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| **General Information**The application has been totally re-designed to improve your experience, especially for studies that are not clinical trials. One of the major changes is that there is one workflow for a new study instead of a separate pathway for exempt or coordinating center applications. Required sections are marked with a red asterisk. **Those questions without a red asterisk need only be answered when applicable.** Your selections on the Study Scope page determine which branching pages are displayed. You may find some content in OSIRIS that no longer has a home in PittPRO, for example, risk determination. Since the IRB makes the final decision, this question has been removed. We tried to list all the main sections in OSIRIS to ease the transition to the PittPRO application. If you have any question, email askirb@pitt.edu or rcco@pitt.edu. |
| **PittPRO application** | **OSIRIS application** |
| **Basic Information** |  - Triage 1.0 - 2.0 - Start Protocol - Cover Sheet 1.0 - Reason for Submission - Cover Sheet 2.0 - 2.2 - Study Title and Protocol Abstract - Cover Sheet 3.0 - 3.9 - PI Information- Cover Sheet 11.0 - Sponsor Protocol & Brochure |
| **Funding Sources**  |  - 7.2 - All Sources of Support Fee Sheet (industry sponsored) |
| **Study Team Members** |  - Cover Sheet 4.0 - Co-Investigators - Cover Sheet 5.0 - 6.3 - Research Staff - 7.1 - Qualifications and Experience of PI and Listed Co-Is |
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| **Study Scope** |  - Cover Sheet 16.0 - Special Research Subject Population |
| **Study Scope to Adults with Impaired Decision-Making Capacity** | - 4.10 - Adult Subjects Capable of Providing Consent |
| **Study Scope (no branching)** |  - 3.5 - Participation of Children |
| **Study Scope branches to Neonate of Uncertain Viability** | - 3.8 - Involvement of Neonates |
| **Study Scope branches to Non-viable Neonates** |
| **Study Scope branches to Non-English Speakers** | - 3.4 – Comprehend English - 2.19.2 – Non-English speaking |
| **Study Scope branches to Nursing Home Patients in PA** | - 2.21 - Study Involves Pennsylvania Nursing Home |
| **Study Scope branches to Pregnant Women** | - 3.7 - Participation of Pregnant Women |
| **Study Scope branches to Prisoners** |  - 3.6 - Participation of Prisoners |
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| **Study Scope branches to Waiver/Alteration of Consent**  |  - 4.7 - Waiver of Informed Consent for Minimal Risk  |
| **Study Scope branches to Waiver to Document Consent** |  - 4.6 - Waiver for Signed Informed Consent |
| **Study Scope branches to Waiver/Alteration of HIPAA Authorization**  |  - 2.14.2 - HIPAA Waiver |
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| **Study Scope branches to Data & Specimens** |  - 2.15 - Collection and Banking of Tissue or Biological Specimens |
| **Study Scope branches to Honest Broker**  |  - 2.13 - Honest Broker for De-Identification |
| **Study Scope branches to Return of Results** | - 2.15.4 - Results from analyses performed on their biological specimens- 4.14 - Outcome of this research study following its completion |
| **Study Scope branches to Fetal Tissue**  |  - 3.9 - Involvement of Fetal Tissues or Organs |
