Human Subjects
Office of Research
UNIVERSITY OF GEORGIA

Moving STUDY (Portal Old System) to PROJECT (Portal New System) and Memory Review

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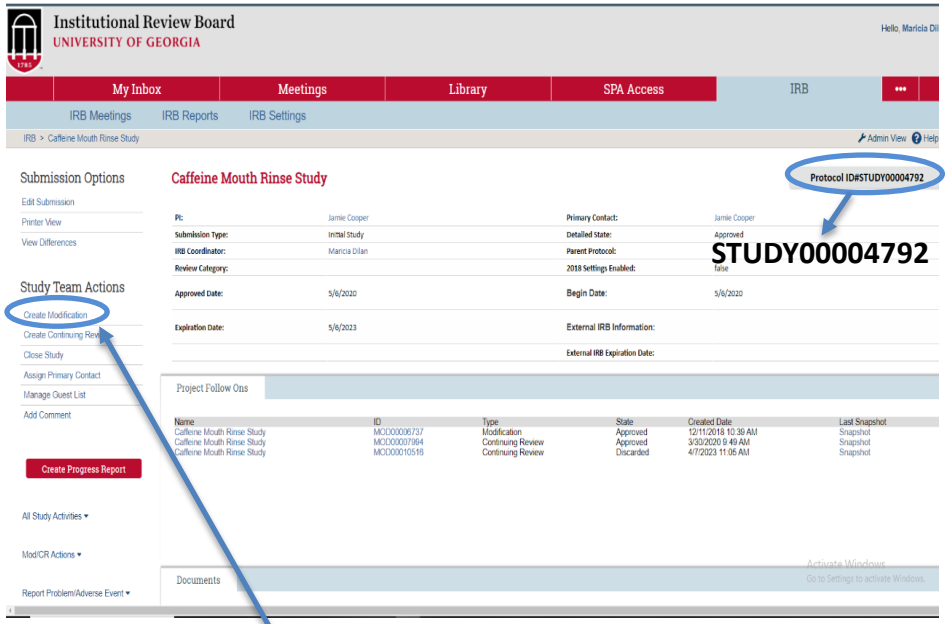
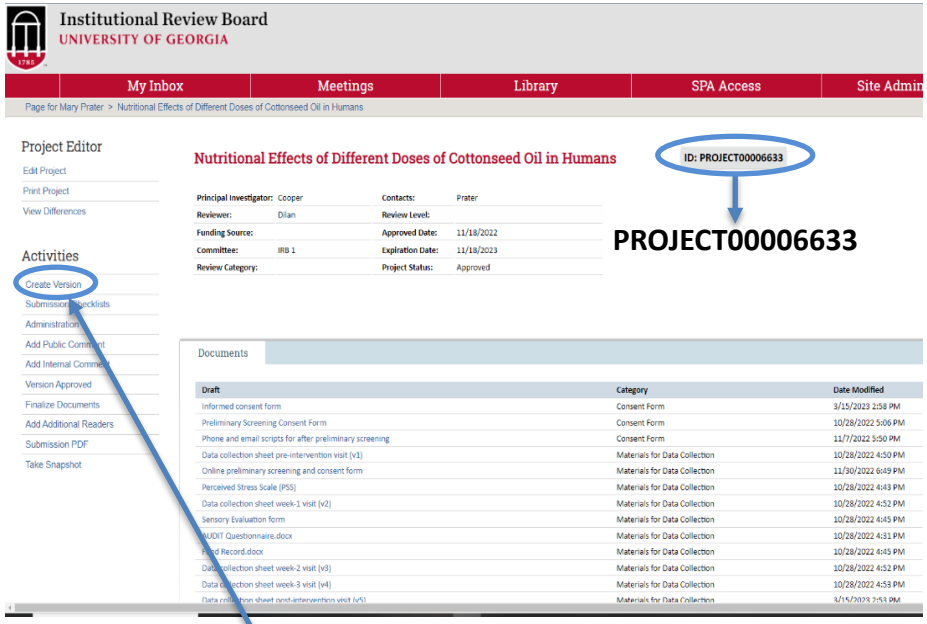
Old System vs New System

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

OR

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

NOTE: For an old study, UGA IRB will still have to apply the pre-2018 Common Rule until it is closed since the study was approved under this 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

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

Memory Review

Study 1 – Memory Review

1. Is the training of research staff sufficient to reduce risk for the blood draw procedure? April 26, 2017 IRB 2 Minutes
2. Should a discussion about moving of the IV catheter to another arm or to a different location of the same arm be added to minimize the risk of phlebitis or superficial vein thrombosis? May 15, 2020 IRB 1 Minutes
3. The submission does not specifically state where the analysis of the blood will take place. If not in a UGA lab, the lab must be identified by name and Material Transfer Agreement (MTA) or other service contract added to documentation
    - This is important to ascertain if the lab is CLIA-certified as this impacts the IRB review of the team's proposal to return individual results to participants

Study 1 – Memory Review (cont.)

4. Is 30 the number needed per the power analysis? If so, the enrollment goal should be adjusted to account for screen-fails and attrition

5. Will parking passes/reimbursement be provided? If not, any costs the participants may encounter should be described in the consent

Study 2 – Memory Review

1. Is the reading level appropriate for the target participants?
2. Risk concern comes from previous discussions of this submission when it was deferred at earlier meetings (before the noncompliance was discovered)
   - Initial determination for another project related to this was **minimal risk** since the children can self-moderate the exercise intensity. The exercise tests are common physical educational activities (August 2021 IRB 1 Minutes)
3. Is 1 person enough to monitor 20 participants?
4. Will parking passes/reimbursement be provided? If not, any costs the participants may encounter should be described in the consent

Study 3 – Memory Review

1. Is 56 the number needed per the power analysis? If so, the enrollment goal should be adjusted to account for screen-fails and attrition
2. What is the amount of encouragement that will be given to the participants. Will this be gentle encouragement, or will investigators push the participants? (April 21, 2017 IRB 1 Minutes)
3. Who will be administering the exercise? Will the PI be always present?
4. Is there an emergency plan? Will study personnel supervising the exercise tests be trained in CPR/AED?
5. Will parking passes/reimbursement be provided? If not, any costs the participants may encounter should be described in the consent

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
- CLIA-Certified labs training

Thank you!