



Human Subjects

Office of Research

UNIVERSITY OF GEORGIA

Moving STUDY (Portal Old System) to PROJECT (Portal New System)

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Old System vs New System

Old System

- Parent ID – **STUDY**
e.g., **STUDY00001122**
- Modification ID – **MOD**
e.g., **MOD00001234**

New System

- Parent ID – **PROJECT**
e.g., **PROJECT00001122**
- Modification ID – **VERSION**
e.g., **VERSION00001234**



Old System vs New System

Old System

New System

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Hello, Maricla Di

My Inbox Meetings Library SPA Access IRB

IRB Meetings IRB Reports IRB Settings

IRB > Caffeine Mouth Rinse Study Admin View Help

Submission Options

Caffeine Mouth Rinse Study

Protocol ID#STUDY00004792

Primary Contact: Jamie Cooper

Detailed state: Approved

STUDY00004792

IRB Coordinator: Maricla Dilan

Parent Protocol:

2018 Settings Enabled: Basic

Approved Date: 5/6/2020

Begin Date: 5/6/2020

Expiration Date: 5/6/2023

External IRB Information:

External IRB Expiration Date:

Project Follow Ups

Name	ID	Type	Status	Created Date	Last Snapshot
Caffeine Mouth Rinse Study	MC00000672	Modification	Approved	12/11/2018 10:30 AM	Snapshot
Caffeine Mouth Rinse Study	MC00000794	Continuing Review	Approved	3/20/2020 9:49 AM	Snapshot
Caffeine Mouth Rinse Study	MC000010518	Continuing Review	Discarded	4/7/2023 11:05 AM	Snapshot

Study Team Actions

- Create Modification
- Create Continuing Review
- Close Study
- Assign Primary Contact
- Manage Guest List
- Add Comment

Create Progress Report

All Study Activities

Mod/CR Actions

Report Problem/Advise Event

Documents

Activate Windows
Go to Settings to activate Windows.

Create Modification

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Page for Mary Prater > Nutritional Effects of Different Doses of Cottonseed Oil in Humans

My Inbox Meetings Library SPA Access Site Admin

Project Editor

Nutritional Effects of Different Doses of Cottonseed Oil in Humans

ID: PROJECT00006633

Principal Investigator: Cooper

Reviewer: Dilan

Funding Source:

Committee: IRB 1

Review Category:

Contacts: Prater

Review Level:

Approved Date: 11/18/2022

Expiration Date: 11/18/2023

Project Status: Approved

Activities

- Create Version
- Submission Checklists
- Administration
- Add Public Comment
- Add Internal Comment
- Version Approved
- Finalize Documents
- Add Additional Readers
- Submission PDF
- Take Snapshot

Documents

Draft	Category	Date Modified
Informed consent form	Consent Form	3/15/2023 2:58 PM
Preliminary Screening Consent Form	Consent Form	10/28/2022 5:06 PM
Phone and email scripts for after preliminary screening	Consent Form	11/7/2022 5:50 PM
Data collection sheet pre-intervention visit (v1)	Materials for Data Collection	10/28/2022 4:50 PM
Online preliminary screening and consent form	Materials for Data Collection	11/30/2022 6:49 PM
Perceived Stress Scale (PSS)	Materials for Data Collection	10/28/2022 4:43 PM
Data collection sheet week-1 visit (v2)	Materials for Data Collection	10/28/2022 4:52 PM
Sensory Evaluation form	Materials for Data Collection	10/28/2022 4:45 PM
NIH Questionnaire.docx	Materials for Data Collection	10/28/2022 4:31 PM
IRB Record.docx	Materials for Data Collection	10/28/2022 4:45 PM
Data collection sheet week-2 visit (v3)	Materials for Data Collection	10/28/2022 4:52 PM
Data collection sheet week-3 visit (v4)	Materials for Data Collection	10/28/2022 4:53 PM
Data collection sheet post-intervention visit (v5)	Materials for Data Collection	3/15/2023 2:53 PM

Create Version

Why Are We Moving STUDY to PROJECT?

In the Continuing Review (CR) form, the PI indicates that enrollment is still open and data collection is ongoing. And, when queried, the PI indicates that active enrollment and data collection would continue for the next year or more.

Exception: Remaining study activities are limited to analysis of private identifiable data and will be closing in a year or so

- Modification does not sync to the Parent Study in the Old system
- There is no way to date-stamp the consent form if PI is still collecting data



What Are Review Options?

1. Continuing Review (and modification review, as applicable) under the old common rule

OR

2. Re-review (like new) under the new common rule



What is the difference now since the new Common Rule?

- Key Information is now required in the consent form [45 CFR 46.116 (a)(5)(i)]
 - It is designed to facilitate prospective participants' understanding of the research and the reasons why one might wish to participate or not participate in the research study
- Eligibility screening requires consent prior to the revision of the Common Rule



What is the difference now since the new Common Rule? (Cont.)

- Under the revised Common Rule, an IRB may approve a proposal for the PI to obtain information (or biospecimens) to screen, recruit, or determine eligibility of prospective subjects for a research study without informed consent [45 CFR 46.116 (g)]
 - Waiver requirement of informed consent for these types of activities has been removed
- This is applicable if:
 - (1) The information is obtained through oral or written communication with the subject (or the subject's legally authorized representative)or
 - (2) Identifiable private information (or identifiable biospecimens) are obtained by accessing records (or stored identifiable biospecimens). This change harmonizes with FDA

IRB Review for CR of STUDY now PROJECT

IRB will still have to apply the pre-2018 Common Rule until the old study is closed since this study was approved under this rule



Continuing Review

(45 CFR 46.109)

1. Number of subjects accrued
2. Unanticipated problems (or adverse events)
3. Withdrawal of subjects
4. Complaints about the research
5. Relevant Information – especially about risk
6. Copy of current informed consent
7. Modifications or amendments



Recap for the study for review

Previous IRB Reviews

- Approved - **6/28/17; 5/6/20**
- Continuing Review – **3 years**
- Risk Determination – **Minimal**
- Waiver of Requirements to Document Informed Consent (signed consent) – **screening part**
- #Participants Requested: **32**
- #Participants Enrolled: **11**

What we will review now

- Continuing Review
 - Enrollment is open
 - Data collection is ongoing
- Modification Request:
 - Removing the 2 students who left UGA
 - Updating protocol and study materials (i.e., flyer, screening consent, consent form) to reflect this change



Helpful Links/Resources:

- [Revised Common Rule \(45 CFR 46\)](#)
- [Consent requirement for Key Information: 45 CF 46.116 \(b\)\(5\)\(i\)](#)
- [General Waiver or Alteration of Consent: Screening, recruiting, or determining eligibility \[45 CFR 46.116 \(g\)\]](#)
- [Review of Modifications – UGA-HRP-058](#)



Thank you!



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