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| **Study Scope branches to Medical Records** | - 2.14 – UPMC/Pitt Protected Health Information |
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| **Study Scope branches to Deception**  |  - 2.12 - Planned Deception |
| **Study Scope branches to Placebo** |  - 2.3.1 – Placebo-controlled Arm |
| **Study Scope branches to Withdraw from Usual Care**  |  - 2.4 - Subjects Withdrawn from Effective Therapy |
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| **Study Scope** |  - Cover Sheet 8.0 - Scientific Review |
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| **Study Scope branches to Drugs** | - Cover Sheet 9.0 - 10.1 - Investigational Drug, IND and IDE - 2.1 - Evaluation of Drug, Biological or Nutritional Supplement |
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| **Study Scope branches to Devices** | - Cover Sheet 9.0 - 10.1 - Investigational Drug, IND and IDE - 2.2 - Evaluation of Device for Safety/Effectiveness |
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| **Research Sites** |  - Cover Sheet 7.0 - CTRC Review  - Cover Sheet 15.0 - Study Site Information - 2.19 - Foreign Country or Culturally Different Site |
| **Study Aims** |  - 1.1 - 1.4 - Objective, Aims, Background and Significance |
| **Recruitment Methods** |  - 4.1 - 4.2 - Recruitment Methods - Version 2 - 6.2 - Subject Compensation |
| **Study Design** |  - 2.3 - Summarize Classification and Methodological Design - 2.11 - Total Duration of Subject's Participation - 2.17 - 2.18 - Outcome Variables and Statistical Analysis - 3.1 – 3.3 – Age, Gender, Subgroups - 3.10 - 3.12 - Total Subjects, Study Subgroups, Statistical Justification - 3.13 - 3.15 - Inclusion/Exclusion Criteria, HIV Serostatus - 5.7 - Endpoints Discontinuing Participation |
| **Research Activities** |  - 2.5 - Screening Procedures - 2.6 - Research Interventions/Interactions - 2.7 - Follow Up Procedures - 2.8 - Questionnaires or Survey Instruments |
| **Consent Process** |  - 4.11 - Point When Informed Consent will be Obtained - 4.12 - 4.14 - Informing Subjects, Exception to Policies for Informed Consent - 4.10 - Adult Subjects Capable of Providing Consent |
| **Consent Forms** |  - 4.9 - Informed Consent Forms - 5.6 - Alternate Diagnostic/Treatment Approaches |
| **Electronic Data Management** |  - 5.15 -Data Security |
| **Data Safety and Monitoring** |  - 5.13 - Monitoring Plan |
| **Risks and Benefits** |  - 5.1 - Risks - Version 2 - 5.2 – Unexpected Disease or Condition- 5.4 - Physical/Psychological Risk to Pregnant Women/Fetus - 5.5 - Risk of Genetic Mutation Leading to Birth Defects- 5.12 - Participation Offers Direct Benefit- 5.14 - Precautions Concerning Privacy- 5.16, 5.17 - Precautions Concerning Confidentiality, - 5.16 - 5.17 – Withdraws and Data Retention- 6.1 - Subjects or Insurance Providers Charged for Procedures |
| **Conflict of Interest** |  - 7.3 - Financial or Equity Interests of PI and Study Team |
| **Ancillary Reviews** | - Cover Sheet 12.0 - 13.0 - Radiation Safety or Biosafety - Cover Sheet 17.0 - Human Stem Cell Research (hSCRO) |
| **Clinical Trial Information** |  - Cover Sheet 18.0 - Clinical Trial - Clinical Trials Registration |
| **Local Supporting Documents** |  - References and other Attachments |

