PENNSTATE CATS IRB Centralized Application Tracking System Institutional Review Board (IRB)

HRP-503 - How to Upload a Protocol for a Converted Study HY - **Conversion of PRAMS Studies to CATS IRB** (01/14/2014)

All Active studies in PRAMS will convert some basic information into the CATS IRB system study record. Researchers will be responsible for adding the current study documents into the CATS study record at the time of the next study Modification or Continuing Review, using the following steps:

1. Select **IRB** in the light blue bar below the CATS IRB banner.
2. Click on the **Active** *tab* in the middle of the screen, and choose the applicable study.
3. Select to **Create Modification / CR.** Choose Modification or Modification and Continuing Review, if appl., then select *Continue.*
   a. For the Modification scope you must select both options: *Other parts of the study* and *Study team member information*
4. If you are completing a Modification and Continuing Review, answer the CR questions first and in #5 add any supporting docs.
5. For the Modification questions, review the questions and any information that pulled in from PRAMS, and revise as needed.
6. Attach the current study documents in the applicable sections: Protocol, Consent Form, Recruitment, and Supporting Docs. The PRAMS original documents will be available in CATS IRB by selecting the Legacy Documents tab when viewing the study, where you may select a document, revise it if needed and add it to CATS. See below for more details about what documents apply.

Protocol Requirements for Ongoing Studies That Transition to CATS

Review Type	When to Upload Protocol Documents	What to Upload
1. **Exempt studies**	When submitting the next modification involving changes to personnel, sponsor or COI for exempt studies	a. Upload the PRAMS application RTF report *(or abstract for paper-based studies)*
2. Expedited studies	When submitting the next modification or continuing review a. If the study is a chart review, or in data analysis, or subject interactions are complete (or there are none) b. If the study involves subject interactions	a. Upload the PRAMS application RTF report (or abstract if paper-based), and the current approved protocol if applicable *Note: These studies will not need a new CATS template protocol* b. Upload a CATS template protocol, or the current approved protocol plus a CATS Site addendum protocol
3. Full board studies	When submitting next modification or continuing review a. For a Full board study in data analysis, or Study with accrual closed and subjects have completed study treatment/intervention but continue in follow-up observation with no research-related procedures	a. Upload current approved protocol* and the PRAMS application RTF report (or abstract if paper-based) *Note: These studies will not need a new CATS template protocol* **Note: See sponsored studies note next page*

	b. For a Full board study open to accrual, or closed to accrual but subjects are still receiving study treatment /intervention, or a full board study in which subjects have completed study treatment/intervention but continue in follow-up observation that would not be considered standard of care	b. Upload the current approved protocol* plus a CATS Site addendum protocol **Note: For sponsored studies with multiple amendments, upload only the latest, IRB approved amendment. All the others will be accessible in the CATS by selecting to view PRAMS Legacy Docs.*

Other Documentation for Ongoing Studies That Transition to CATS

Upload all the current documents associated with the research, selecting the latest approved versions from the Legacy Documents for the study.

DOCUMENTATION TYPE	EXAMPLES	NOTES
CONSENT DOCUMENTATION	**HMC Consent forms, HMC Summary Explanation of Research, HMC Consent Scripts**	**Revise the consent form as explained below:** • If you do not need any other revisions, make these changes only: o Leave the version date as is (latest approved version) o Remove the stamp box in the header o Remove the list of other investigators from page 1 • If you have revisions to make in the consent form: o Update the version date now o Revise the document using tracked changes ▪ Make any revisions that you need ▪ Make all changes needed to match the new Consent Form template in the CATS IRB Library. **Upload on Consent-Recruitment Page in CATS IRB submission**
RECRUITMENT DOCUMENTATION	**HMC Recruitment materials and HMC Phone Screening Procedures /Questionnaires**	**Upload on Consent-Recruitment Page in CATS IRB submission**
DATA COLLECTION	**Current surveys, questionnaires, interview/focus group questions, etc.**	**Upload in Supporting Document Page in CATS IRB** **Select Category – Data Collection Instrument**
SUPPORTING DOCUMENTATION	**Certificate of Confidentiality**	**Upload in Supporting Documents Page in CATS IRB** **Select appropriate category or other**