University of Washington

Clinical Research Proposal Process Improvement Project

- Office of Research
- Research and Graduate Education, School of Medicine
- Health Sciences Administration

October 2009

Table of Contents

Appendices

I. Project Overview

A. Genesis of the Project

Research is the engine that powers the University of Washington (UW). In the biomedical arena, clinical trials are critical to this research mission. Although the UW had attracted substantial research dollars, there was concern that internal work processes hampered UW's ability to secure funding, especially from industry sponsors.

- In the past, UW had experienced an increasing number of industry-sponsored studies that were closed either before negotiations with the sponsor were completed or very soon after the contract was signed and the study opened to enrollment.
- The UW and its partners had difficulty in initiating some studies in a timely fashion which meant lost research opportunities, lost revenue, unreimbursed start-up expenses and lost staff effort.
- The Cancer Consortium was seeking to expand its solid-tumor cancer research program, especially industry-sponsored studies.

Conversations between Mary Lidstrom, Vice Provost for Research, and John Slattery, Vice Dean for Research and Graduate Education in the School of Medicine, over several years focused on how best to facilitate the clinical research proposal process. Because Vice Provost Lidstrom had already made improved staffing, expanded staff training, and process improvements high priorities for units within the Office of Research, Drs. Lidstrom and Slattery agreed to create a partnership whereby both offices would support a cross-organizational, cross-institutional Clinical Research Process Improvement project.

Because units of the Office of Environmental Health and Safety played an important role in the clinical research proposal process, the project partnership was expanded to include Kathryn Waddell as a co-Executive Sponsor. In early 2008, the Executive Sponsors asked Richard J. Meisinger, Jr., Assistant Dean in the Office of Research and Graduate Education, to lead a year-long process improvement project. The project kick-off occurred in October, 2008.

B. Project Goal/Outcomes/Deliverables

The project goal, outcomes and deliverables were developed during the first step of the project: project startup. These elements were part of the project charter document which is attached as Appendix A. The project charter document was approved by the Project Executive Sponsors and Steering Committee.

<u>Project Goal</u>:

- For clinical research, reduce the time between the initial submission of the proposal and final approval to enroll patients to 90 days.

  As the project progressed, words were added to clarify the goal: "For **industry-sponsored** clinical research **studies**, reduce the time between the initial submission of the proposal and final approval to enroll patients to 90 days. **For all other clinical research studies, reduce the time between the initial submission of the proposal and final approval to enroll patients**."

Outcomes:

- Stakeholders (Principal Investigators, Reviewers, etc.) who participate in the process have knowledge about the complete process and understand their role in the process.
- Stakeholders know what needs to happen when.
- Stakeholders know who is responsible for what.
- Stakeholders know the status of any proposal.
- Patients benefit by being able to enroll in clinical studies.

Deliverables

- A plan for process improvements that reduce the time between initial submission of the proposal and final approval to enroll patients.

  Process Improvements were made as the project progressed. The **plan** for process improvements covers those improvements that could not be made during the life of the project due to additional time requirements to make policy changes, negotiate cross-organizational or cross-institutional changes, etc.

- A Clinical Research Handbook ("Cookbook") that includes:
  - Process documentation.
  - Checklists – what activities need to happen when.
  - Timeline standards.
  - Definition of roles/responsibilities.
- A plan consistent with the Research Roadmap for a tracking system that monitors status/location of a proposal on the review pipeline.

Measurements

- Days it takes from the time that the principal investigator submits a proposal until the research study is approved, funded and ready to enroll subjects. Include descriptive statistics such as mean, median and dispersion.
- Days it take for approvals within discrete units, e.g. OSP, HSD, Radiation Safety, etc. (including definition of start, stop and suspension times). Include descriptive statistics such as mean, median and dispersion.

As the project progressed, the Measurement statements were changed to the following:

"Time it takes from when the principal investigator submits a proposal until the research study is approved, funded and ready to enroll subject. Include descriptive statistics such as the man, median, and dispersion."

"Time it takes for approvals within discrete units, e.g. OSP, HSD, Radiation Safety, etc. (including definition of start, stop and suspension times). Include descriptive statistics such as mean, median and dispersion."

C. Project Start/End/Boundaries/Assumptions

Like the project goal, outcomes and deliverables, the Clinical Research process start, end, project boundaries and assumptions were developed during the project startup phase. The purpose of defining the process start and end was to create a common understanding of the span of the process up for review and improvement. Defining boundaries for the process created a common understanding of what could be changed and created strategic points for measuring time. Boundaries arranged by the following categories are included in the Project Charter, Appendix A:

- Policies/Procedures/Contracts
- Financial
- Organizational/Human Resources
- Technology
- Timeline
- Facilities

With many stakeholders involved, it's easy for people to have ideas about what will or will not happen that have not been verbally articulated. The assumptions listed below resulted from Steering Committee discussions during project startup and were also included in the Project Charter.

- Project success is dependent upon the cooperation and participation of stakeholders involved in the process.
- The purpose of the project is not the elimination of jobs but to improve the efficiency and effectiveness of the process.
- The total cost of the process will not be increased.
- Creating greater capacity to handle more proposals would be an added benefit, considering the current economic climate, the increase in the number of proposals being submitted and the increased dependence on central offices for support.

- During this process improvement, we want to focus on the commonalities of proposals (the 90-95%) and not the 5-10% that represents "exceptions to the rule" or rare occurrences.

D. Project Roles

Managing an improvement project for a cross-organizational, cross-institutional process required a project structure that included stakeholder involvement across that spectrum. Vertical representation starting with executive sponsorship was also key to the project's success. The following groups comprised the project structure and met on a regular or ad hoc basis.

- Executive Sponsors. The Executive Sponsors chartered the project and provided executive level guidance for the project. The Executive Sponsors met on a bi-monthly basis. See Appendix A for Executive Sponsor membership.
- Steering Committee. The Steering Committee was comprised of senior and mid-level managers plus subject matter experts. The Steering Committee's key role was to grapple with process operational issues, then make decisions about how the process could best work, facilitate staff participation in process improvement work, make decisions and raise policy issues to the Executive Sponsors. The Steering Committee met on a monthly basis. See Appendix A for Steering Committee membership.
- Cross-organizational/Cross-Institutional Ad Hoc Workgroups. Several ad hoc workgroups were convened during the course of the year-long project. This approach was based upon a "hook and un-hook" strategy of calling the right people together to focus on a part of the process then disbanding the workgroup as soon as their work was completed. Initially four ad hoc workgroups worked on parts of the process that had been identified as high priorities:

    - Consent Forms
    - Radiation Safety/Institutional Biosafety
    - Implant and Investigational Devices
    - Interim Tracking System

    Each of these workgroups investigated and documented their part of the process, identified areas for improvement and suggested solutions (see Section III). Additionally, an Overall Process workgroup focused on cross-process issues. The charter for each of the five groups is included in Appendix B.

    Additionally, for parts of the process not already covered, subject matter experts gathered into ad hoc groups (one for each functional area listed below) to accomplish similar work. Team members for each group are listed in Appendix C.
    - Human Subjects Division (HSD)
    - Office of Sponsored Programs (OSP)

- Clinical Research Budget & Billing (CRBB)
- Significant Financial Interest (SFI)
- Cancer Consortium (CC)
- Protocol Office/Scientific Review Committee (SRC)

- Project Director, Consultant and Project Manager. Richard Meisinger, Jr., Ph.D, Assistant Dean for Planning and New Initiatives was selected by the Executive Sponsors to direct the project. Laura Walker of The Walker Company was hired to provide the project approach, process improvement methodology, framework and best practices. Ann Wold was hired as Project Manager for the year-long life of the project. These three individuals served as the core team moving the project along on a day-to-day basis.

II. Project Steps

Appendix D lists the following high-level project steps with more detailed tasks under each.

A. Project Startup and Kickoff

During the project startup phase, the Project Director and Consultant met individually with key stakeholders to share background information, collect their input and build support for the project. This input was used to develop the draft project goal, outcomes, and deliverables and was also used to define the process start, end, boundaries and project assumptions. At the kickoff meetings for the Executive Sponsors and the Steering Committee, this draft information was presented to the members. The project documents were then modified and finalized. Additionally, a Communication Plan was developed to carry out a strategy of involving and communicating with as many stakeholders as possible.

B. Investigation, Data Gathering, and Documentation

This was the first time that stakeholders from across the process had the opportunity to come together in a formal way to work on this process. Although stakeholders knew their own piece of the process intimately, there were many questions about how the process worked outside of their area of purview. Even stakeholders who had more of a cross-organizational, cross-institutional view raised many unanswered questions. The ad hoc workgroups provided a forum to raise questions and issues while documenting the process. Key findings from this work included the following:

- Stakeholders did not know who owned the process and wanted the ownership defined.

- The complete cross-organizational, cross-institutional process had not been documented.
- In many cases, the process was difficult to graphically represent because so many permutations existed. In some areas, a process did not really exist, it was ad hoc and person dependent.
- Principal Investigators (PIs) and Study Coordinators (SCs), especially those inexperienced with the process:
  - Were often confused about where to start the proposal process.
  - Were unsure of what to do when.
  - Did not necessarily know what materials to put together for whom.
  - Did not understand the dependencies in the process.
  - Expressed frustration in not knowing the status of a proposal.
  - Wished for more knowledge about the process.
- The existing, web-based Clinical Research Handbook contained useful information but was difficult to navigate.
- Although some units were collecting metric information (how many, how long, etc.), cross-organizational, cross-institutional baseline data did not exist.
- Data being collected existed in at least five different systems.
- The status of a proposal could not be tracked across the whole process.

The work of the ad hoc workgroups resulted in a set of process flowcharts (Appendix E) that encompass the total process. The set covers the following areas:

- Clinical Research Budget & Billing
- Radiation Safety (UW & SCCA)
- Institutional Biosafety (UW & SCCA)
- Implant & Investigational Devices (UWMC & HMC)
- Significant Financial Interest
- Human Subjects Division/IRBs (UW, CC-IRB, WIRB)
- Cancer Consortium
  - Protocol Office
  - Institutional Review Office (IRO)/CC-IRB
  - Scientific Review Committee
- Office of Sponsored Programs

The flowcharts were developed at a medium detail level in order to provide a clear understanding of the process. The flowcharts will be an important component of the Clinical Research Handbook, a tool that can be used to educate process stakeholders.

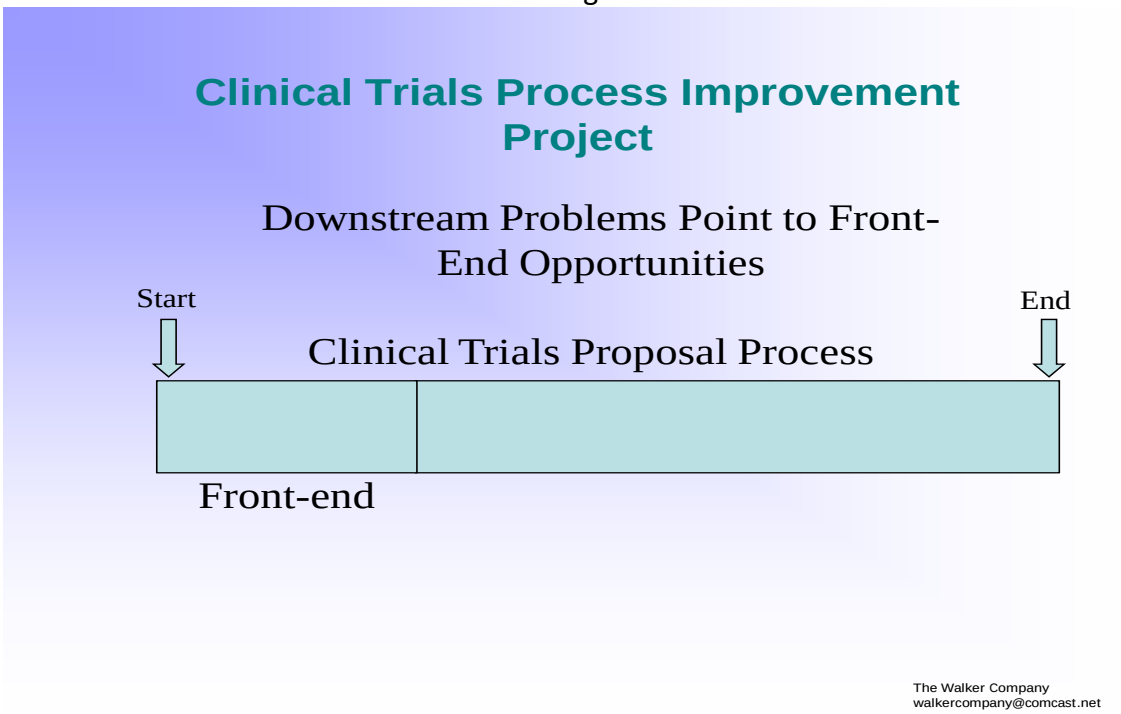
C. Design Process Changes & Improvements

Documenting the process provided the opportunity to question, redesign and in some cases build segments of the process from the ground up. Across the workgroups a key theme emerged from the conversations: downstream problems in the process were the

result of key questions not being answered at the front-end of the process. In fact, the "front-end" was not acknowledged as the start of the process since each functional area concentrated on the start of their part of the process. This discovery led to asking the following questions:

1. What questions should the PI/SC ask at the front-end?
2. What decision-making needs to occur?
3. Based upon the answers to these questions, what materials should be put together and sent to whom?

Figure A



The first of the above three questions led to defining the following key questions that a PI/SC should ask up-front:

1. Which IRB will the proposal be submitted to?
2. Will a Radiation Safety Review be required?
3. Will an Institutional Bio safety review be required?
4. Will an Implant and Investigational Device review be required?
5. Will the proposal need to be reviewed by the Scientific Review Committee?
6. Will a Significant Financial Interest review be required?

Defining and answering the front-end questions proved to be more complex than initially anticipated, especially for Radiation Safety and Institutional Biosafety. Decision-making for these questions is included on the process flowcharts and will be available as part of the Clinical Research Handbook.

Answers to the key questions impacted the materials that the PI/SC must put together and deliver (electronically or manually) to numerous organizational units. For example,

CRBB required a collection of documents and/or forms in order to develop the study budget/billing grid. HSD required a collection of documents and/or forms in order to submit the proposal to the IRB. Some "packages" were required for all studies, e.g. OSP, HSD-IRB while other packages were required based upon study characteristics, e.g. Radiation Safety or Institutional Biosafety. Some documents were common across multiple packages, e.g. the protocol. In all, approximately fourteen possible packages were defined. Like the decision-making required for the key questions, the "package" definitions will be included in the Clinical Research Handbook. In this document, they are included as Appendix F.

Defining key questions, decision-making and document/form packages was not the only emphasis in making changes and improvements. As the different parts of the process were documented, workgroups looked for the following in order to streamline the process.

- Handoffs between offices
- Queues
- Duplication of effort
- Rework

D. Make Recommendations and Get Buyoff

Many improvements did not need to wait until the end of the project to gain the support of the Steering Committee and Executive Sponsors. Decisions regarding these improvements were made during the life of the project and are detailed in Appendix G. They cover many important aspects of the process that impact time and efficiency.

Improvements to Specific Parts of the Process

1. Flowcharts of current/optimum process were developed.
2. An online Clinical Research Handbook was conceptualized, designed, planned and is under development.
3. Front-end questions to be answered by the PI/SC were defined. Decision trees to answer questions were developed. Definitions, examples & contacts for consultation will be included in the Clinical Research Handbook.
4. "Packages" of required documents/forms based upon answers to the front-end questions were developed.
5. Handoffs and multiple entries of the same data were eliminated.
6. UWMC & SCCA agreed to streamline separate Radiation Safety reviews into one process with a common form.
7. UWMC & HMC agreed to streamline separate Implant and Investigational Device reviews into one process with a common form.
8. Revised account authorizations/electronic funding actions to allow a project to make expenditures for start-up needs before subjects are enrolled in a study.

Enabling the Process

9. Executive Sponsors own the process. R. Meisinger is the agent of the Executive Sponsors.
10. A Clinical Research Administrator will be hired to further develop and maintain the Clinical Research Handbook, support the Steering Committee and provide project management support for improvement projects initiated by the Committee.
11. Contacts (individuals) will be identified for each part of the process to help stakeholders navigate the Clinical Research Proposal process.
12. Established process for Study Coordinators to obtain read-only SPAERC access.

Management Information/Metrics

13. Status points for each part of the process that are currently collected in organizational unit data systems were identified. Status points have also been identified that are not currently collected but have been cited as being potentially useful status information for stakeholders.

Standards

14. Master contract agreements have been and will continue to be developed.
15. Developed internal risk management matrix for clinical trial agreements & reviewed risk management strategies with UW Risk Management Office.

Appendix G also indicates whether additional action items need to be accomplished in order to fully implement the improvements. The next section details the improvements that fall into the "recommended" category.

III. Project Deliverables

A. A Plan for Process Improvements

Other improvements landed on the "recommended" list for some of the following reasons: 1) more discussion was required; 2) additional details needed to be worked out; 3) there was not enough time to implement the change during the formal project; and/or, 4) the improvement had not yet been ranked to determine its priority for implementation. The recommended improvements have been organized into the following five categories.

Improvements to Specific Parts of the Process

1. Radiation Safety: Determine whether to start the Radiation Safety review before or after SRC approval.

2. Scientific Review Committee: Clarify which study proposals will be reviewed by the SRC.
3. Consent Form: Create a central electronic location where stakeholders can find the most recent version of the Consent Form.
4. Consent Form: HSD is the contact/clearing house for all suggested changes to the Consent Form.
5. Consent Form: HSD does not send proposal applications to WIRB until the Consent Form is completed.
6. Consent Form: Resolve the following questions: 1) When the IRB requests changes in the Consent Form, how best can these be communicated to CRBB so that the budget can be prepared accurately? 2) How can CRBB communicate early enough with HSD about potential incentive payments or subject reimbursements to avoid having the IRB review the Consent Form multiple times? 3) What is the best way to make sure that the Consent Form language is in alignment with the budget & contract?
7. Pricing: Provide required clinical information to hospital service centers so they can generate pricing pages. Establish a central point of distribution for pricing sheet requests. For UWMC, develop a price list that can be used for developing preliminary budgets.
8. Confidentiality Agreements: Establish a formal process for CDAs when institutional signature required.
9. Institutional Biosafety: Have a joint preliminary review when IBC is required at both SCCA & UW then PI can answer all questions at once.
10. Significant Financial Interest: Streamline submission of disclosure letter along with electronic eGC1 & SFI disclosure form. Current submission is manual (to submit electronically requires change in UW confidentiality rules & GIM10 policy); allow SFI review to begin early in the process.
11. Timely submission to IRB for government/foundation proposals. HSD: 1) develops a process to work with the schools/departments so they are notified of "intent to fund;" 2) develops a process to work with Grants and Contract Accounting so they are notified when an advance budget is assigned to a proposal; or, 3) publishes a deadline rule specifying the time required to process the proposal application for IRB approval.
12. Subject Injury Billing. Clarify subject injury policies and billing among organizational units (OSP, HSD, CRBB, UW Medicine).
13. UW Human Subjects Injury Compensation Program. Clarify program.
14. Medicare Secondary Payer. Clarify and resolve uncertainties regarding Medicare Secondary Payer issues among organizational units (OSP, AGO, HSD, CRBB).

Enabling the Process

15. Design, implement and staff a Clinical Research Service Center that:
    a. Provides front-end triage support to PIs/SCs.
    b. Provides status on proposals.
    c. Helps PIs/SCs navigate the process.

d. Coordinates existing training related to the Clinical Research Proposal Process & identifies new stakeholder training needs.

   See Appendix I for more details on the Clinical Research Service Center Responsibilities.

16. Provide orientation to the Clinical Research Handbook to help PIs/SCs navigate the process.
17. Implement a bi-weekly telecon between OSP & CRBB to share negotiation strategy on proposal applications.
18. Integrate non-industry sponsored clinical trials (federal, foundation, academic and other non-profit) and industry sponsored clinical trials into OSP's Clinical Trial Group.

Management Information/Metrics

19. Encourage each organizational unit to identify, collect and report metrics desired by stakeholders.
20. Acquire a management information system to automate the Clinical Research Proposal Process (out of scope, falls under the Research Roadmap project).

Standards

21. For investigator initiated studies, develop standards for protocols.
22. Establish standard naming conventions for the documents being used throughout the process.
23. Establish a name/number for each proposal so it can be referred to in the same way across the process.
24. Develop Intellectual Property language/procedures that are relevant for industry studies.

Pre-Proposal Study Merit Evaluation

25. Determine if it is appropriate to perform front-end triage at the departmental level to gauge if a study has sufficient merit to start through the proposal process.
26. To manage proposal workload, establish prioritization guidelines.

Appendix H contains background information on each of the recommended improvements including the next step to be taken to move the item forward.

B. Clinical Research Handbook

Prior to the start of this project, the tool available to PIs and SCs was the web-based Clinical Trials Administrative Start-Up Handbook. This handbook was originally developed at the UW School of Medicine to ensure that the administrative start-up process for industry-sponsored clinical trials could be accomplished as quickly and efficiently as

possible. Over time the handbook evolved to present information not only about the start-up process but also included other practical information related to clinical research.

Although the Handbook contained useful information, it was difficult to navigate and did not reflect the information generated during this Clinical Research Proposal Process Improvement Project. Consequently, the need for a new, regularly updated "Clinical Research Handbook" (CRH) was recognized and its design and development is a major deliverable of this project.

During the analysis phase of designing the new Handbook, options in the following categories were considered:

- Technology. What hardware and software is available and will work best for an online handbook?
- Design/Functionality. What approach will allow the user to find the information they want most efficiently?
- Content. What information will be most useful to the users?

Appendix J provides the detail of the analysis that was presented to the Steering Committee and Executive Sponsors. Discussion and decision-making led to the following approach for the Handbook:

- Technology
  - Host the CRH on UW Technology servers.
  - Use Drupal software, an open source, content management system.
- Design/Functionality
  - Present information to users in a clear, concise manner while still providing a depth of information for those who wish to utilize the handbook for more in-depth guidance.
  - Provide multiple ways to enter and find information in the handbook.
  - Use a combination of searchable text pages and navigable process maps. Allow the user to click on a process activity and access more information. This could be an informational box, link to another website, a contact list, a form, an online document or any other number of informative resources.
- Content
  - Format information (flowcharts, checklists, decision trees) that has been gathered as part of the Clinical Research Proposal Process Improvement Project to fit the new Handbook.
  - Convert information currently contained in the Clinical Trials Administrative Start-Up Handbook. Do not convert information that is out of date, inaccurate or has been replaced by information generated during the project.

Appendix K, the Project Plan for the Handbook provides additional detail related to technology, design/functionality, content, cost and schedule. The first phase of the CRH is scheduled for a January 2010 release.

C. A Plan for an Interim Tracking System

UW does not currently have a system that tracks metric data across the entire Clinical Research Proposal Process. In fact, there are more than five systems that organizational units use for managing their internal processes. Since these systems were not built with the idea of using the data for metrics purposes, organizational units who are reporting metrics have invested considerable time and resources in adapting their systems.

In a best case scenario, metric data would be collected across the entire process and be available for two key purposes:

1. To track the number, kind (i.e. industry, government, foundation sponsored), etc. of proposals.
2. To tract the status of a proposal – where it is in the process, time it has spent in each part of the process, etc.

Long term, one of the Research Roadmap project's goals is to implement an automated system for the proposal process that includes the ability to track and report metrics. The analysis for the Clinical Research Proposal Process project focused on the requirements for building and implementing an Interim Tracking System that would fill the gap of a few to several years until the Research Roadmap solution is implemented.

The analysis (see Appendix L for details) pointed to several steps that would be required in order to provide process metrics:

1. Identify metric information desired by stakeholders.
2. Identify data points that match the information desired.
3. Determine which data points are currently collected in one of the computer systems.
4. Match the data points desired with data elements in the various systems.
5. Determine a method for extracting the data points from each system.
6. Consolidate the extracted data in one location.
7. Develop a user interface to provide the information to stakeholders.

Further investigation revealed that building an Interim Tracking System would require a significant investment of time and resources. Due to the constrained economic climate and budget reductions at UW, it could not be assumed that resources could be dedicated to building the Interim Tracking System. Consequently, moving forward on this project deliverable became one of three options under consideration (see Appendix M). Discussions with the Steering Committee resulted in the modification of the original project deliverable to reflect the realities of the current environment and still assemble building blocks that offer short term benefits, move the organizations toward cross-process measurements and contribute to the longer term Research Roadmap effort. The recommendation is as follows:

Encourage each organizational unit to identify, collect and report metrics desired by stakeholders.

The following work accomplished during the project will be helpful to the organizational units as they embark on this work.

- Systems that contain metric information have been identified.
- Using the process flowcharts, data/status points desired by stakeholders have been identified. A summary of the key status points can be found in Appendix N.
- Data element information for PIRO/DORA, SAGE/SPAERC/StatusTracker has been collected.

Those units with tracking systems already in place (HSD, Cancer Consortium) are sources of advice for those units starting work in this area. This work must be coordinated and interface with the work of the Research Roadmap. The task of making sure this coordination occurs rests with the Steering Committee.

IV. Post Project Activities

A. Action Items for Achieved and Recommended Improvements

Appendices G and H contain more detailed information about the achieved and recommended improvements including the next steps for each item. In the "next steps" column, some designations have been used consistently to indicate the status of the achievement or recommendation. These designations include:

- Complete. No further action is required.
- In progress. The item is currently being worked on.
- Ongoing. The item is implemented and will continue to be developed or added to in some way.
- Implement. The item can be put into practice as part of the Clinical Research Proposal process.
- Steering Committee establishes priority. The Steering Committee will determine the relative priority of this item and determine when work starts on it. This may include decision-making about moving ahead on the item at all.
- Start immediately. Next steps on this item should be started shortly after November 1, 2009.
- Out of scope. This item is not part of the project.

These appendices are the important post-project documents because they detail the work that continues after the formal project end on October 31, 2009 and can be used as the project plan for such.

B. End of Project/Post-Project Communication Plan

Appendix O, the end of project/post-project communication plan was developed by going through the original project plan and identifying: 1) those stakeholders who should be communicated with at the end or post-project; 2) what information should be conveyed to the stakeholders; and 3) who should convey the information. These communication tasks should begin in November, 2009.

UNIVERSITY OF WASHINGTON
CLINICAL RESEARCH PROPOSAL REVIEW PROCESS IMPROVEMENT
PROJECT CHARTER

1. **NAME OF PROCESS:** Clinical Research Proposal Review Process

2. **PROJECT ROLES**
   - Executive Sponsors:
     - Mary Lidstrom, Vice Provost for Research,
     - John Slattery, Vice Dean for Research and Graduate Education, School of Medicine,
     - Kathryn Waddell, Executive Director, Health Sciences Administration

   - Key Stakeholders
     - Health Sciences Administration, School of Medicine - Dick Meisinger
     - Health Sciences Administration, School of Medicine, Clinical Research Budgeting and Billing - Diane Merz
     - Health Sciences Administration, School of Medicine, Division of Oncology - Sue Hammond/Sonja Stella
     - Office of Research – Debbie Flores
     - Office of Research – Jeff Cheek
     - Office of Research, Human Subjects Division - Karen Moe
       1. UW IRB
       2. WIRB
       3. CC-IRB
     - Office of Research, Office of Sponsored Programs - Lynn Chronister
     - Principal Investigators/Faculty - Dr. Larry Robinson
     - Cancer Consortium (UW, Fred Hutch, Children's, Seattle Cancer Care Alliance) – Marc Provence/Barb Berg
     - Environmental Health & Safety - Barbara McPhee
       - EH&S, UW Radiation Safety Committee - Stan Addison
       - Institutional Bio Safety Committee - JoAnn Kauffman
     - ORIS/SAGE - Darcy Van Patten/Jim Kresl

   - Ad Hoc/As Needed Stakeholder Representation
     - Cancer Consortium Science Review Committee
     - UW hospital CFOs
     - Grants and Contracts Administration [involvement via OSP]
     - Technology Transfer Office [involvement via OSP]
     - Attorney General's Office [involvement via OSP]
     - Risk Management [involvement via OSP]
     - Electronic Medical Records (EMR)
     - SCCA Radiation Safety Committee
     - Implant & Investigational Device Committees

   - Steering Committee
     - Dick Meisinger
     - Diane Merz
     - Sue Hammond/Sonja Stella
     - Debbie Flores

- Jeff Cheek
- Karen Moe
- Lynne Chronister
- Dr. Larry Robinson
- Marc Provence/Barb Berg
- Barbara McPhee
- Stan Addison
- JoAnn Kauffman
- Darcy Van Patten/Jim Kresl

- Principal Investigators Advisory Group
  - Dr. Larry Robinson (liaison from the steering committee)
  - Dr. Goldberg (Cardiology)
  - Dr. Sylvia Lucas (Neurology)
  - Dr. Ajay Gopal (Oncology, from S. Hammond)
  - Dr. John Thompson (Oncology, from S. Hammond)
  - Dr. Julie Gralow (Oncology, from S. Hammond)
  - Rep from international trials

3. PROJECT GOAL/OUTCOMES/DELIVERABLES:

- <u>Goal</u>
  - For clinical research proposals, reduce the time between the initial submission of the proposal and final approval to enroll patients to 90 days.

- <u>Outcomes</u>
  - Stakeholders (Principal Investigators, Reviewers, etc.) who participate in the process have knowledge about the complete process and understand their role in the process
  - Stakeholders know what needs to happen when
  - Stakeholders know who is responsible for what
  - Stakeholders know the status of any proposal
  - Patients benefit by being able to enroll in clinical studies

- <u>Deliverables</u>
  - A plan for process improvements that reduce the time between initial submission of the proposal and final approval to enroll patients
  - A Clinical Research Handbook (“Cookbook”)
    - Process documentation
    - Checklists – What activities need to happen when
    - Timeline standards
    - Definition of roles/responsibilities
- A plan, consistent with the research roadmap, for a tracking system that monitors status/location of a proposal on the review pipeline.

- <u>Measurements</u>

UNIVERSITY OF WASHINGTON
CLINICAL RESEARCH PROPOSAL REVIEW PROCESS IMPROVEMENT
PROJECT CHARTER

- Days it takes from the time the principal investigator submits a proposal until the research study is approved, funded and ready to enroll subjects. Include descriptive statistics such as mean, median & dispersion.
- Days it takes for approvals within discrete units, e.g. OSP, HSD, Radiation Safety, etc. (including definition of start, stop and suspension times). Include descriptive statistics such as mean, median & dispersion.

4. START/END OF PROCESS:

Start	End
A principal investigator initiates a research proposal. Assumption: PI submits a complete proposal.	The research study is approved, funded and ready to enroll subjects. Assumption: the PI is able to enroll subjects – that means having a budget number.

*

5. BOUNDARIES:

- What are the non-negotiable givens that will impact improving this process?
- What are some of the known constraints that will impact improving this process and, therefore, must be taken into account?

Policies/Procedures/Contracts:

In	Out
• Changing policies & procedures • Changing how contracts are done when acting as the fiscal agent for UW	• Policies & procedures mandated by law, e.g. compliance driven

Financial:

In	Out
• Project funding for 1 year	• Additional funds • Project funding past 1 year

Organizational/Human Resources:

In	Out
• Project resources: Project Director, Project Manager, Consultant • Changing staff duties (consistent with the laws & policies that govern HR) • Changing how staff do the work • Changing organizational structure • Identification where staffing is inadequate	• Additional project funding • Augmentation to staff in the short term

Technology:

UNIVERSITY OF WASHINGTON
CLINICAL RESEARCH PROPOSAL REVIEW PROCESS IMPROVEMENT
PROJECT CHARTER

In	Out
• May implement a portal tool to track proposals – an interim solution that improves tracking, visibility & status • Changes to the current system if the changes reduce manual movement of paper or eliminate steps	• Access to dedicated technology resources • Implementing a new technology system

Timeline:

In	Out
• 1 year project timeline • Implementing "short term fixes" • Determining resources required for implementation at end of this 1 year project • Implementation of Clinical Research Handbook ("cookbook")	• Project extension beyond 1 year

Facilities:

In	Out
• Changing office layout • Changing how paper flows through the physical facilities, e.g. moving paper from one physical location to another, moving physical paper to electronic format	• New/different facilities

6. **ASSUMPTIONS** [What are some of the critical assumptions that will impact the improving this process?]
   - Project success is dependent upon the cooperation and participation of stakeholders involved in the process.
   - The purpose of the project is not the elimination of jobs but to improve the efficiency and effectiveness of the process.
   - The total cost of the process will not be increased.
   - Creating greater capacity to handle more proposals would be an added benefit, considering the current economic climate, the increase in the number of proposals being submitted and the increased dependence on central offices for support.
   - During this process improvement, we want to focus on the commonalities of proposals (the 90-95%) and not the 5-10% that represents "exceptions to the rule" or rare occurances.

UNIVERSITY OF WASHINGTON
CLINICAL RESEARCH PROPOSAL REVIEW PROCESS IMPROVEMENT PROJECT
"CLINICAL RESEARCH PROPOSAL REVIEW PROCESS" AD HOC WORKGROUP CHARTER

1. **NAME OF PROCESS:** Clinical Research Proposal Review Process

2. **PROJECT ROLES**
   - Ad Hoc Workgroup
     - Michael Corn, Office of Sponsored Programs
     - Debbie Flores, Office of Research
     - Sue Hammond, School of Medicine, Division of Oncology
     - Diane Merz, Clinical Research Budget & Billing Support Office (CRBB)
     - Karen Moe, Human Subjects Division
     - Darcy Van Patten, Office of Research Information Services (ORIS)
     - Jennifer Yahne, FHCRC Planning and Strategic Development

   - Ad Hoc Workgroup Lead
     - Lynne Chronister, Office of Sponsored Programs

   - Ad Hoc Workgroup Facilitator
     - Laura Walker

   - Guidance for Ad Hoc Workgroup
     - Project Director, Richard Meisinger
     - Project Manager, Ann Wold

   - Oversight for Ad Hoc Workgroup
     - Steering Committee

3. **PROJECT GOAL/OUTCOMES/DELIVERABLES:**
   - <u>Goal</u>
     - Document the current workflow, analyze the complete Clinical Research Proposal Review process at a high level and make recommendations for improvements.
       - Define terms to be used commonly across the process.
       - Define initial submission.
       - Determine a common numbering system (or a crosswalk system) for proposals that can be used across the process.
       - Eliminate queues, handoffs, rework and duplication of effort.
     - Clarify roles and responsibilities.

   - <u>Outcomes</u>
     - Stakeholders:
       - Are using the same terms to refer to the same things.
       - Know the definition of initial submission and what's included.
       - Have a common number for referring to a proposal.
       - Understand and can navigate the process.

UNIVERSITY OF WASHINGTON
CLINICAL RESEARCH PROPOSAL REVIEW PROCESS IMPROVEMENT PROJECT
"CLINICAL RESEARCH PROPOSAL REVIEW PROCESS" AD HOC WORKGROUP CHARTER

- Deliverables
  - A process flowchart of the proposed Clinical Research Proposal Review process.
  - A glossary of common terms.
  - A description of the common numbering system.

- Process Measurements
  - Determine process metrics that measure:
    - The start and finish of the review in each unit plus any suspension periods.
    - Handoffs, queues, rework and duplication of effort.
  - Build into the process a way to collect the measurement data.

4. START/END OF PROCESS:

Start	End
A principal investigator initiates a research proposal.	The research study is approved, funded and ready to enroll subjects.

5. BOUNDARIES:

- What are the non-negotiable givens that will impact improving this process?
- What are some of the known constraints that will impact improving this process and, therefore, must be taken into account?

Policies/Procedures/Contracts:

In	Out
• Changing policies & procedures •	• Policies & procedures mandated by law, e.g. compliance driven

Financial:

In	Out
•	• Additional funds

Organizational/Human Resources:

In	Out
• Changing staff duties (consistent with the laws & policies that govern HR) • Changing how staff do the work • Changing organizational structure • Identification where staffing is inadequate	• Augmentation to staff in the short term

Technology:

In	Out
• Use of existing technology	• Access to dedicated technology

UNIVERSITY OF WASHINGTON
CLINICAL RESEARCH PROPOSAL REVIEW PROCESS IMPROVEMENT PROJECT
"CLINICAL RESEARCH PROPOSAL REVIEW PROCESS" AD HOC WORKGROUP CHARTER

• Changes to the current system if the changes reduce manual movement of paper or eliminate steps	resources • Implementing a new technology system

Timeline:

In	Out
•	•

Facilities:

In	Out
• Changing office layout • Changing how paper flows through the physical facilities, e.g. moving paper from one physical location to another, moving physical paper to electronic format	• New/different facilities

6. **ASSUMPTIONS** [What are some of the critical assumptions that will impact the improving this process?]

7. **QUESTIONS TO BE ANSWERED**
   - Common language:
     - Where does UW vary from national norms?
     - Where do we disagree on terminology within UW?
   - Measuring "processing" time:
     - What data is required by each unit before the clock begins?
     - What characterizes a complete review in each unit?
     - Number of times a staff or formal review committee handles a particular submission?
     - Number of deferrals of action by committees?

UNIVERSITY OF WASHINGTON
CLINICAL RESEARCH PROPOSAL REVIEW PROCESS IMPROVEMENT PROJECT
"IMPLANT & INVESTIGATIONAL DEVICES" AD HOC WORKGROUP CHARTER

1. NAME OF PROCESS: Approval of Implant & Investigational Devices

2. PROJECT ROLES

- Ad Hoc Workgroup
  - Bill Anton, Program Operations Manager/Operating Room Support Services
  - Scott Desmond, Compliance Officer/Compliance Office, Harborview Medical Center
  - Barbara Hunziker, Senior Compliance Analyst/Compliance Office, Harborview Medical Center
  - Audrey Lee, Clinical Research Federal Program Operations Specialist, Clinical Research Budget and Billing Support Office (CRBB)
  - Donald Millbauer, Director of Operative Services, Operating Room, Harborview Medical Center
  - Lisa Westlund, Compliance Officer/UWMC Office of Compliance

- Ad Hoc Workgroup Lead
  - Richard Meisinger

- Ad Hoc Workgroup Facilitator
  - Ann Wold

- Guidance for Ad Hoc Workgroup
  - Project Director, Richard Meisinger
  - Consultant, Laura Walker

- Oversight for Ad Hoc Workgroup
  - Steering Committee

3. PROJECT GOAL/OUTCOMES/DELIVERABLES:

- <u>Goal</u>
  - Document the current roles and responsibilities.
  - Build an approval process for implant and investigational devices that integrates the business practices around implant and investigational devices into the overall Clinical Research Proposal Review Process.

- <u>Outcomes</u>
  - Stakeholders understand the process and their roles and responsibilities related to the process.
  - Under roles and responsibilities, the sequencing of approvals, e.g. between CRBB and the Implant and Investigational Committee are clearly delineated.
  - Medicare policies and procedures are implemented into the proposed process.

- <u>Deliverables</u>

- Process flowcharts that incorporate implant and investigational devices into the overall process.

- Process Measurements
  - Build into the process a way to measure how long it takes to accomplish the Implant and Investigational Approval steps.
  - Build into the process a way to collect the measurement data.

4. START/END OF PROCESS:

Start	End
Ad Hoc Workgroup defines	Ad Hoc Workgroup defines

*

5. BOUNDARIES:

- What are the non-negotiable givens that will impact improving this process?
- What are some of the known constraints that will impact improving this process and, therefore, must be taken into account?

Policies/Procedures/Contracts:

In	Out
• Changing policies & procedures •	• Policies & procedures mandated by law, e.g. compliance driven

Financial:

In	Out
•	• Additional funds

Organizational/Human Resources:

In	Out
• Changing staff duties (consistent with the laws & policies that govern HR) • Changing how staff do the work • Changing organizational structure • Identification where staffing is inadequate	• Augmentation to staff in the short term

Technology:

In	Out
• Use of existing technology • Changes to the current system if the changes reduce manual movement of paper or eliminate steps	• Access to dedicated technology resources • Implementing a new technology system

Timeline:

UNIVERSITY OF WASHINGTON
CLINICAL RESEARCH PROPOSAL REVIEW PROCESS IMPROVEMENT PROJECT
"IMPLANT & INVESTIGATIONAL DEVICES" AD HOC WORKGROUP CHARTER

In	Out
•	•

Facilities:

In	Out
• Changing office layout • Changing how paper flows through the physical facilities, e.g. moving paper from one physical location to another, moving physical paper to electronic format	• New/different facilities

6. **ASSUMPTIONS** [What are some of the critical assumptions that will impact the improving this process?]

7. **QUESTIONS TO BE ANSWERED**
   - Can this review happen simultaneously with other aspects of the overall Clinical Research Proposal Review Process?
     - Final approval of NIIDR form is dependant upon approval of HSRC application (?), so these must be done concurrently.
   - Are there redundant financial reviews (CRBB and Device and Implant committee)?
     - What is the financial responsibility of the committee/council?
     - Financial clearance is necessary part of the process (?)
   - As part of the final process, can we implement more standard communication between the relevant offices?
   - What are the connections to specific research proposals?
   - Are there any relationships with IRBs?
   - Is it appropriate to try to apply metrics?
   - How does the committee/council work?
     - What is the membership?
     - How often do they meet?
     - Approximately how many requests are handled per year?
   - What are the issues with the current process?
   - Suggestions for improvement?

UNIVERSITY OF WASHINGTON
CLINICAL RESEARCH PROPOSAL REVIEW PROCESS IMPROVEMENT PROJECT
"CONSENT FORMS" AD HOC WORKGROUP CHARTER

1. NAME OF PROCESS: Consent Forms Review

2. PROJECT ROLES

- Ad Hoc Workgroup
  - Arna Elezovic, Human Subjects Division
  - Karen Hansen, FHCRC Institutional Review Office
  - Rick Hudson, EH&S, Radiation Safety Office
  - Jennifer Jones, FHCRC Protocol Office
  - JoAnn Kauffman, EH&S, Institutional Biosafety
  - Jason Malone, Institute for Translational Health Sciences (ITHS)
  - Diane Merz, Clinical Research Budget & Billing Support Office (CRBB)
  - Adina Robinson, Office of Sponsored Programs

- Ad Hoc Workgroup Lead
  - Wendy Brown, HSD

- Ad Hoc Workgroup Facilitator
  - Ann Wold

- Guidance for Ad Hoc Workgroup
  - Project Director, Richard Meisinger
  - Consultant, Laura Walker

- Oversight for Ad Hoc Workgroup
  - Steering Committee

3. PROJECT GOAL/OUTCOMES/DELIVERABLES:

- <u>Goal</u>
  - Build a review process for Consent forms that integrates the business practices around Consent forms into the overall Clinical Review Proposal Review Process.
  - Clarify roles and responsibilities.

- <u>Outcomes</u>
  - Stakeholders understand and can successfully navigate the Consent Forms Review process.
  - Stakeholders understand what part of the consent form needs to be reviewed by each unit (clarity roles and responsibilities).

- <u>Deliverables</u>
  - Process flowcharts that incorporate Consent Form reviews into the overall process.

- <u>Process Measurements</u>

- Build into the process a way to measure the time it takes each unit to review the Consent Form.
- Build into the processes a way to collect the measurement data.

4. START/END OF PROCESS:

Start	End
Ad Hoc Workgroup defines	Ad Hoc Workgroup defines

5. BOUNDARIES:

- What are the non-negotiable givens that will impact improving this process?
- What are some of the known constraints that will impact improving this process and, therefore, must be taken into account?

