Human Subjects
Office of Research
UNIVERSITY OF GEORGIA

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

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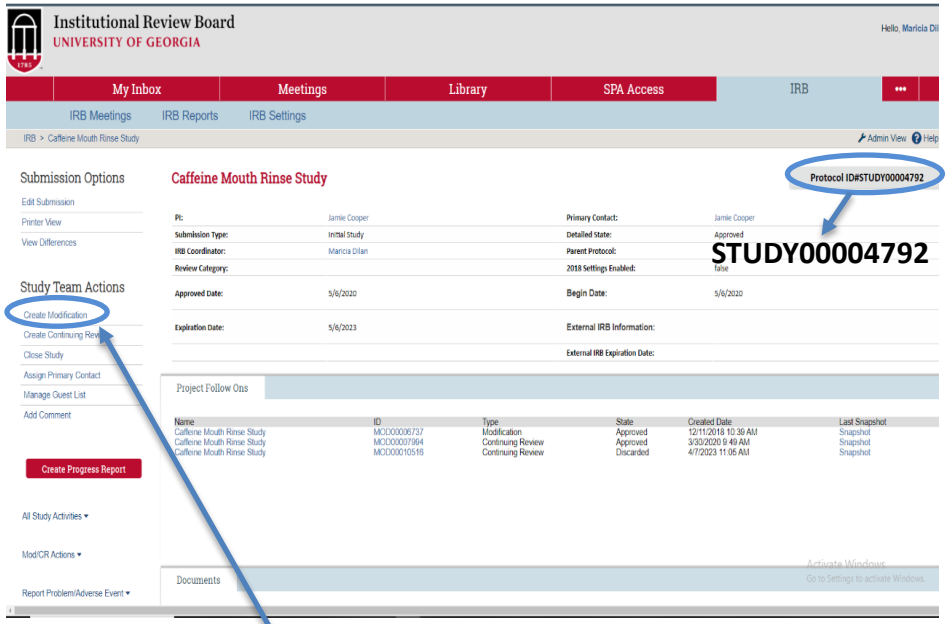
Old System vs New System

Old System	New System
• Parent ID – STUDY e.g., **STUDY00001122**	• Parent ID – PROJECT e.g., **PROJECT00001122**
• Modification ID – MOD e.g., **MOD00001234**	• Modification ID – VERSION e.g., **VERSION00001234**

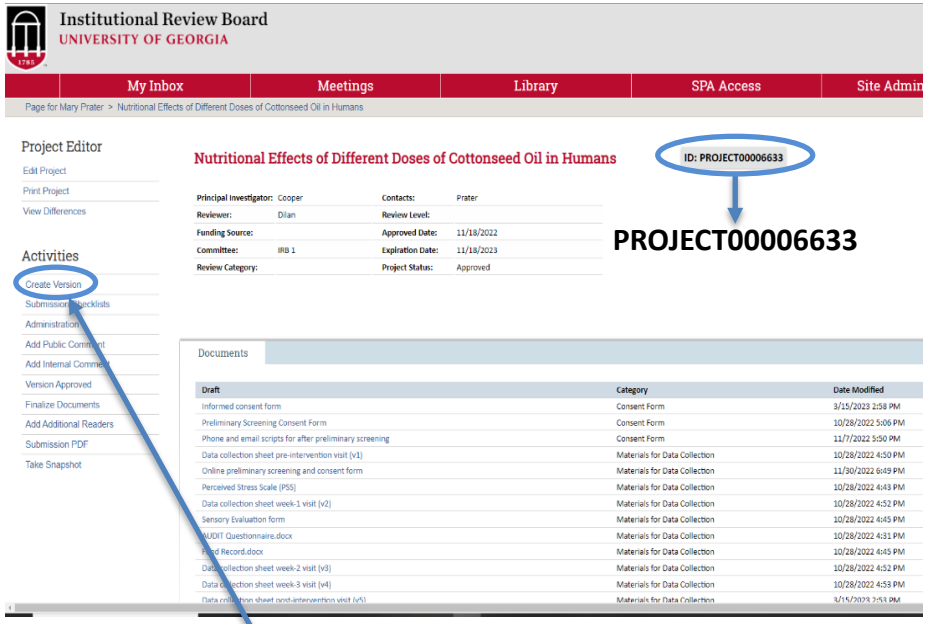
Old System vs New System

Old System



Create Modification

New System



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!