**Common Errors During Transition**

**General Issues:**

1. All studies that are open to enrollment or closed to enrollment but research procedures continue must be transitioned into PittPRO at the time of continuing review with the exception of the following:
	1. Studies where Pitt is serving as the IRB of Record
	2. Studies where Pitt has ceded review to another IRB to serve as IRB of Record
	3. Studies that have been released from continuing review (these will transition at a later date)

It is important that transitions be submitted at least 5 weeks in advance of the expiration date to ensure that the study doesn’t expire. This is especially important for studies that require full board review.

1. Utilize the Tip Sheet above when submitting a transition into PittPRO. It provides a mapping of questions in OSIRIS to questions in PittPRO.
2. If a modification is in progress in OSIRIS, do not transition the study into PittPRO until the modification has been approved in OSIRIS. This will help to ensure that the most currently approved study is being transitioned.
3. Study team members no longer involved and documents that are no longer being used (and will not be used in the future) can be removed **but you are not permitted** to make ANY other changes at the time of transition.
4. Do not rename documents during this process. The IRB coordinator assigned to the transition will be conducting a historical review between OSIRIS and PittPRO to ensure consistency. Renaming documents can cause a delay in the review process. During the Pre-Review, the IRB coordinator may request that you change a document name. This is because all documents that are approved by the IRB are automatically added to the approval letter and we want to make sure the documents are appropriately named.
5. Remove footers on ALL PAGES of the consent document. We have been finding them on some of the pages after the consents are finalized. This will force the study team to have to submit a modification to make a correction because the IRB staff no longer has administrative functions. Instructions:
	1. Open the draft consent document from OSIRIS, Section 4.9 (make sure to go to the DRAFT section), save the document to your computer, remove the footer from all pages but leave a 1” margin at the bottom of each page so the watermark in PittPRO is visible, correct any formatting issues but DO NOT make any wording changes. This is the consent version that will be uploaded into PittPRO.
6. Studies involving ONLY a medical record review do not require fiscal review so do not load that form into PittPRO.
7. Do not attach the data security assessment form (DSA) that was uploaded into OSIRIS. Those questions are now located within the application under Electronic Data Management. You can use the information on the previously approved DSA to complete the questions in that section.

**Application Issues:**

1. Funding source: It is important to list ALL funding sources in this section. It is especially important since PittPRO will be integrated into the PERIS solution at some point. We need to ensure consistent information between the two systems.
	1. If you need to include a Fee Sheet, this is the section where it will be uploaded. Click on “external funding,” use the Add button under #2 and attach the file in #4 on the pop up page.
	2. If you are requesting a fee waiver, you still have to complete the Fee Sheet and click the box indicating a request for waiver. There is no other place in the system to request this.
2. Study team: Include research coordinators as there is no other place to list personnel in the application. Include qualifications if the research coordinator will be conducting research procedures (obtaining informed consent, administering measures, etc.).
3. Study Scope: Make sure to be accurate in your selections on this page. This is what the system uses to provide the necessary pages of the application required for completion.
	1. For waivers, choose the correct option:
		1. Waiver/alteration of consent means that you previously had a complete waiver (no consent process) or part of the consent process was altered (SECTION 4.7 of OSIRIS)
		2. Waiver to document consent means that you previously had some type of “verbal” or “electronic” consent process approved (SECTION 4.6 of OSIRIS)
		3. Waiver/Alteration of HIPAA means that you previously had a waiver of HIPAA Authorization approved (SECTION 2.14.2 of OSIRIS)
4. Recruitment Methods: Leave at least a 1” margin on recruitment material so that the approval watermark applied by the system is visible.
	1. If you are using an advertisement with pull tabs, upload that document under Local Supporting Documents instead of in this section as the watermark will be “pulled off” with the tabs.
	2. At this time, material designed using Publisher has not been able to be watermarked. If you need to use this software, upload those ads into Local Supporting Documents.
5. Study design #2: Do not include the research activities in this section. In this section, summarize the general classification (e.g., descriptive, experimental) and methodological design (e.g., observational, cross-sectional, longitudinal, randomized, open-label single-blind, double-blind, placebo-controlled, active treatment controlled, parallel arm, cross-over arm) of the proposed research study.
6. Study design #3: Do not include endpoints for withdrawing subjects in this section as this is addressed elsewhere in the application. We are looking for the main outcome variables that will be evaluated in this study. These can be found in item 2.17 of your OSIRIS protocol.
7. Research Activities: There is no longer separate sections to outline screening and follow up procedures. All procedures being done (screening, study, and follow-up) go under this section. They should appear in that order with headings as applicable: screening – study procedures – follow-up.
8. Screening for recruitment should go under the Recruitment section rather than in the Research Activities section.
9. Consent Process, item 5: Only request this exception if you previously had one approved (SECTION 4.13 of OSIRIS). This is NOT applicable to exempt studies or studies that involve a waiver of consent for all procedures/populations.
10. Do not “data dump” into the Local Supporting Documents page. There are places throughout the application to upload documents. Only include documents in this section if there isn’t another section in PittPRO to put them.
11. Uploading/Accessing Documents: Once a study is approved, you will find the approved documents (including the watermarked consent) under the Documents tab on the main study page. Make sure to use the consent documents under the “Final” column. If you need to make changes to the documents, utilize the version under the “Draft” column.