Policies/Procedures/Contracts:

In	Out
• Changing policies & procedures •	• Policies & procedures mandated by law, e.g. compliance driven

Financial:

In	Out
•	• Additional funds

Organizational/Human Resources:

In	Out
• Changing staff duties (consistent with the laws & policies that govern HR) • Changing how staff do the work • Changing organizational structure • Identification where staffing is inadequate	• Augmentation to staff in the short term

Technology:

In	Out
• Use of existing technology • Changes to the current system if the changes reduce manual movement of paper or eliminate steps	• Access to dedicated technology resources • Implementing a new technology system

Timeline:

In	Out
•	•

Facilities:

In	Out

• Changing office layout • Changing how paper flows through the physical facilities, e.g. moving paper from one physical location to another, moving physical paper to electronic format	• New/different facilities

6. ASSUMPTIONS [What are some of the critical assumptions that will impact the improving this process?]

7. QUESTIONS TO BE ANSWERED

- Which units currently review consent forms?
- What aspect of the consent forms is reviewed by each unit (e.g., patient financial responsibility, relationship to contract language)?
- What version (draft #) is being reviewed by each unit?
- Which units can require changes in the consent form?
- How is the requirement to change a consent form transmitted? To whom?
- To which units are modified consent forms sent?
- How do units reviewing consent forms communicate with one another?

UNIVERSITY OF WASHINGTON
CLINICAL RESEARCH PROPOSAL REVIEW PROCESS IMPROVEMENT PROJECT
"TRACKING" AD HOC WORKGROUP CHARTER

1. NAME OF PROCESS: Interim System to Track Status of Proposal

2. PROJECT ROLES

- Ad Hoc Workgroup
  - Candy Grossman, Human Subjects Division
  - Jennifer Jones, FHCRC Protocol Office
  - Karl Neumann, Office of Sponsored Programs
  - Sonja Stella, School of Medicine, Division of Oncology
  - Dorsee Zaballero, Clinical Research Budget & Billing Support Office (CRBB)

- Ad Hoc Workgroup Lead:
  - Jim Kresl, Office of Research Information Services (ORIS)

- Ad Hoc Workgroup Facilitator
  - Ann Wold

- Guidance for Ad Hoc Workgroup
  - Project Director, Richard Meisinger
  - Consultant, Laura Walker

- Oversight for Ad Hoc Workgroup
  - Steering Committee

3. PROJECT GOAL/OUTCOMES/DELIVERABLES:

- Goal
  - Develop an inventory of tracking systems currently in use.
  - Develop recommendations for interim approaches that improve the transparency of tracking.
  - Identify issues and challenges that need to be addressed as part of developing the interim solution.
  - Evaluate the interim solution options. Assess cost/benefit, resource requirements, etc. Channel through any prioritization processes (e.g. roadmap or data consolidation project governance).
  - Select interim solution and work with Steering Committee and Executive Sponsors to secure resources.

    Note: This shorter term effort does not eliminate the need to perform a complete requirements analysis for a tracking system (associated with the Research Roadmap). It's to take a look at what can be done in the short term while the longer-term effort proceeds.

- Outcomes
  - A plan for an interim tracking system that allows:
    - Principal Investigators and unit staff to determine the status of a proposal.

- Stakeholders to understand the tracking system and their responsibility for maintaining the system.

- Deliverables
  - Process flowcharts for the Interim Tracking System that include:
    - How the system works
    - How the system is updated
    - How someone accesses the system to determine the status of a proposal
  - Technological infrastructure requirements
  - Standardized reports, e.g. monthly

- Process Measurements
  - Build into the process a way to measure whether or not Principal Investigators and units are able to determine the status of proposals.
  - Build into the process a way to collect the measurement data, e.g. success rate in determining status of proposal.

4. START/END OF PROCESS:

Start	End
The first time a Principal Investigator submits something that they will want to know the status on.	When the Principal Investigator has approval to enroll subjects.

*

5. BOUNDARIES:

- What are the non-negotiable givens that will impact improving this process?
- What are some of the known constraints that will impact improving this process and, therefore, must be taken into account?

Policies/Procedures/Contracts:

In	Out
• Changing policies & procedures •	• Policies & procedures mandated by law, e.g. compliance driven

Financial:

In	Out
•	• Additional funds

Organizational/Human Resources:

In	Out
• Changing staff duties (consistent with the laws & policies that govern HR) • Changing how staff do the work • Changing organizational structure	• Augmentation to staff in the short term

• Identification where staffing is inadequate	

Technology:

In	Out
• Use of existing technology • Changes to the current system if the changes reduce manual movement of paper or eliminate steps	• Access to dedicated technology resources • Implementing a new technology system

Timeline:

In	Out
•	•

Facilities:

In	Out
• Changing office layout • Changing how paper flows through the physical facilities, e.g. moving paper from one physical location to another, moving physical paper to electronic format	• New/different facilities

6. **ASSUMPTIONS** [What are some of the critical assumptions that will impact the improving this process?]

7. **QUESTIONS**
   - Who needs to have access to the updates?
   - How frequently must information be updated?
   - Who is responsible for providing updated information on a regular basis?
   - Who is responsible for maintaining the tracking system?
   - What data points and data currently exist that can be incorporated into an interim tracking system?

UNIVERSITY OF WASHINGTON
CLINICAL RESEARCH PROPOSAL REVIEW PROCESS IMPROVEMENT PROJECT
"INSTITUTIONAL BIOSAFETY/RADIATION SAFETY" AD HOC WORKGROUP CHARTER

1. NAME OF PROCESS:

- Institutional Biosafety approval process
- Radiation Safety approval process

2. PROJECT ROLES

- Ad Hoc Workgroup
  - Lisa Dunnwald, Nuclear Medicine
  - Steve Johnson, SCCA Biosafety Committee
  - Karen Moe, Human Subjects Division
  - Marc Provence, Cancer Consortium
  - Dr. Lupe Salazar, School of Medicine, Division of Oncology
  - Sonja Stella, School of Medicine, Division of Oncology

- Ad Hoc Workgroup Co-Leads
  - Stanley Addison, EH&S, Radiation Safety Office
  - JoAnn Kauffman, EH&S, Institutional Biosafety Office

- Ad Hoc Workgroup Facilitator
  - Ann Wold

- Guidance for Ad Hoc Workgroup
  - Project Director, Richard Meisinger
  - Consultant, Laura Walker

- Oversight for Ad Hoc Workgroup
  - Steering Committee

3. PROJECT GOAL/OUTCOMES/DELIVERABLES:

- <u>Goals</u>
  - Document the current workflow, analyze and recommend improvements (short and long term) to the Institutional Biosafety and Radiation Safety processes.
  - Clarify roles and responsibilities.
  - Locate the policies and procedures that impact these processes and provide as part of the process information.
  - Strengthen the Institutional Safety/IRB connection.
  - Strengthen the Radiation Safety/IRB connection.

- <u>Outcomes</u>
  - Stakeholders understand and can successfully navigate the Institutional Biosafety and Radiation Safety processes.

- <u>Deliverables</u>

UNIVERSITY OF WASHINGTON
CLINICAL RESEARCH PROPOSAL REVIEW PROCESS IMPROVEMENT PROJECT
"INSTITUTIONAL BIOSAFETY/RADIATION SAFETY" AD HOC WORKGROUP CHARTER

- A process flowchart of the proposed Institutional Biosafety process.
- A process flowchart of the proposed Radiation Safety process.
- A common data template for IRBs and Radiation Safety Committee.

- Process Measurements
  - Build into the process a way to measure the time it takes for a proposal to go through the Institutional Biosafety process.
  - Build into the process a way to measure the time it takes for a proposal to go through the Radiation Safety process.
  - For IBC and Radiation Safety, build into the processes a way to measure the number of proposals where action is deferred to subsequent Committee Meetings.
  - Build into the processes a way to collect the measurement data.

4. START/END OF PROCESS:

Institutional Biosafety

Start	End
Ad Hoc Workgroup defines	Ad Hoc Workgroup defines

Radiation Safety

Start	End
Ad Hoc Workgroup defines	Ad Hoc Workgroup defines

5. BOUNDARIES:

- What are the non-negotiable givens that will impact improving this process?
- What are some of the known constraints that will impact improving this process and, therefore, must be taken into account?

Policies/Procedures/Contracts:

In	Out
• Changing policies & procedures •	• Policies & procedures mandated by law, e.g. compliance driven

Financial:

In	Out
•	• Additional funds

Organizational/Human Resources:

In	Out
• Changing staff duties (consistent with the laws & policies that govern HR) • Changing how staff do the work • Changing organizational structure	• Augmentation to staff in the short term

• Identification where staffing is inadequate	

Technology:

In	Out
• Use of existing technology • Changes to the current system if the changes reduce manual movement of paper or eliminate steps	• Access to dedicated technology resources • Implementing a new technology system

Timeline:

In	Out
•	•

Facilities:

In	Out
• Changing office layout • Changing how paper flows through the physical facilities, e.g. moving paper from one physical location to another, moving physical paper to electronic format	• New/different facilities

6. **ASSUMPTIONS** [What are some of the critical assumptions that will impact the improving this process?]

7. **QUESTIONS TO BE ANSWERED**
   - What is the nature of the formal communications between the IRBS and IBC?
   - How do the respective staffs communicate?
   - Does a PI go directly to the IBC/staff, or is he/she directed by the IRB?
   - If a research subject potentially can be moved between several clinical facilities, do multiple IBCs need to be involved in the review/approval process?
   - To which IRB does the Radiation Safety Committee report?
   - What is the nature of the formal communications between the IRBs and the RSC?
   - How do the respective staffs communicate?
   - What is the complimentarity of reviews between UW and SCCA RSCs?
   - How can the Memorandum of Agreement on the distinction between routine care and research care for studies involving radiation be refined?
   - Certain kinds of proposals require an NIH/OBA review. Which proposals? How much time does this take? How is the PI notified?

Approval of Implant & Investigational Devices Ad Hoc Workgroup

~~Anton, Bill~~	~~Operating Room Support Services~~
Brown,Wendy	Human Subjects Division
Desmond, Scott	Compliance Office, Harborview Medical Center
Hunziker, Barbara	Compliance Office, Harborview Medical Center
Lee, Audrey	Clinical Research Budget and Billing Support Office (CRBB)
Millbauer, Donald	Operating Room, Harborview Medical Center
Robinson, Adina	Office of Sponsored Programs
Westlund, Lisa	UWMC Office of Compliance

Clinical Research Proposal Review Process Ad Hoc Workgroup

Chronister, Lynn	*Office of Sponsored Programs*
Corn, Michael	Office of Sponsored Programs
Flores, Debbie	Office of Research
Grossman, Candy	Human Subjects Division / Research
Hammond, Sue	Medicine, Div of Oncology
Merz, Diane	Clinical Research Budget & Billing Support Office
Moe, Karen	Human Subjects Division
Van Patten, Darcy	Office of Research Information Services (ORIS)

Consent Forms Review Process Ad Hoc Workgroup

Brown, Wendy	*Human Subjects Division*
Elezovic, Arna	Human Subjects Division
Hansen, Karen	FHCRC Institutional Review Office
Hudson, Rick	Radiation Safety Office, Environmental Health & Safety
Kauffman, JoAnn	Research and Biological Safety Office, Environmental Health and Safety
Malone, Jason	Dean of Medicine
Merz, Diane	Clinical Research Budget & Billing Support Office
Riddle, James	FHCRC Institutional Review Office
Robinson, Adina	Office of Sponsored Programs

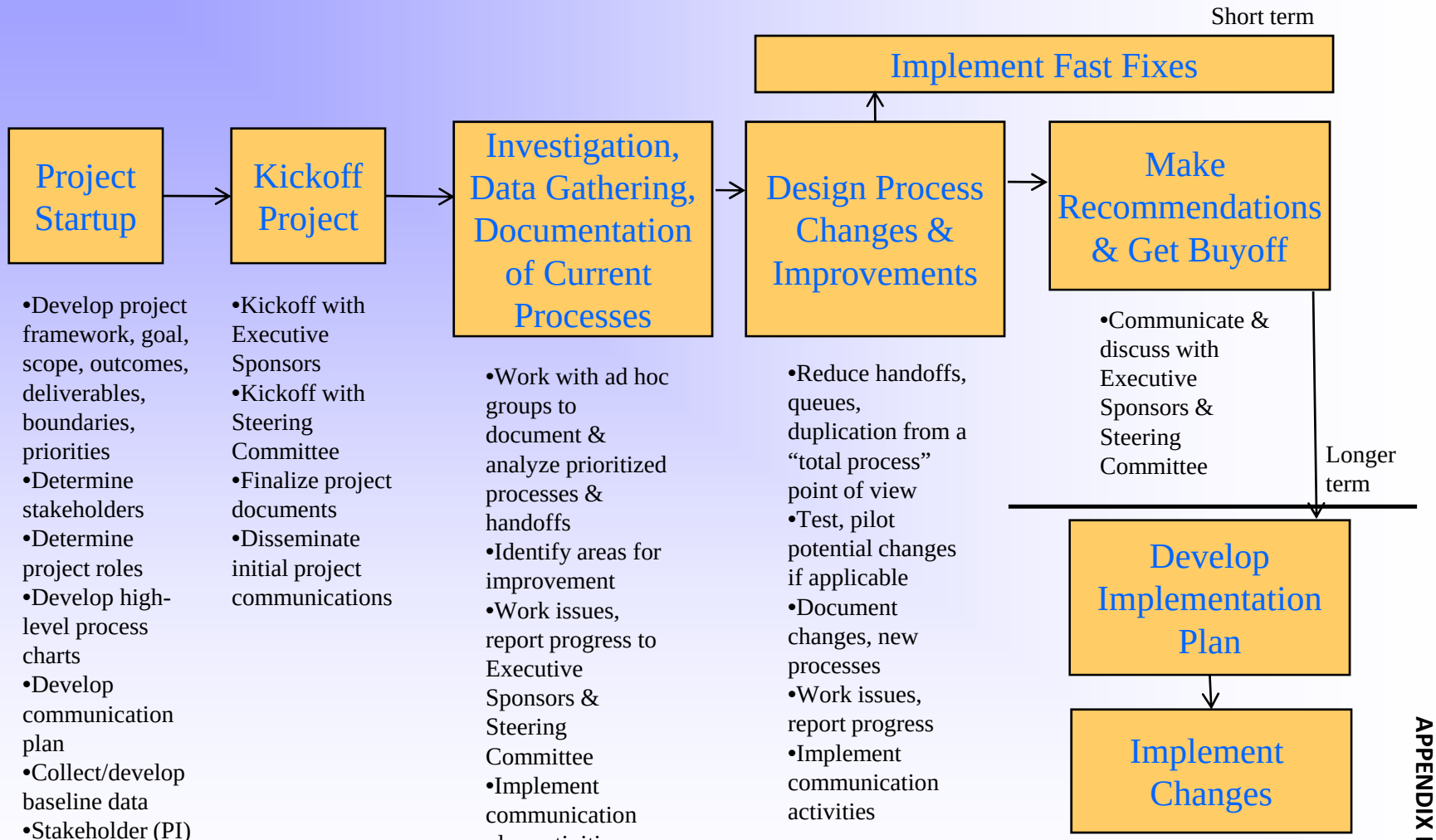
Institutional Biosafety/Radiation Safety Ad Hoc Workgroup

Addison, Stanley	*Environmental Health and Safety*
Hudson, Rick	Radiation Safety Office, Environmental Health & Safety
Kauffman, JoAnn	*Research and Biological Safety Office, Environmental Health and Safety*
Moe, Karen	Human Subjects Division
Provence, Marc	Cancer Consortium, Medicine
Stella, Sonja	Medicine, Division of Oncology

Tracking System Ad Hoc Workgroup

Chronister, Lynn	Office of Sponsored Programs
Kresl, Jim	*ORIS, Office of Research*
Merz, Diane	Clinical Research Budget & Billing Support Office
Moe, Karen	Human Subjects Division
Stella, Sonja	Medicine, Division of Oncology
Van Patten, Darcy	Office of Research Information Services (ORIS)
Zaballero, Dorsee	Clinical Research Budget & Billing Support Office

Clinical Research Startup Process
High-Level Project Steps



D1

APPENDIX D

The Walker Company
walkercompany@comcast.net

Appendix E
Index of Process Maps

Pages

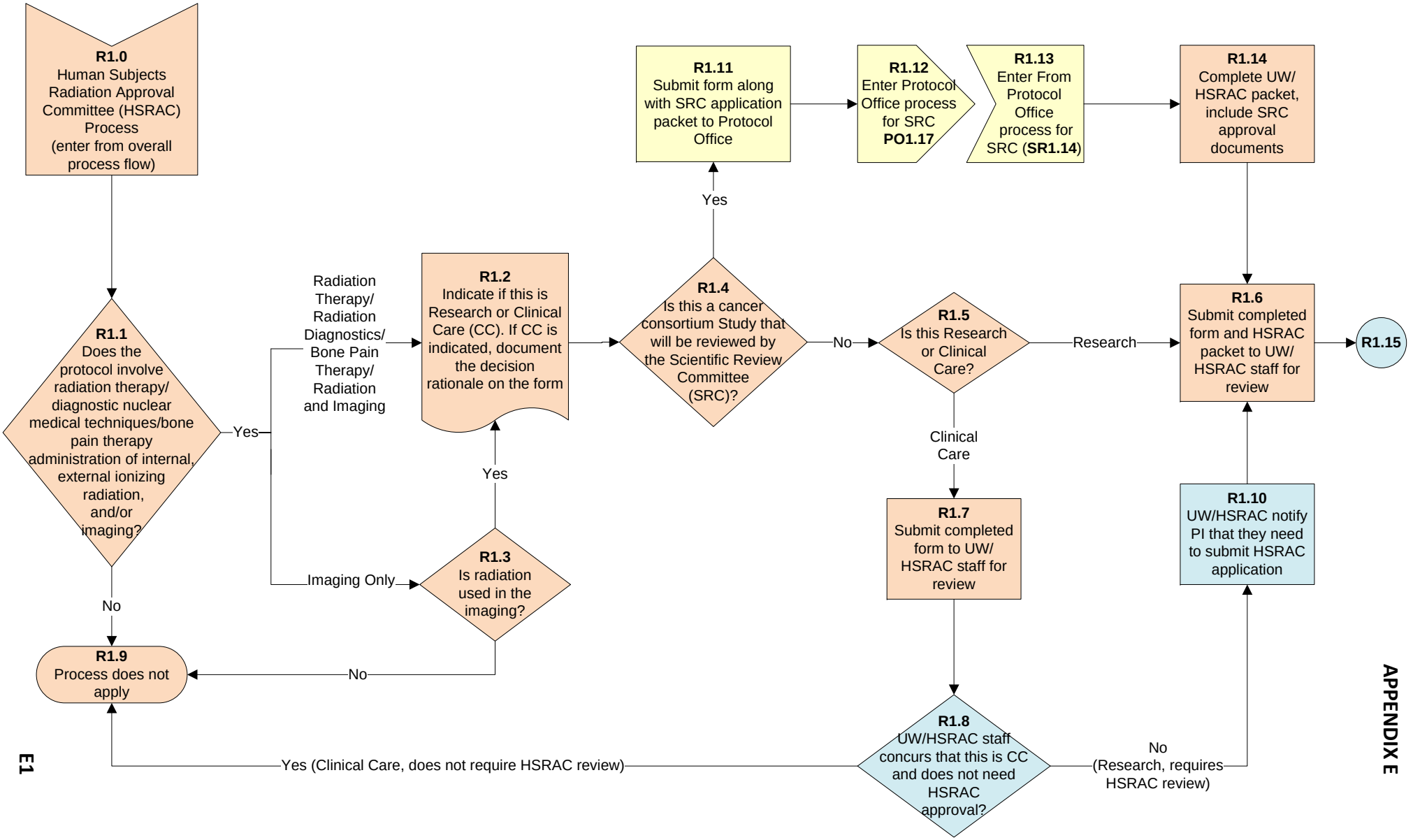
University of Washington

Clinical Research Proposal Review Process Improvement Project

Human Subjects Radiation Approval Committee Process

FINAL as of 9/1/09

Key	
	Common Process (Performed by investigator)
	SCCA Specific Process
	CommonProcess/Performed at Separate Facilities
	HSRAC Process



E1

APPENDIX E

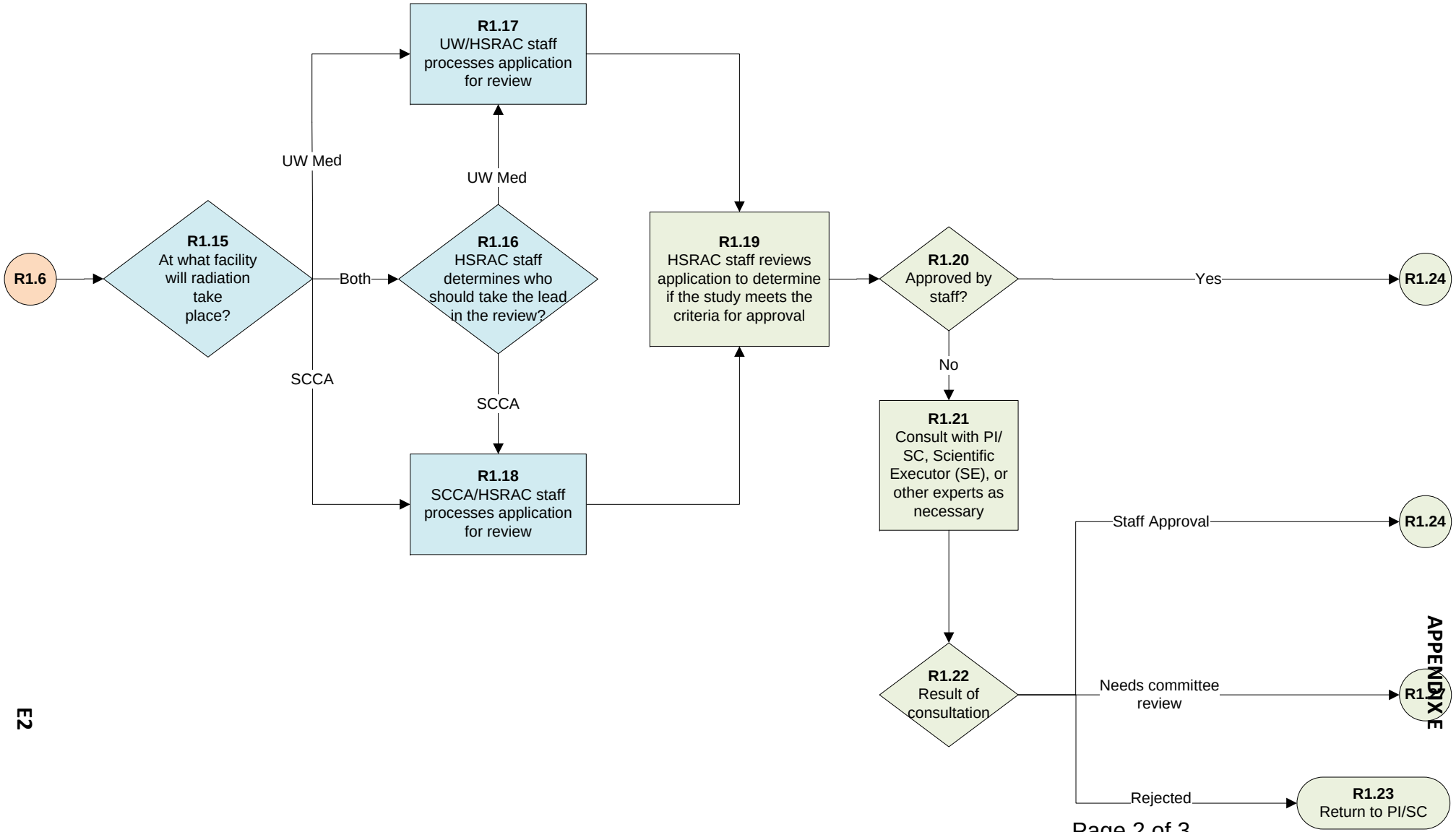
University of Washington

Clinical Research Proposal Review Process Improvement Project

Human Subjects Radiation Approval Committee Process

FINAL as of 9/1/09

Key	
	Common Process (Performed by Investigator)
	SCCA Specific Process
	CommonProcess/Performed at Separate Facilities
	HSRAC Process



APPENDIX E

E2

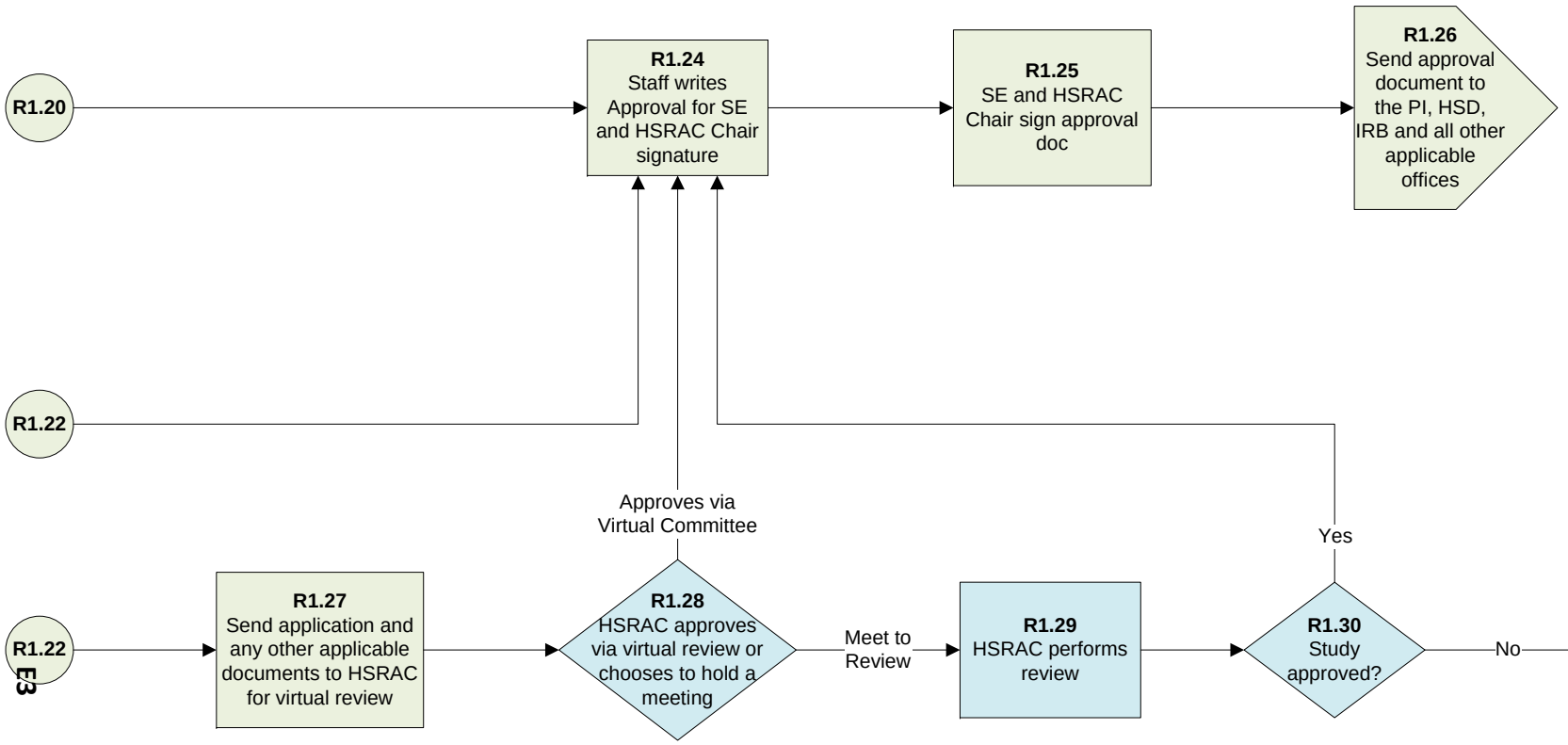
University of Washington

Clinical Research Proposal Review Process Improvement Project

Human Subjects Radiation Approval Committee Process

FINAL as of 9/1/09

Key	
	Common Process (Performed by Investigator)
	SCCA Specific Process
	CommonProcess/Performed at Separate Facilities
	HSRAC Process



E3

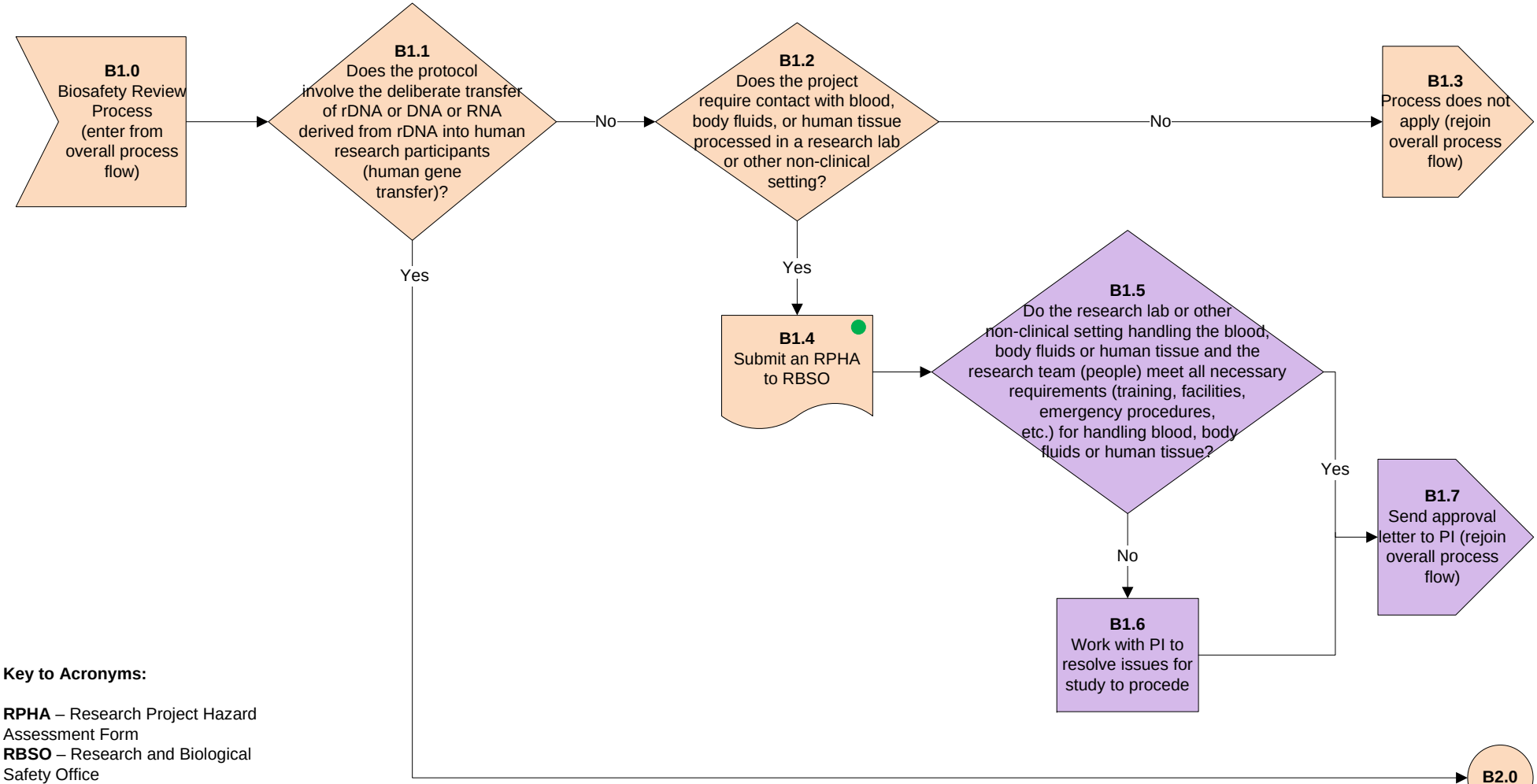
APPENDIX E

University of Washington

Clinical Research Proposal Review Process Improvement Project

UW Biosafety Review Process | FINAL as of 8/19/09

Key	
	PI process
	OBA/RAC process
	RBSO/IBC process



Key to Acronyms:

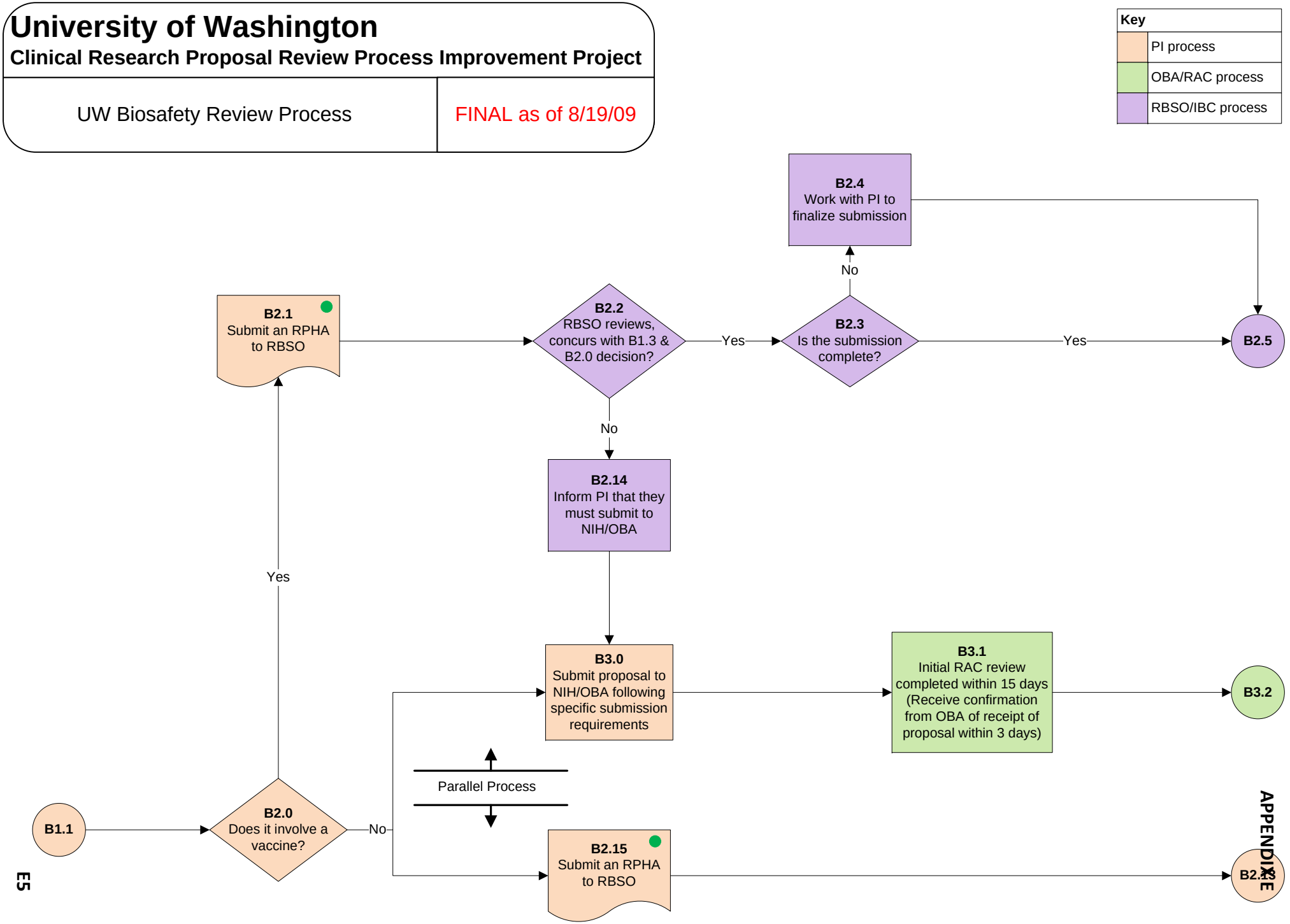
RPHA – Research Project Hazard Assessment Form
RBSO – Research and Biological Safety Office
BBP – Blood Borne Pathogen
OBA - Office of Biotechnology Activities (NIH)
RAC - Recombinant DNA Advisory Committee (NIH)
IBC – Institutional Biosafety Committee
rDNA – Recombinant DNA

APPENDIX E

University of Washington

Clinical Research Proposal Review Process Improvement Project

UW Biosafety Review Process | FINAL as of 8/19/09

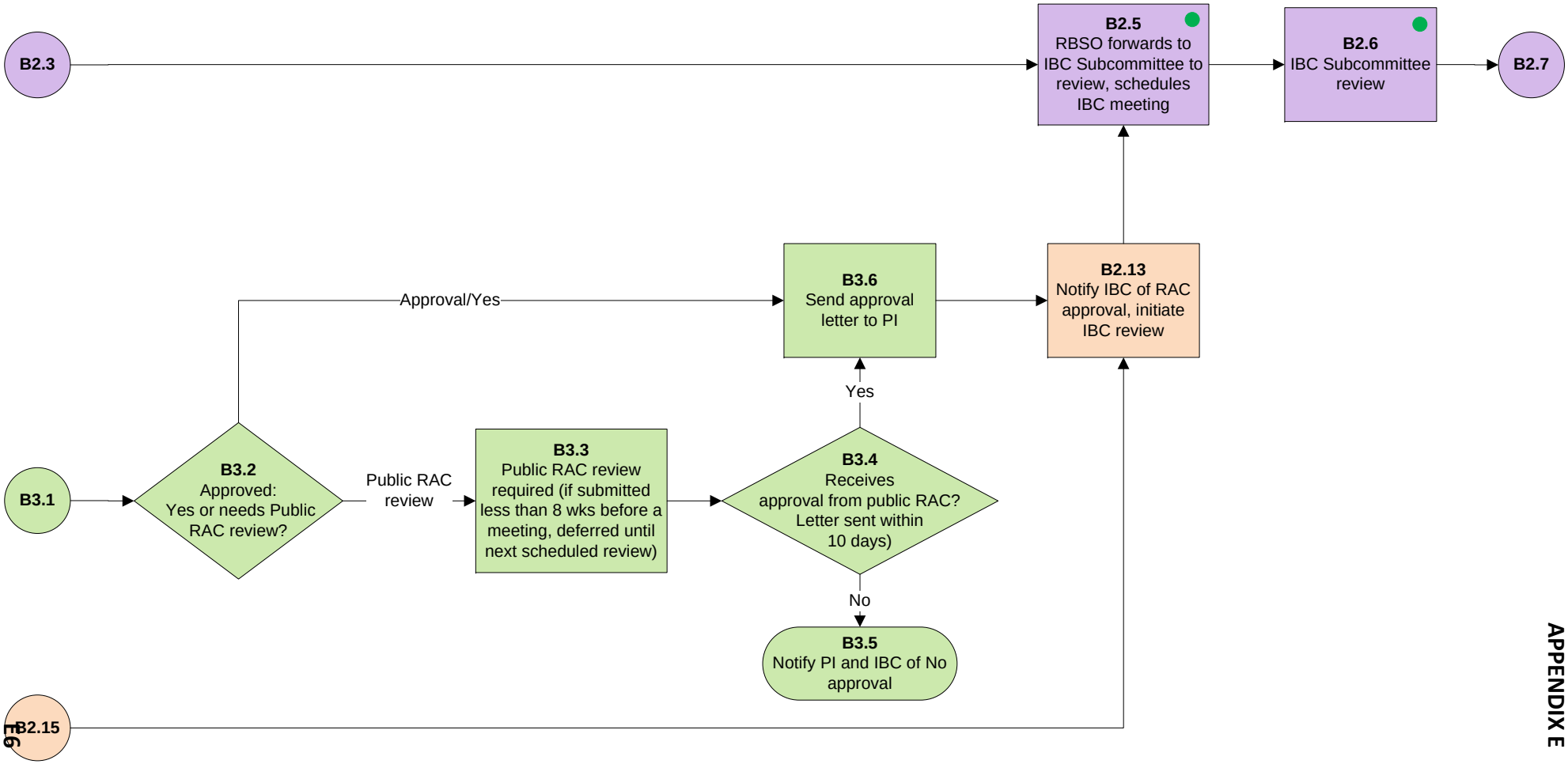


University of Washington

Clinical Research Proposal Review Process Improvement Project

UW Biosafety Review Process | FINAL as of 8/19/09

Key
PI process
OBA/RAC process
RBSO/IBC process



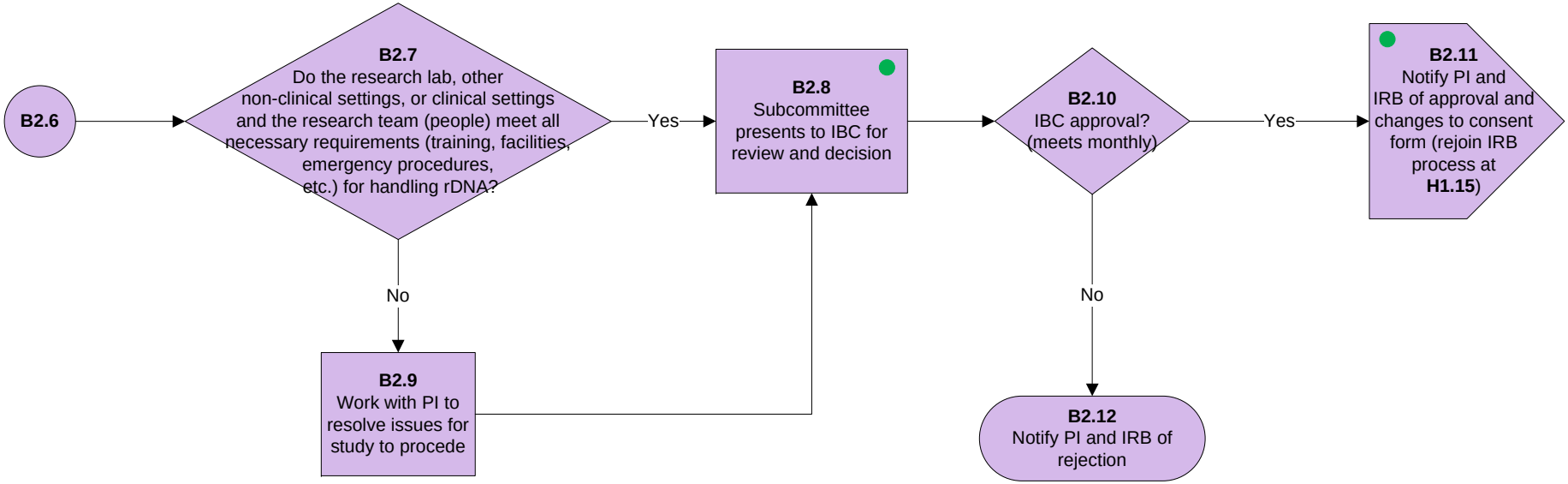
APPENDIX E

University of Washington

Clinical Research Proposal Review Process Improvement Project

UW Biosafety Review Process	FINAL as of 8/19/09

Key	
	PI process
	OBA/RAC process
	RBSO/IBC process



E7

APPENDIX E

University of Washington

Clinical Research Proposal Review Process Improvement Project

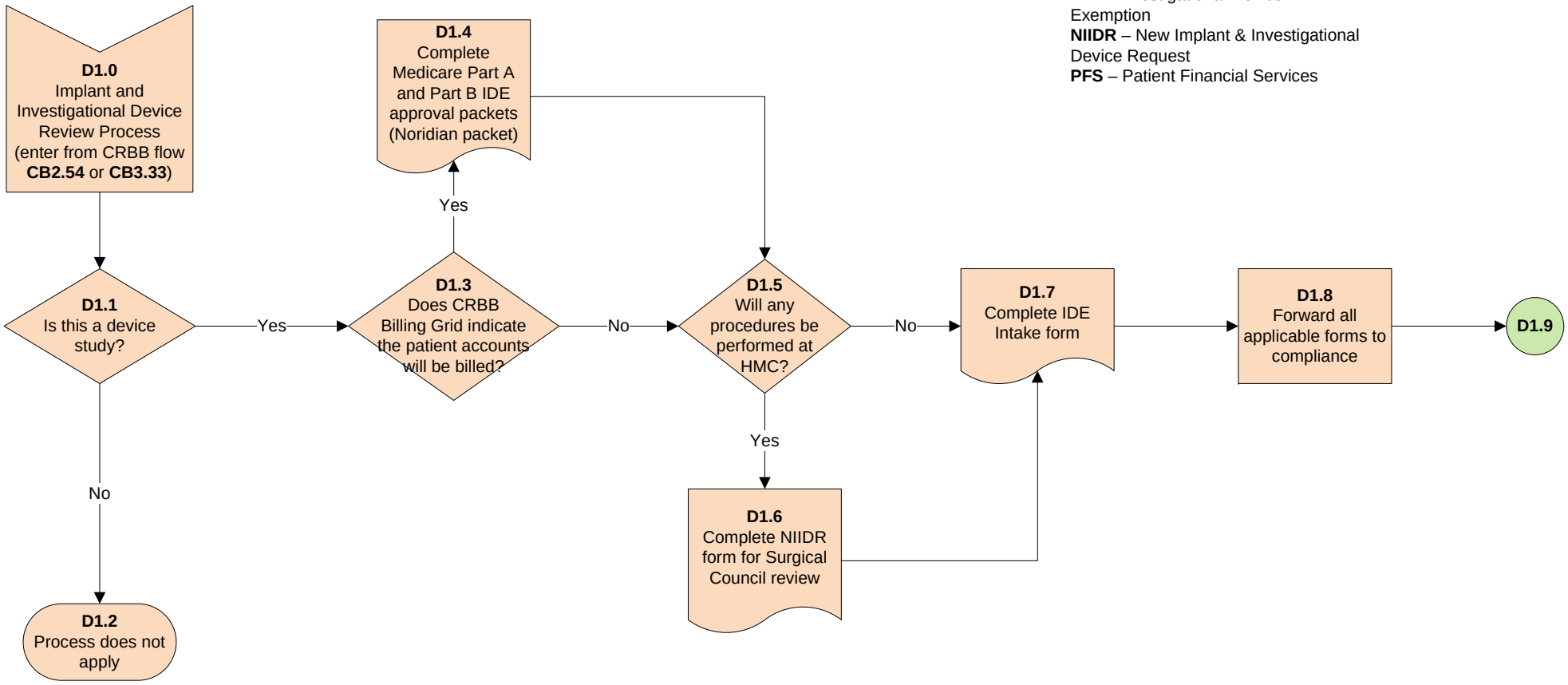
Implant and Investigational Device Review Process

