of charge, to anyone interested in the research or who wishes to conduct their own analysis of the data. We will therefore have no control over how these data are used. However, all data will be anonymised before it is made available, and therefore, there will be no way to identify you from the research data. Open access to research findings and access to data is considered the best research practice and is a requirement of many funding bodies and journals. As a large proportion of research is publicly funded, the outcomes of the research should be made publicly available. Sharing data helps to maximise the impact of investment through wider use and encourages new avenues of research.

What will happen to the blood samples I provide?

Once you have posted your blood samples, they will be received by the Sussex Pathology Laboratory. At the laboratory, they will exclusively test for the biomarkers requested (which you will be informed of upon completing the study). No other analyses will be carried out on the sample, including no genetic testing. Any blood sample you provide will be destroyed 7 days after it arrives at the laboratory.

Who has reviewed the study?

The name of the ethics committee which reviews our applications is the School of Psychological Science Research Ethics Committee (which is a subcommittee of the Faculty of Life Sciences Ethics Committee). Ethics reference I.D. 27342.

Data Protection Privacy Notice: What are my rights under the data protection legislation?

The University of Bristol is the data controller for the personal data collected for this research project. Your personal data will be processed for the purposes outlined in this notice. The legal basis for processing your personal data will be that this research is a task in the public interest, that is the University of Bristol considers the lawful basis for processing personal data to fall under Article 6(1)(e) of GDPR (public task) as the

processing of research participant data is necessary for learning and teaching purposes and all research with human participants by staff and students has to be scrutinised and approved by one of The University of Bristol's Research Ethics Committees.