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Informed Consent Form (ICF)

BASIC TEMPLATE

Note: An ICF is an official document with legal impacts. Each institution has their own template which is pre-approved typically by the legal team and that template should be followed. This document is purely created for educational purposes. The distribution or use of this document in any manner without the owner's prior approval is not authorized.

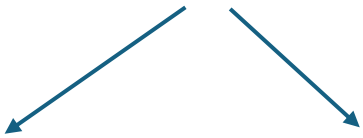
COVER PAGE:

The cover page contains the most essential parts of an ICF, such as the full study title, a brief title or acronym to refer to the study, name of study doctor/PI, Emergency Contact Number for study team or study doctor (Phone), regular contact for study team (email of study coordinator), name of Study Sponsor, etc. Below is an example

Study Title	Full title as it appears on REB submission/protocol
REB Approval#	Assigned by institutional REB
Study Doctor	Name & Contact
Emergency Contact	24/7 contact for a study staff/nurse/investigator

FOOTER:

The footer of every page of the ICF must contain the version date and page number. It is ideal to paginate as 'page X of XX' so participant knows if they have missed a page in error.



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Notes: The introduction describes the study to the participant in simply terms. The language recommendations are for 4th -6th grade level language in simple English without too much jargon. This section must describe the disease model in question, why this participant has been invited to participate in this study, what is the CURRENT standard of care for that condition, where the LIMITATIONS in knowledge currently are, what this EXPERIMENTAL drug or procedure is trying to achieve.

INTRODUCTION (example):

You are being invited to take part in a research study examining how chocolate consumption may influence various aspects of human health. Before you decide whether to participate, it is important that you understand why the research is being done and what your participation will involve. This form provides information to help you make an informed choice.

Researchers are interested in learning more about how different types and amounts of chocolate may affect factors such as mood, energy levels, and general well-being. While chocolate is widely consumed, its potential health impacts are not fully understood. Your participation will help contribute to a better scientific understanding of these effects.

Please read the following information carefully. You may ask questions at any time. Taking part in this study is entirely voluntary, and you may choose not to participate or to withdraw at any point without penalty.

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Note: This following section should describe WHY the study is being done. Is it aiming to bring better cute? Better pain management? Improve quality of life? Increase life expectancy? Show that shorter duration of treatment can achieve the same as an existing drug? Find an easier route of therapy?

Purpose of the Study (example)

The purpose of this study is to explore how consuming different types and amounts of chocolate may affect factors such as mood, energy levels, cognitive performance, and general well-being. Although chocolate is widely consumed, its health impacts are not fully understood. This study aims to contribute to a better scientific understanding of these effects.

Note: This section must report any conflict of interest for the institution or the research team or study doctor.

CONFLICT OF INTEREST:

The study investigator, The Brown Feminist, has accepted funds from Chocolate International as speaking fees at their annual conference in 2025.

OR

There are no conflicts to report for this study.

WHAT PARTICIPATION INVOLVED:

If you agree to participate, you will be asked to:

- Complete a brief questionnaire about your general health and dietary habits.
- Consume a specified type and amount of chocolate *[describe: e.g., dark, milk, placebo]* over a *[duration]* period.
- Attend *[number]* study sessions, each lasting approximately *[time]*.

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- Complete assessments such as mood surveys, cognitive tasks, or physiological measurements (e.g., heart rate, blood pressure), depending on the study design.
- Report any changes in your well-being during the study period.
  You may withdraw at any time without penalty.

WHY YOU HAVE BEEN INVITED

You are being asked to participate because you are an adult aged *[age range]* who meets the eligibility criteria for this study. You do not need to be a regular chocolate consumer to take part.

POTENTIAL RISKS OF PARTICIPATION

This study involves minimal risk. Possible risks include:

- Mild digestive discomfort or sensitivity to chocolate ingredients (e.g., caffeine, sugar, dairy).
- Temporary changes in mood or energy levels.
- Allergic reactions if you have known sensitivities to chocolate or its components.
- Mild fatigue from completing questionnaires or cognitive tasks.
  If you have allergies or dietary restrictions, please inform the research team before participating.

POTENTIAL BENEFITS

You may not receive direct personal benefits from participating. However, your participation may help researchers better understand how chocolate affects human health, which could inform future dietary recommendations and health research.

Note: This segment can describe if the participations will find out test results (the tests will be done free of charge), they can get free consultations from a nutritionist, they will get compensation or otherwise.

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CONFIDENTIALITY

Your privacy will be protected throughout the study. Specifically:

- Your data will be identified by a participant code, not your name.
- All information will be stored securely on password-protected systems.
- Only authorized members of the research team will have access to your data.
- Study results may be published or presented, but your identity will never be revealed.

VOLUNTARY PARTICIPATION & RIGHT TO WITHDRAW

Participation is entirely voluntary. You may choose not to participate or to withdraw at any time without affecting your relationship with *[institution]* or access to services. If you withdraw, you may request that your data be removed from the study.

DATA SECURITY, CONFIDENTIALITY, RETENTION

Note: It must be disclosed how much risk there is for a potential future data breach and all the steps being taken to minimize breach of private health data of participant. Where cyber data is stored (e.g. in secure servers, password protected), how long they will be stored, when they will be deleted, etc. should be described. How de-identification or anonymization take place prior to publication should be described. If data will be linked to other datasets using identifiers, of genetic data or other clinical samples will be retained for other studies in the future, all must be disclosed.

TIMELINE

The timeline is an important element particularly for the participants. It should describe the total duration of the study, including the number of in-person or vistual patient visits,

number of surveys and other commitment by the participant, timeline of data collection, expected timeline of analysis and publications, when they can find out about their randomization arm, final results, etc. Expected start and end dates should be mentioned.

COMPENSATION

[Describe compensation, reimbursement for travel, or state that there is none.]
Compensation is not dependent on completing the study.

Questions or Concerns

If you have questions about the study, please contact:

Principal Investigator: *[THE BROWN FEMINIST]* **Email:** *[Email]* **Phone:** *[Phone]*

If you have concerns about your rights as a participant, you may contact:

> **Research Ethics Board:** *[REB/IRB contact information]*
> **Consent Statement**

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By signing below, you confirm that:

- You have read and understood the information in this consent form.
- Your questions have been answered.
- You voluntarily agree to participate in this study.
- You understand that you may withdraw at any time.

Participant Name: _____

Signature: _____

Date: _____

Note: Some studies will allow substitute decision makers (SDM) to content on behalf of patients, this must be clearly mentioned here. Some participants require an interpreter due to language barrier and so a witness and interpreter must also sign alongside the participant.

Name of person conducting consenting discussion (research staff/pi):

_____

Signature: _____

Date: _____