FINAL as of 8/25/09

Key	
	Common Process (Performed by investigator)
	Compliance Process

Key to Acronyms:

HMC – Harborview Medical Center
IDE – Investigational Device Exemption
NIIDR – New Implant & Investigational Device Request
PFS – Patient Financial Services



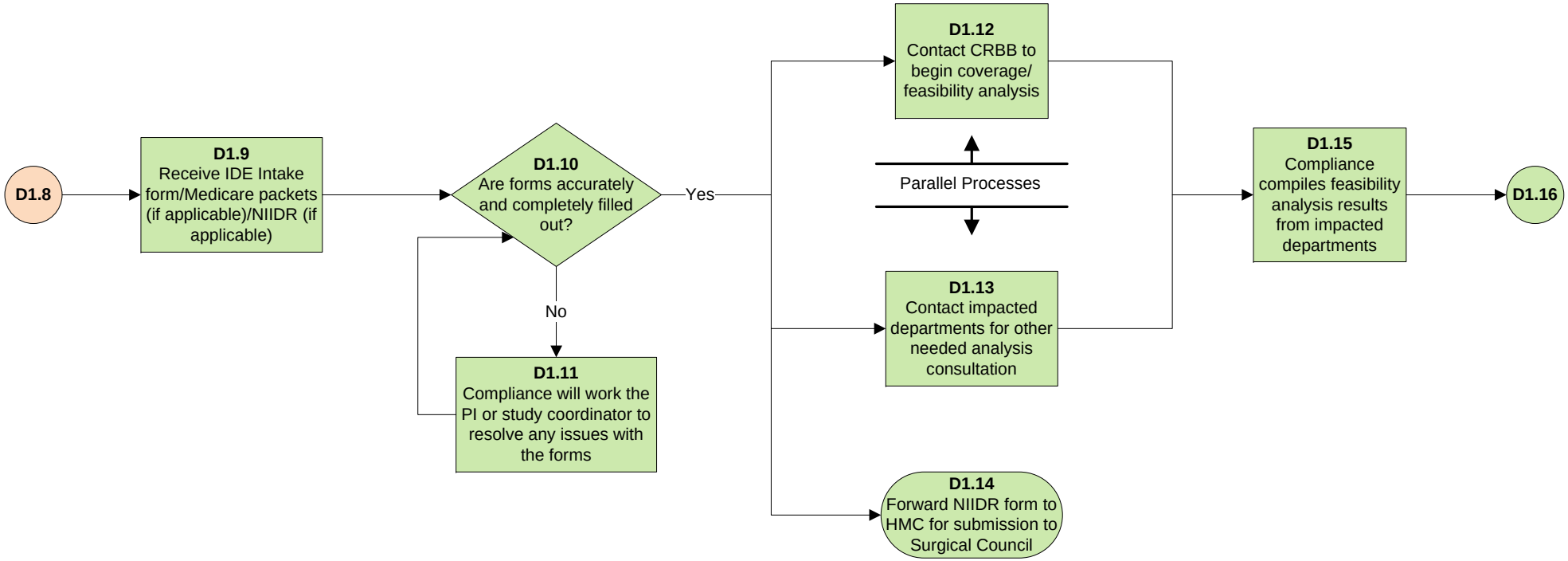
E8

APPENDIX E

University of Washington

Clinical Research Proposal Review Process Improvement Project

Implant and Investigational Device Review Process	FINAL as of 8/25/09



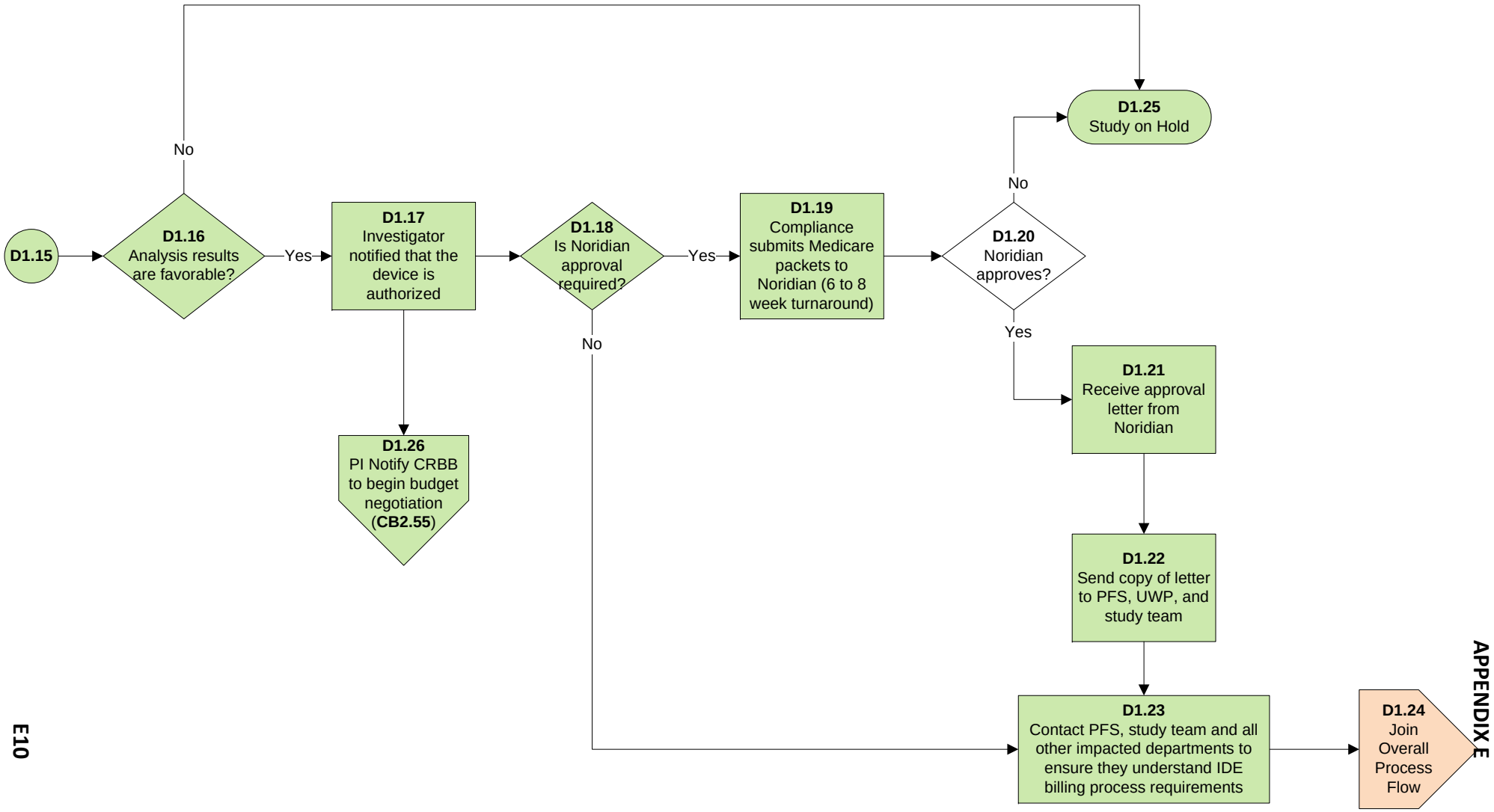
E9

APPENDIX E

University of Washington

Clinical Research Proposal Review Process Improvement Project

Implant and Investigational Device Review Process	FINAL as of 8/25/09

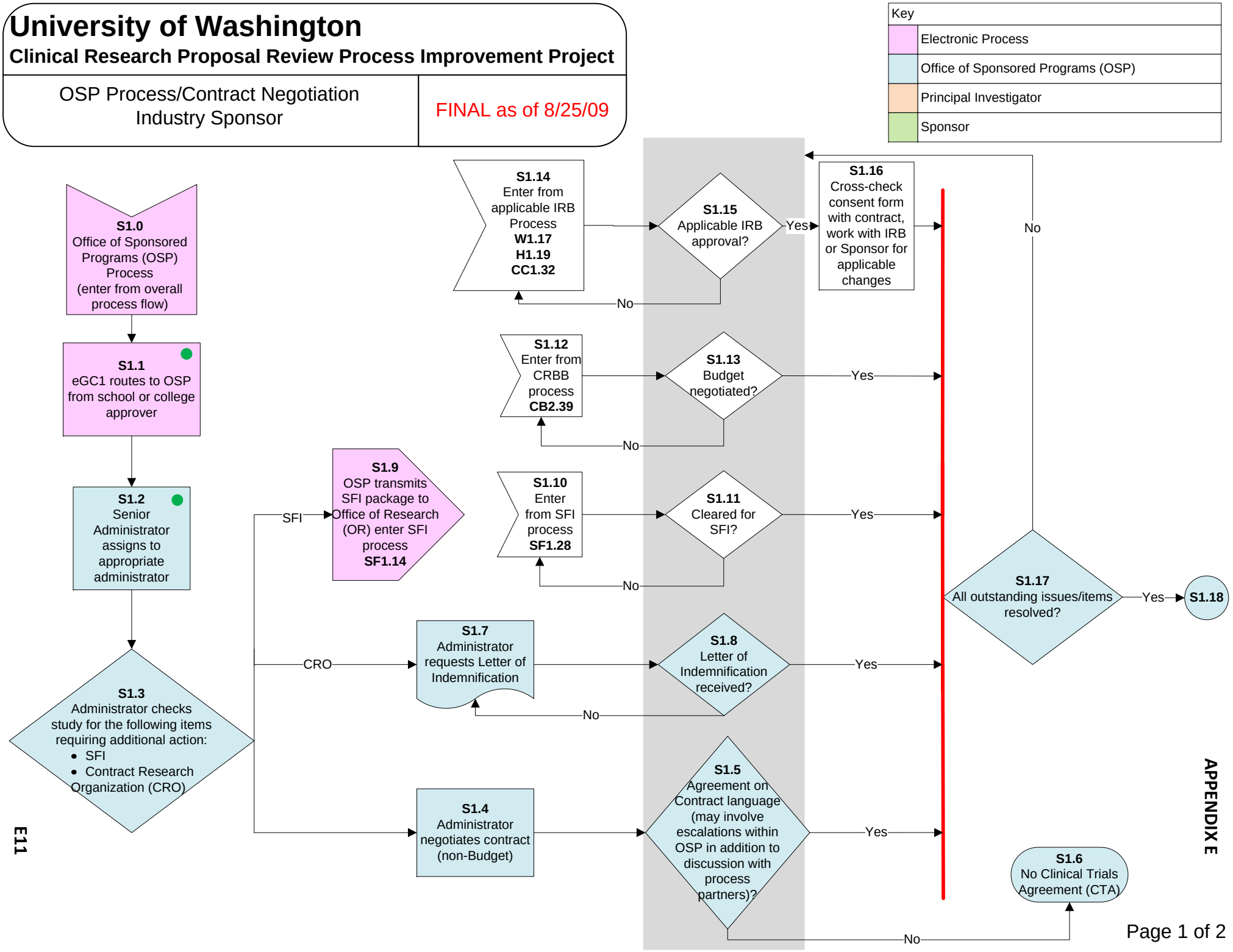


University of Washington

Clinical Research Proposal Review Process Improvement Project

OSP Process/Contract Negotiation
Industry Sponsor

FINAL as of 8/25/09

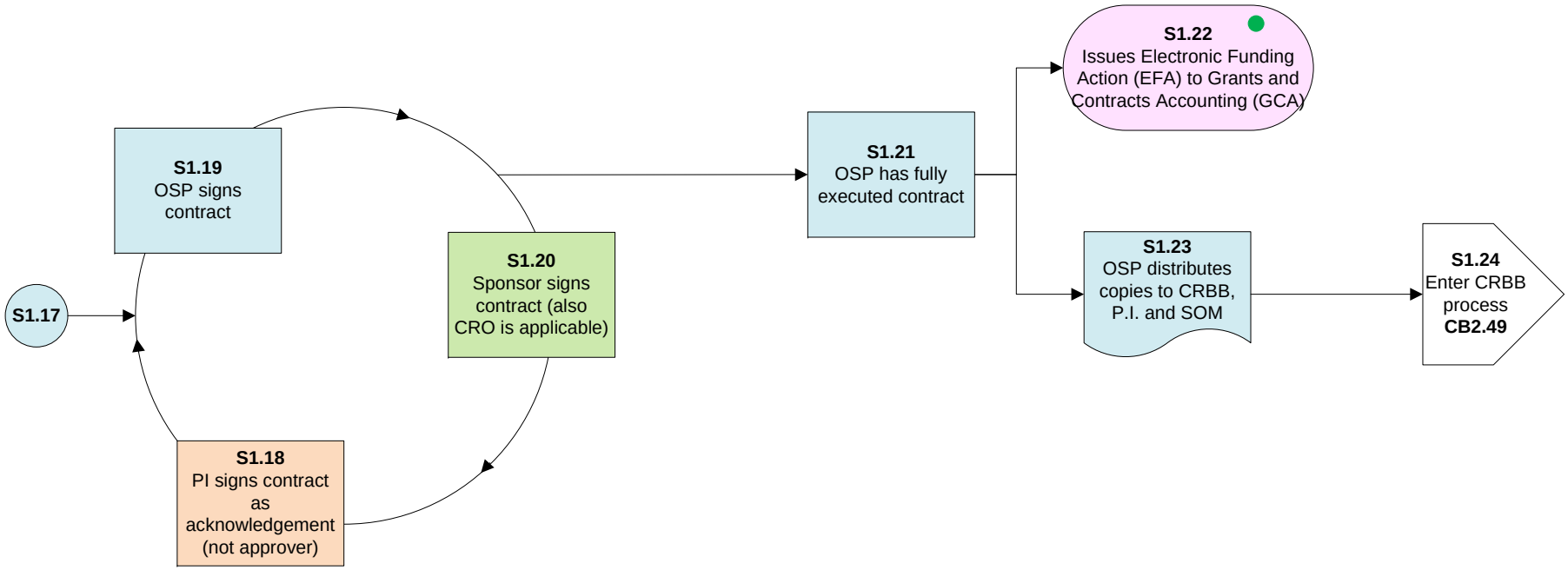


University of Washington

Clinical Research Proposal Review Process Improvement Project

OSP Process/Contract Negotiation Industry Sponsor	FINAL as of 8/25/09

Key	
	Electronic Process
	Office of Sponsored Programs (OSP)
	Principal Investigator
	Sponsor



E12

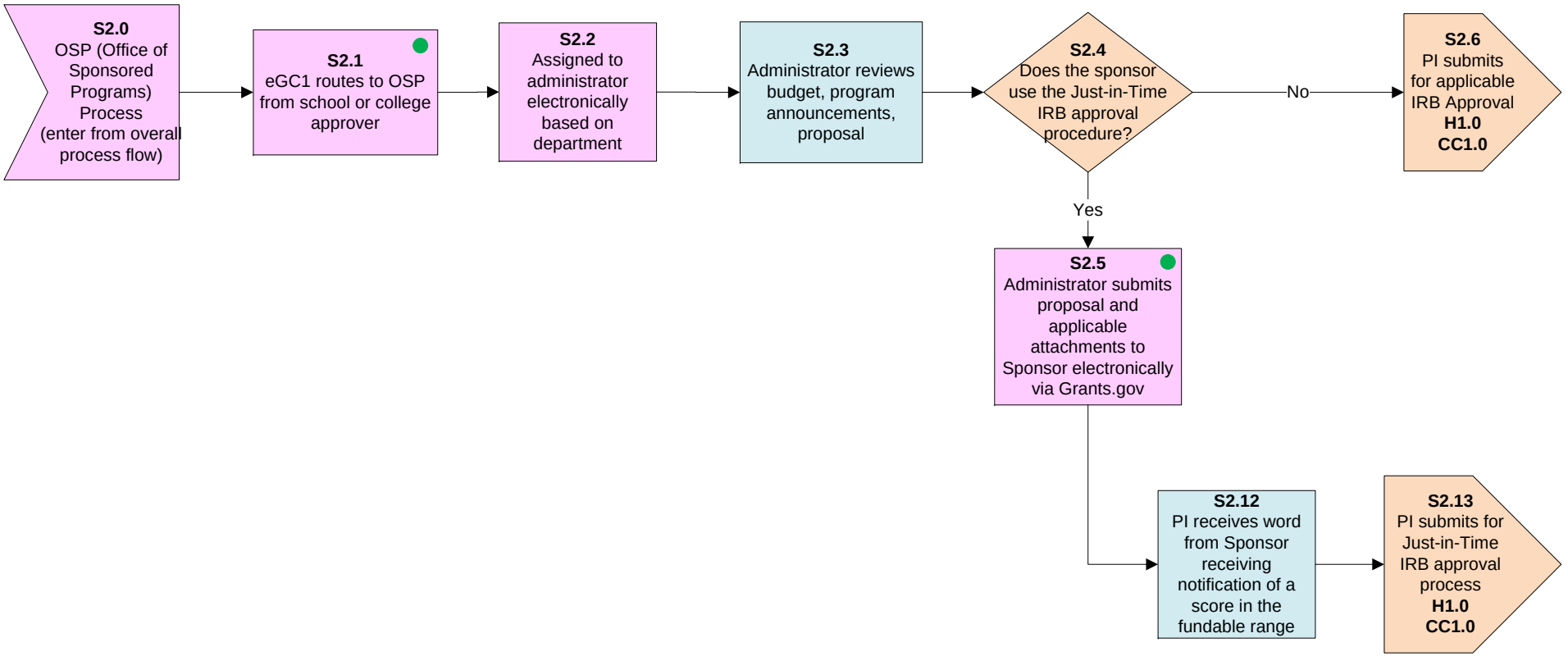
APPENDIX E

University of Washington

Clinical Research Proposal Review Process Improvement Project

OSP Process/Proposal Government	FINAL as of 8/25/09

Key	
	Electronic Process
	Office of Sponsored Programs (OSP)
	Principal Investigator
	Sponsor



E13

APPENDIX E

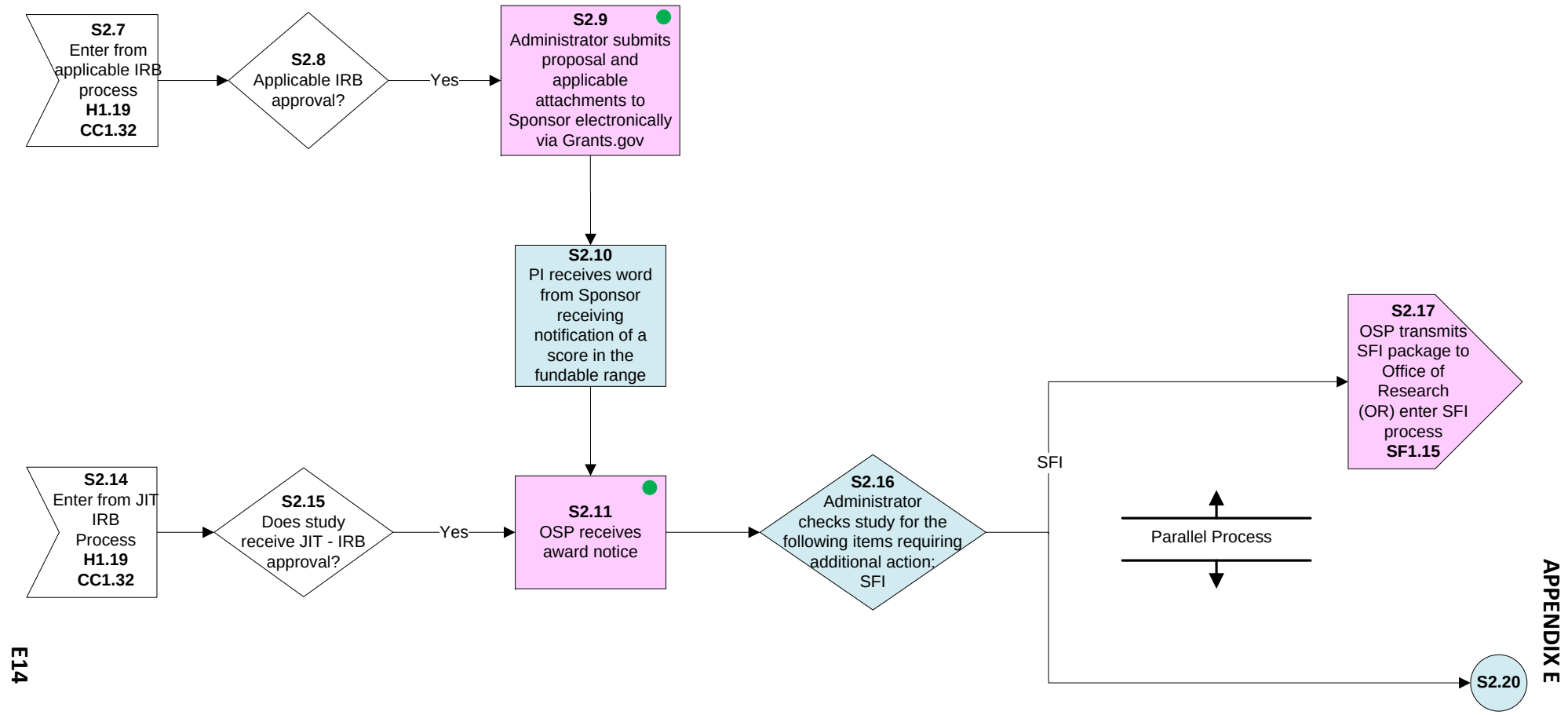
University of Washington

Clinical Research Proposal Review Process Improvement Project

OSP Process/Proposal Government

FINAL as of 8/25/09

Key	
	Electronic Process
	Office of Sponsored Programs (OSP)
	Principal Investigator
	Sponsor



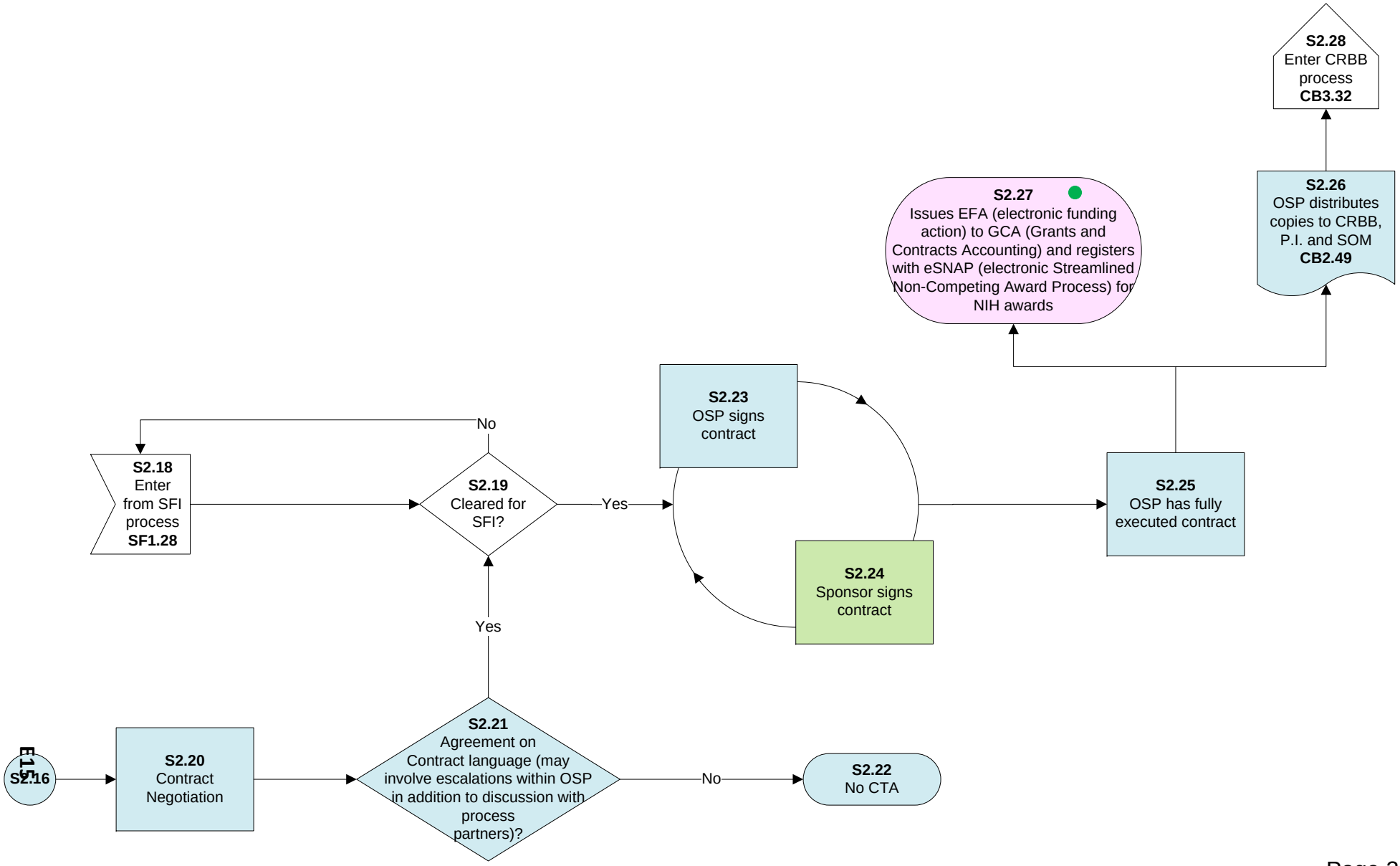
University of Washington

Clinical Research Proposal Review Process Improvement Project

OSP Process/Proposal Government

FINAL as of 8/25/09

Key	
	Electronic Process
	Office of Sponsored Programs (OSP)
	Principal Investigator
	Sponsor



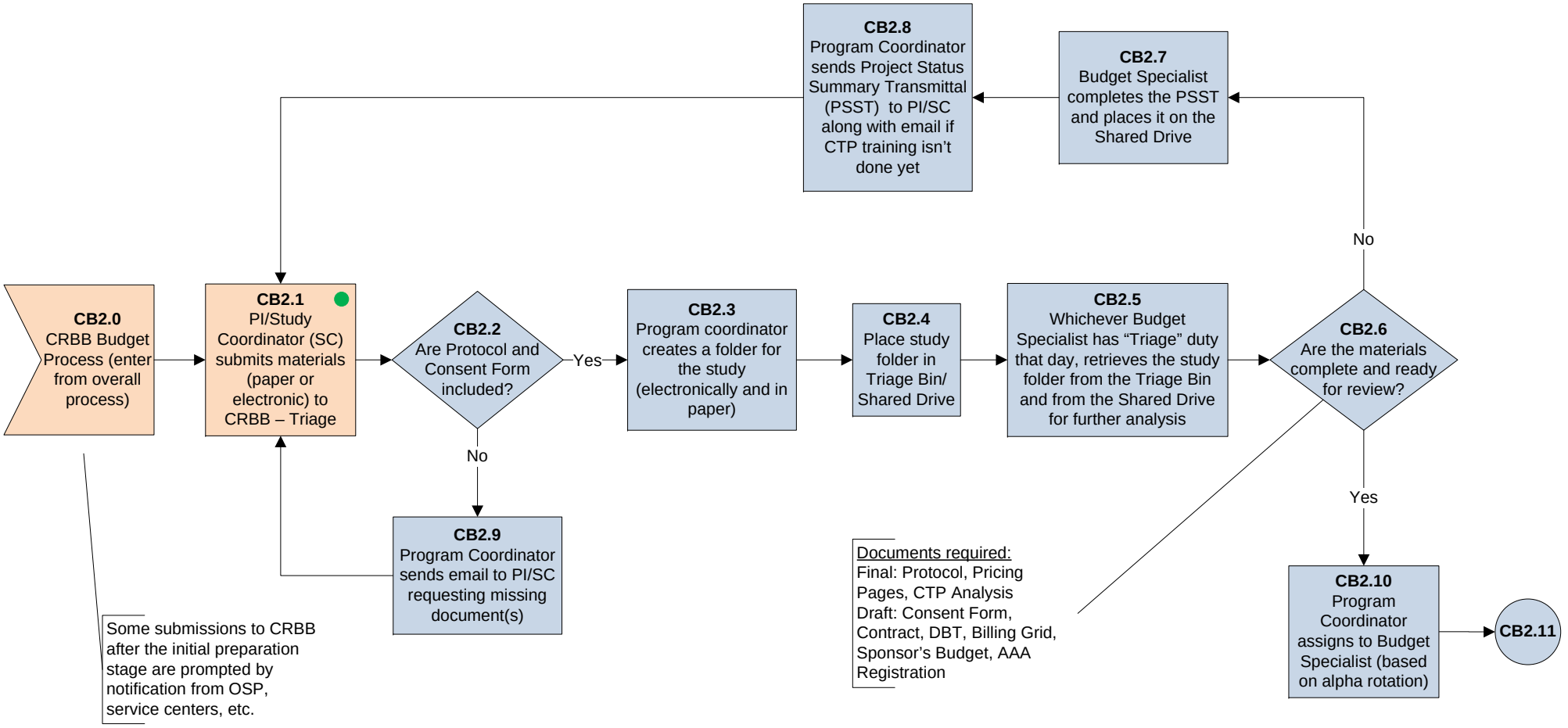
APPENDIX E

University of Washington

Clinical Research Proposal Review Process Improvement Project

CRBB Process
Budget Preparation - Industry

FINAL as of 10/23/09



Key	
	PI process
	CRBB process
	Div Admin or Dept Dir process
	Sponsor process
	OSP process

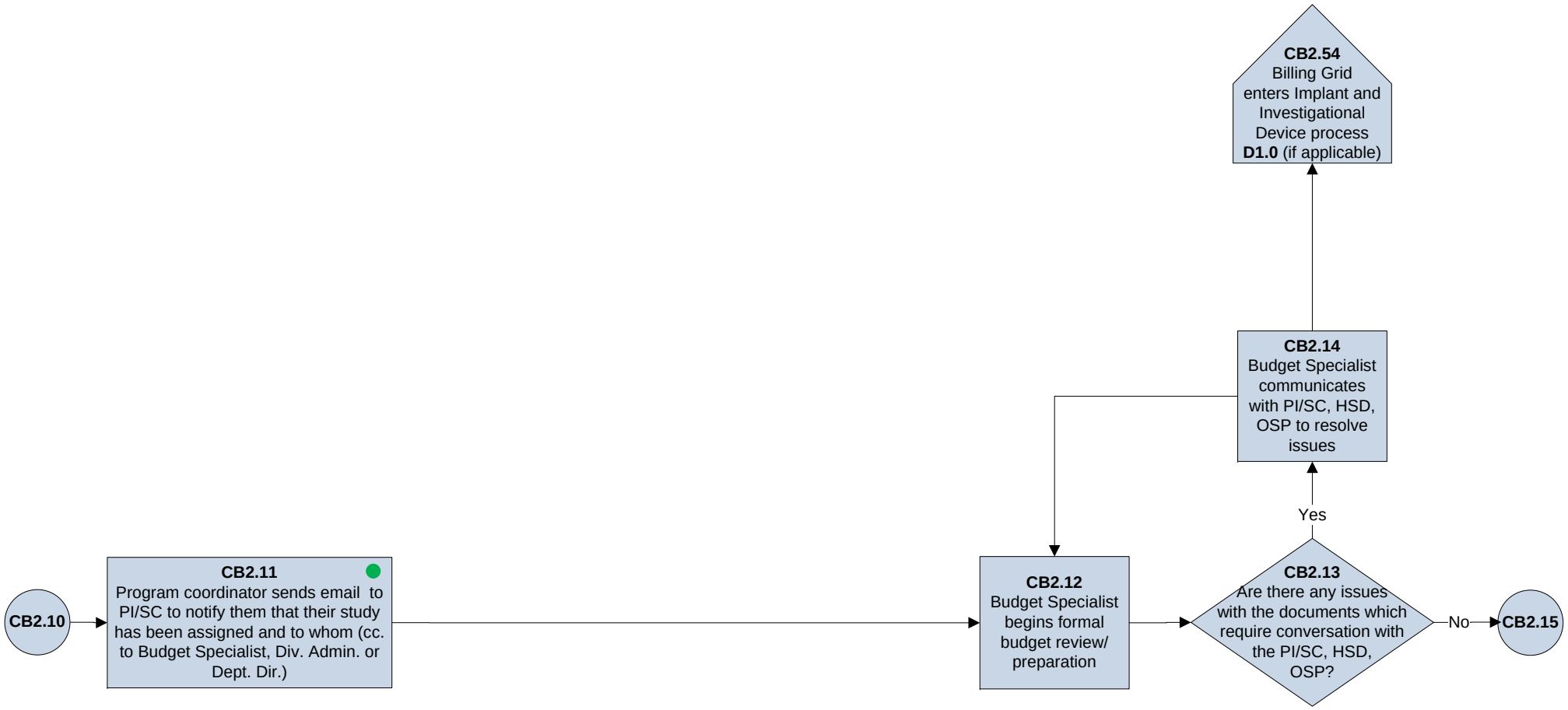
E16

APPENDIX E

University of Washington

Clinical Research Proposal Review Process Improvement Project

CRBB Process Budget Preparation - Industry	FINAL as of 10/23/09



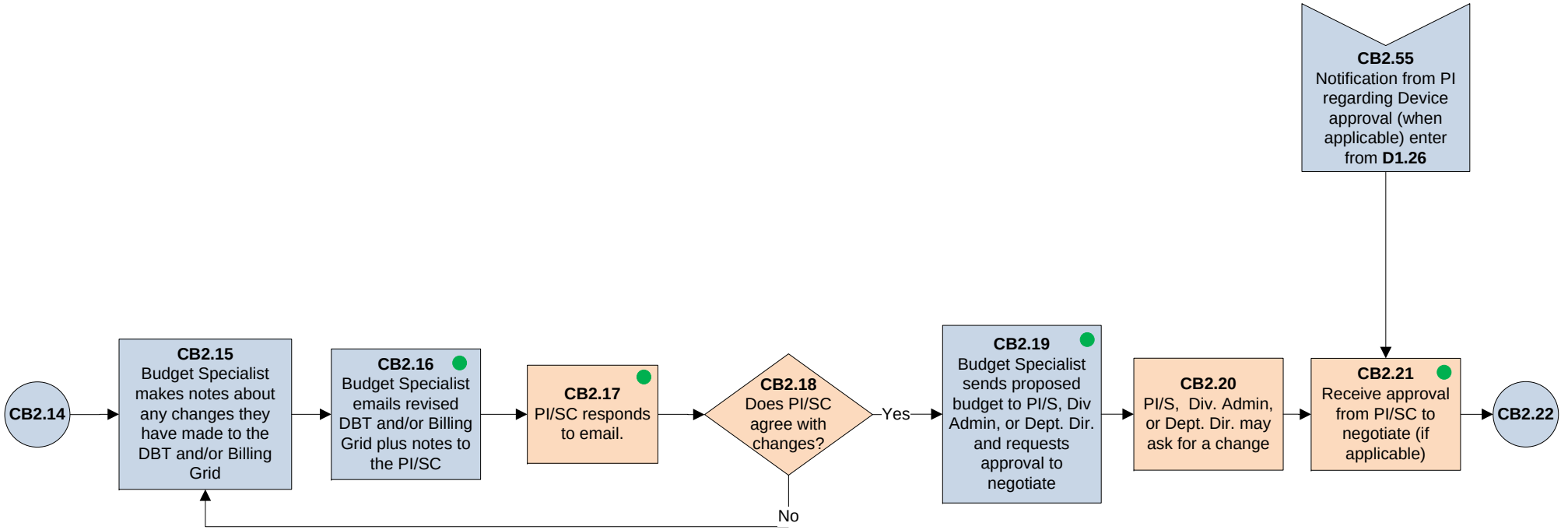
E17

APPENDIX E

University of Washington

Clinical Research Proposal Review Process Improvement Project

CRBB Process Budget Preparation - Industry	FINAL as of 10/23/09



E18

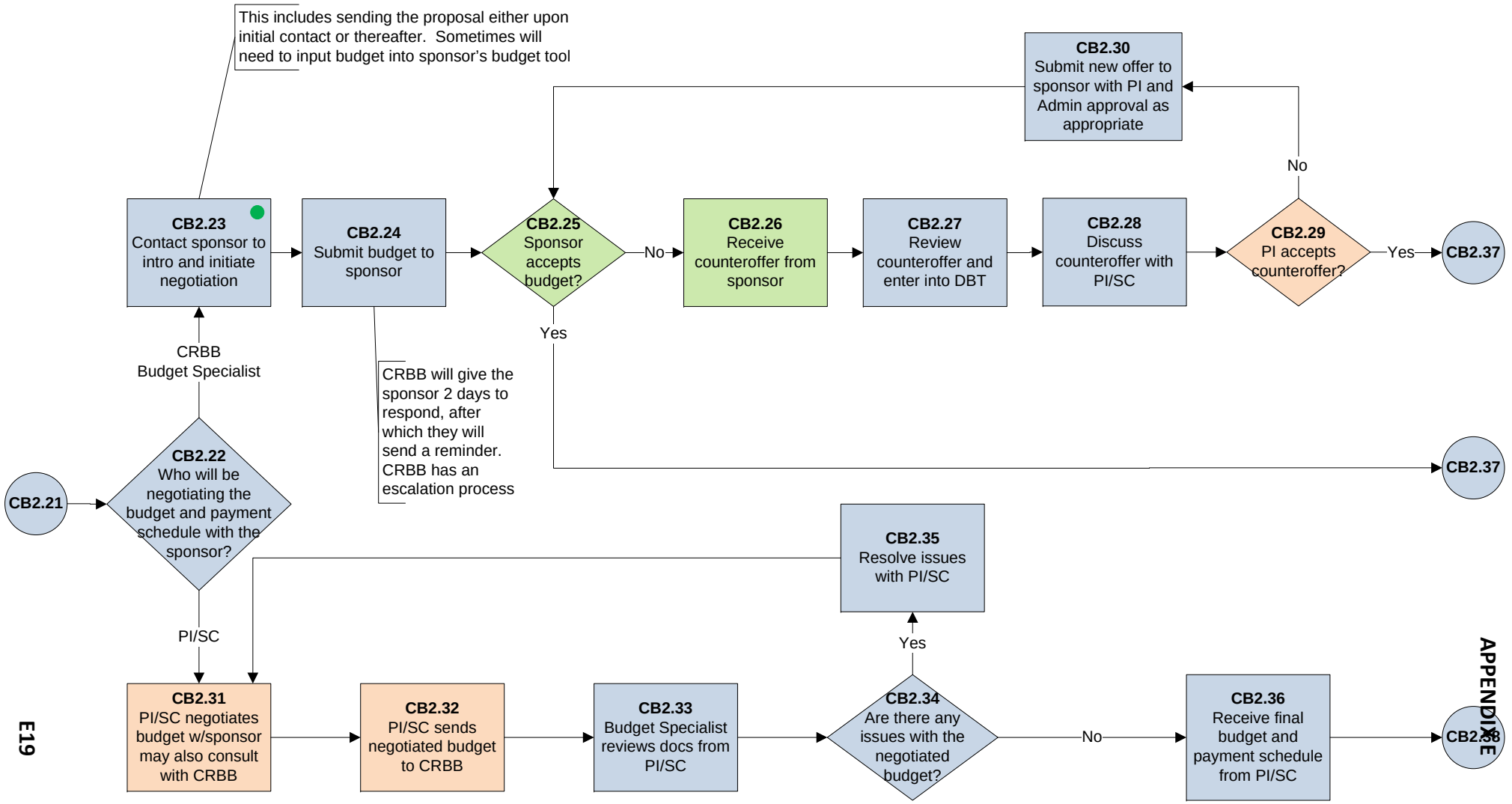
APPENDIX E

University of Washington

Clinical Research Proposal Review Process Improvement Project

CRBB Process
Budget Negotiation - Industry

FINAL as of 10/23/09

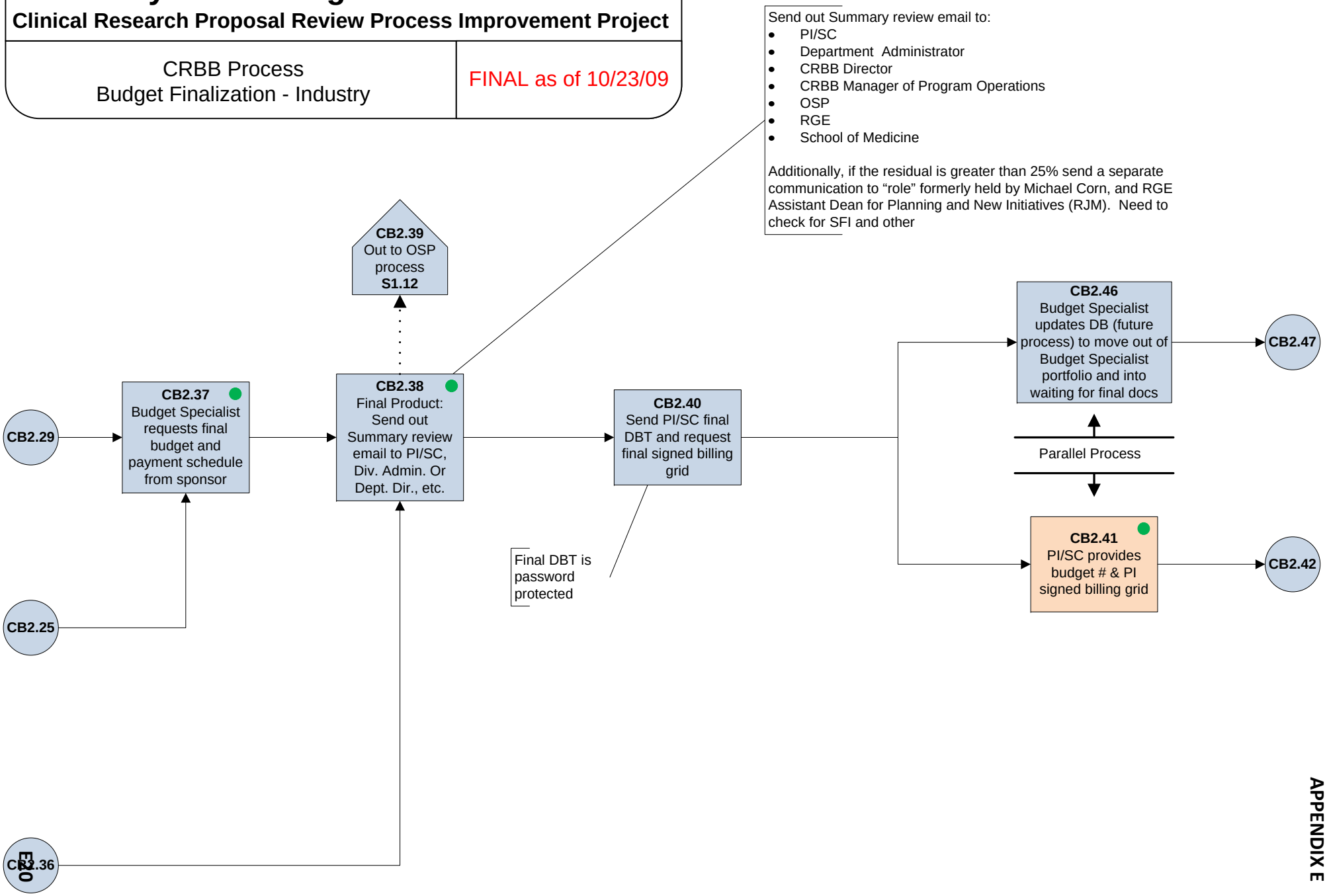


University of Washington

Clinical Research Proposal Review Process Improvement Project

CRBB Process
Budget Finalization - Industry

FINAL as of 10/23/09



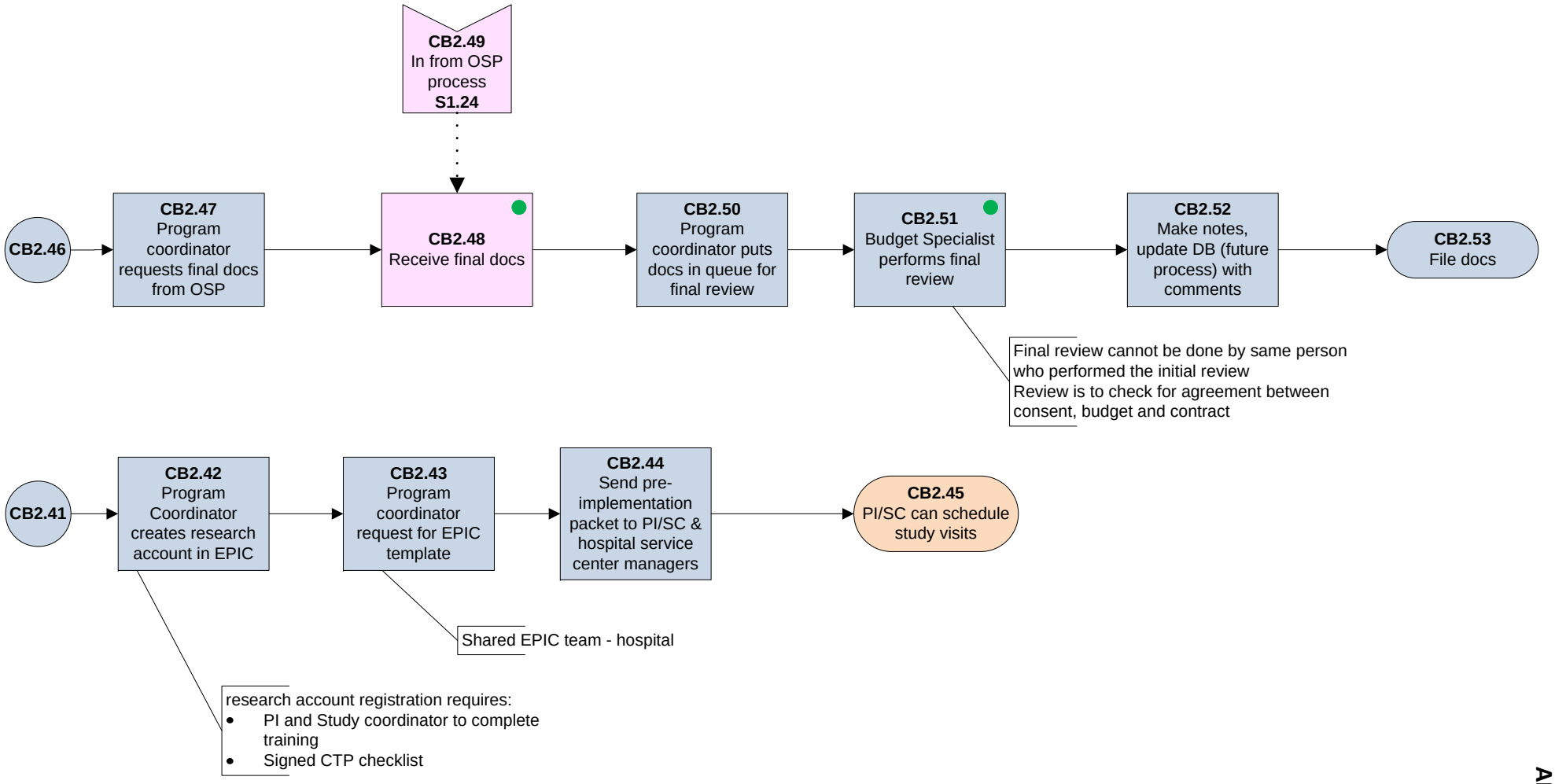
APPENDIX E

University of Washington

Clinical Research Proposal Review Process Improvement Project

CRBB Process
Budget Finalization - Industry

FINAL as of 10/23/09



E21

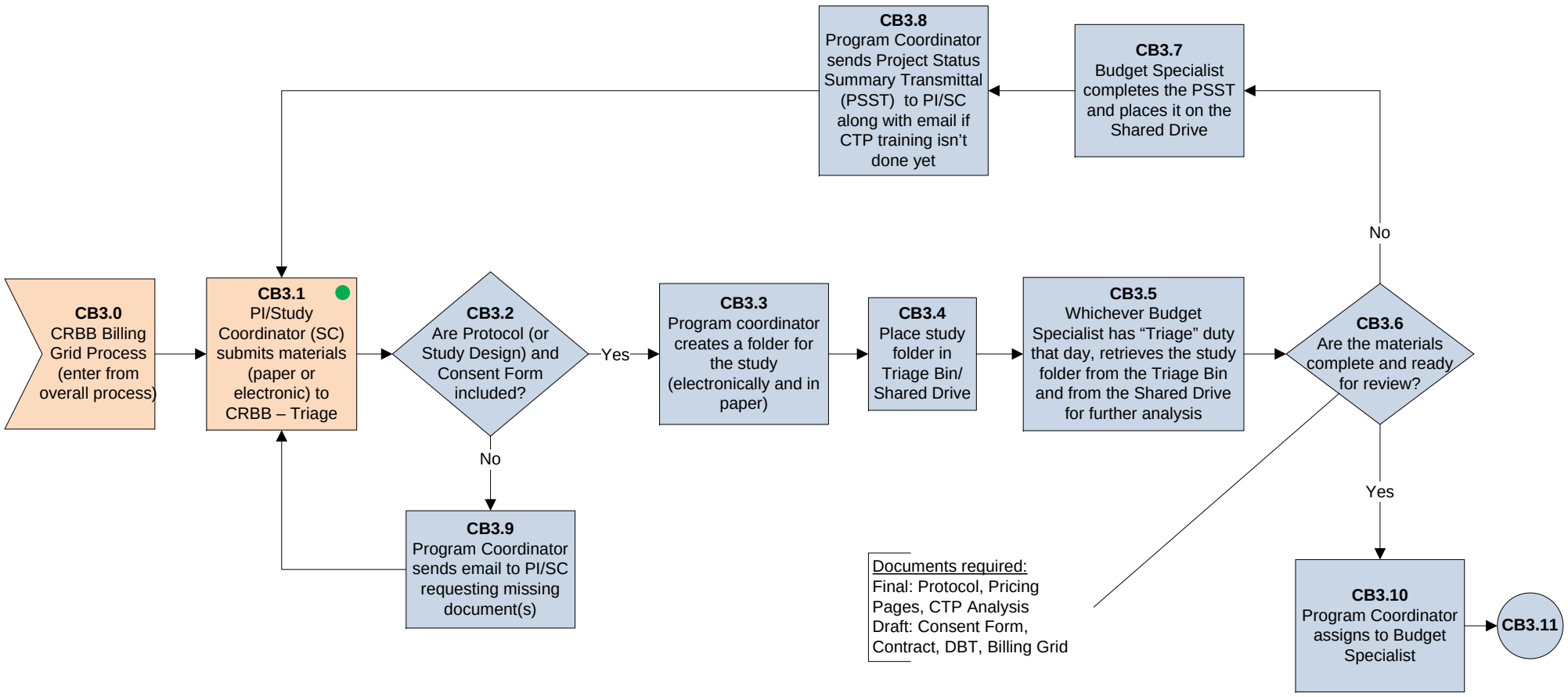
APPENDIX E

University of Washington

Clinical Research Proposal Review Process Improvement Project

CRBB Process
Billing Grid Prep – Non-Industry

FINAL as of 10/23/09



Key	
	PI process
	CRBB process
	Div Admin or Dept Dir process
	Sponsor process
	OSP process

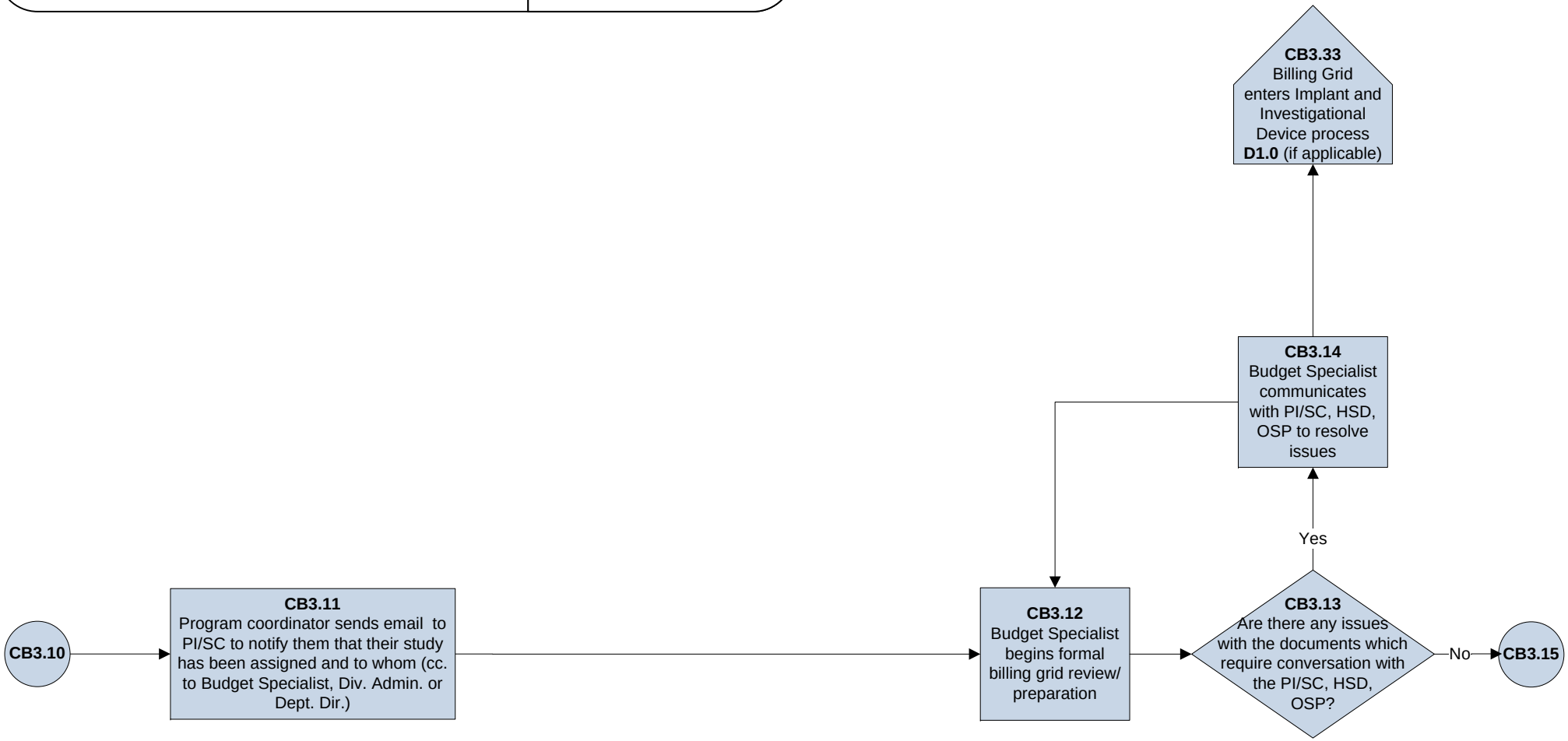
E22

APPENDIX E

University of Washington

Clinical Research Proposal Review Process Improvement Project

CRBB Process Billing Grid Prep – Non-Industry	FINAL as of 10/23/09



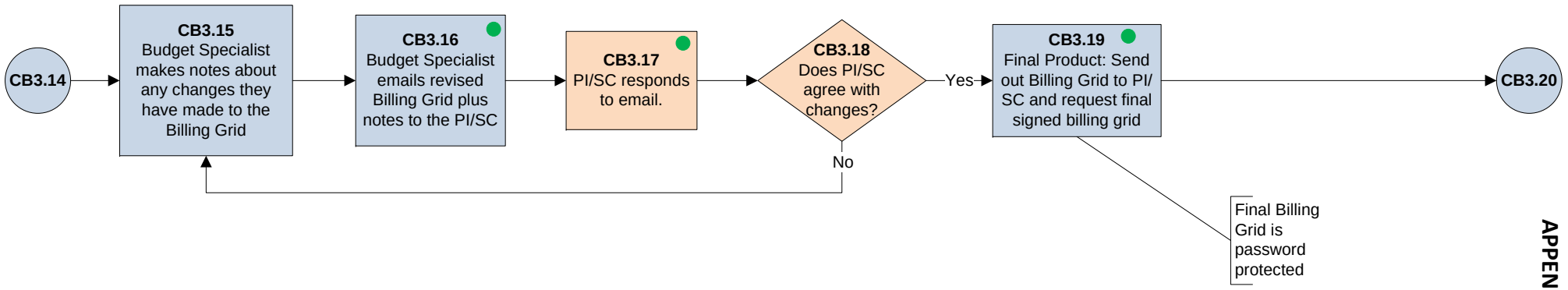
E23

APPENDIX E

University of Washington

Clinical Research Proposal Review Process Improvement Project

CRBB Process Billing Grid Final – Non-Industry	FINAL as of 10/23/09



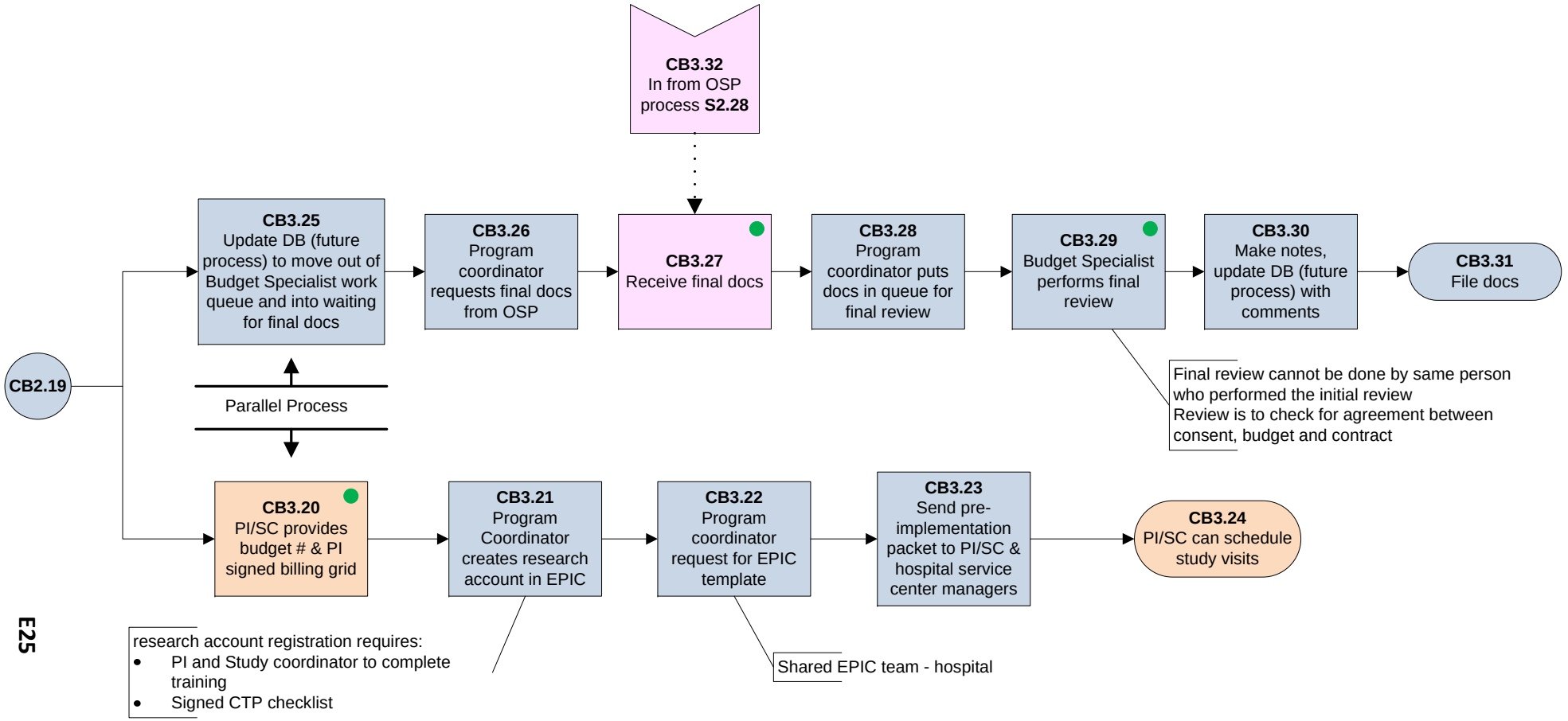
E24

APPENDIX E

University of Washington

Clinical Research Proposal Review Process Improvement Project

CRBB Process Billing Grid Final – Non-Industry	FINAL as of 10/23/09



E25

APPENDIX E

University of Washington

Clinical Research Proposal Review Process Improvement Project

UW HSD / UW-IRB Process | FINAL as of 9/3/09

Key	
	PI process
	HSD process
	UW-IRB process
	consultant process

H1.0 IRB-UW process (enter from overall process or from PO process **PO1.22**)

H1.1 PI/Study Coordinator (SC) submits materials to HSD (paper submission)

H1.2 Initial intake by front desk staff: date stamp, data entry, assign to IRB committee

H1.3 Are all necessary signatures present?

Yes

No

H1.4 Contact PI/SC to obtain signatures/ resolve issues

H1.5 IRB staff screens the application to determine if it is ready for full board review and if a consultant is needed.

If necessary engage consultant

Parallel Process

H1.6 Is it ready for full board review?

Yes

No

H1.7 Administrator assigns to primary reviewer for review and assigns review date, determines if consultant is needed (if not already done in H1.5)

If necessary engage consultant

H1.9 Provide materials to consultant

H1.10

Parallel Process

H1.8

H1.28

- Is it complete?
- Is it understandable (college-level lay language)?
- Are there regulatory issues that have to be incorporated in the full board review?
- Are there ethical considerations?

Advise PI that they need committee reviews: e.g. Radiation Safety, IBC, I & ID, IND, if applicable

Each committee has 2-3 staff who support it:
- Administrator
- Review Coordinator

Program Coordinator

General notes about application

The "Packet" should be:
- IRB application
  - standard list of attachments : items which are included as attachments as part of the application
- Items that the researcher has to fill out separately as a template

For the IRB the Protocol is not considered a "stand-alone" document, what is transcribed to the IRB application takes precedence over what is in the Protocol

Which IRB committee a study is assigned to is mostly random. There are 7 committees (3 behavioral/3 medical/ 1 hybrid), most clinical trials are medical.

The exceptions are:
- Emergency Medicine
- hESC (human embryonic stem cell research)

They are assigned to a specific IRB

E26

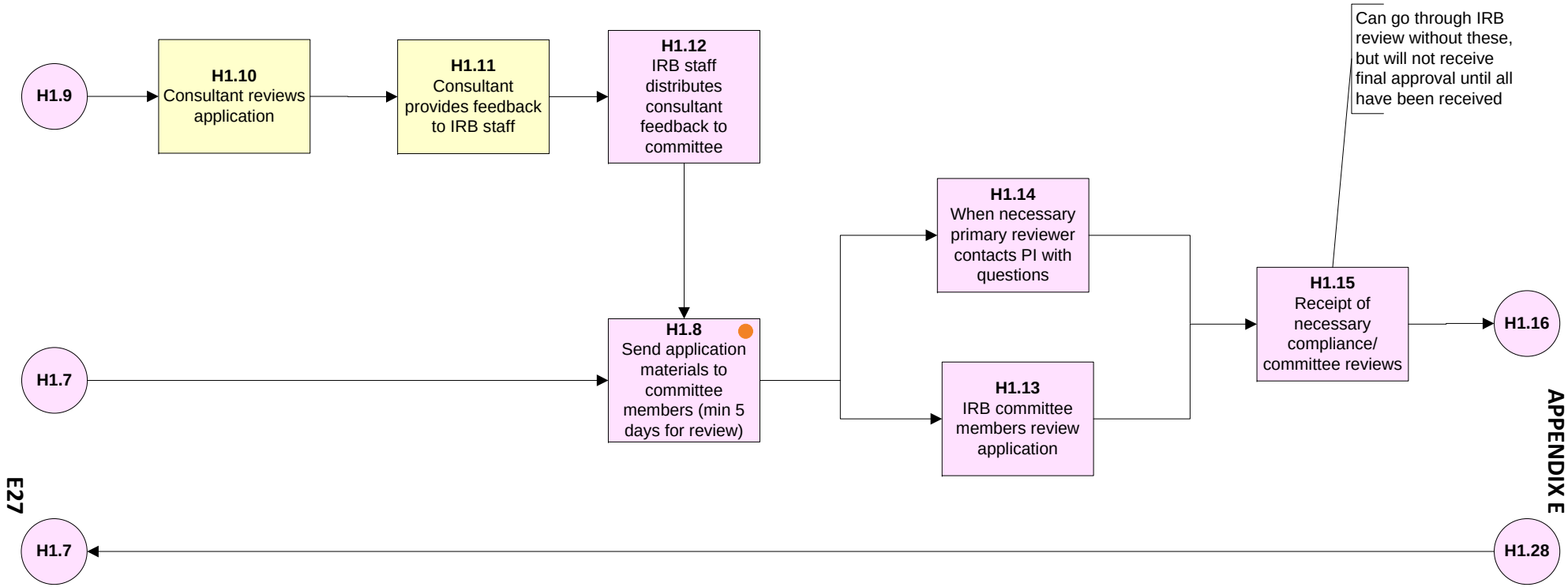
APPENDIX E

University of Washington

Clinical Research Proposal Review Process Improvement Project

UW HSD / UW-IRB Process | FINAL as of 9/3/09

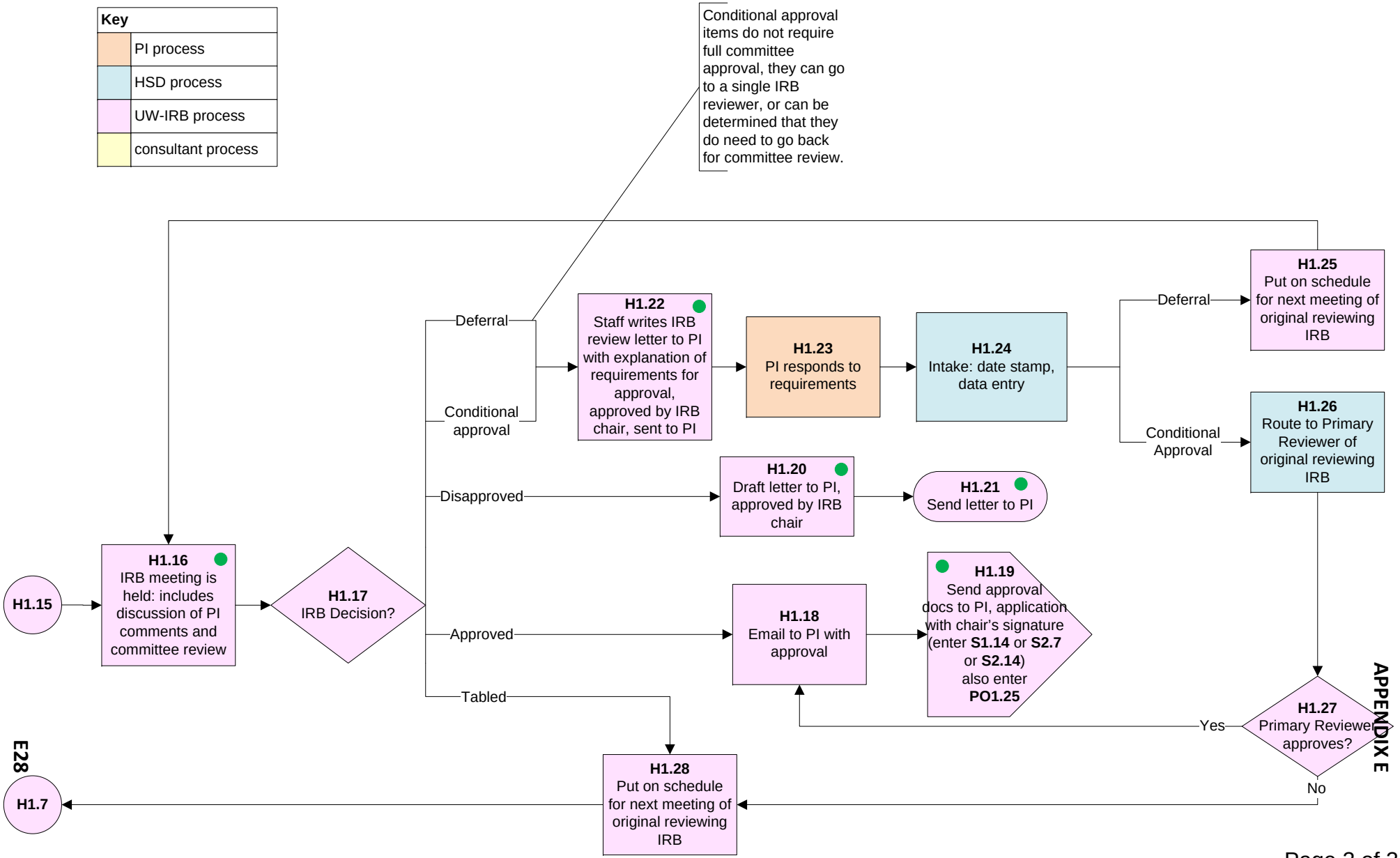
Key	
	PI process
	HSD process
	UW-IRB process
	consultant process



University of Washington

Clinical Research Proposal Review Process Improvement Project

UW HSD / UW-IRB Process | FINAL as of 9/3/09



University of Washington

Clinical Research Proposal Review Process Improvement Project

UW HSD / WIRB Process

FINAL as of 9/3/09

Key	
	PI process
	HSD process
	WIRB process
	UW-IRB process

W1.0
HSD-WIRB process (enter from overall process or from PO process **PO1.21**)

W1.1
PI/Study Coordinator (SC) submits materials to HSD (electronically)

HSD (not acting as UW-IRB)
Receive via PDF or MS word attachments
Email to hsdinfo@u.washington.edu

W1.2
HSD Compliance Analyst monitors email account for new submissions (backup is HSD Assistant Director for Quality & Compliance)

W1.3
HSD Compliance Analyst screens document to verify if eligible for WIRB submission and UW requirements are met

Yes

W1.5
HSD Compliance Analyst prints materials and gives to HSD Front Desk Staff

Print:
- WIRB Cover Sheet (sign)
- Consent Form (stamp)
- Confidentiality Agreement (sign)

Consent Form receives UW Stamp to show that compensation language has been screened (Analyst acting as UW-IRB rep)

W1.6
Initial intake by front desk staff: data entry, assign to IRB committee – mark "W" for WIRB

W1.7
Front desk scans coversheet, consent form sends to PI/SC

Also send:
- electronically to CC-Protocol Office for applicable Oncology studies
- Paper to UW-Radiation Safety (regardless of RS involvement)

W1.8
PI submits application to WIRB

W1.9
WIRB notifies HSD (electronically) that application has been received

W1.10
Enter WIRB review process

No

W1.4
Contact PI/SC with instructions (join applicable IRB process)

E29

APPENDIX E

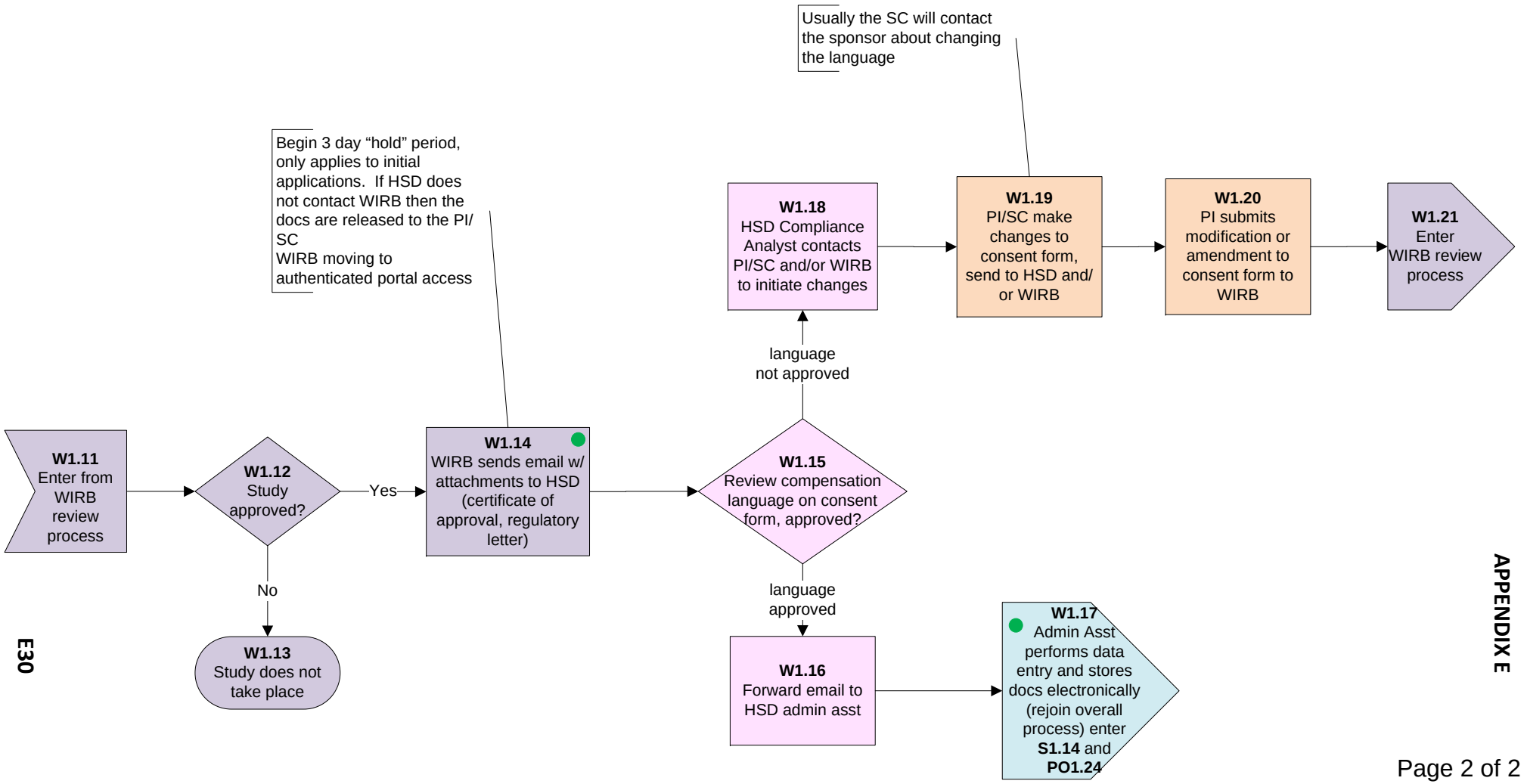
University of Washington

Clinical Research Proposal Review Process Improvement Project

UW HSD / WIRB Process

FINAL as of 9/3/09

Key	
	PI process
	HSD process
	WIRB process
	UW-IRB process



E30

APPENDIX E

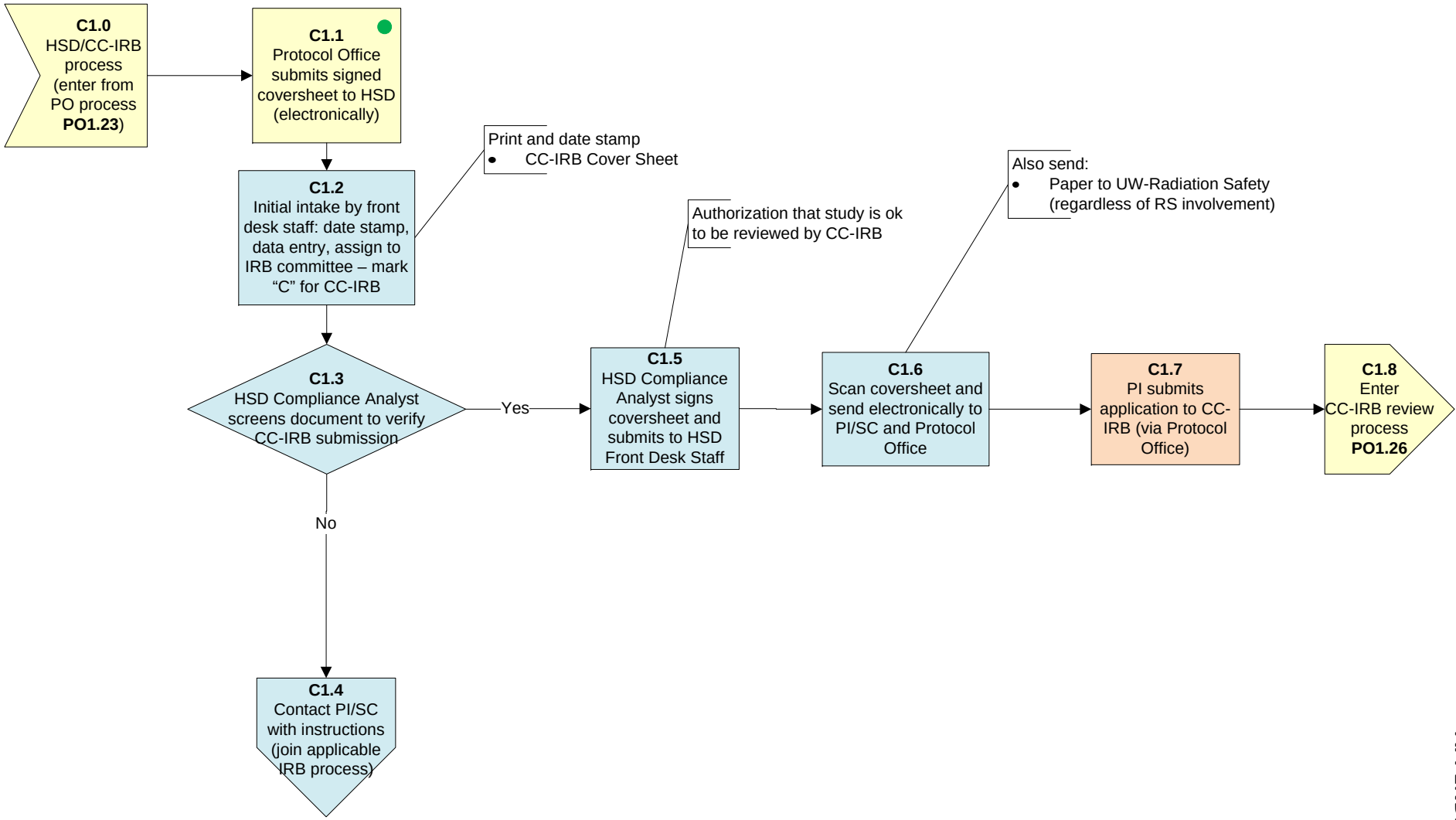
University of Washington

Clinical Research Proposal Review Process Improvement Project

UW HSD / CC-IRB Process

FINAL as of 9/3/09

Key	
	PI process
	HSD process
	Protocol Office process



E31

APPENDIX E

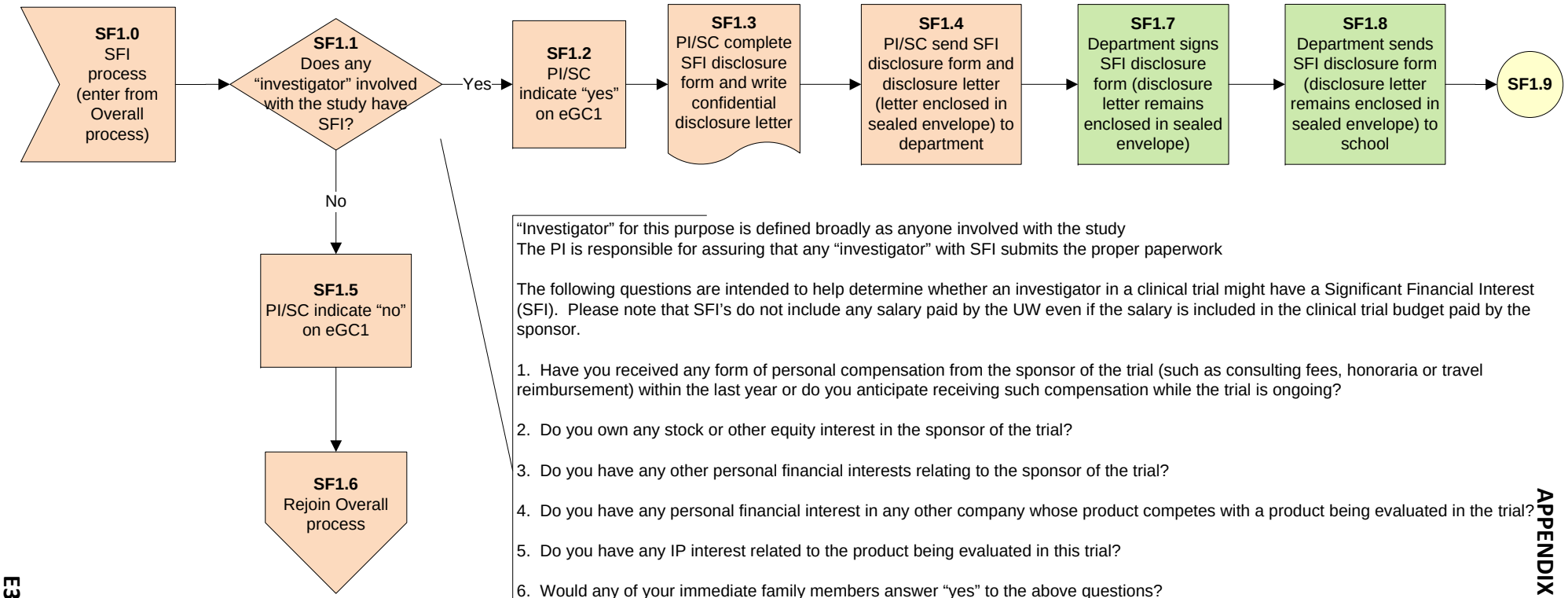
University of Washington

Clinical Research Proposal Review Process Improvement Project

Significant Financial Interest (SFI) Process

FINAL as of 8/26/09

Key	
	PI process
	Department process
	School process
	OSP process
	OR process
	RGE process



"Investigator" for this purpose is defined broadly as anyone involved with the study
The PI is responsible for assuring that any "investigator" with SFI submits the proper paperwork

The following questions are intended to help determine whether an investigator in a clinical trial might have a Significant Financial Interest (SFI). Please note that SFI's do not include any salary paid by the UW even if the salary is included in the clinical trial budget paid by the sponsor.

1. Have you received any form of personal compensation from the sponsor of the trial (such as consulting fees, honoraria or travel reimbursement) within the last year or do you anticipate receiving such compensation while the trial is ongoing?

2. Do you own any stock or other equity interest in the sponsor of the trial?

3. Do you have any other personal financial interests relating to the sponsor of the trial?

4. Do you have any personal financial interest in any other company whose product competes with a product being evaluated in the trial?

5. Do you have any IP interest related to the product being evaluated in this trial?

6. Would any of your immediate family members answer "yes" to the above questions?

If an investigator answers "yes" to any of these questions, the investigator may be required to disclose a financial interest and have a review as required by Grants Information Memorandum No. 10 (GIM 10), the University's Significant Financial Interest Disclosure Policy. Any investigator answering "yes" to any of these questions should review GIM 10, http://www.washington.edu/research/osp/gim/gim10.html, and obtain advice on whether the investigator is required to submit a Significant Financial Interest Disclosure Form with the Form eGC1 for the trial.

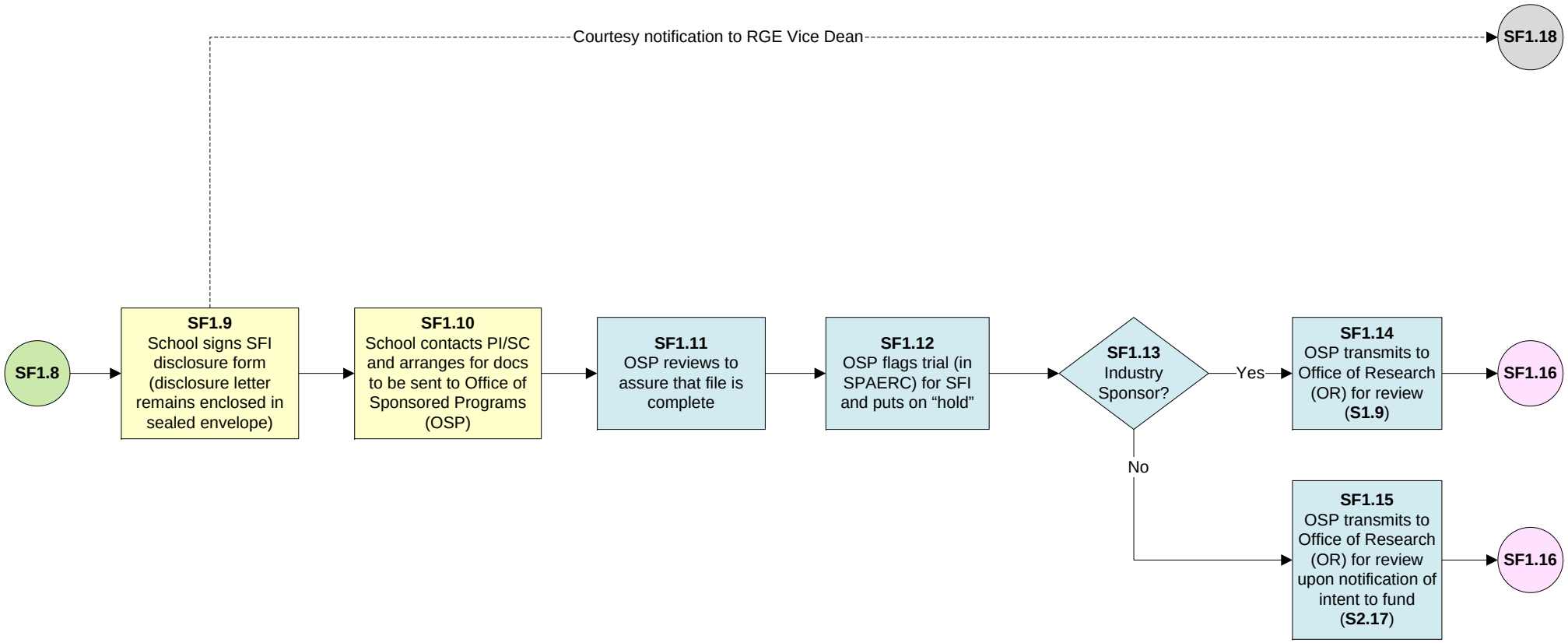
APPENDIX E

E32

University of Washington

Clinical Research Proposal Review Process Improvement Project

Significant Financial Interest (SFI) Process | FINAL as of 8/26/09



Key	
	PI process
	Department process
	School process
	OSP process
	OR process
	RGE process

E33

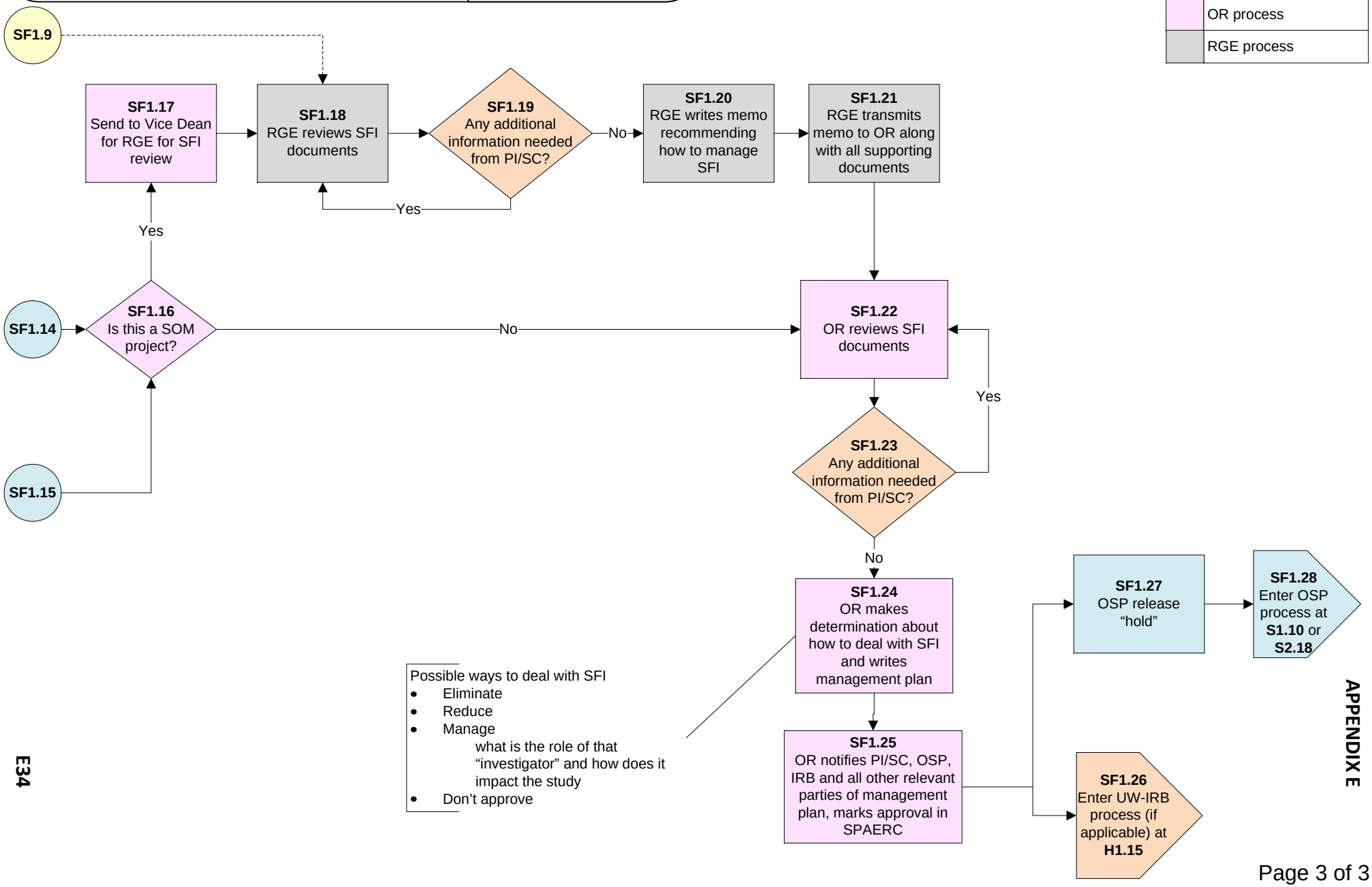
APPENDIX E

University of Washington

Clinical Research Proposal Review Process Improvement Project

Significant Financial Interest (SFI) Process | FINAL as of 8/26/09

Key	
	PI process
	Department process
	School process
	OSP process
	OR process
	RGE process



E34

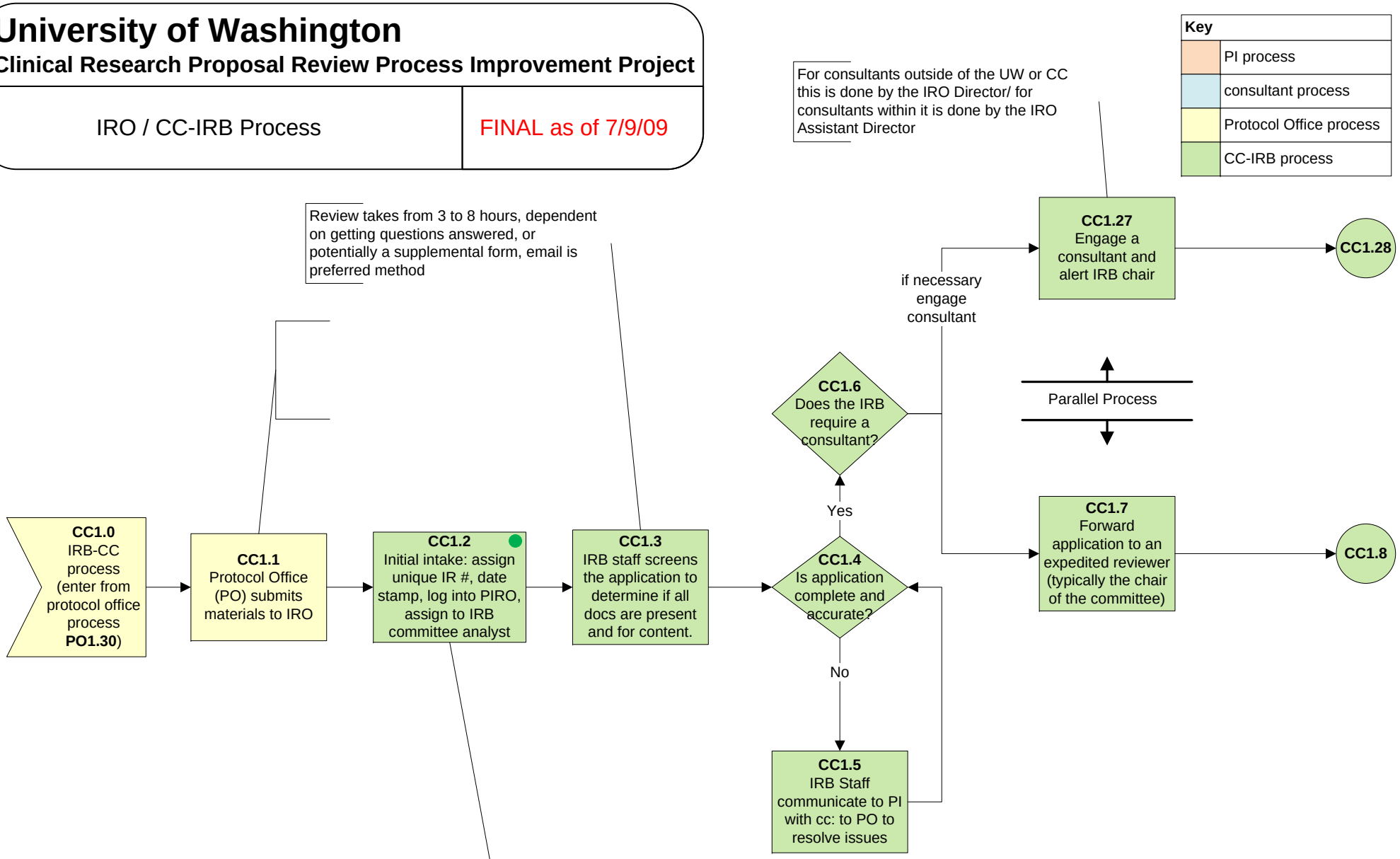
APPENDIX E

University of Washington

Clinical Research Proposal Review Process Improvement Project

IRO / CC-IRB Process

FINAL as of 7/9/09



There are 3 IRB committees, CC-IRB committees are Committees A & B

Each IRB Committee has 1 analyst and 1 admin staff, they will share the workload with other IRB committees when necessary

A particular study may be assigned to a particular IRB (A or B) dependent on expertise, but is typically assigned to the IRB with the next upcoming meeting (each meets 1/per month)

E35

APPENDIX E

University of Washington

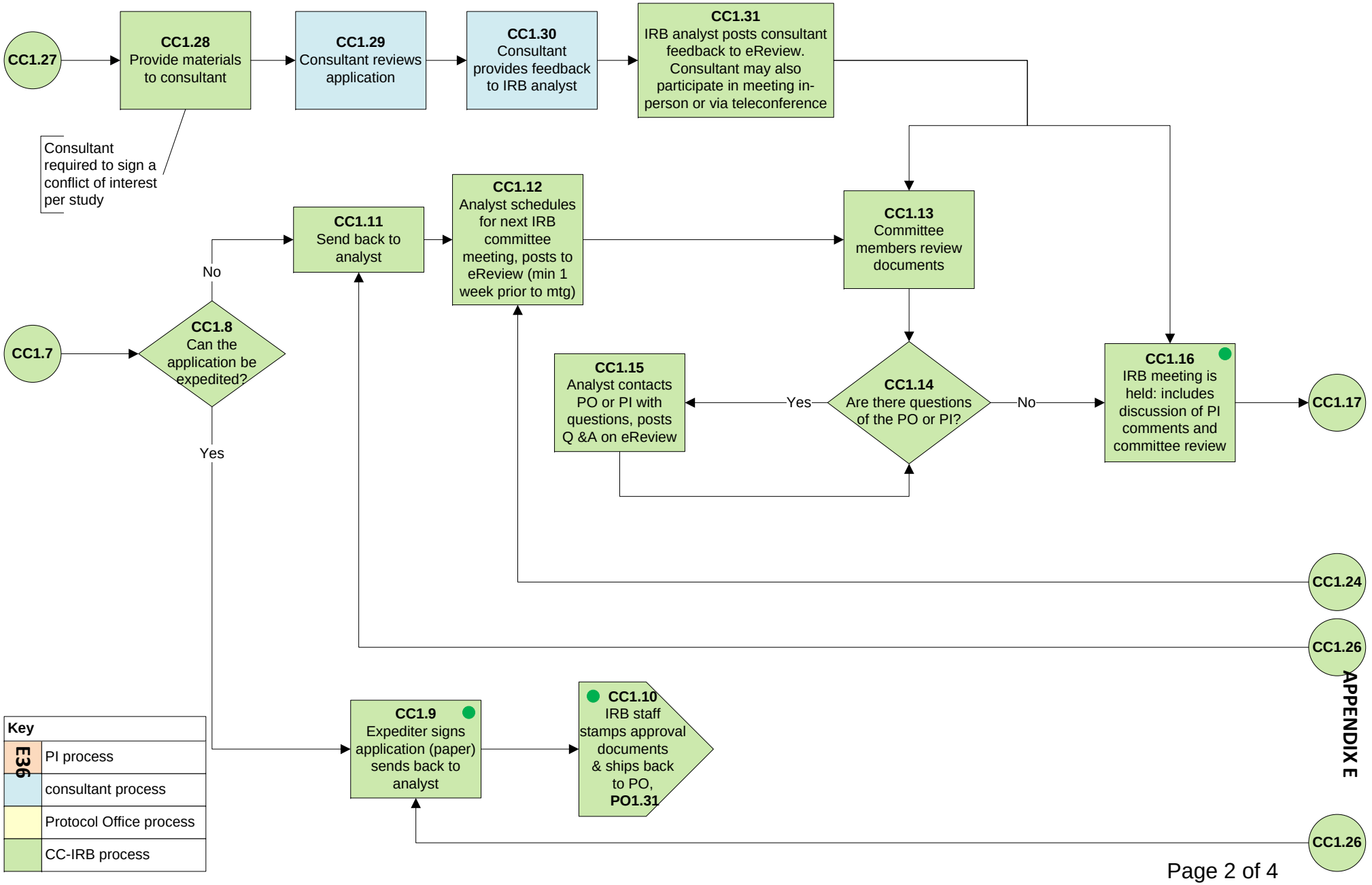
Clinical Research Proposal Review Process Improvement Project

IRO / CC-IRB Process

FINAL as of 7/9/09

CC1.12 Analyst tasks
- Create agenda
- Organize documents for review
- Data entry
- Scan documents in preparation for posting to eReview
- Email alert

CC1.16 Committee reviews up to 5 new studies per meeting, in addition to continuations, modifications, non-compliance issues, etc. PI may participate in the meeting if invited by the committee



APPENDIX E

University of Washington

Clinical Research Proposal Review Process Improvement Project

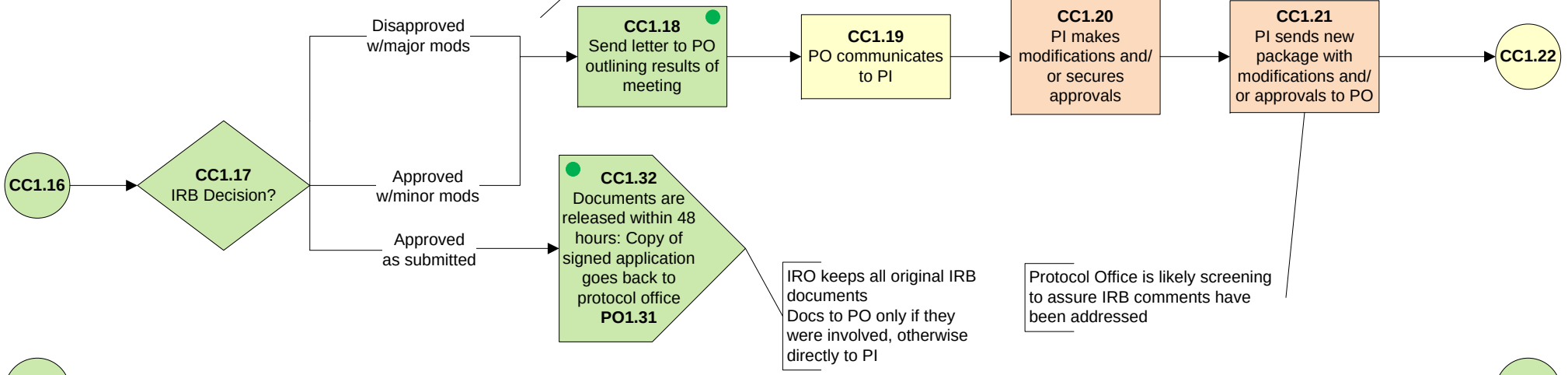
IRO / CC-IRB Process | FINAL as of 7/9/09

Key	
	PI process
	consultant process
	Protocol Office process
	CC-IRB process

Approved as submitted
- all committee approvals must be there
- Signed contract (fully executed CTA) or Grant.
- Office of General Council has approved consent form (only applies to Industry Sponsored research with a CTA)
- This type of approval does not happen often with new studies

Approved with minor modifications required
- Missing regulatory committee approval (e.g. Radiation Safety, Biosafety)
- Does not have fully executed CTA
- Committee required minor changes ("simple concurrence")

Disapproved with major modifications
- Generally requires big changes
- Goes through full review
- Unknowns that go beyond "simple concurrence"



CC1.12 ← CC1.24

CC1.11 ← CC1.26

CC1.9 ← CC1.26

APPENDIX E

E37

University of Washington

Clinical Research Proposal Review Process Improvement Project

IRO / CC-IRB Process | FINAL as of 7/9/09

Key	
	PI process
	consultant process
	Protocol Office process
	CC-IRB process

General notes about the IRB

The FHCRC-IRB also serves as the CC-IRB. The IRB oversees approximately 1,200 open protocols, approximately 10% (150) of those are specific to the CC-IRB. The IRB processes about 250 new applications per year, approximately 10% of those are for the CC-IRB (not all of which require full committee review – reference to the max of 5 new protocols on each meeting)

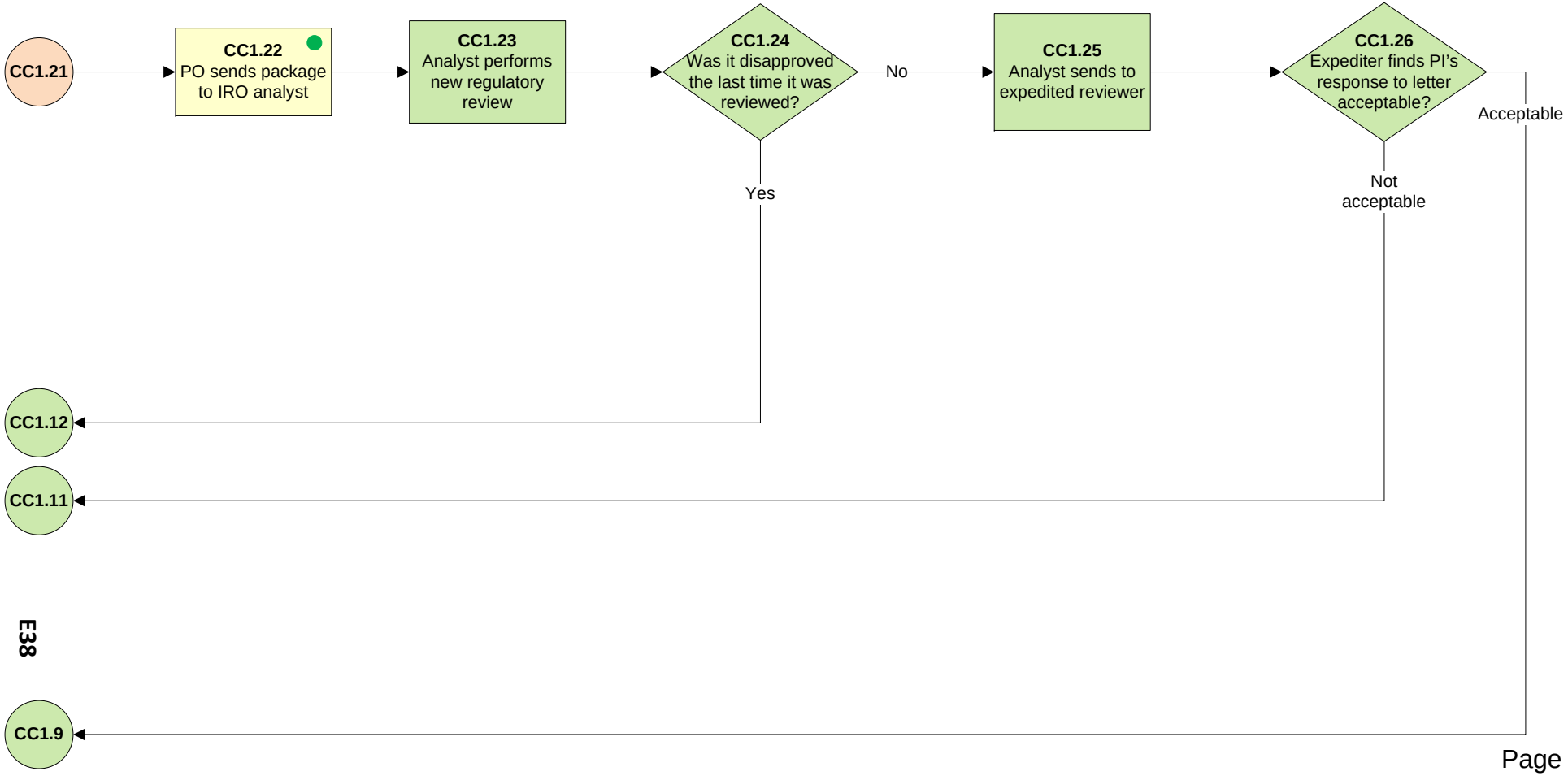
It is rare for studies to go directly to the IRO without first going through the Protocol Office

The IRO will do pre-screening of applications prior to Protocol Office submission when asked.

The process for the IACUC (also administered by the IRO) is very similar to the process for the IRB

IRB committees will review applications that have not yet received approval from other regulatory committees (e.g. Radiation Safety), except for the Scientific Review Committee – they require SRC approval prior to review. This requirement applies only to CC-IRB, not all reviews conducted by FHCRC IRB require SRC review.

If it is determined that the study must go through full committee review again, it is assigned to the same committee that did the original review



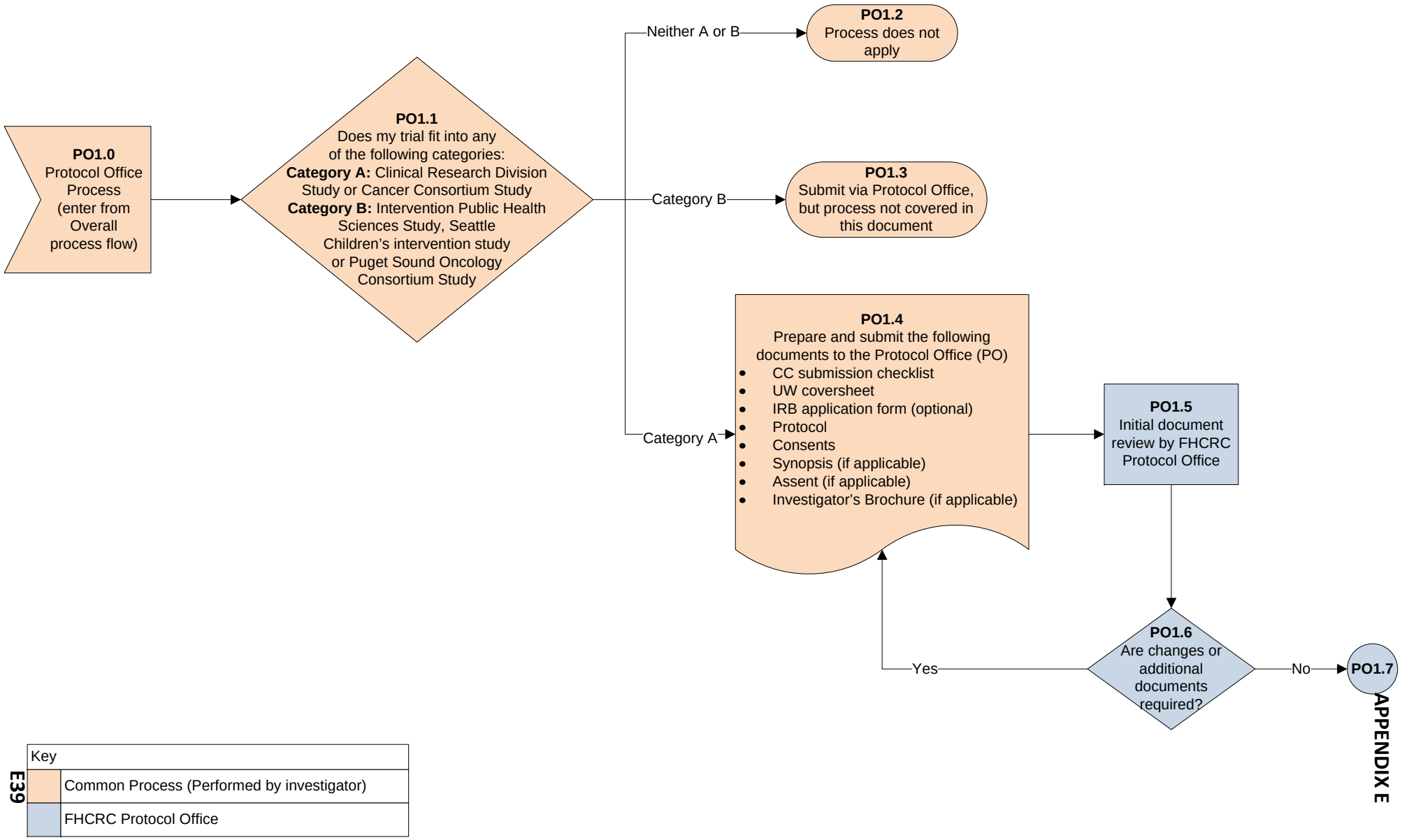
E38

APPENDIX E

University of Washington

Clinical Research Proposal Review Process Improvement Project

Protocol Office Process	FINAL as of 7/17/09



E39

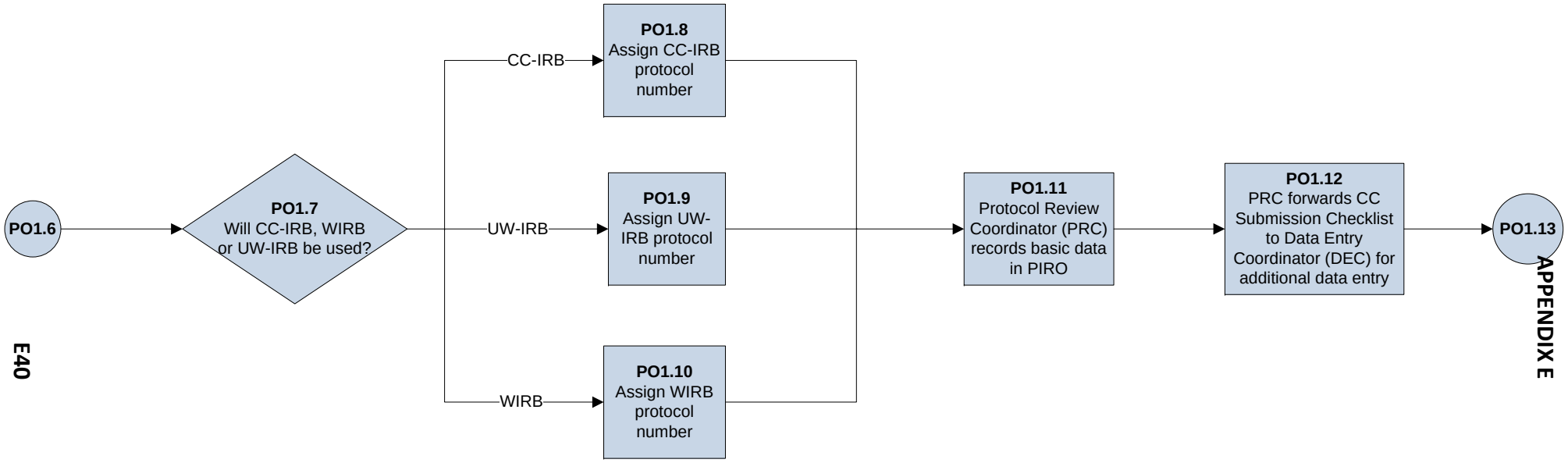
APPENDIX E

University of Washington

Clinical Research Proposal Review Process Improvement Project

Protocol Office Process	FINAL as of 7/17/09

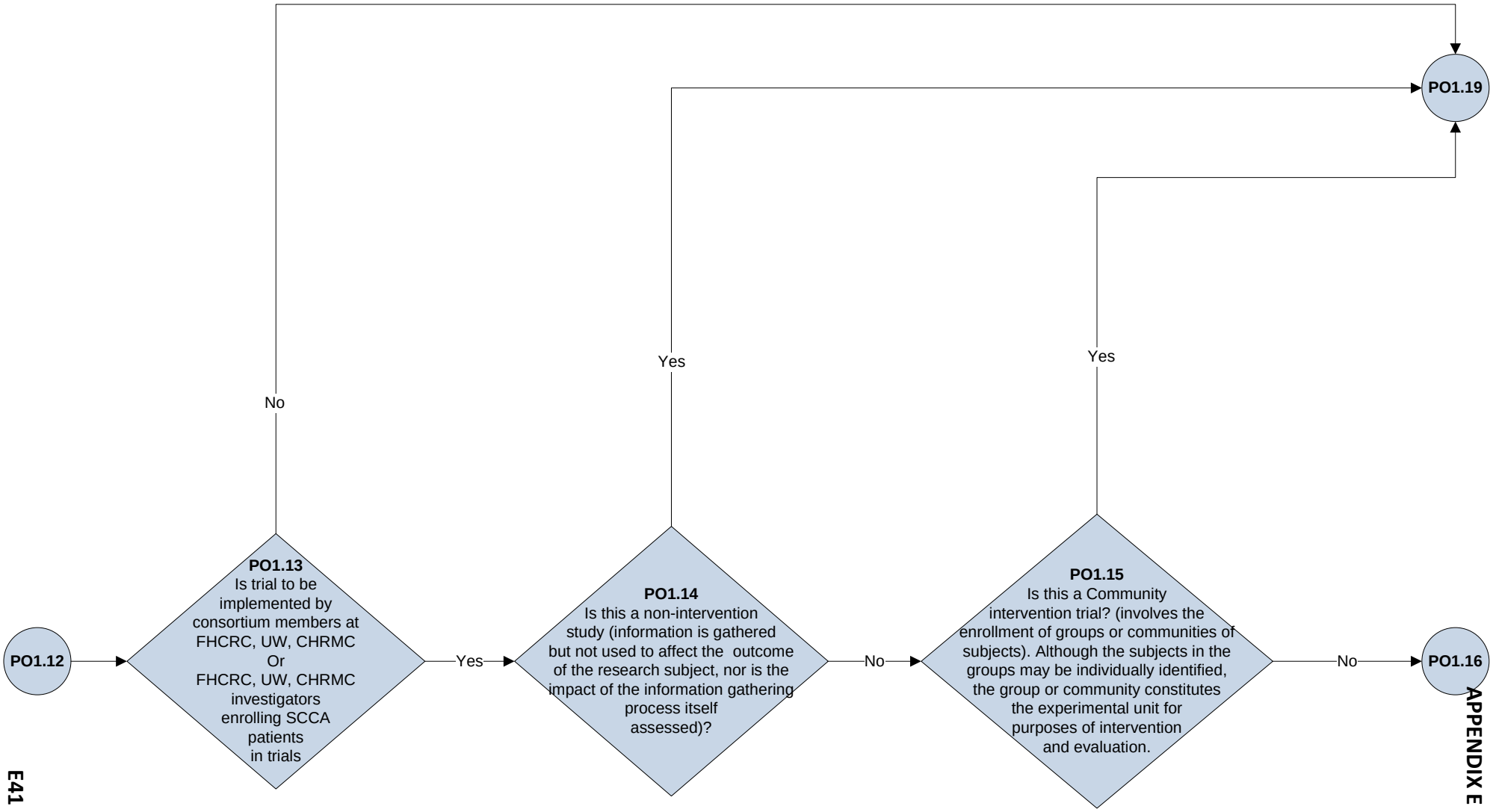
Key	
	Common Process (Performed by investigator)
	FHCRC Protocol Office
	Scientific Review Committee (SRC)



University of Washington

Clinical Research Proposal Review Process Improvement Project

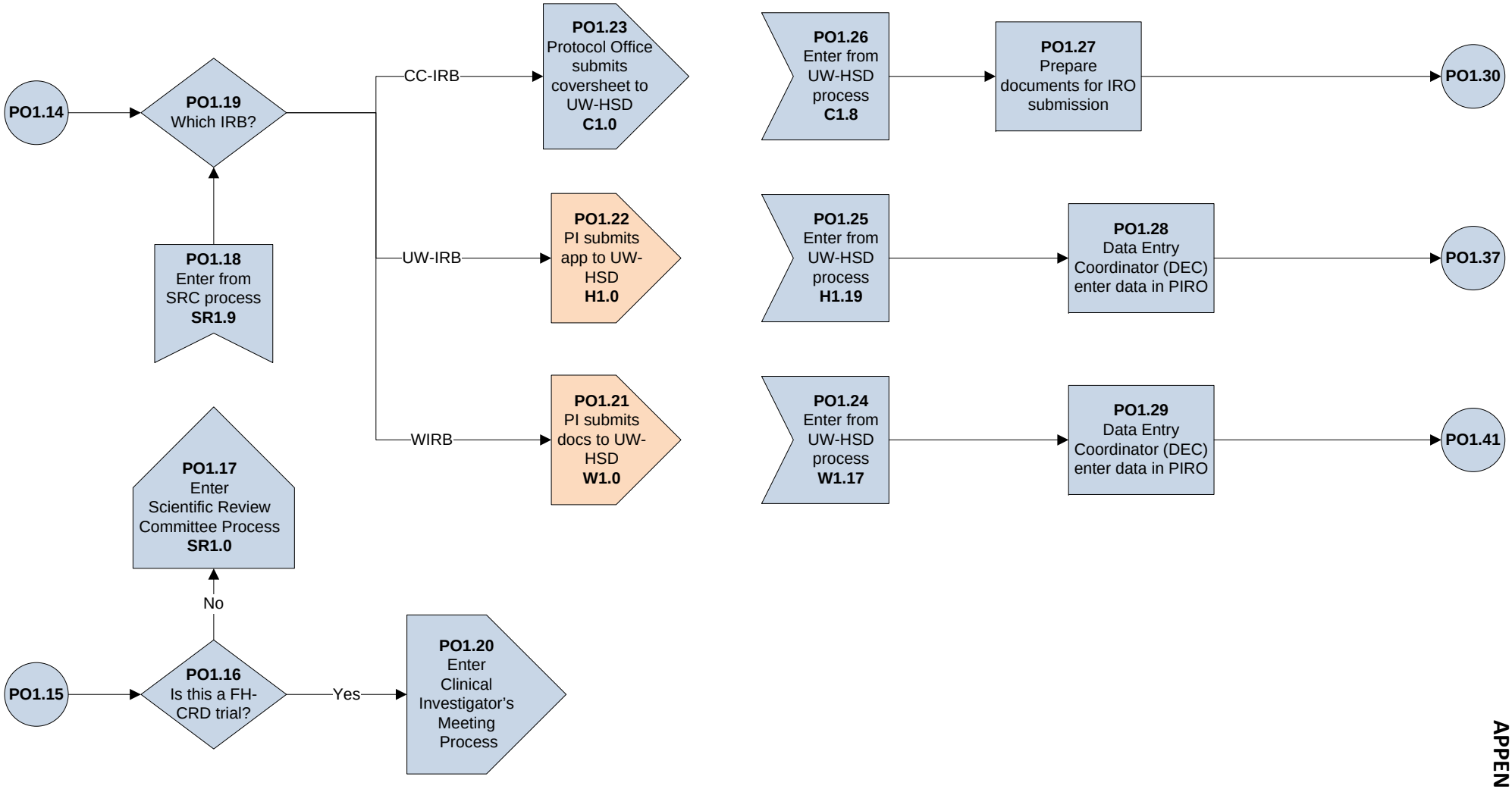
Protocol Office Process	FINAL as of 7/17/09



University of Washington

Clinical Research Proposal Review Process Improvement Project

Protocol Office Process | FINAL as of 7/17/09



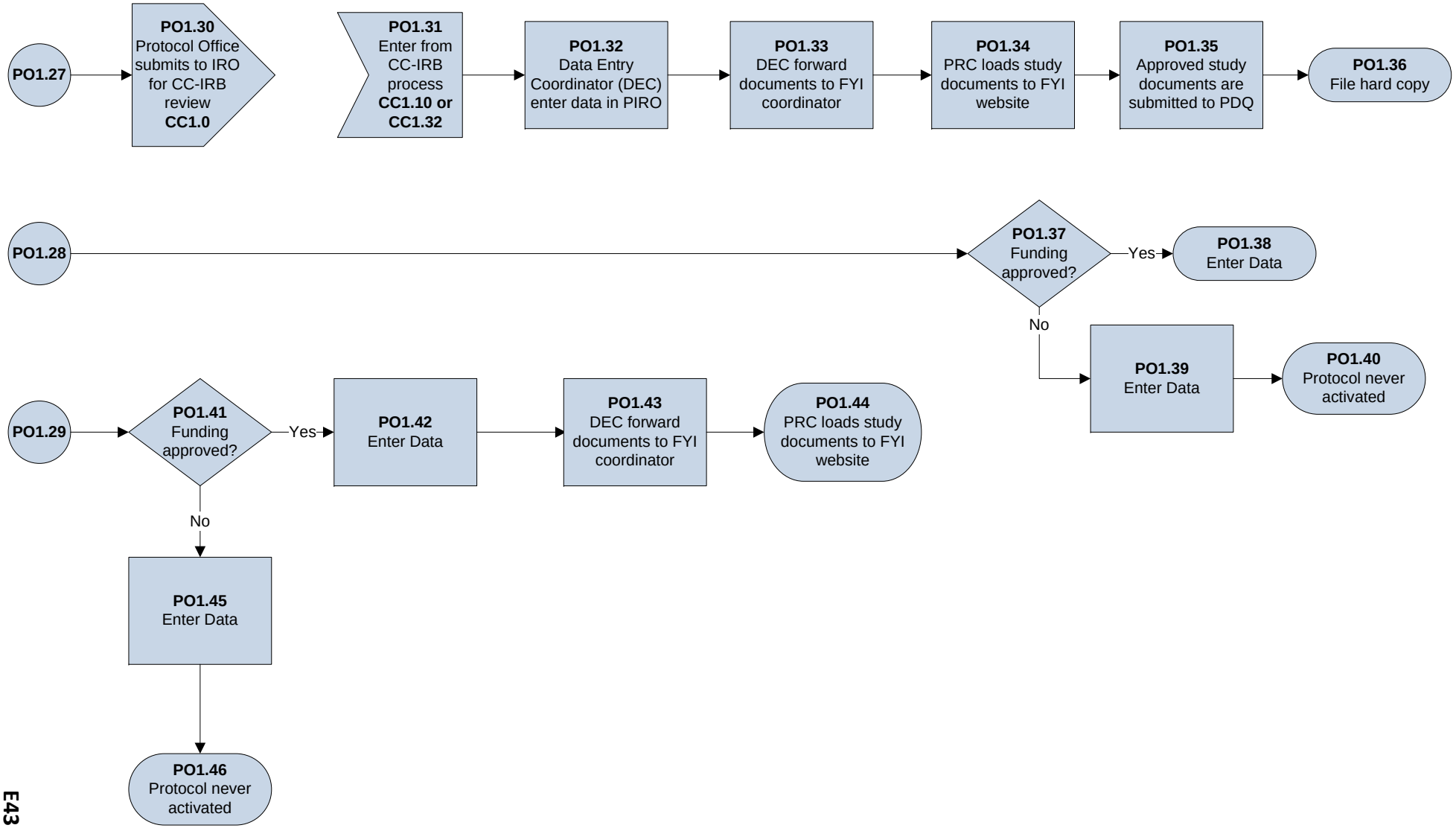
E42

APPENDIX E

University of Washington

Clinical Research Proposal Review Process Improvement Project

Protocol Office Process	FINAL as of 7/17/09



E43

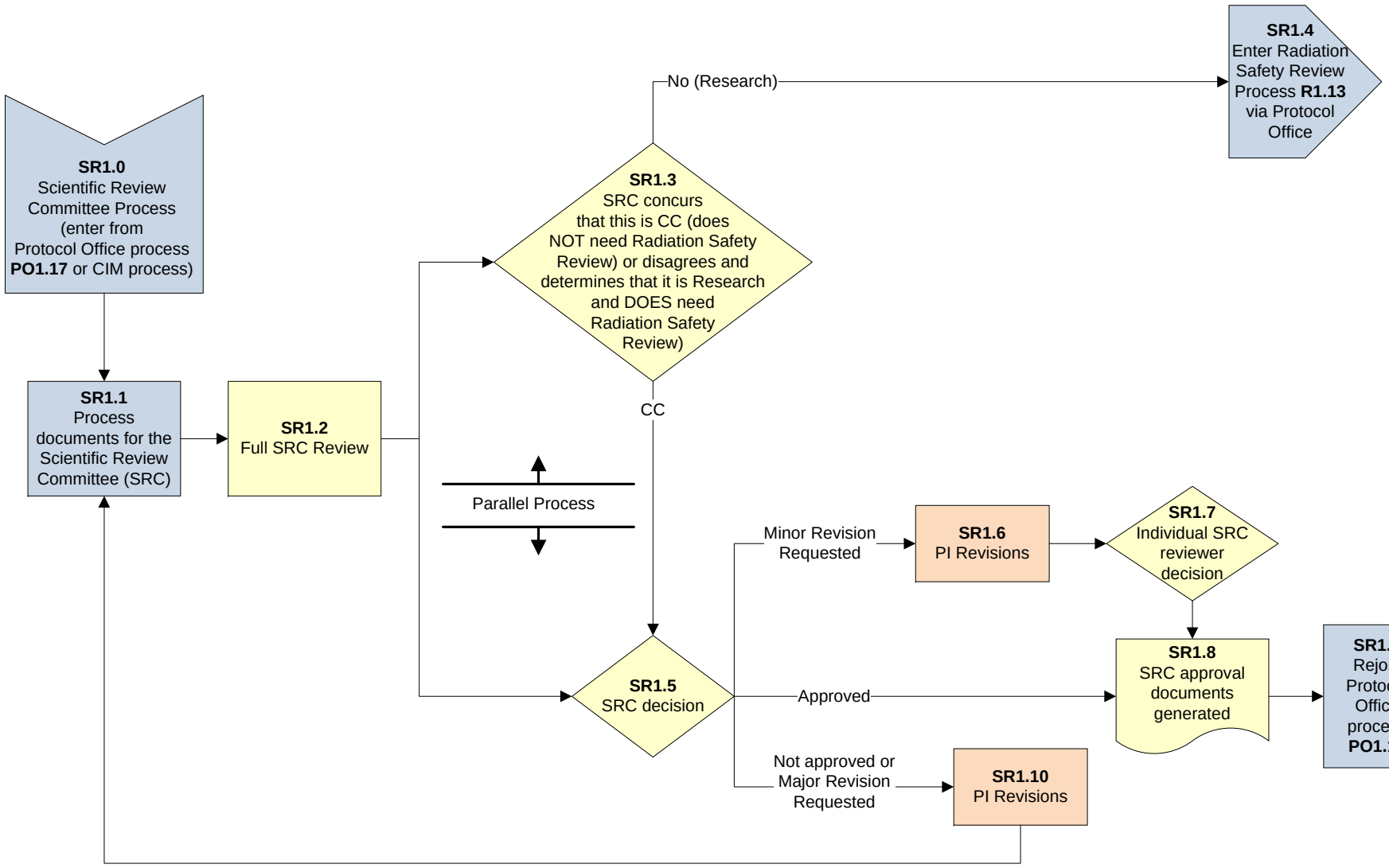
APPENDIX E

University of Washington

Clinical Research Proposal Review Process Improvement Project

Scientific Review Committee Process | FINAL as of 7/17/09

Key	
	Common Process (Performed by investigator)
	FHCRC Protocol Office
	Scientific Review Committee (SRC)



E44

APPENDIX E

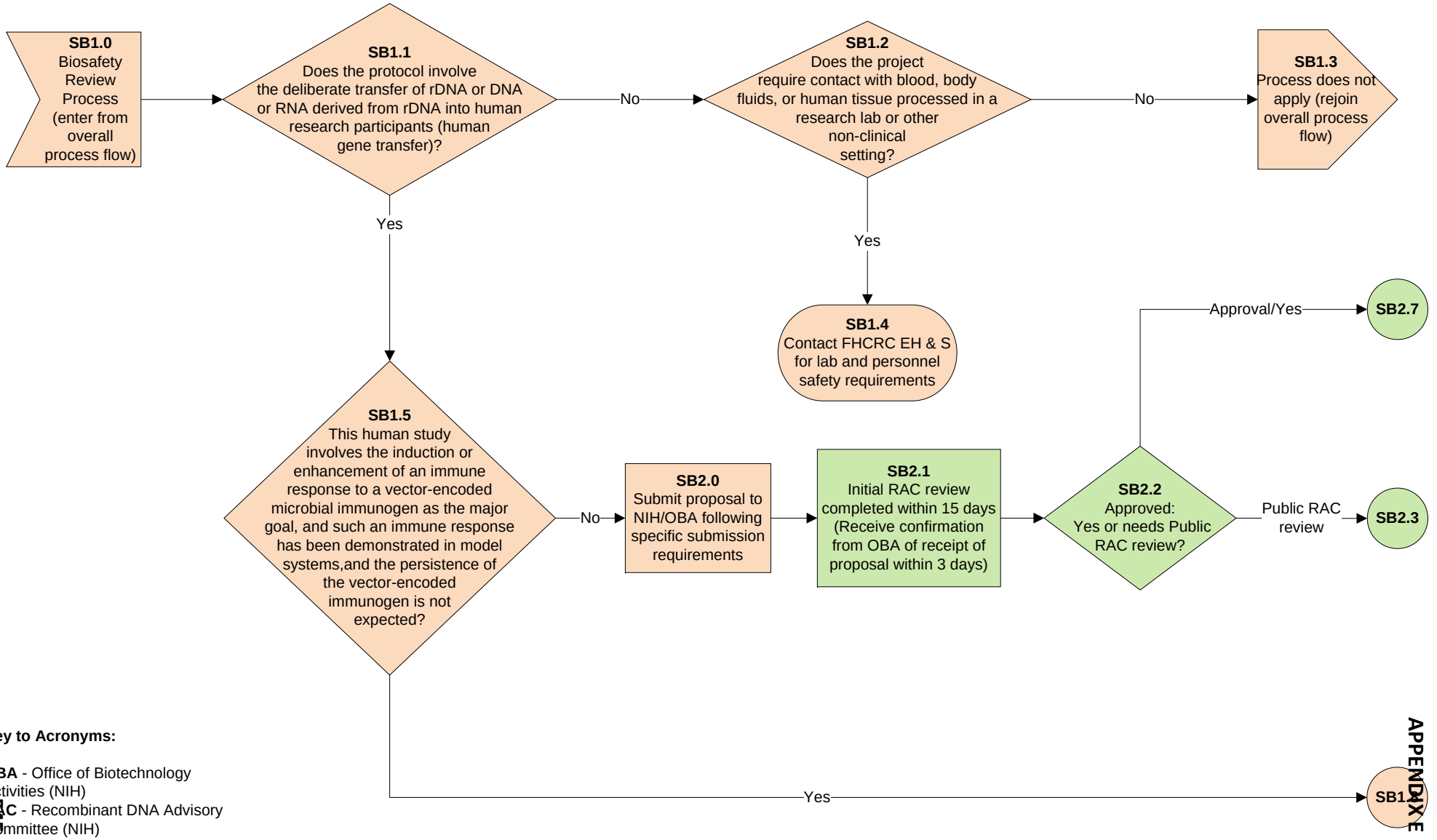
University of Washington

Clinical Research Proposal Review Process Improvement Project

SCCA Biosafety Review Process

FINAL as of 8/25/09

Key	
	PI process
	OBA/RAC process
	RIO/IBC process



Key to Acronyms:

OBA - Office of Biotechnology Activities (NIH)
RAC - Recombinant DNA Advisory Committee (NIH)
IBC – Institutional Biosafety Committee
rDNA – Recombinant DNA
BSO – Biological Safety Officer

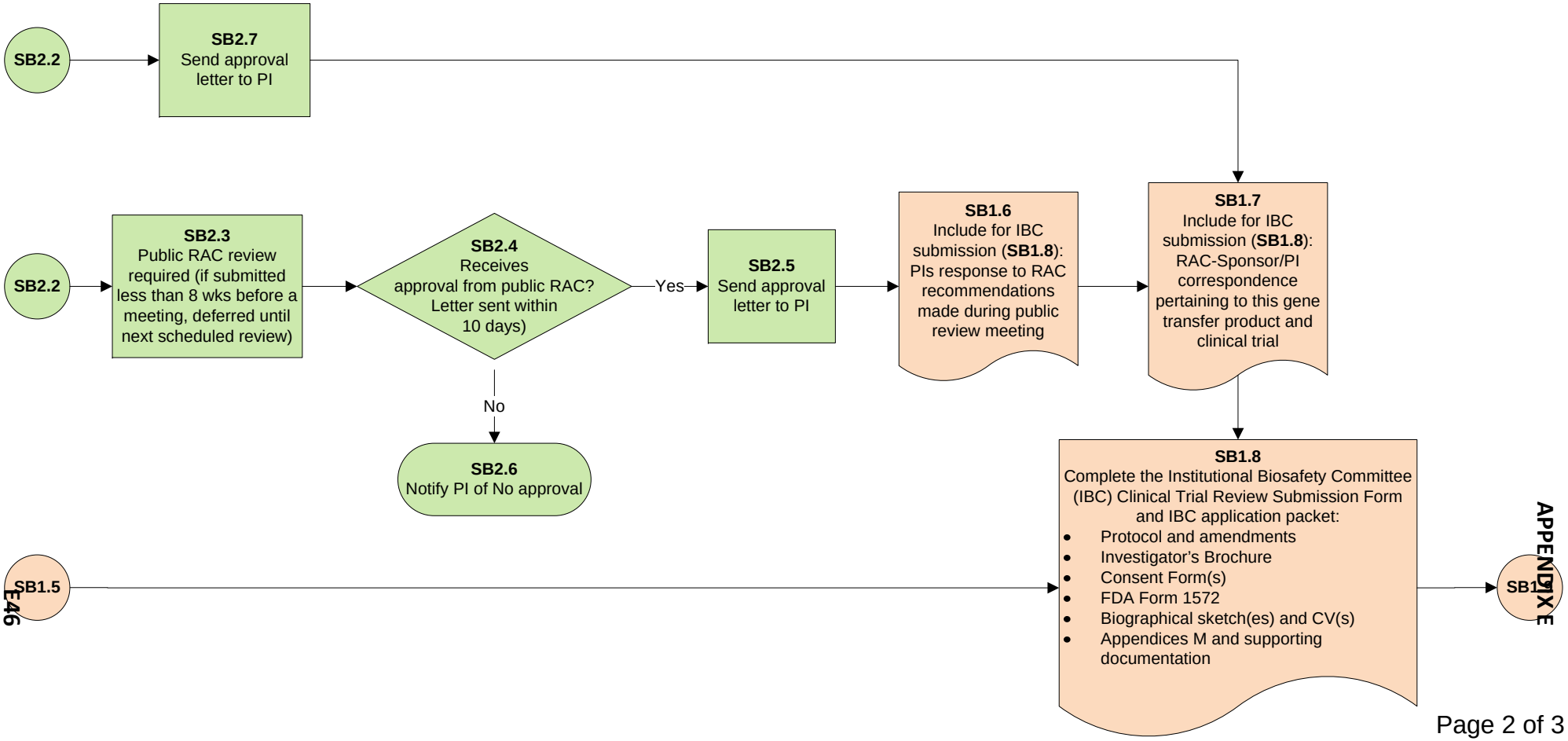
APPENDIX E

University of Washington

Clinical Research Proposal Review Process Improvement Project

SCCA Biosafety Review Process | FINAL as of 8/25/09

Key	
	PI process
	OBA/RAC process
	RIO/IBC process



APPENDIX E

E46

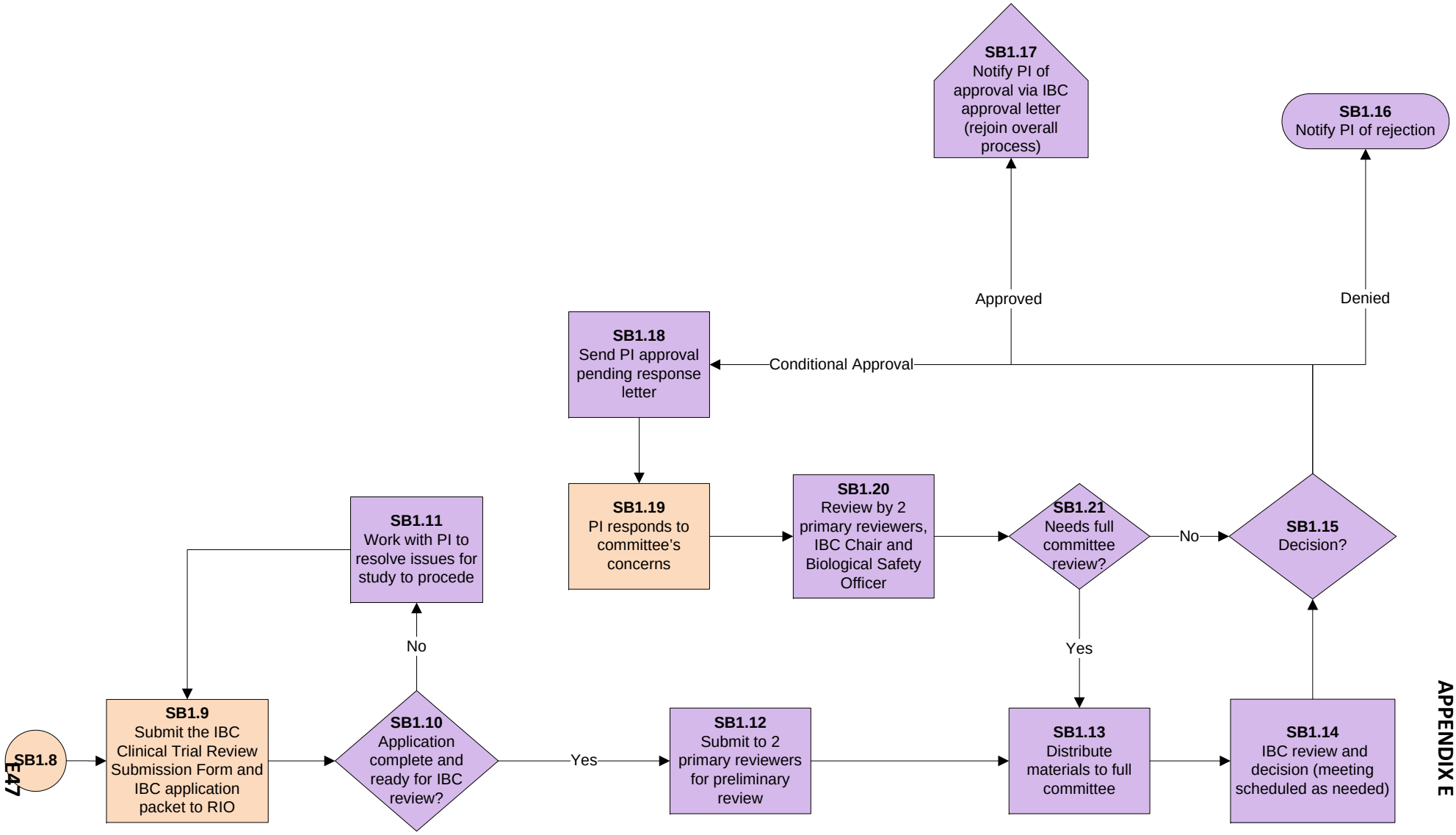
University of Washington

Clinical Research Proposal Review Process Improvement Project

SCCA Biosafety Review Process

FINAL as of 8/25/09

Key
PI process
OBA/RAC process
RIO/IBC process



E47

APPENDIX E

eGC1								
Initiated by:		Industry	Non-UW Investigator	UW Investigator			Non-UW Investigator	Government
Sponsored (Funded) by:		Industry			Dept	Government / Non-Profit		
Form Name		**1**	**5**	**2**	**4**	**3**	**6**	**7**
	Protocol	R	R	R	NA	OE	OE	OE
	Consent Form	R	R	R	NA	OE	OE	OE
	Contract	R	R	R	NA	R*	R*	R*
	Budget (Sponsor's)	R	R	R	NA	NA	NA	NA
	SFI GIM-10 Disclosure Form (Manual Process)	R	R	R	R	R	R	R
1 of 3 (whichever applies)	IRB Application	IR	IR	IR	NA	IR	IR	IR
	IRB Application – WIRB	IR	NA	NA	NA	NA	NA	NA
	IRB Application – CC	IR	IR	IR	NA	IR	IR	IR
	eGC1	R	R	R	NA	R	R	R
	Grant	NA	NA	NA	NA	R	R	R
* Contracts are required when the sponsor requires one, some government awards and some non-profit awards have contracts and others do not.								

CRBB							
Initiated by:	Industry	Non-UW Investigator	UW Investigator			Non-UW Investigator	Government
Sponsored (Funded) by:	Industry			Dept	Government / Non-Profit		
Form Name	**1**	**5**	**2**	**4**	**3**	**6**	**7**
Protocol	R	R	R	NA	NA	NA	NA
Study Design	NA	NA	NA	R	R	R	R
Consent Form	R	R	R	R	R	R	R
Contract	R	R	R	NA	NA	NA	NA
Budget (Sponsor's)	R	OE	OE	NA	NA	NA	NA
Budget (Coordinating Center's)	NA	OE	NA	NA	NA	OE	NA
Clinical Trials Policy Analysis Checklist	R	R	R	R	R	R	R
AAA Packet w/Pricing Pages	R	R	R	R	R	R	R
Draft Detailed Budget Tool	R	R	R	O	O	O	O
Billing Grid	R	R	R	R	R	R	R
Funding Letter	NA	NA	NA	NA	R	R	R

AAA Packet							
Initiated by:	Industry	Non-UW Investigator	UW Investigator			Non-UW Investigator	Government
Sponsored (Funded) by:	Industry			Dept	Government / Non-Profit		
Form Name	**1**	**5**	**2**	**4**	**3**	**6**	**7**
Clinical Trial Planning and Implementation Form (CTPI)	WA	WA	WA	WA	WA	WA	WA
AAA (Account) Registration Form	R	R	R	R	R	R	R
UW Pricing Pages	WA	WA	WA	WA	WA	WA	WA
HMC Pricing Pages	WA	WA	WA	WA	WA	WA	WA
Cost Center or Service Center Specific Forms	WA	WA	WA	WA	WA	WA	WA

Research Implementation Office (RIO) - SCCA							
Initiated by:	Industry	Non-UW Investigator	UW Investigator			Non-UW Investigator	Government
Sponsored (Funded) by:	Industry			Dept	Government / Non-Profit		
Form Name	**1**	**5**	**2**	**4**	**3**	**6**	**7**
Protocol	R	R	R	OE	OE	OE	OE
Investigator's Brochure	WA	WA	WA	WA	WA	WA	WA
Instructions for Use (Device)	WA	WA	WA	WA	WA	WA	WA
Consent Form	R	R	R	R	R	R	R
Clinical Trials Policy Analysis Checklist	R	R	R	R	R	R	R
Clinical Trial Planning and Implementation Form (CTPI)	R	R	R	R	R	R	R

WIRB							
Initiated by:	Industry	Non-UW Investigator	UW Investigator			Non-UW Investigator	Government
Sponsored (Funded) by:	Industry			Dept	Government / Non-Profit		
Form Name	**1**	**5**	**2**	**4**	**3**	**6**	**7**
Protocol	R						
Investigator's Brochure	WA						
Instructions for Use (Device)	WA						
Consent Form	R						
HIPAA Authorization Form	R						
UW Confidentiality Agreement	R						
FDA Form 1572	WA						
FDA Device Letter	WA						
Full or Partial HIPAA Waiver	R						
UW/WIRB Cover Sheet	R						
Investigator's Medical Licenses	R						
Investigators' CV(s)	R						
Sponsor Authorization to Pay WIRB	R						
SRC Approval	R						
IRB Application - WIRB	R						

HSD (for WIRB studies)							
Initiated by:	Industry	Non-UW Investigator	UW Investigator			Non-UW Investigator	Government
Sponsored (Funded) by:	Industry			Dept	Government / Non-Profit		
Form Name	**1**	**5**	**2**	**4**	**3**	**6**	**7**
Protocol	R						
Consent Form	R						
HIPAA Authorization Form	R						
UW Confidentiality Agreement	R						
UW/WIRB Cover Sheet	R						
IRB Application - WIRB	R						

UW-IRB							
Initiated by:	Industry	Non-UW Investigator	UW Investigator			Non-UW Investigator	Government
Sponsored (Funded) by:	Industry			Dept	Government / Non-Profit		
Form Name	**1**	**5**	**2**	**4**	**3**	**6**	**7**
Protocol	R	R	R	OE	OE	OE	OE
Investigator's Brochure	WA	WA	WA	WA	WA	WA	WA
Instructions for Use (Device)	WA	WA	WA	WA	WA	WA	WA
Consent Form	R	R	R	R	R	R	R
HIPAA Authorization Form	R	R	R	R	R	R	R
UW Confidentiality Agreement	R	R	R	R	R	R	R
IRB Application - UW	R	R	R	R	R	R	R
Full or Partial HIPAA Waiver	R	R	R	R	R	R	R

CC-IRB							
Initiated by:	Industry	Non-UW Investigator	UW Investigator			Non-UW Investigator	Government
Sponsored (Funded) by:	Industry			Dept	Government / Non-Profit		
Form Name	**1**	**5**	**2**	**4**	**3**	**6**	**7**
Protocol/Activity Plan and/or entire Grant Application	R	R	R	OE	OE	OE	OE
Investigator Brochure (if applicable), drug booklet or information sheet supplied by the drug company (sponsor)	WA	WA	WA	WA	WA	WA	WA
Instructions for Use (Device)	WA	WA	WA	WA	WA	WA	WA
Consent Form	R	R	R	R	R	R	R
HIPAA Authorization Form (UW)	R	R	R	R	R	R	R
UW Confidentiality Agreement	R	R	R	R	R	R	R
FDA Form 1572	WA	WA	WA	WA	WA	WA	WA
FDA letter with the IND/IDE assignment number and PI confirmation letter or documentation of FDA approval from the sponsor	WA	WA	WA	WA	WA	WA	WA
HIPAA Authorization to Use, Create and Share Health Information for Research	R	R	R	R	R	R	R
UW/CC-IRB Cover Sheet	R	R	R	R	R	R	R
Repository, Registry or Databank Supplement (Form)	WA	WA	WA	WA	WA	WA	WA
Protocol Synopsis	WA	WA	WA	WA	WA	WA	WA
SRC Approval	R	R	R	R	R	R	R
IRB Application - CC	R	R	R	R	R	R	R
Protocol Disposition Form (PDF)	R	R	R	R	R	R	R
Funding Source Document (FSD)	R	R	R	R	R	R	R

IBC (SCCA)							
Initiated by:	Industry	Non-UW Investigator	UW Investigator			Non-UW Investigator	Government
Sponsored (Funded) by:	Industry			Dept	Government / Non-Profit		
Form Name	**1**	**5**	**2**	**4**	**3**	**6**	**7**
Protocol	R	R	R	R*	R*	R*	R*
Investigator's Brochure	R	R	R	R	R	R	R
Consent Form	R	R	R	R	R	R	R
FDA Form 1572	R	R	R	R	R	R	R
IBC Clinical Trial Review Submission Form	R	R	R	R	R	R	R
Investigators' CV(s)	R	R	R	R	R	R	R
NIH Appendix M	R	R	R	R	R	R	R
†Correspondence from NIH/OBA/RAC	R	R	R	R	R	R	R

* IBC requires a protocol/clinical protocol, etc regardless of the funding source for the study. No exceptions.
† RAC Commentary from review of the protocol - and any additional RAC-Sponsor or -investigator correspondence. The UW IBC must receive the RAC's comments.

IBC (UW)							
Initiated by:	Industry	Non-UW Investigator	UW Investigator			Non-UW Investigator	Government
Sponsored (Funded) by:	Industry			Dept	Government / Non-Profit		
Form Name	**1**	**5**	**2**	**4**	**3**	**6**	**7**
Protocol	R	R	R	R*	R*	R*	R*
Investigator's Brochure	R	R	R	R	R	R	R
Consent Form	R	R	R	R	R	R	R
Research Project Hazard Assessment (RPHA) Form	R	R	R	R	R	R	R
Investigators' CV(s)	R	R	R	R	R	R	R
NIH Appendix M	R	R	R	R	R	R	R
†Correspondence from NIH/OBA/RAC	R	R	R	R	R	R	R

* IBC requires a protocol/clinical protocol, etc regardless of the funding source for the study. No exceptions.
† RAC Commentary from review of the protocol - and any additional RAC-Sponsor or -investigator correspondence. The UW IBC must receive the RAC's comments.

RSC (UW)								
Initiated by:		Industry	Non-UW Investigator	UW Investigator			Non-UW Investigator	Government
Sponsored (Funded) by:		Industry			Dept	Government / Non-Profit		
Form Name		**1**	**5**	**2**	**4**	**3**	**6**	**7**
	Protocol	R	R	R	R*	R*	R*	R*
	Consent Form	R	R	R	R	R	R	R
1 of 3 (whichever applies)	IRB Application	R	R	R	R	R	R	R
	IRB Application – WIRB	R	NA	NA	NA	NA	NA	NA
	IRB Application – CC	R	R	R	R	R	R	R
	Radiation Safety Application	R	R	R	R	R	R	R
*Protocol or Literature Review								

RSC (SCCA)								
Initiated by:		Industry	Non-UW Investigator	UW Investigator			Non-UW Investigator	Government
Sponsored (Funded) by:		Industry			Dept	Government / Non-Profit		
Form Name		**1**	**5**	**2**	**4**	**3**	**6**	**7**
	Protocol	R	R	R	OE	OE	OE	OE
	Consent Form	R	R	R	R	R	R	R
1 of 3 (whichever applies)	IRB Application	R	R	R	R	R	R	R
	IRB Application – WIRB	R	NA	NA	NA	NA	NA	NA
	IRB Application – CC	R	R	R	R	R	R	R
	Radiation Safety Application	R	R	R	R	R	R	R

I & ID							
Initiated by:	Industry	Non-UW Investigator	UW Investigator			Non-UW Investigator	Government
Sponsored (Funded) by:	Industry			Dept	Government / Non-Profit		
Form Name	**1**	**5**	**2**	**4**	**3**	**6**	**7**
Protocol	R	R	R	OE	OE	OE	OE
Consent Form	R	R	R	R	R	R	R
New Implant & Investigational Device Form (NIIDR)	R	R	R	R	R	R	R
Instructions for Use (Device)	R	R	R	R	R	R	R
FDA Device Letter	R	R	R	R	R	R	R

SRC (CC)							
Initiated by:	Industry	Non-UW Investigator	UW Investigator			Non-UW Investigator	Government
Sponsored (Funded) by:	Industry			Dept	Government / Non-Profit		
Form Name	**1**	**5**	**2**	**4**	**3**	**6**	**7**
Protocol	R	R	R	OE	OE	OE	OE
Investigator's Brochure	WA	WA	WA	WA	WA	WA	WA
Instructions for Use (Device)	WA	WA	WA	WA	WA	WA	WA
Consent Form	R	R	R	R	R	R	R
Cancer Consortium Submission Checklist	R	R	R	R	R	R	R

ITHS								
Initiated by:		Industry	Non-UW Investigator	UW Investigator			Non-UW Investigator	Government
Sponsored (Funded) by:		Industry			Dept	Government / Non-Profit		
Form Name		**1**	**5**	**2**	**4**	**3**	**6**	**7**
	Protocol	R	R	R	R*	R*	R*	R*
	Investigator's Brochure	WA	WA	WA	WA	WA	WA	WA
	Instructions for Use (Device)	WA	WA	WA	WA	WA	WA	WA
	Consent Form	R	R	R	R	R	R	R
	HIPAA Authorization Form	R	R	R	R	R	R	R
1 of 3 (whichever applies)	IRB Application	R	R	R	R	R	R	R
	IRB Application – WIRB	R	NA	NA	NA	NA	NA	NA
	IRB Application – CC	R	R	R	R	R	R	R
	AAA Packet w/Pricing Pages	R	R	R	R	R	R	R
	Draft Detailed Budget Tool	R	R	R	R	R	R	R
	Radiation Safety Application	WA†	WA†	WA†	WA†	WA†	WA†	WA†
	Research Project Hazard Assessment (RPHA) Form	WA	WA	WA	WA	WA	WA	WA
	IBC Clinical Trial Review Submission Form	WA	WA	WA	WA	WA	WA	WA
	ITHS CRC Utilization Forms	R	R	R	R	R	R	R
	New Implant & Investigational Device Form (NIIDR)	WA	WA	WA	WA	WA	WA	WA
	Billing Grid	R	R	R	R	R	R	R
	Documentation of Human Subjects Training	R	R	R	R	R	R	R

* ITHS require a protocol regardless of the funding source for the study. If a PI hasn't already developed one, they will provide them with a template. For simple studies this may only require a minimal amount of information but everyone has to submit one. No exceptions.

† Occasionally ITHS requires proof of RSC approval for certain studies or where it's not clear that this has been provided and noted by the IRB.

KEY	
R	Required
IR	If requested
OE	If one exists or is a close approximation
WA	When Applicable
O	Optional
NA	Not Applicable
1	Industry Initiated & Industry Sponsored
2	UW Investigator Initiated & Industry Sponsored
3	UW Investigator Initiated & Government or Non-Profit Funded
4	UW Investigator Initiated & Department Funded
5	Non-UW Investigator Initiated & Industry Funded
6	Non-UW Investigator Initiated & Government Funded
7	Government Initiated & Government Sponsored

University of Washington
Clinical Trials Process Improvement Project
Achieved Improvements - Appendix G

	Achieved Improvement	Issue Resolved/To be Resolved	Stakeholder Responsible	Next Steps
1	Executive sponsors own the process. R. Meisinger is the agent of the Executive Sponsors	At the start of the project, no one knew who owned the process since it spanned organizational boundaries. Stakeholders wanted ownership defined.	Executive Sponsors	Complete
2	An online Clinical Research Handbook was conceptualized, designed, planned and is under development.	Create an easily accessible place where current information about the Clinical Research Proposal process is available to stakeholders.	RGE	In progress. The first phase of the Handbook will be released in January 2010.
3	Flowcharts of the current/optimum process were developed.	Processes were not documented. There was confusion about how parts of the process worked. Parts of the process were informal and varied. Personnel changes caused processes to "fall apart" because they were person dependent. Relationships between parts of the process were not well understood.	RGE	In progress. Include flowcharts in Clinical Research Handbook.
4	Key front-end questions to be answered by the PI/SC were defined. Decision trees to answer questions were developed. Definitions, examples & contacts for consultation will be included in the Clinical Research Handbook.	Do I need a Radiation Safety review? Do I need an Institutional Biosafety review? Which IRB do I use? These were questions that could be difficult to answer. Failure to raise and answer the questions in the front-end of the process caused delays, restarts & rework downstream.	Questions are answered by PI/SC. RGE provides information to aid in the decision-making via the Clinical Research Handbook.	In progress. Include In Clinical Research Handbook.

University of Washington
Clinical Trials Process Improvement Project
Achieved Improvements - Appendix G

	Achieved Improvement	Issue Resolved/To be Resolved	Stakeholder Responsible	Next Steps
5	Packages' of required documents/forms based upon answers to the front-end questions were developed.	The answers to the front-end questions determined the materials that must be put together for the proposal package. Previously, people had used their own "cheat sheets" but there had been no common definition of what needed to be submitted and to whom.	PI/SC completes the "packages." Units (e.g. HSD, OSP, CRBB, etc. update the package requirements)	In progress. Include In Clinical Research Handbook
6	Master agreements have been posted on the OSP website and additional agreements will continue to be developed.	Let PIs/SCs know which industry sponsors have master agreements.	OSP	Complete
7	Handoffs within the CRBB part of the process were decreased & multiple entries of the same information eliminated.	Non-value added steps.	CRBB	Implement
8	For the SFI process, OSP added the eGC1# to SFI disclosure form	An audit trail was needed in case the SFI disclosure form became separated from the eGC1.	OSP	Complete. New form is posted online.
9	Status points' for each part of the process that are currently collected in organizatonal unit data systems were identified. Status points have also been identified that are not currently collected in information systems but have been cited as being potentially useful status information for stakeholders.	Some status points existed but points across the Clinical Trials Proposal process had not been identified. Status points must be indentified in order to develop an interim tracking system.	RGE	Complete. Organizational units can use identified status points to develop metrics for their units as a first step toward a cross-process tracking system.

University of Washington
Clinical Trials Process Improvement Project
Achieved Improvements - Appendix G

	Achieved Improvement	Issue Resolved/To be Resolved	Stakeholder Responsible	Next Steps
10	Part of the 'to be hired' Clinical Research Administrator's job will be to further develop and maintain the Clinical Research Handbook.	The Handbook must be continually updated in order to remain relevant.	RGE	In progress. Complete Clinical Research Administrator position description, get HR approval & hire.
11	The Clinical Research Administrator will provide staff support to the Steering Committee and will provide project management support for improvement projects initiated by the Committee.	The Clinical Research Administrator takes over this function from the Project Consultant and Project Manager.	RGE	In progress. Complete Clinical Research Administrator position description, get HR approval & hire.
12	The UWMC & SCCA agreed to streamline separate Radiation Safety reviews into one process with a common form.	Previously, the PI/SCs had to do one process for UWMC and another for SCCA, separate applications for each.	Radiation Safety - UWMC & SCCA	In progress. Implement pilot to test this approach.
13	UWMC & HMC agreed to streamline separate Implant & Investigational Device reviews into one process with a common form.	Previously, the PI/SCs had to do one process for UWMC and another for HMC, separate applications for each.	Compliance for UWMC & HMC	In progress. Develop new form and implement new process.
14	Contacts (individuals) will be identified for each part of the process to help stakeholders navigate the Clinical Research Proposal process.	When the PIs/SCs had questions, they did not know who to call.	RGE	In progress. Include contact information in the Clinical Research Handbook.
15	HSD & Radiation Safety reached agreement to continue to transmit all IRB approval notices to Radiation Safety (manually).	The question had been raised regarding whether all notices should be sent and whether they should be sent manually or electronically.	HSD & Radiation Safety	Complete. In the longer term, consider sending only those cover sheets with RS. Send cover sheets electronically.
16	CRBB is the responsible agent for identifying Medicare Secondary Payer (MSP) issues and communicating the issues to HSD, OSP and the PI & SC.	Need to clarify roles and responsibilities related to MSP.	CRBB	In progress. CRBB develops process and communicates process to HSD, OSP and PIs/SCs.

University of Washington
Clinical Trials Process Improvement Project
Achieved Improvements - Appendix G

	Achieved Improvement	Issue Resolved/To be Resolved	Stakeholder Responsible	Next Steps
17	OSP will not hold up contract signing in order to perform a review of the Consent Form.	Need to clarify OSP's role related to the Consent Form.	HSD	In progress. Determine whether HSD wants OSP to conduct a post-contract review of the Consent Form to ensure that no subjects are enrolled until the Consent Form and contract are aligned. Per HSD, a final review is a regulatory requirement.
18	Common definitions for "adverse effect" and "complications" have been developed	There is no common definition of these terms and this causes confusion among stakeholders.	HSD	In progress. If any inconsistencies remain, reconcile the definitions & publish in the Clinical Research Handbook.
19	CRBB is responsible for managing the exemption policy for the ORCA care plan. CRBB should communicate with HSD about exemptions.	Need to clarify roles and responsibilities related to ORCA care plan.	CRBB	In progress. CRBB notifies IRB committees of the new process and provides contact information.
20	Related to contract amendments & extensions, CRBB reviews residuals before OSP negotiates contract. CRBB reviews others on a case-by-case basis as determined by OSP.	Need to clarify OSP & CRBB roles and responsibilities related to contract amendments & extensions.	OSP/CRBB	In progress. CRBB partners with OSP to develop process. CRBB initiates.
21	CRBB develops a standard template that identifies all UW representatives & roles and provides this to sponsors.	Sponsors confused about UW contacts and roles and responsibilities.	CRBB	In progress. CRBB shares template with OSP.
22	CRBB does not perform "final review" after budget documents are signed and sent to PI/SC.	Are these process steps value added?	CRBB	CRBB discontinues performing this function.

University of Washington
Clinical Trials Process Improvement Project
Achieved Improvements - Appendix G

	Achieved Improvement	Issue Resolved/To be Resolved	Stakeholder Responsible	Next Steps
23	Agreement that SFI disclosure letter will continue to be sent manually since switching to electronic requires a change in UW & GIM10 policies.	Currently, the letter is sent manually in a sealed envelope. With changes in confidentiality around SFI, explore whether the letter can be sent electronically with the eGC1 & disclosure form.	SFI	Complete
24	Developed internal risk management matrix for clinical trial agreements & reviewed risk management strategies with UW Risk Management Office.	Provides OSP with more authority to negotiate contracts & speeds up the negotiation process.	OSP	Complete
25	Revised and streamlined clinical trial check processing. This eliminated steps for OSP & facilitates official accounting for a study.	Clarify roles and responsibilities between OSP & GCA related to check processing.	OSP	Complete
26	Revised account authorizations/electronic funding actions for clinical trials. This allows a project to make expenditures for start-up needs before subjects are enrolled in a study.	This eliminates a procedure called "advance budgets" and enables a project to establish and account even if the money has not been received from the sponsor. Accordingly, a study can run a deficit until the sponsor does transfer funds to the study account. The department is ultimately responsible if expenditures are made and an account is not funded.	OSP	Complete
27	Established process for SCs to obtain read-only SPAERC access.	SCs have access to information about their proposal.	OSP	Complete

University of Washington
Clinical Trials Process Improvement Project
Recommended Improvements - Appendix H

	Recommendation for Improvement	Issue Resolved/To be Resolved	Stakeholder Responsible	Next Steps
1	Option 1: Radiation Safety does not wait for SRC approval before starting their review if the PI/SC anticipates Radiation Safety Review is required. Option 2: Radiation Safety starts review after receiving SRC approval.	Waiting for SRC approval means the Radiation Safety review gets started later than it could.	Radiation Safety	In progress. Discuss options with Steering Committee.
2	Clarify which study proposals will be reviewed by the SRC.	There is confusion regarding the studies that need to go to the SRC.	SRC	In progress. Ask Sonja for documented agreement.
3	Determine if it is appropriate to perform front-end triage at the departmental level to gauge if a study has sufficient merit to start through the proposal process.	Are there studies that should not even start through the process? Note: Oncology is performing analysis on a retrospective of studies that will be helpful in exploring this topic.	RGE	Steering Committee establishes priority. Explore this at some point in the future after other process improvements have been implemented
4	To manage proposal workload, establish prioritization guidelines.	Should some studies be higher priority than others? Currently, all studies are assumed equal in importance.	RGE	Steering Committee establishes priority.
5	Design, implement & staff a Clinical Research Service Center that: 1) provides front-end 'triage' support to PI/SC so key questions are answered, packages assembled and sent to the right places at the right times; 2) provides status on proposals; and, 3) helps PIs/SCs navigate the complete process.	Front-end process activities greatly influence the success and efficiency of downstream process activities. Currently, there is not a central place for PIs/SCs to go for support as they initiate and attempt to navigate the Clinical Trials Proposal process.	RGE	In progress. Clinical Research Administrator will be FTE #1. Clinical Research Administrator will perform a subset of all activities planned for the Service Center.

University of Washington
Clinical Trials Process Improvement Project
Recommended Improvements - Appendix H

	Recommendation for Improvement	Issue Resolved/To be Resolved	Stakeholder Responsible	Next Steps
6	Provide orientation to the Clinical Research Handbook to help PIs/SCs navigate the process, including completing the forms and documents required in the "packages."	Frequently, stakeholders report that forms/documents are missing from the proposal packages, information is missing on a form or document and/or forms/documents are improperly filled out. This causes rework loops as corrections are made. [OSP has surveyed stakeholders & found that PIs/SCs want orientation on how to initiate research.]	RGE	Start immediately. Plan orientation for stakeholders.
7	Encourage each organizational unit to identify, collect and report metrics desired by stakeholders	Although multiple units are collecting some data that might be used to determine the status of a proposal, the data reside in multiple systems that were not built to provide status information. Currently, the capability to status a proposal across the whole process does not exist. Additionally, data do not exist to determine the time it takes a proposal to go through the whole process.	Each organizational unit.	Steering Committee establishes priority, facilitates continuing conversations and coordinates metrics work with the Research Roadmap project.
8	Establish universal reference # [perhaps the "registration number" that may be used for the interim tracking system].	A single proposal is referred to by many numbers - each unit has their own - this causes great confusion.	RGE	Steering Committee establishes priority.
9	Acquire a management information system to automate the Clinical Trials Proposal Process. This would be a web-based system that stores & tracks all study proposal documents. Information would be entered once and populated to the relevant documents.	Out of scope - Research Roadmap	Office of Research	Out of scope.

	Recommendation for Improvement	Issue Resolved/To be Resolved	Stakeholder Responsible	Next Steps
10	Option 1: HSD publishes a deadline rule (like OSP's GIM19) specifying the time required to process the proposal application for IRB approval. Option 2: HSD develops a process to work with the schools/departments so they are notified as soon as "intent to fund" is known. That way HSD can remind the PI to complete the IRB application as soon as possible. Option 3: HSD develops a process to work with Grants and Contract Accounting so they are notified when an advance budget is assigned to a proposal. That way HSD can remind the PI to complete the IRB application as soon as possible.	Timely submission to IRB for government/foundation funded proposals.	HSD	In progress. HSD makes recommendation to Steering Committee. Option 1: HSD drafts policy, consults with constituents, then pilots draft policy with selected departments. At the end of pilot, HSD finalizes policy & communicates policy to stakeholders. Option 2: HSD develops process for getting "intent to fund" information from the schools/departments. *(HSD - are additional resources required?).* Option 3: HSD develops process for acquiring advanced notification of advance budget assignment. *(HSD, are additional resources required?).*
11	Create a central electronic location where stakeholders can find the most recent version of the Consent form.	The consent form can change during the proposal process and stakeholders who review it do not necessarily know if they are looking at the most recent version.	HSD	In progress. HSD is working with ORIS to develop a central location for the Consent Form.

	Recommendation for Improvement	Issue Resolved/To be Resolved	Stakeholder Responsible	Next Steps
12	HSD is the contact/clearing house for all suggested changes to the Consent Form.	Role/responsibility related to the Consent Form unclear.	HSD	Start Immediately. HSD works with Radiation Safety, Institutional Biosafety, Investigational Drugs and the PIs/SCs to develop clearing house process. *(HSD, are additional resources required?)* .
13	HSD does not send proposal applications to WIRB until the Consent Form is completed.	Elimination of rework. If Consent Form is modified, then application has to go back through WIRB process.	HSD	Start immediately. HSD drafts policy, consults with constituents then pilots draft policy with selected departments. At the end of pilot, HSD finalizes policy & communicates policy to stakeholders. *(HSD, are additional resources required?)* .
14	Resolve the following questions related to the Consent Form: 1) When IRB requests changes in the Consent Form, how best can these be communicated to CRBB so that the budget can be prepared accurately? 2) How can CRBB communicate early enough with HSD about potential incentive payments or subject reimbursements to avoid having the IRB review the Consent Form multiple times? 3) What is the best way to make sure that the Consent Form language is in alignment with the budget & contract?	Keeping abreast of Consent Form changes.	HSD/CRBB	In progress. HSD & CRBB will meet to resolve these questions.

University of Washington
Clinical Trials Process Improvement Project
Recommended Improvements - Appendix H

	Recommendation for Improvement	Issue Resolved/To be Resolved	Stakeholder Responsible	Next Steps
15	Define the process for cooperative group and intergroup studies.	Related to Radiation Safety & SRC. These may be cancer studies that do not go through SRC. From H. Vesselle mtg. 7/28/09.		In progress. Consult with Sonja Stella.
16	For investigator initiated studies, develop standards for protocols to increase quality.	Protocols can be difficult to decipher.		Steering Committee establishes priority. Requires initiation of a project.
17	Provide required clinical information to hospital service centers so they can generate pricing pages.	Service Centers report they do not have the required clinical information needed in order to perform the pricing function.	RGE	In progress. Diane Merz reports new process to Steering Committee & provides process information for Clinical Research Handbook.
18	Establish a central point of distribution for pricing sheet requests.	For SCCA studies, PIs/SCs send pricing requests to the Research Implementation Office (RIO, S. Johnson & G. Roper) and they interface with the service centers. This works well and it's easier to tell when a particular service center might be experiencing problems in responding to requests. This is a suggestion to have the same type of process on the UWMC side.	RGE	In progress. Diane Merz reports new process to Steering Committee & provides process information for Clinical Research Handbook.
19	For UWMC, develop a price list that can be used for developing preliminary budgets.	SCCA has developed a price list (not yet posted online) of the 100 most requested prices that can be used for preliminary pricing purposes. When the actual budget is developed, the regular pricing pages process must still be used.	RGE	In progress. CRBB to implement as part of Pricing Pages project.

University of Washington
Clinical Trials Process Improvement Project
Recommended Improvements - Appendix H

	Recommendation for Improvement	Issue Resolved/To be Resolved	Stakeholder Responsible	Next Steps
20	Establish master confidentiality agreements (CDAs) with industry sponsors that frequently fund studies. Establish a formal process for processing CDAs when an institutional signature is required. Track status of CDAs.	More industry sponsors are requiring an institutional signature on the CDA. This is a suggestion to develop master CDAs (one per industry sponsor) with participating institutions (e.g. UW, FHCRC, etc.) signing the master CDA.	OSP	Steering Committee establishes priority.
21	Establish standard naming conventions (a glossary) for the documents being used throughout the Clinical Trials Proposal process.	Referring to the same form/document using different names causes confusion.	RGE	Steering Committee establishes priority & determines where "glossary of record" resides.
22	Establish a name/number for each proposal so it can be referred to in the same way across the process	Proposals are referred to by different names across the process which causes confusion.	RGE	Steering Committee establishes priority.
23	Expand "Industry Relations" coordinated effort.	Example: Eli Lilly visit.	OSP	Ongoing
24	Have a joint preliminary review when IBC is required at both SCCA & UW then PI can answer all questions at once.	Currently, the PI has to answer questions about the study twice, once for SCCA and once for UWMC.	EH&S	Steering Committee establishes priority. Determine if there are enough studies to make this worthwhile.
25	Develop Intellectual Property (IP) language/procedures that are relevant for industry studies.	IP policy covers an extensive range that is not relevant when an investigator is using an industry sponsor's drug. In this case, there is no IP for the PI and the PI knows this. Sometimes, the proposal gets bogged down related to IP when it does not need to.		In progress. Sonja will talk to Mac. He can help frame this for discussion with Tech Transfer and OSP. Dick will talk to OSP.
26	Invest in "Study Manager" tool for study administration.	Out of scope but a really good idea!		Out of scope.
27	Revise the CRBB website - make it more user friendly & intuitive	Out of scope		Out of scope.

	Recommendation for Improvement	Issue Resolved/To be Resolved	Stakeholder Responsible	Next Steps
28	Determine possible impacts to the Clinical Trials Proposal process on the new Administrative Policy Statement (APS) on data security.	Will researcher have new obligations?	HSD	In progress. Discuss with K. Moe.
29	Implement a bi-weekly telecon between OSP & CRBB to share negotiation strategy on proposal applications.	How can CRBB & OSP communicate the status of each others' negotiations to help prioritize the workload?	CRBB/OSP	In progress. CRBB (K. Hilty) arranges a 3 month pilot.
30	For Significant Financial Interest process, streamline submission of disclosure letter along with electronic eGC! & SFI disclosure form. To submit electronically, requires a change in UW confidentiality rules & GIM10 policy.	Current submission is manual and separate from the eGC1 and SFI disclosure form.	SFI	Steering Committee establishes priority.
31	Integrate non-industry sponsored clinical trials (federal, foundation, academic and other non-profit) and industry sponsored clinical trials into OSP's Clinical Trial Group.	This organization change within OSP combines all of the office's clinical research expertise in one area (Michael, Karl & Brandon). For example, it might be necessary to negotiate with a third party sponsor (e.g. an industry sponsor) on a government or foundation-sponsored grant. The industry sponsor may be supplying a drug or device as part of the study. Also, even on a government/foundation funded grant, there might be a contract with another site. Expertise for all of these contractual issues will be centered in one place within OSP.	OSP	Implement new organization change.
32	Clarify subject injury billing and policies with other offices (HSD, CRBB, UW Medicine).	Achieve consistent UW position so all UW offices are operating from the same script when dealing with outside agencies.	OSP	OSP convenes stakeholders to achieve, document and implement consistent process across offices.

	Recommendation for Improvement	Issue Resolved/To be Resolved	Stakeholder Responsible	Next Steps
33	Clarify and resolve uncertainties regarding Medicare Secondary Payer issues with other offices (AGO, HSD, CRBB).	Achieve consistent UW position so all UW offices are operating from the same script when dealing with outside agencies.	OSP	OSP convenes stakeholders to achieve, document and implement consistent process across offices.
34	Clarify and update UW Human Subjects Injury Compensation Program.	Achieve consistent UW position so all UW offices are operating from the same script when dealing with outside agencies.	Risk Management	Convene stakeholders to achieve, document and implement consistent process across offices.

University of Washington
Clinical Trials Process Improvement Project

Possible Responsibilities/Duties for Clinical Research Service Center	**Possible Responsibilities/Duties for Clinical Research Administrator (FTE#1)**
Manage, maintain and continue to develop the Clinical Research Handbook	Manage, maintain and continue to develop the Clinical Research Handbook
Facilitate clinical research proposal process: • Provide "front end" triage support • Provide advice & information about the process to stakeholders • Assist stakeholders in process problem resolution • Serve as liaison across the process (e.g. UW, SCCA, FHCRC,CHMC)	Facilitate clinical research proposal process: • Provide "front end" triage support • Provide advice & information about the process to stakeholders • Assist stakeholders in process problem resolution • Serve as liaison across the process (e.g. UW, SCCA, FHCRC,CHMC)
Coordinate existing training related to Clinical Research Proposal Process & identify new stakeholder training needs	Coordinate existing training related to Clinical Research Proposal Process & identify new stakeholder training needs
Track & report status of study proposals • Collect & report data, for example the time from submittal of proposal to enrollment of subjects (possibly use dashboards/scorecard) • Refine process measures	
Manage Clinical Research Data, e.g. • How many studies • $ amount • How much is clinical • Etc.	
Staff Steering Committee & working groups	Staff Steering Committee
Provide project management for improvement projects	Provide project management for improvement projects
Provide pool of Research Coordinators	
Support StudyManager software package	
Support industry sponsor relations	
Support subject recruitment	
Support continuous improvement of the Clinical Research Proposal Process	Support continuous improvement of the Clinical Research Proposal Process
Maintain Clinical Trials Discussion Group Listserve	
Review information from PIs & register studies on clinicaltrials.gov (Move function from HSD)	
Develop, implement & maintain a Clinical Trials website.	
Create additional tools that customers can use to navigate the process	
Assist PIs & SCs in using tools such as the Clinical Research Handbook to navigate the process	
Create the systems (e.g. administrative) required for efficient Service Center operation	
Manage Service Center Staff	

Design/Functionality

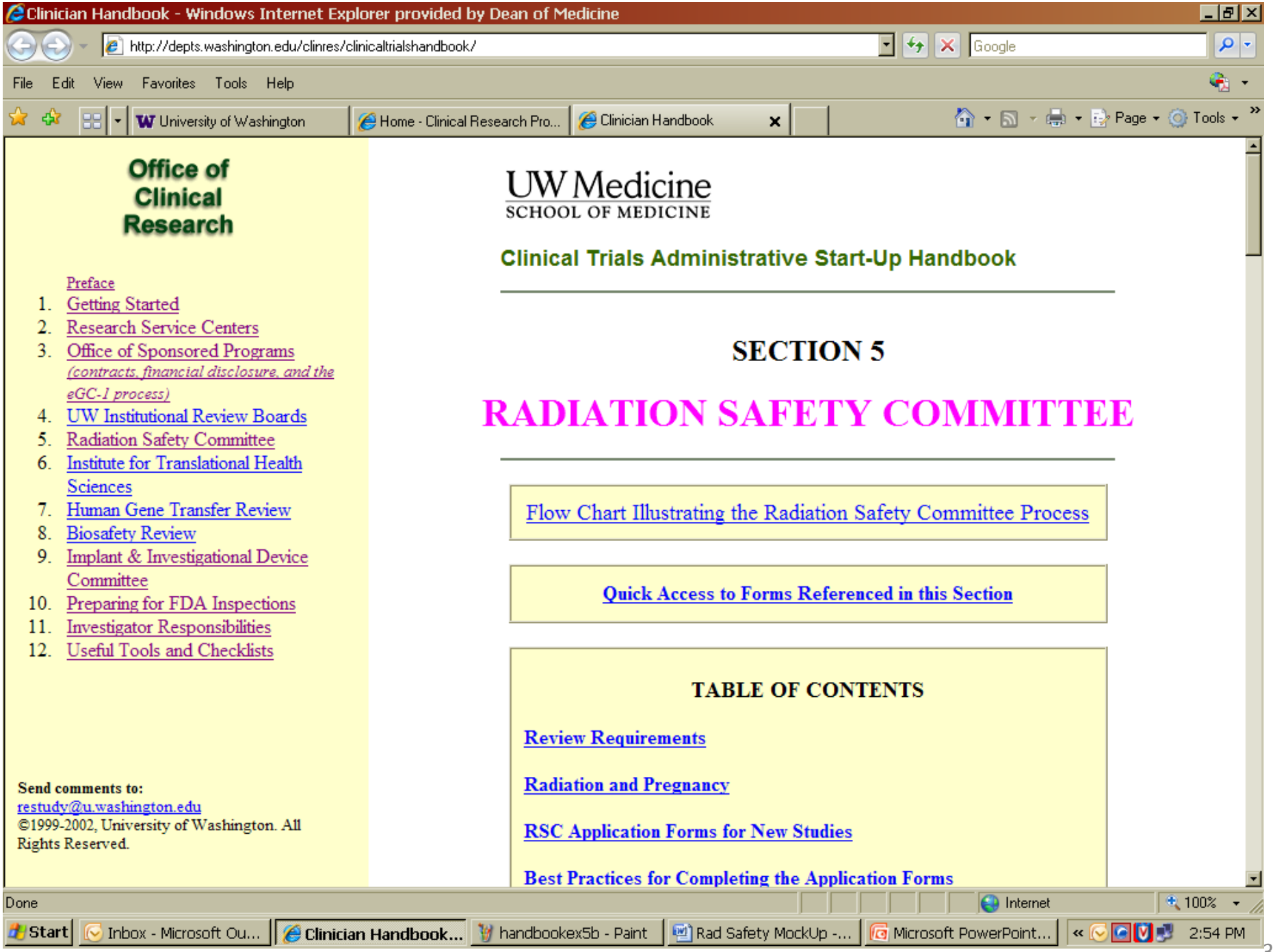
Clinical Trials Start-Up Handbook

Design/Functionality Ideas: Clinical Trials Start-Up Handbook

	Current	Idea #1	Idea #2	Idea #3
❖**Method**				
	❑Text Based	❑Text Based	❑Text Based, combined with leading question and answer	❑Graphics Based, combined with informative text
❖**Navigation**				
	❑Table of Contents	❑Table of Contents ❑Index ❑Search	❑Table of Contents	❑Graphical/Tree Structure table of Contents
❖**Pros**				
	❑Simple ❑Based on existing UW design	❑Simple ❑Based on existing UW design ❑Multiple navigation methods	❑Good method for new investigators	❑Good high-level View of process
❖**Cons**				
	❑Requires navigating through text	❑Requires navigating through text	❑Limited navigability, requires step-by-step	❑Limited search (keyword) capability
❖**Based on:**				
	UW Medicine: Office of Clinical Research Clinical Trials Administrative Start-Up Handbook	**UW Medicine** Guide to Electronic Grant Submission	**Emory University** Protocol Routing and Approval Process	**Stanford/Packard Center for Translational Research in Medicine** Process Maps: Stanford Clinical Research

Current

Screenshot

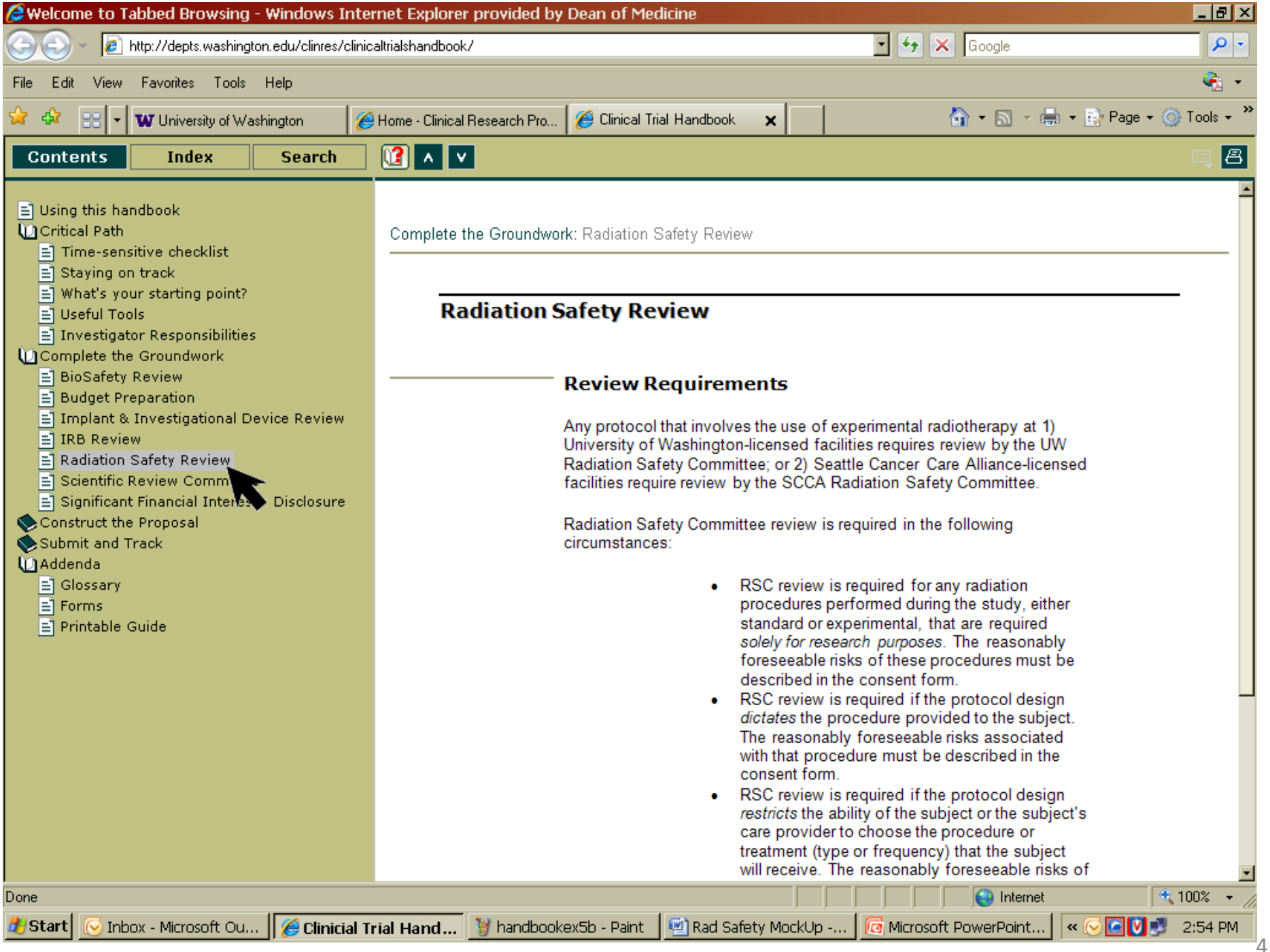


J3

APPENDIX J

Idea #1: Table of Contents View

Mock-Up
Screenshot 1 of 3

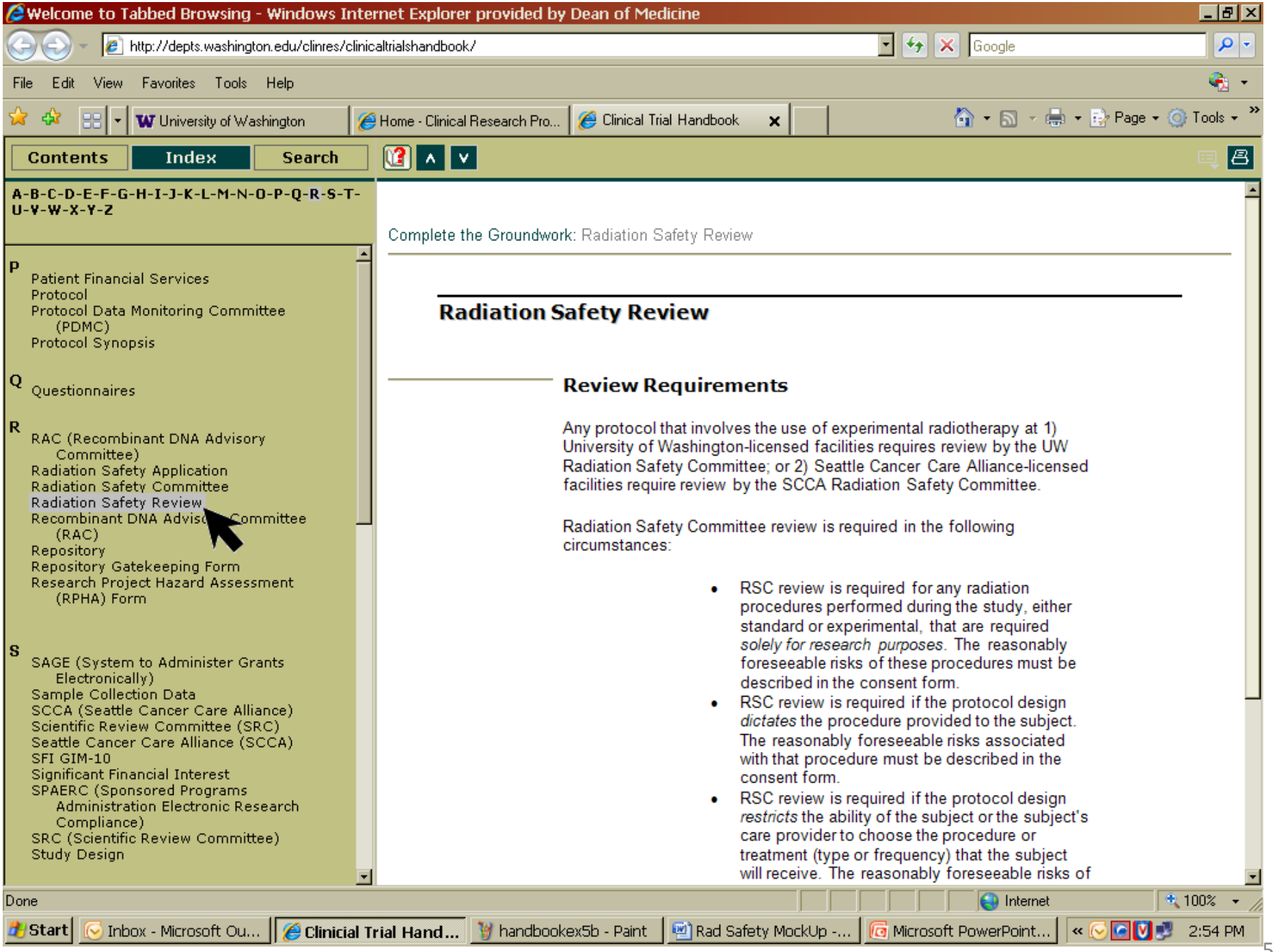


J4

APPENDIX J

Idea #1: Index View

Mock-Up
Screenshot 2 of 3

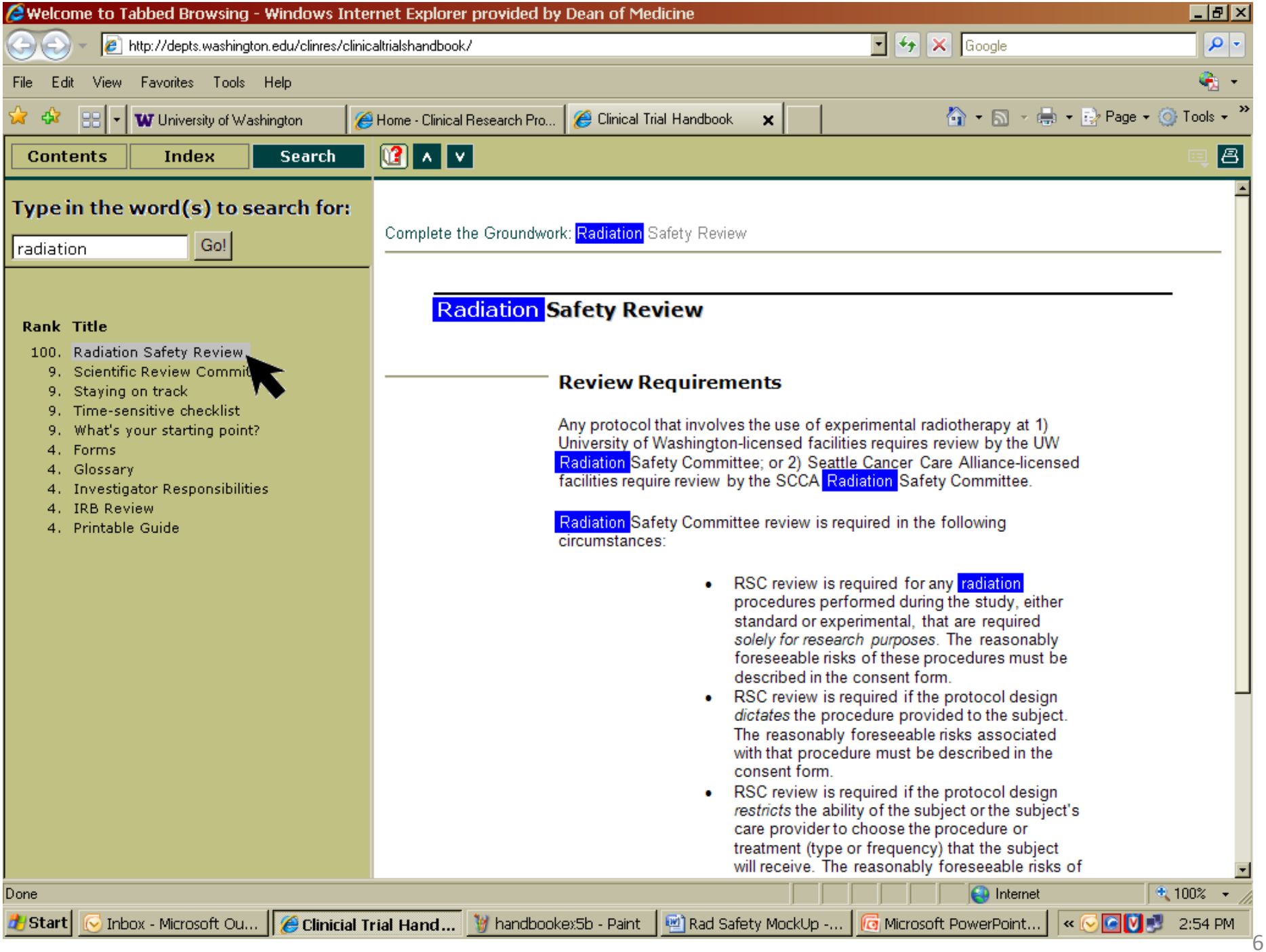


J5

APPENDIX J

Idea #1: Search View

Mock-Up
Screenshot 3 of 3

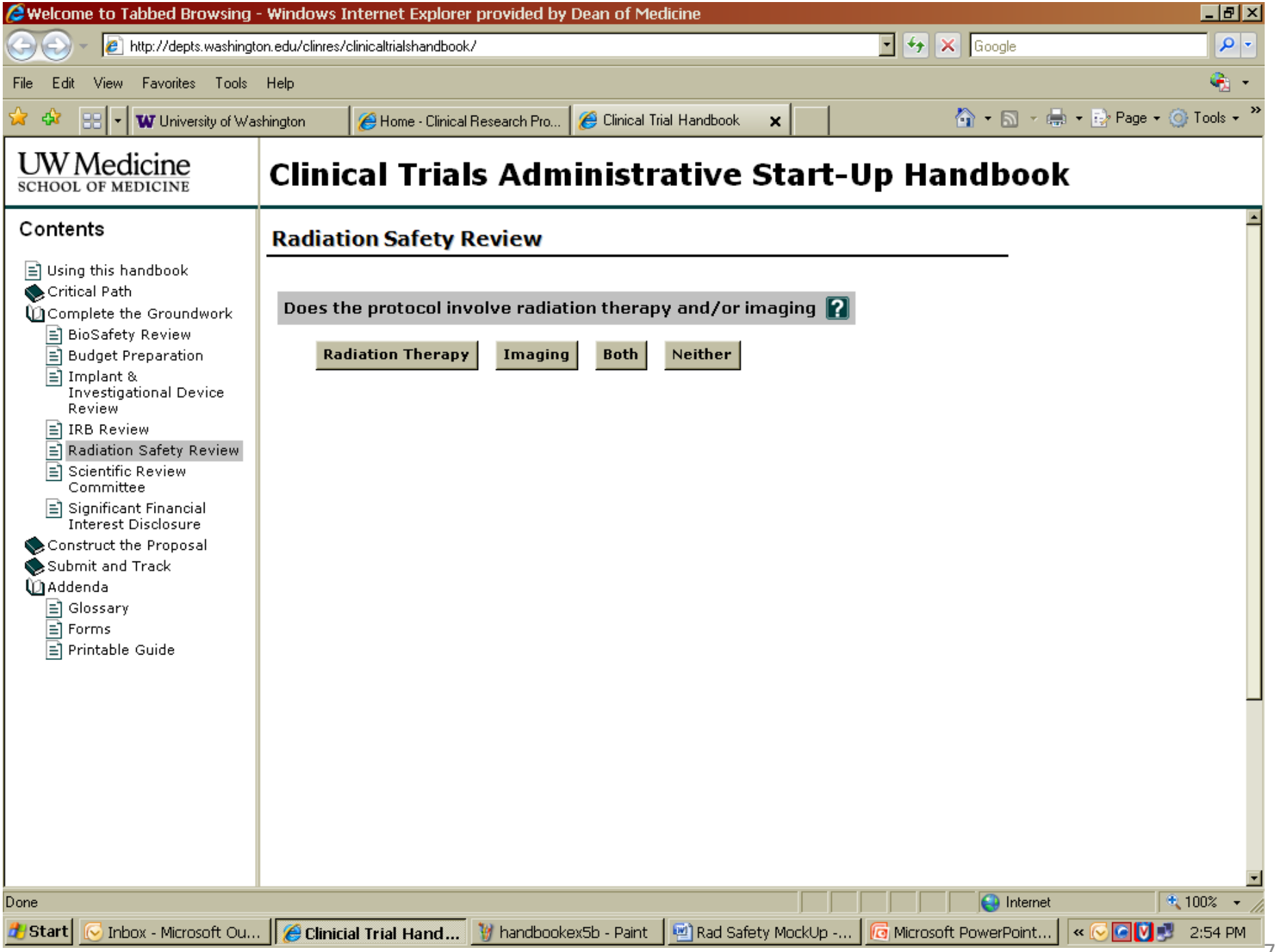


16

APPENDIX J

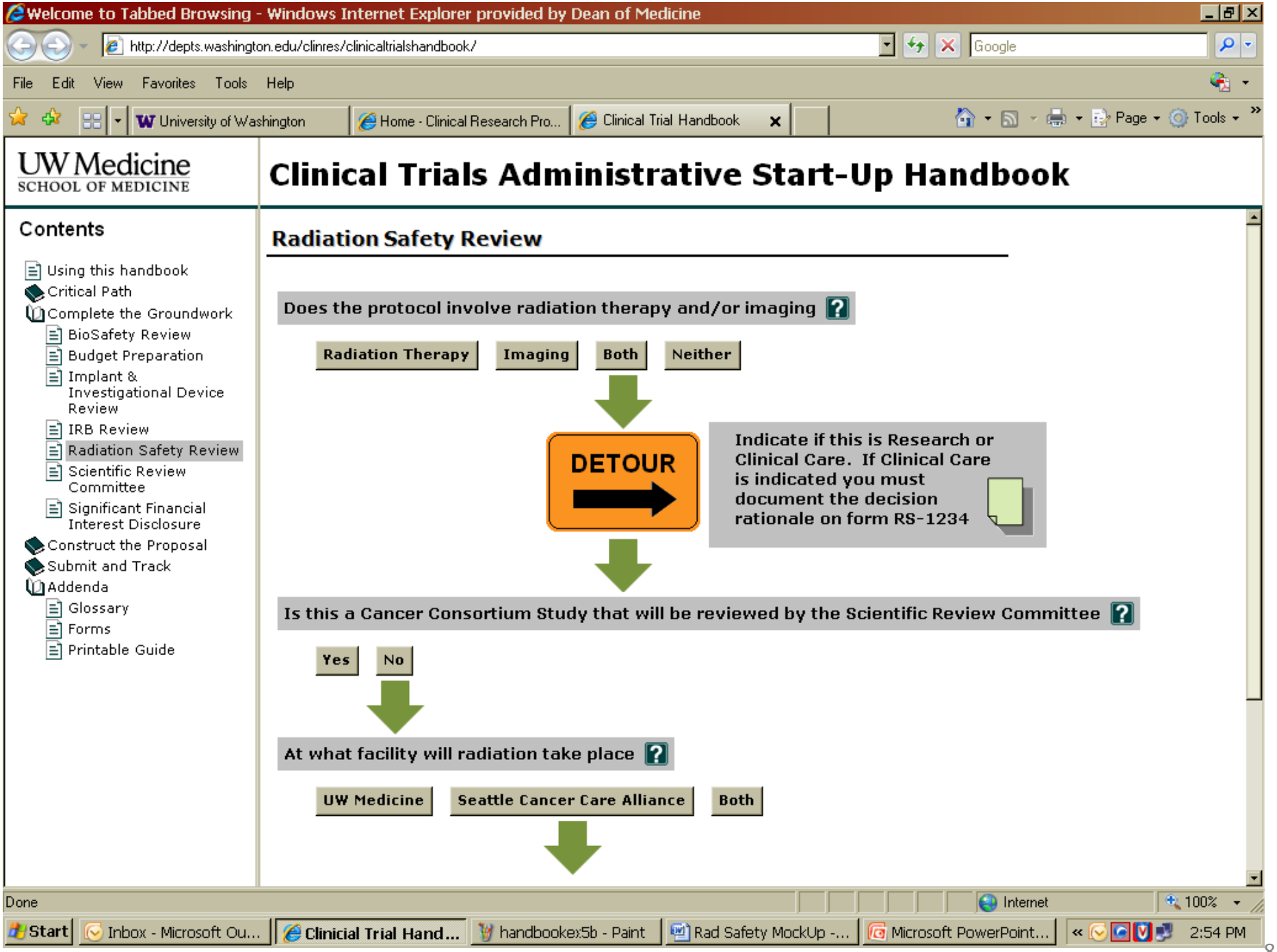
Idea #2: Initial User View

Mock-Up
Screenshot 1 of 3



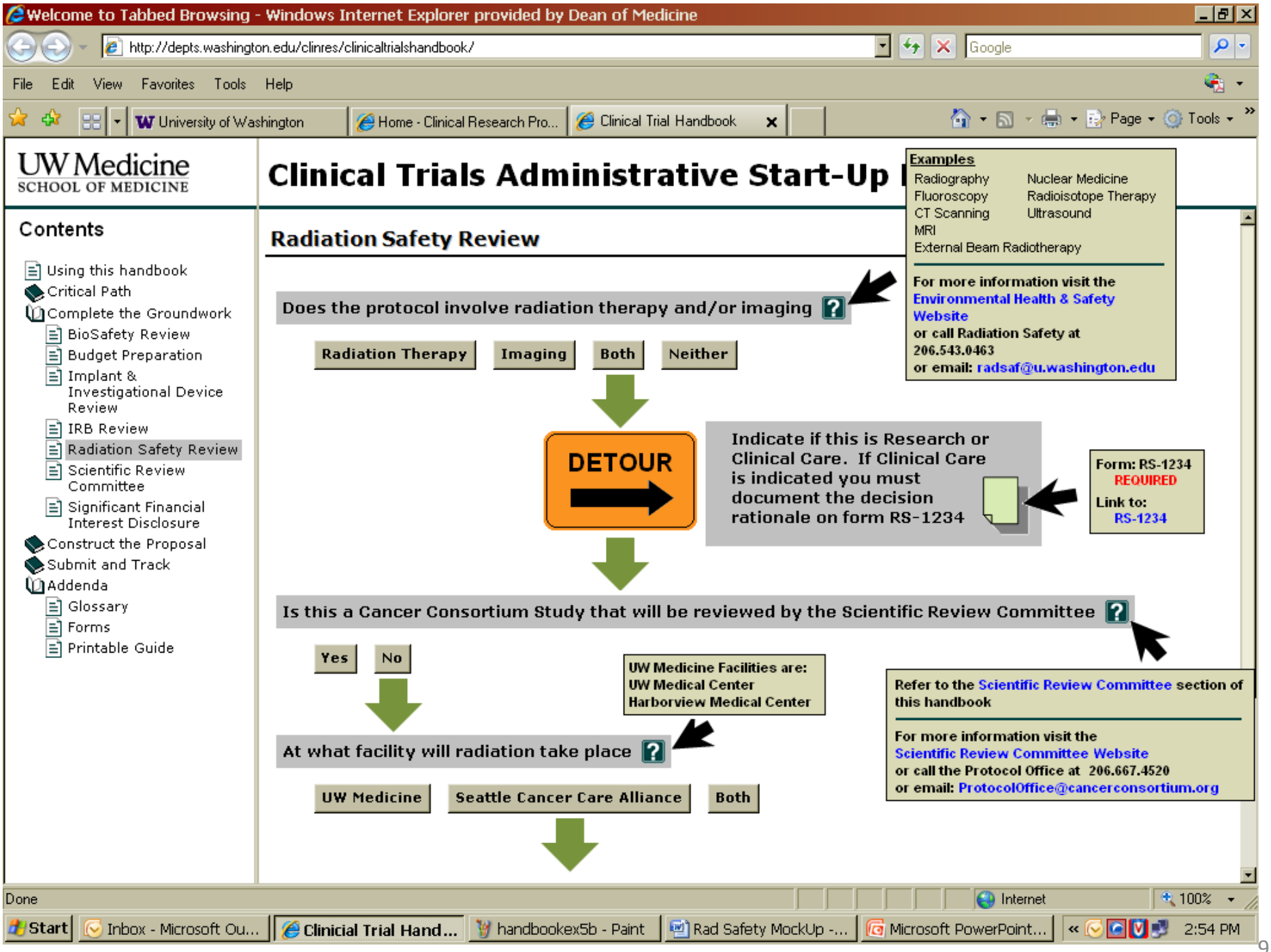
Idea #2: User view after answering questions

Mock-Up
Screenshot 2 of 3



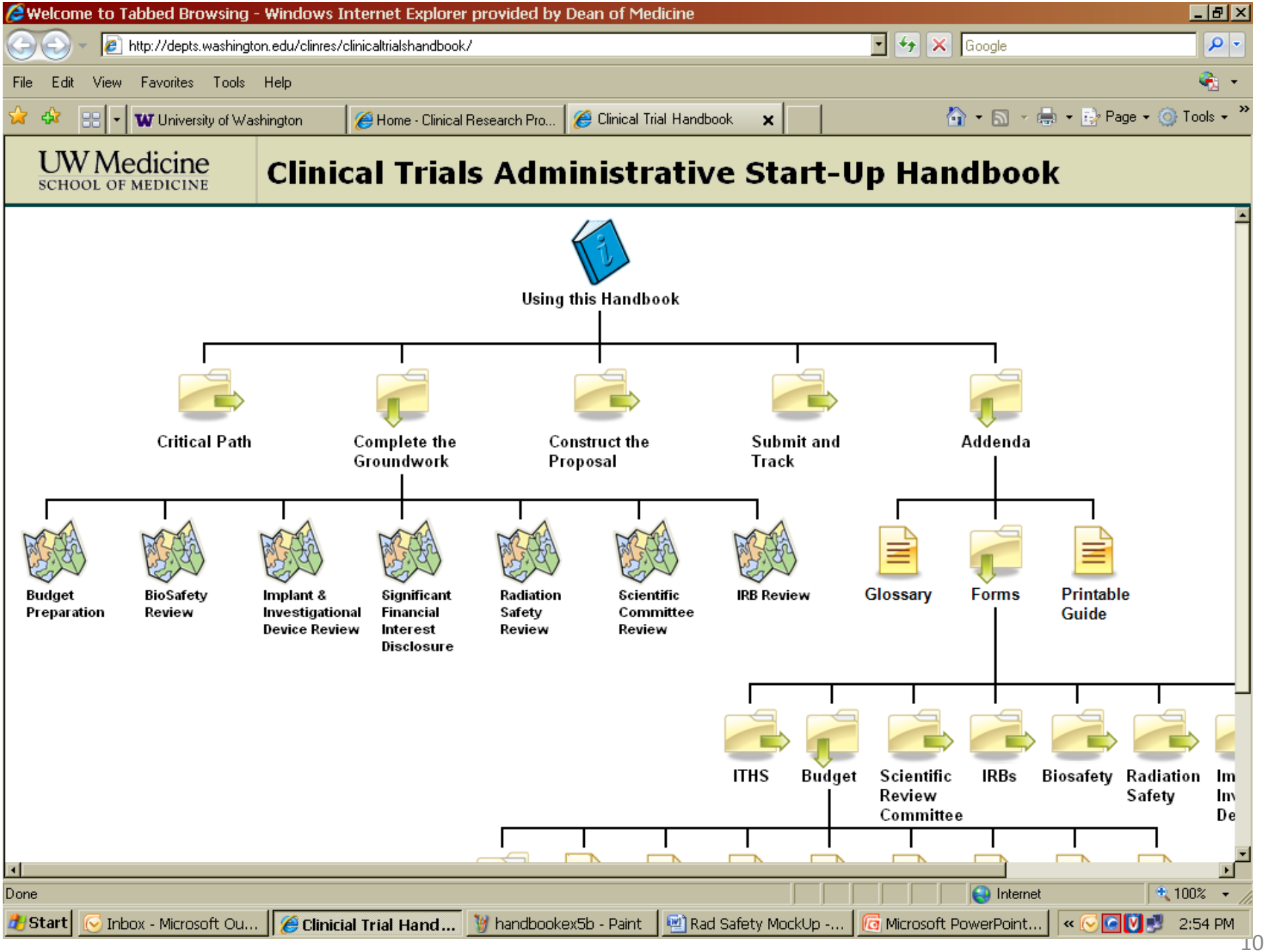
Idea #2: User view with information callouts shown

Mock-Up
Screenshot 3 of 3



Idea #3: User initial high-level view with some open files

Mock-Up
Screenshot 1 of 3

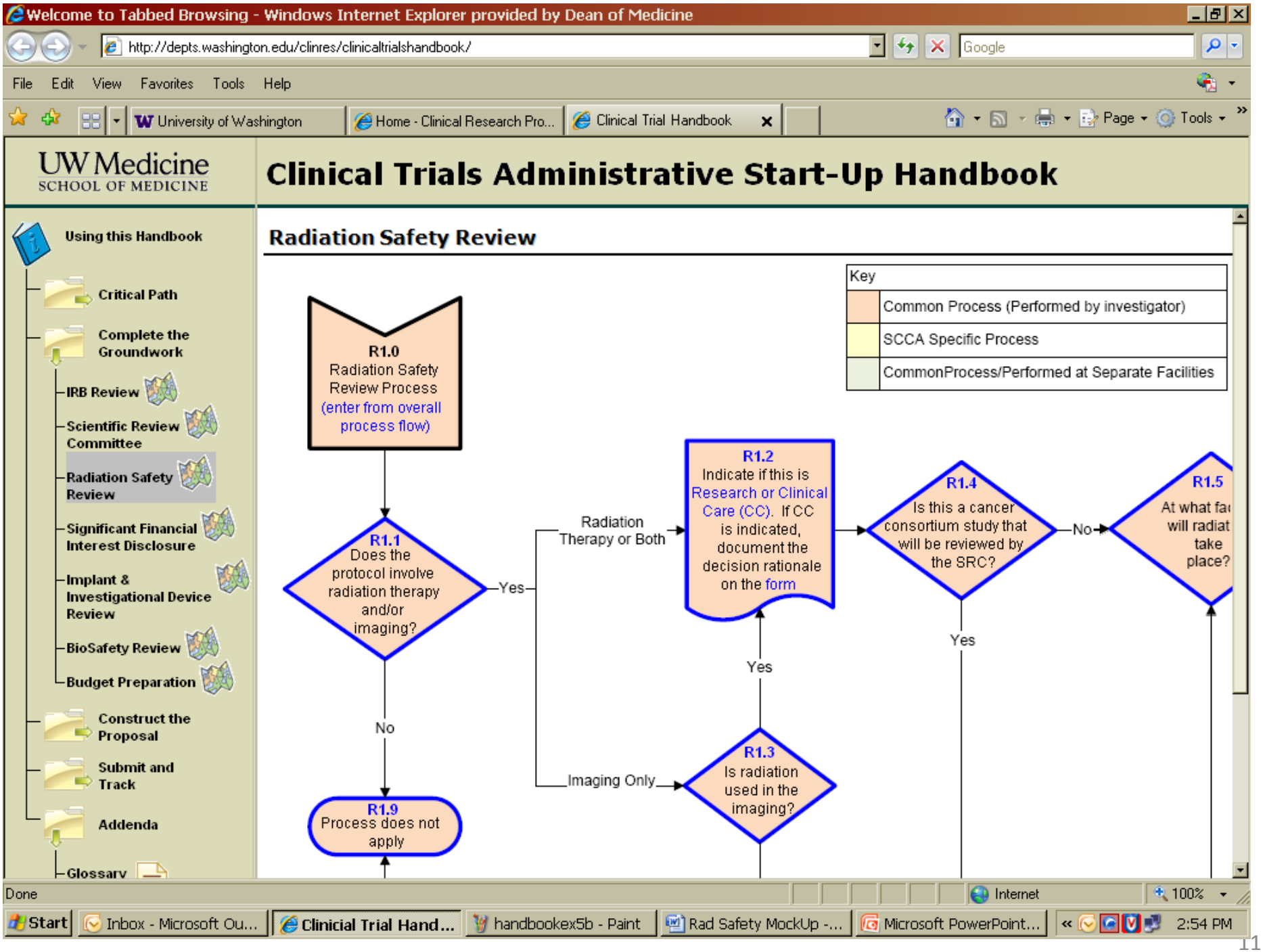


J10

APPENDIX J

Idea #3: Initial User View of chosen item

Mock-Up
Screenshot 2 of 3

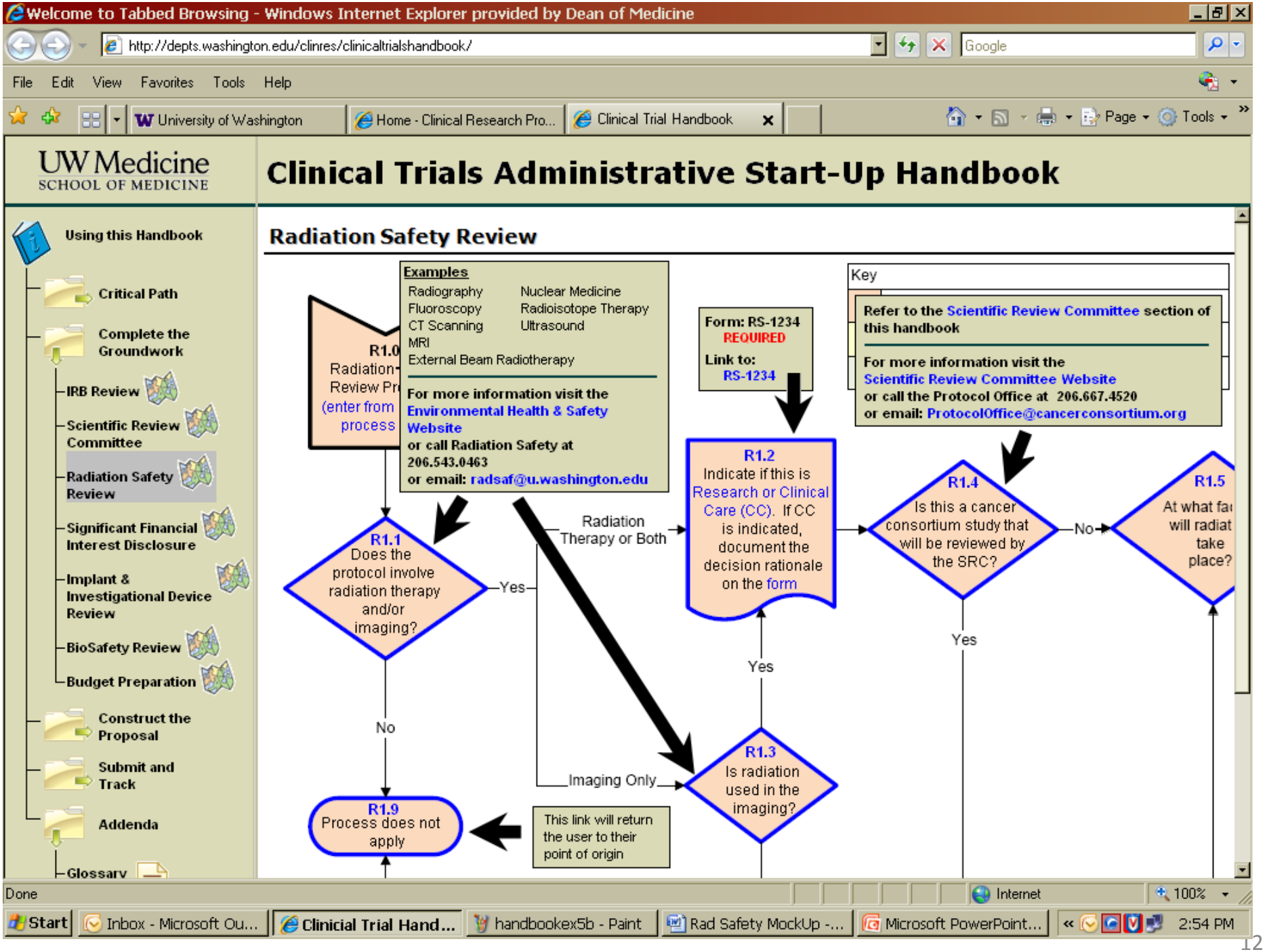


J11

APPENDIX J

Idea #3: User view with information callouts shown

Mock-Up
Screenshot 3 of 3



J12

APPENDIX J

Technology Overview

Clinical Trials Start-Up Handbook

What is a Content Management System? *

A CMS is server software that manages content (text, images and data) separate from the designed page layout that you view in your browser. Because content is kept separate from design (usually in a database), it is relatively easy to develop and deploy new layouts, navigation and style elements.

A CMS also:
gives your website a more consistent look and feel
makes it easier to meet accessibility standards
gives your content writers and producers a tool to review and publish/unpublish content

Content Management Systems Being Used at UW

Drupal
Plone
Sharepoint
Wordpress
Joomla
Wiki (various)

•Information from UW Creative Communications website

Technology: CMS Options Explored

	Drupal	Plone	SharePoint
❖UW CMS User Survey*			
	Ranked #1 in Popularity (16 respondents) Ranked #1 in User Satisfaction	Tied for #2 in Popularity (11 respondents) Ranked #2 in User Satisfaction	Tied for #2 in Popularity (11 respondents) Ranked #3 in User Satisfaction
❖Sampling of UW Users			
	•Evans School of Public Affairs •Facilities Services •Department of Biostatistics •Risk Management •Office of Research	•Department of Radiology •Learning & Scholarly Technologies •Health Evidence Resource for Washington State	•Foster School of Business •The Information School •Department of Psychiatry and Behavioral Sciences •Human Resources Information Systems

❖Common Characteristics/Requirements

- ❑Easily integrate with other web sites and applications
- ❑Can accommodate UW's existing netid service
- ❑Uses standard programming language(s)
- ❑Will integrate with UW existing technical infrastructure
- ❑Adheres to accepted programming standards and best practices
- ❑Has a robust user community (both at UW and Publicly)
- ❑Variety of third-party support (including training) available
- ❑Vendor and/or users are committed to ongoing technical and functional development and improvements
- ❑Thorough documentation available

•**Content Management Systems use at the UW** **by** Oren Sreebny, Executive Director of Emerging Technology in UW Technology, Published January 26, 2009
54 respondents; Other systems in use: Wordpress, Joomla, Wiki, Movable Type, Ektron, Confluence, TextPattern, Alfresco, and several custom systems.

J15

APPENDIX J

Technology: CMS Options Explored

	Drupal	Plone	SharePoint
❖**What is It?**			
	Open source modular framework and Content Management System (CMS)	Open source Content Management System (CMS)	A collection of products and software elements
❖**System Requirements**			
▪Approximate Cost (software only)	Free	Free	▬ Not Free
▪License	GNU GPL (free)	GNU GPL (free)	▬ Commercial, per CPU
▪Operating System	Any	Any	▬ Windows
❖**Applications:**			
▪Discussion Forum	Yes	Free Add On	Yes
▪Document Management	▬ Limited	Yes	Yes
▪Events Calendar	Free Add On	Yes	Yes
▪Hierarchical Content Browse	Yes	Yes	▬ Limited
▪Link Management	Free Add On	Yes	Yes
▪Search engine	Yes	Yes	Yes
▪Syndicated Content (RSS)	Yes	Yes	Yes
▪User Contributions	Yes	Yes	Yes

J16

APPENDIX J

Handbook: Next Steps for Analysis

Technology

- ❑Selection of Technology
- ❑Description of chosen Technology
- ❑Define Technology Owner(s)
- ❑Define Technology Oversight
  - ▪define who will be responsible for quality control
  - ▪define help-desk function
- ❑Upfront (start-up) cost
  - ▪software
  - ▪hardware
  - ▪labor
- ❑Maintenance (ongoing) cost
  - ▪software
  - ▪hardware
  - ▪labor
- ❑Implementation Timeline (includes design and content portions)
- ❑Data source detail
  - ▪define how data will be obtained
  - ▪define how data will be stored
  - ▪define how data accuracy and integrity will be maintained

Design/Functionality

- ❑Selection of Design/Functionality
- ❑Description of chosen Design/Functionality
- ❑Fit-Gap analysis
  - ▪Design/Functionality –vs- chosen technology
- ❑Estimate of time needed to complete design plan
- ❑Mock-up final design
- ❑Documentation of design standards for future additions

Content

- ❑Define Content of Phase Release
  - ▪initial release
  - ▪enhancements
  - ▪ideal (limitless time/limitless budget)
- ❑Define Content Owner(s)
- ❑Define Content Oversight
- ❑Define Content maintenance standards
  - ▪scheduling
  - ▪versioning

Project Plan

Clinical Trials Handbook

❑Project Plan: Table of Contents

❑Introduction

A Brief History

The Clinical Trials Administrative Start-Up Handbook was originally developed at the University of Washington School of Medicine in order to ensure that the administrative start-up process for industry-sponsored clinical trials could be accomplished as quickly and efficiently as possible. Over time, the Handbook evolved to present practical information not only about the start-up process of industry-sponsored clinical trials but also about other practical information relating to clinical research.

This project plan outlines the strategy and details for the January 2010 release of the next major iteration of the Clinical Trials Handbook. The new handbook is one of the deliverables for the Clinical Research Proposal Review Process Improvement Project. The end result is meant to include the following items:

- Process documentation
- Checklists – What activities need to happen when
- Timeline standards
- Definition of roles/responsibilities

Additionally, the existing handbook will be recast into the new handbook format, providing a solid base upon which to build this and future iterations of the Clinical Trials Handbook .

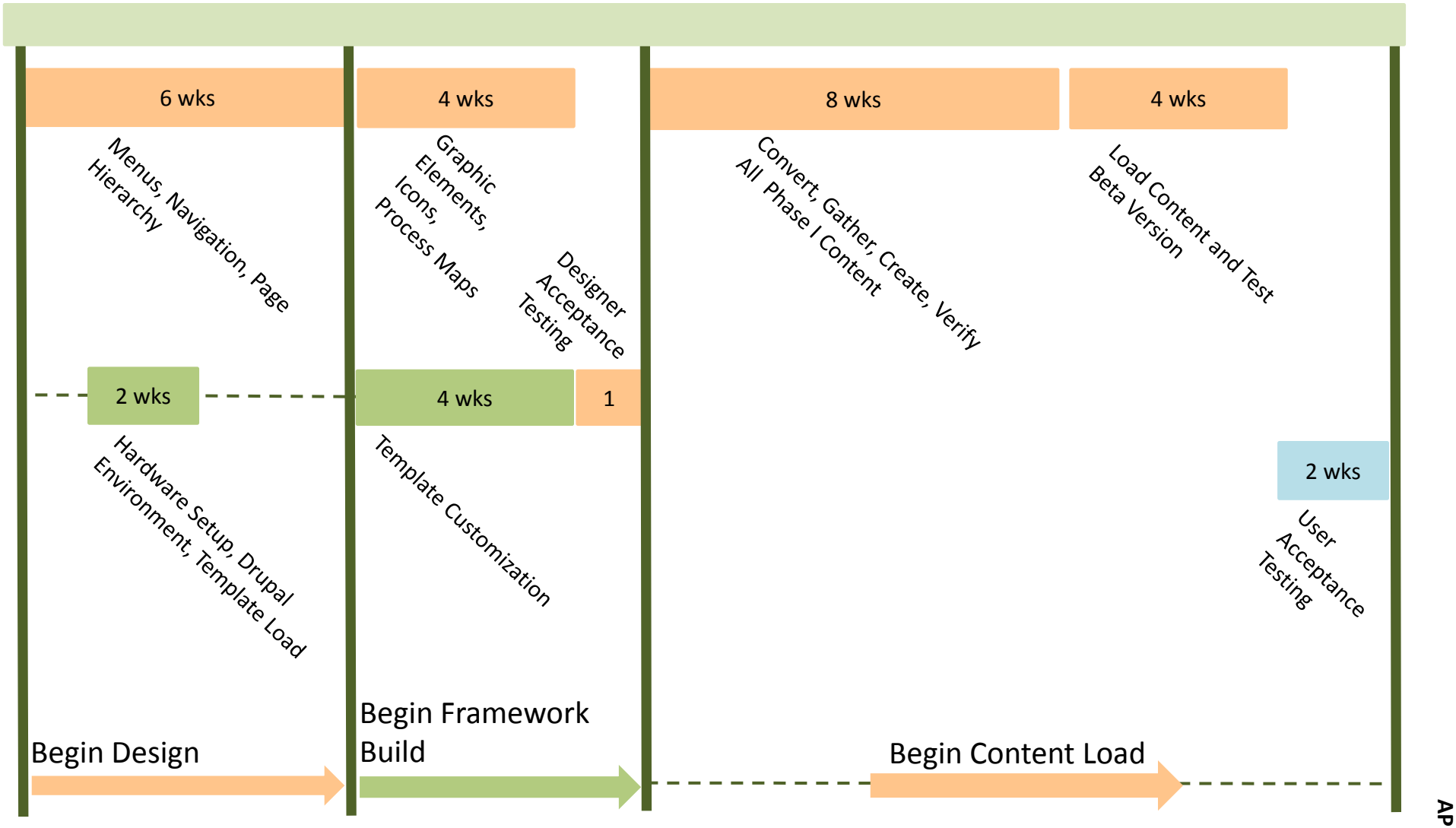
Intended Audience

The handbook is addressed to all researchers who conduct clinical trials at the UW and it's affiliates. We hope that the handbook will be especially useful for new clinical trials researchers. Although experienced researchers may already have developed handbooks of their own, we hope that some parts of this handbook will also be helpful to them. Note that investigators conducting clinical trials on site at the Veterans Affairs Puget Sound Health Care System (VAPSHCS) may have different or additional requirements for the administrative start-up process.

K3

APPENDIX K

❑Implementation Timeline (estimate)



K4

APPENDIX K

❑Cost (startup and ongoing)

	Service Provider	Cost	
		Startup	Ongoing/ annually
❑**Design**	oResearch and Graduate Education	No charge	No charge
❑**Technical**			
•Hardware	oUW Technology	No charge	$600
•Software	oDrupal / open source content management platform	No charge	No charge
•Labor	oCreative Communications	$10,000	$1,000
	oORIS	No charge	
	oResearch and Graduate Education	No charge	No Charge
❑**Content**	oResearch and Graduate Education	No charge	No charge
Total Cost estimate		$10,000	$1,600

K5

APPENDIX K

Project Plan

Clinical Trials Handbook

Design/Functionality

K6

APPENDIX K

❑Description of Design/Functionality

The design of the Clinical Trials Handbook is intended to present information to users in a clear, concise manner while still providing a depth of information for those who wish to utilize the handbook for more in-depth guidance.

The information in the handbook will be delivered utilizing a combination of the following pages:

❑**Searchable text pages**

Some information (e.g. instructions, rules, regulations) is best delivered in the traditional written format. These pages will be key-word searchable.
Pages 10 and 11 of the design section of this document are examples of this type of page.

❑**Navigable process maps**

A navigable process map presents the user with a logical flow diagram of a given process. Many of the graphical elements of this process map will be "clickable", meaning they will allow the user to access more information about whatever is contained in that element. This could be an informational box, a link to another website, a contact list, a form, and online document, or any other number of informative resources.
Page 12 of the design section of this documents shows an example of this type of page.

❑**Pages which incorporate inline frames**

An inline frame will display another website, or document (including scrollbars and borders) within the page without opening a separate window. Many of the areas which affect the clinical trials start-up process already have their own websites. Rather than trying to duplicate the information contained on those websites, this handbook will display them where applicable.
Page 13 of the design section of this documents shows an example of this type of page.

❑Fit-Gap Analysis: Design/Functionality – vs – Technology (Drupal)

Design/Functionality	Drupal (basic template provided by ORIS)	Solution
❑Discussion Forum	Yes	●
❑Document Management	Limited	Not an issue because of small number of people who will be editing documents
❑Events Calendar	Free Add On	Minor additional resources to implement
❑Hierarchical Content Browse	Yes	●
❑Inline Frames	No	Will require additional resources to implement
❑Link Management	Free Add On	Minor additional resources to implement
❑Navigable Image Maps	No	Will require additional resources to implement
❑Search engine	Yes	●
❑Syndicated Content (RSS)	Yes	●
❑User Contributions	Yes	●

● = design/functionality and technology are a match

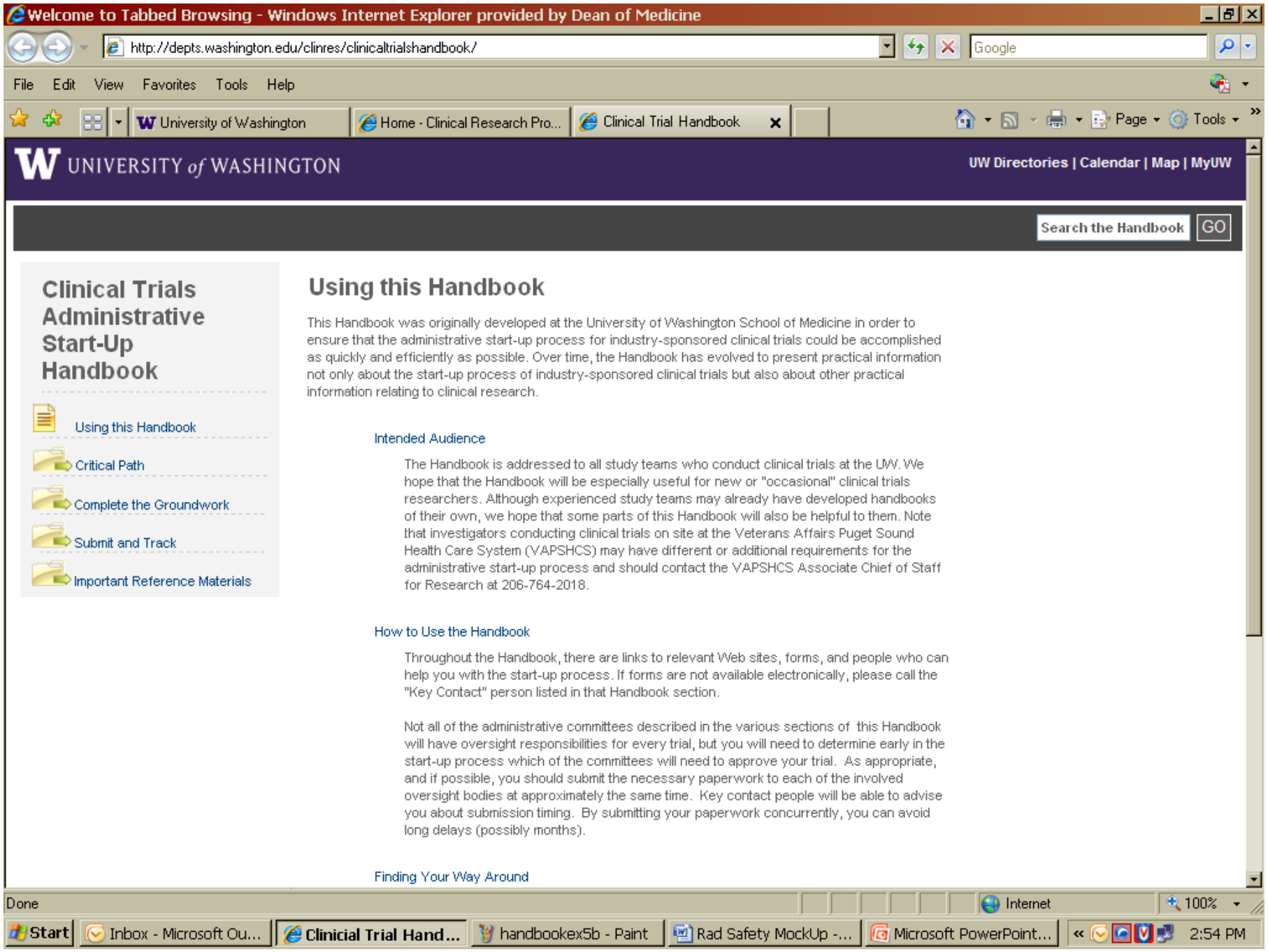
K8

APPENDIX K

❑Design Plan Timeline Estimate

Design/Functional Element	Time: Plan and Document
❑Menus This is what the user will see across the top of the page and on the left side of the screen. Menus provide information to help navigate the content and links.	1 week
❑Navigation This is what drives the menus. It is a roadmap that tells the programmer what to display on the menus.	1 week
❑Page Hierarchy This is what drives the navigation. It is the bulk of the work that will go on behind the scenes prior to loading any content. It requires deciding how things should be organized and how the site should be structured.	4 weeks
❑Graphic Elements/Icons Any icons, pictures, illustrations, special diagrams, etc. will need to be created in advance for inclusion on the website. This time estimate includes design and creation of image files.	2 weeks
❑Process Maps Creation of process maps for web display and printer friendly versions	2 weeks
Total Time to produce a complete design plan for use by a web programmer to build the framework for the handbook site, does not include content load.	10 weeks

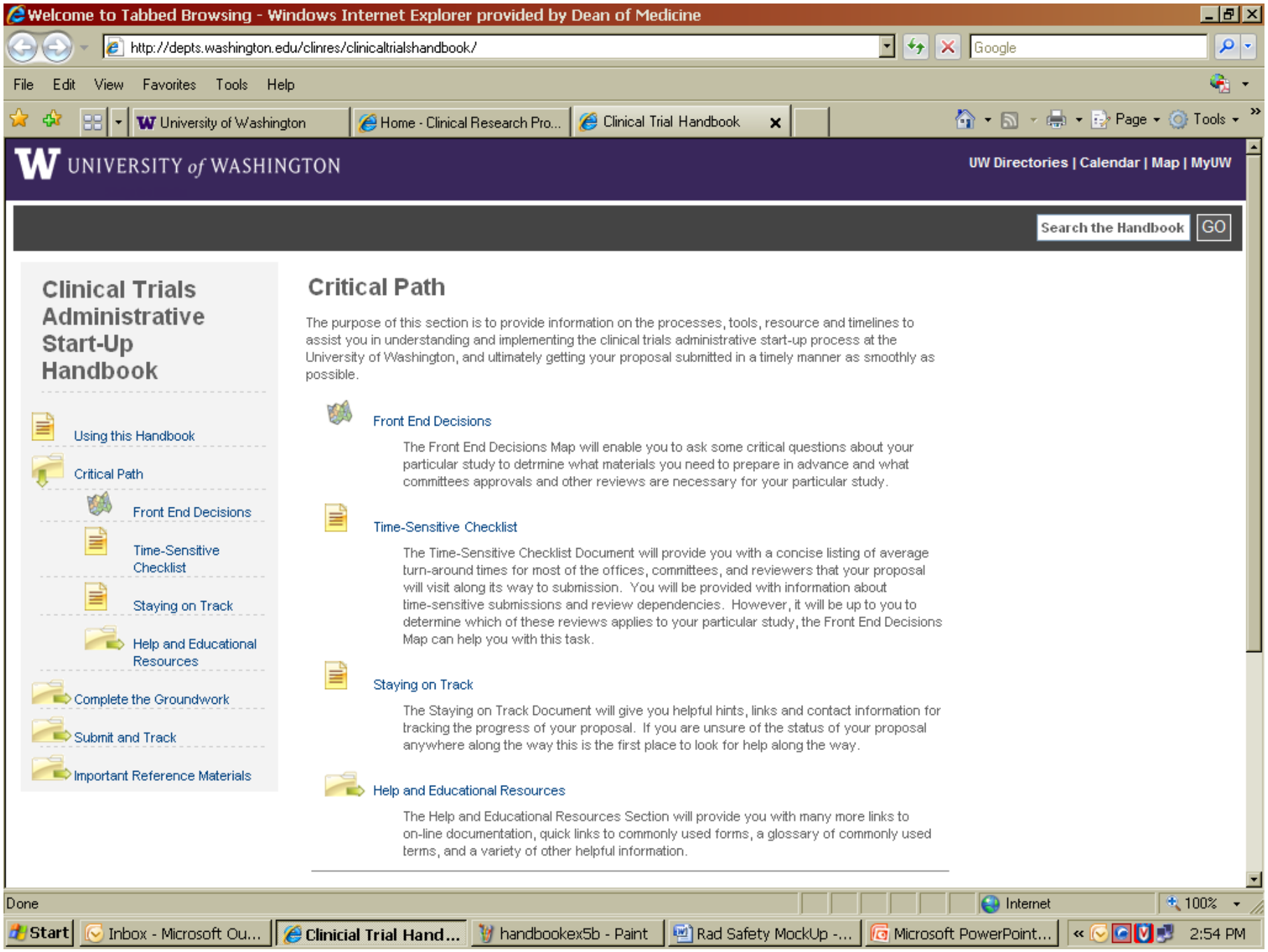
❑Final Design/Mock-Up



K10

APPENDIX K

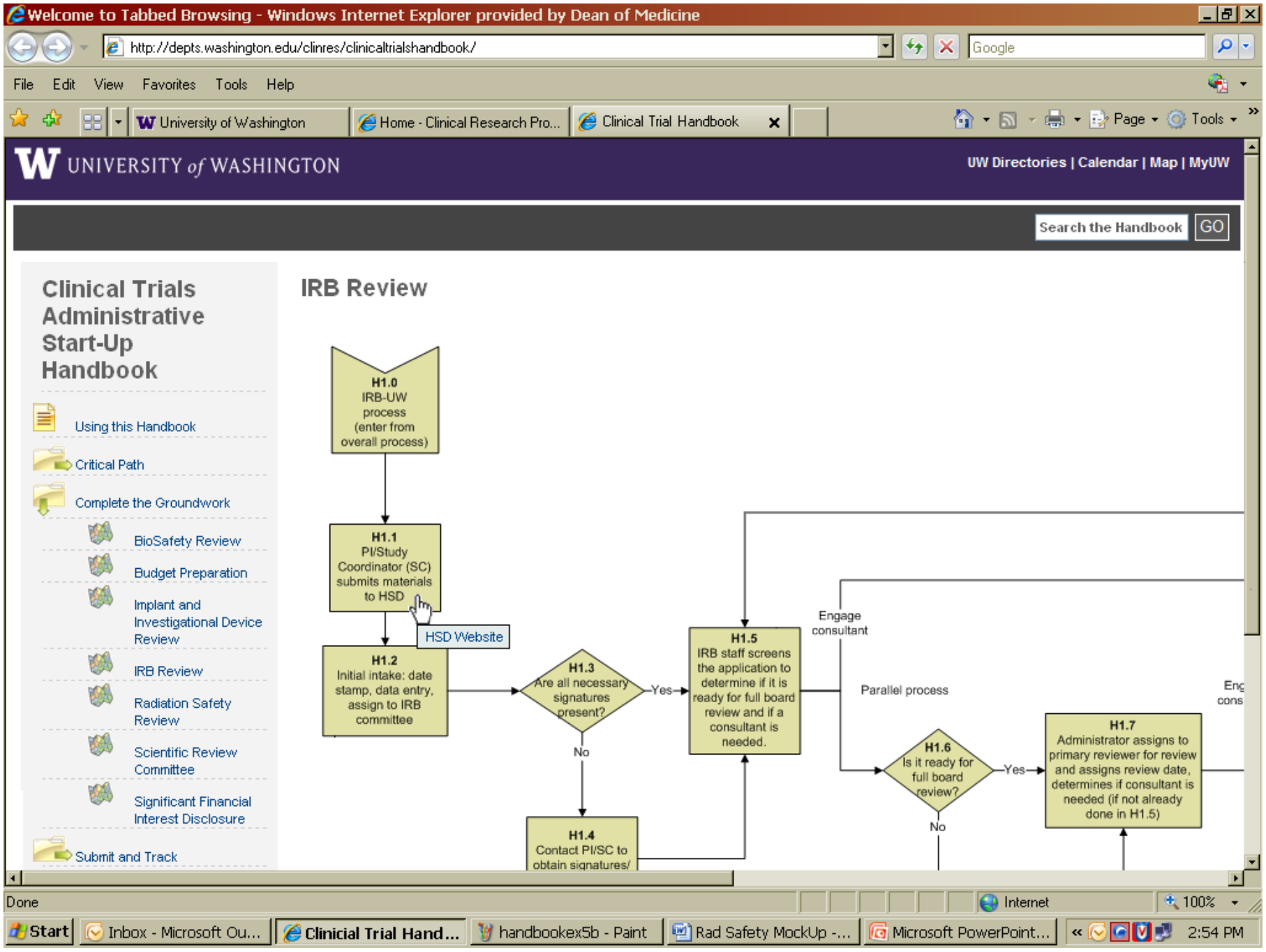
❑Final Design/Mock-Up



K11

APPENDIX K

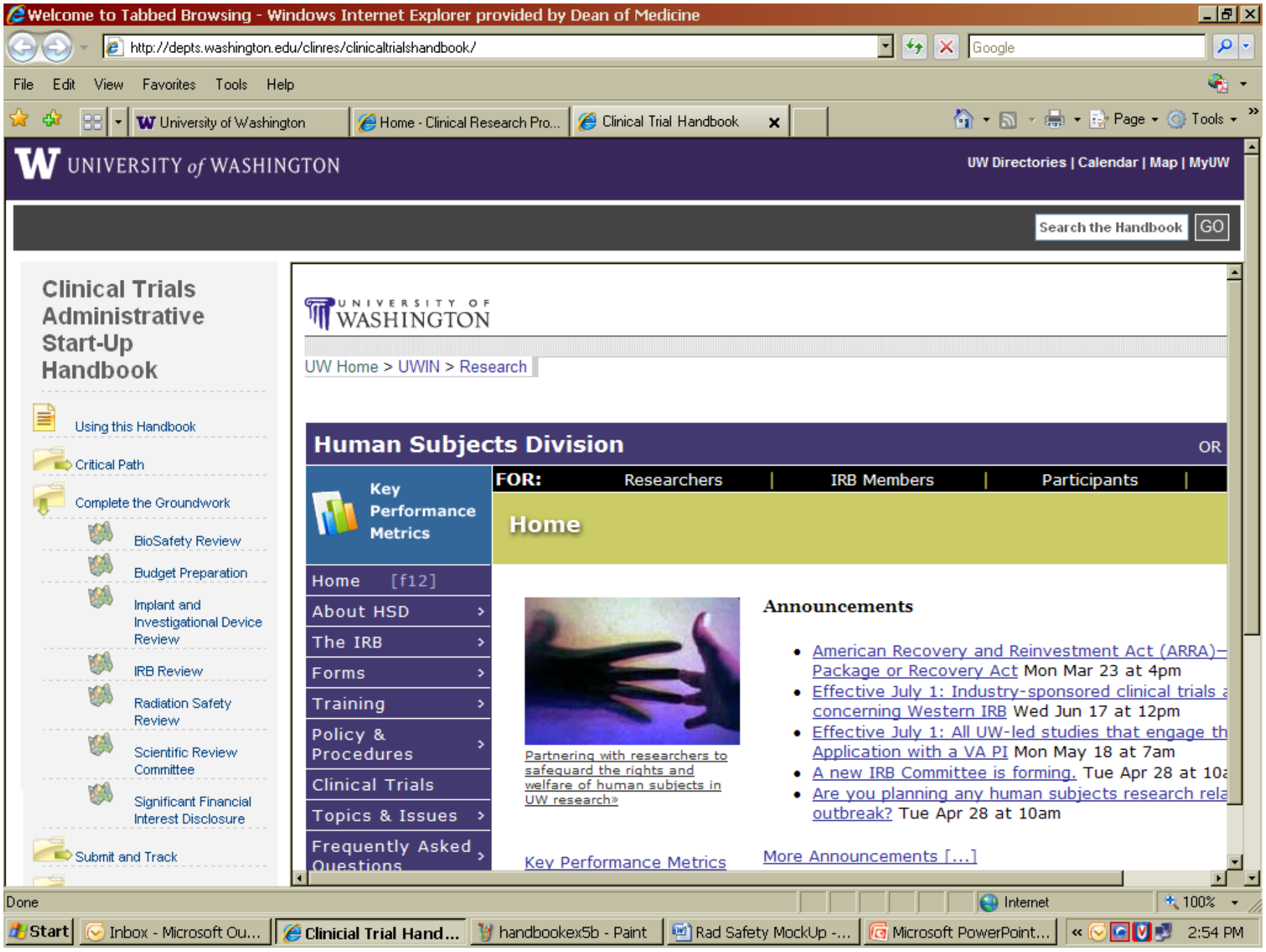
❑Final Design/Mock-Up : Navigable Process Map



K12

APPENDIX K

❑Final Design/Mock-Up : Inline Frame



K13

APPENDIX K

❑Documentation of Design Standards for Future Revisions/Additions

Documentation of design standards will be completed as a part of the execution of this project plan. Design standards will be the result of a combination of several sources: UW Updated Graphics and Logo System documentation, a standards compliant theme developed by ORIS, an RGE specific design guide for the handbook.

The purpose of a design standards document is to ensure a distinct, consistent, and well-managed visual identity for the handbook. This identity is intended to represent the handbook as a unique product with its own content and purpose, but still clearly indicate that the handbook is a product of the University of Washington, intended to serve the UW Medicine community and it's affiliates.

Documentation of design standards is intended to address the following aspects of the handbook:

- ❑logos
- ❑color palettes
- ❑typography (font sizes and styles)
- ❑iconography
- ❑visual cohesiveness
- ❑page layouts
- ❑menu structure
- ❑navigation
- ❑user experience
- ❑readability
- ❑ease of use

Project Plan

Clinical Trials Handbook

Technology

What is a Content Management System (CMS)? *

A CMS is server software that manages content (text, images and data) separate from the designed page layout that you view in your browser. Because content is kept separate from design (usually in a database), it is relatively easy to develop and deploy new layouts, navigation and style elements.

A CMS also:
gives your website a more consistent look and feel
makes it easier to meet accessibility standards
gives your content writers and producers a tool to review and publish/unpublish content

Content Management System in Use at UW

Drupal
Plone
Sharepoint
Wordpress
Joomla
Wiki (various)

K16

APPENDIX K

•Information from UW Creative Communications website

❑Description of Technology (continued)

Drupal: What is It?

Open source modular framework and Content Management System (CMS)

UW CMS User Survey*

Ranked #1 in Popularity (16 respondents)

Ranked #1 in User Satisfaction

Characteristics/Requirements

- ❑Easily integrate with other web sites and applications
- ❑Can accommodate UW's existing netid service
- ❑Uses standard programming language(s)
- ❑Will integrate with UW existing technical infrastructure
- ❑Adheres to accepted programming standards and best practices
- ❑Has a robust user community (both at UW and Publicly)
- ❑Variety of third-party support (including training) available
- ❑Vendor and/or users are committed to ongoing technical and functional development and improvements
- ❑Thorough documentation available

Sampling of UW Users

- ❑Evans School of Public Affairs
- ❑Facilities Services
- ❑Department of Biostatistics
- ❑Risk Management
- ❑Office of Research

Applications *(highlights)*

- ❑Discussion Forum
- ❑Document Management
- ❑Events Calendar
- ❑FAQ Management
- ❑Hierarchical Content Browse
- ❑Link Management
- ❑Search engine
- ❑Site Map
- ❑Syndicated Content (RSS)
- ❑User Contributions
- ❑Wiki

•**Content Management Systems use at the UW** **by** Oren Sreebny, Executive Director of Emerging Technology in UW Technology, Published January 26, 2009
54 respondents; Other systems in use: Wordpress, Joomla, Wiki, Movable Type, Ektron, Confluence, TextPattern, Alfresco, and several custom systems.

❑Technology Owner(s)

Ownership of the Clinical Trials Handbook technology should be divided into two categories, Hardware and Software.

❑Hardware (Infrastructure) Ownership

The Clinical Trials Handbook will be hosted on UW Technology servers. There is currently no charge for the use of UW Technology server space; however, this is expected to change and will be discussed later in the costing portions of this plan.

UW Technology will be responsible for any maintenance and updates associated with the servers which house the handbook.

Consequently, handbook usage will be constrained by the common maintenance schedule (and associated downtimes), or unexpected technical issues which affect the UW Technology servers.

Additionally, handbook usage will be bound by the same development, testing, and security protocols in use at UW Technology.

❑Software Ownership

Although Drupal is an open source (free) product, whoever installs and maintains it is considered the "owner" of the software. In the case of the handbook, ORIS (Office of Research Information Services) will be the owner. ORIS will be responsible for any ongoing maintenance, upgrades, and patches and fixes associated with Drupal.

The handbook will be expected to adhere to the same development, coding, design and testing standards used by other applications owned by ORIS.

There is currently no charge proposed for ongoing services provided by ORIS; however, this could change if future versions of the handbook require programming or maintenance services above and beyond basic levels. This will be discussed further in the costing portions of this plan.

Additionally, ORIS will not be providing any programming for the initial setup of the handbook.

❑Technology Oversight

	Quality Control	Help Desk Function
❑**Hardware**	Quality control for the servers which house the handbook will adhere to the UW Technology support approach. UW Technology works to assure that the University's current and future technology needs are being met, and strives to utilize the best of current and emerging technologies.	ORIS utilizes a bug tracking mechanism called FogBugz. An email is sent to a centralized mailbox and analyzed to determine the nature of the problem. Technical issues are routed to the appropriate technical help-desk. •Hardware issues are routed to UW Technology
❑**Software**	ORIS will assure quality control for the Drupal installation by applying patches and fixes as necessary and analyzing new software version releases for desired functionality.	•Software issues are routed to ORIS •Content related issues will be routed to the Office of Research and Graduate Education .
❑**Content**	The Office of Research and Graduate Education will be responsible for assuring that the content of the handbook is accurate and that where changes are made to supporting websites or documentation that those changes are reflected in the handbook.	In addition to the email routing from FogBugz, RGE will seek to provide phone support for help-desk issues. Technical issues will be routed to the appropriate technical area. Content related issues will be handled internally, or where appropriate referred to a different functional area.

K19

APPENDIX K

❑Upfront (start-up) Cost

	Service Provider	Cost
❑**Hardware**	UW Technology	Currently No charge for departmental account on UW Technology servers.
❑**Software**	Drupal / open source content management platform	No charge for software or licensing
❑**Labor**		
•Hardware (setup)	UW Technology	No charge
•Software (setup)	Creative Communications – Environment Create	$1,000
	ORIS - Template	No charge
•Design	Research and Graduate Education	No charge
	Creative Communications	$1,000
•Programming	Creative Communications	$4,500
•Graphic Design	Research and Graduate Education	No charge
	Creative Communications	$1,000
•Content Load	Research and Graduate Education	No charge
	Creative Communications	$1,000
•Miscellaneous	15% Contingency	$1,500
Total Cost estimate for Handbook Start-Up		$10,000

K20

APPENDIX K

❑Maintenance (ongoing) Cost

	Service Provider	Cost/per year
❑**Hardware**	UW Technology	Currently no charge for departmental account on UW Technology servers; however, this is expected to change at any time. Unknown what the charges will be, estimate using private hosting cost estimate: $600
❑**Software**	Drupal / open source content management platform	No charge for software or licensing
❑**Labor**		No charge for routine work from ORIS, handbook specific customization (estimate is for work performed by either service provider): $1,000
•Programming	Creative Communications ORIS	
•Content Load	Research and Graduate Education	No charge
Total Cost estimate for ongoing handbook maintenance and customization (if applicable)		$1,600

K21

APPENDIX K

❑Technology Implementation Timeline Estimate

Technology Phase	Time
❑**Hardware Setup** Handbook owner (RGE) will submit a request to UW Technology for the setup of a departmental server account.	3 days
❑**Drupal Environment Creation** Creative Communications will install and secure Drupal and its supporting database and create user accounts for staff access to the administrative pages.	1 week
❑**Drupal Template Load** Creative Communications will install templates provided by ORIS.	2 days
❑**Drupal Template Customization** Creative Communications will make changes to ORIS supplied templates to reflect changes approved during the design process. Some changes may be required for iframes and large image display.	4 weeks
❑**Designer Acceptance Testing** RGE will review and test completed handbook framework to assure that all design requirements have been accommodated and to submit additional requirements that had not previously been anticipated. This time includes programming for those changes.	1 week
Total Time to have a Drupal framework available to begin loading content	7 weeks

K22

APPENDIX K

Project Plan

Clinical Trials Handbook

Content

❑Content of Release Phases

❑Phase I

- **Existing Handbook Content**
  - ▪Information which is currently contained in the Clinical Trails Administrative Start-Up Handbook that pertains to the start-up phase of the proposal review process will be converted to fit the new handbook format.
  - ▪Information which is outdated or inaccurate, or has been replaced by information in the new content section of this plan will not be converted.
- **New Content**
  - ▪Information which has been gathered in the course of the Clinical Research Proposal Review Process Improvement Project will be formatted to fit the new handbook and included where appropriate.

❑Future Phases (TBD)

- **Existing Handbook Content**
  - ▪Information which is currently contained in the Clinical Trails Administrative Start-Up Handbook that was not included in Phase I, but which is still accurate and pertinent to any phase of clinical trials will be converted to fit the new handbook format.
- **New Content**
  - ▪Any new information which is gathered as a result of ongoing process improvement, user input, committee recommendations, or other initiatives will be considered for inclusion in future releases.

❑Content Gather and Load Timeline Estimate

Content Steps	Time
❑**Conversion of Existing Handbook Content** Some information currently contained in the Handbook will be converted to fit the new handbook format (see Appendix A: Outline of Existing Handbook).	2 weeks
❑**Gather/Create New Content** Results of previous meetings, research and documentation will be presented in a cohesive, consistent format and integrated (where appropriate) with existing content (from existing handbook).	4 weeks
❑**Verify All Phase I Content** All Phase I content will be reviewed for accuracy, consistency, and completeness	2 weeks
❑**Load All Content** All Phase I content will be loaded into the new Drupal handbook framework.	2 weeks
❑**Internal Review of Handbook Beta Version** ❑RGE project staff will review the completed beta version prior to user acceptance testing and make any necessary changes.	2 weeks
❑**User Acceptance of Handbook Beta Version** User acceptance testing by pre-determined user group, make any necessary changes prior to go-live	2 weeks
Total Time to convert, gather, create, load and test content	14 weeks

K25

APPENDIX K

❑Content Owner(s)

For the purpose of the ownership discussion, the content contained in the Clinical Trials Handbook can be divided into two categories, Primary Content and Secondary Content.

❑Primary Content Ownership

- Primary Content is the content which is directly loaded and/or entered by the editor of the handbook. As owner of the primary content the Office of Research and Graduate Education will be responsible for assuring that the content of the handbook is accurate and complete.
- Examples of Primary content include: process maps; glossary information; policy and procedure information written specifically for inclusion in the handbook (regardless of the subject of those policies and procedures); instructional, or informational text written specifically for inclusion in the handbook; links included with any text written specifically for inclusion in the handbook.

❑Secondary Content Ownership

- Secondary content is the content which is accessed by either linking or by entry or uploads from staff outside of the Office of Research and Graduate Education. For example, Human Subject Division will be responsible for the content of their own website and any information, links, forms, documents, etc. contained on that website.
- The Office of Research and Graduate Education will be responsible for content to the extent of assuring that where changes are made to supporting websites or documentation those changes are reflected in the handbook. E.g. links are kept current, referenced forms are current, contact information is current.
- In some cases, staff from areas outside of the Office of Research and Graduate Education may be given access to directly update select sections of the handbook. Those areas will be responsible for assuring that the information they contribute is accurate and kept up to date.

❑Content Oversight

Oversight for the content of the Clinical Trials Handbook will be the responsibility of the Clinical Trials Process Improvement Project steering committee. The steering committee will be supported by the Office of Research and Graduate Education. The editor of the handbook will be Office of Research and Graduate Education staff. Content oversight responsibilities will be divided as follows between the editor and the steering committee.

❑Ongoing maintenance and quality assurance

The editor will be responsible for assuring that information is accurate, up to date, and reflects mandated requirements. Any changes necessary to fulfill this mission will be at the discretion of the editor and will not require pre-approval from the committee. A high-level summary of this type of activity will be provided to the committee during regularly scheduled meetings.

❑Minor content and/or functionality changes/additions

In response to user feedback, suggestions, industry trends, etc. the editor may make minor additions to the content and/or functionality of the handbook without prior approval from the committee.

Examples of this level of activity include:

- new content sections associated with existing content.
- new links associated with existing content.
- new display techniques which enhance the user experience but do not change the overall look and feel of the site.
- new graphics which enhance the user experience but do not change the overall look and feel of the site.

The committee will be provided with a detailed listing of all changes for post-review.

K27

APPENDIX K

❑Content Oversight (continued)

❑**Major content and/or functionality changes/additions**

The editor will submit to the committee for approval any new content sections or new functionality which provide information or functionality not previously contained in the handbook. Which change the overall look and feel of the site, and which greatly change the user experience.

The editor will also respond to requests for any level of change (maintenance, minor or major) from the steering committee.

These changes may be in response to user feedback, suggestions, industry trends, technology innovations, etc .

Examples of major content and/or functionality changes/additions fitting this criteria include:

- Addition of new process maps not previously included
- Addition of new information about a process, committee, service center, facility, etc. not previously included.
- Addition of a training component.
- New method of site navigation which may either replace the current navigation or provide an additional navigation method such that the user experience will change greatly.
- Change to the color scheme, icons, graphics that greatly alter the look of the site.
- Removal of large sections of existing content.

K28

APPENDIX K

❑Appendix: Outline of Existing Handbook

Preface

- ❑Purpose of the Handbook
- ❑Intended Audience
- ❑How To Use the Handbook
- ❑Other Help

1. Getting Started
   - ❑Flow Chart
   - ❑Confidentiality Agreements
   - ❑Is your trial feasible?
   - ❑Clinical Research Training
   - ❑Using Medical Records
   - ❑Financial Planning
   - ❑Indirect Costs
   - ❑The Clinical Research Budget and Billing office (CRBB)
     - oWhy CRBB was created
     - oHow CRBB is organized
     - oBest Practices for working with CRBB
       - •When working with CRBB
       - •When building your budget
       - •When negotiating your budget
       - •When sending your eGC-1 packet for review
     - oRequesting a Budget Number
     - oThe AAA Trial Registration System
     - oKey Contacts

K29

APPENDIX K

❑Appendix: Outline of Existing Handbook

- oTimeline
- ❑Enrollment/Recruitment Incentives
- ❑Credentialing
- ❑Hazardous Substance Training and Certification
- ❑Registering and Publicizing Your Study

2. Research Service Centers
   - ❑General Information
   - ❑Investigational Drug Service (IDS) at UWMC
   - ❑Investigational Drug Service (IDS) at HMC
   - ❑Radiology Research Services (RRS) - UWMC and South Lake Union
     - oAbout RRS at UWMC
     - oBest Practices for Using the UWMC Radiology Research Services
     - oKey Contacts
     - oTimeline
   - ❑Radiology Research Services (RRS) at HMC
     - oAbout RRS at HMC
     - oBest Practices for Using the RRS at HMC
     - oKey Contacts
     - oTimeline
   - ❑Laboratory Services
     - oDepartment of Laboratory Medicine
       - •Research Testing Services (RTS)
       - •AAA Research Testing Services
     - oBest Practices for using Laboratory Medicine

❑Appendix: Outline of Existing Handbook (continued)

- oLaboratory Medicine testing services key contacts
- oLaboratory Medicine Research Testing Service Timelines
- oNorthwest Lipid Research Laboratories (NWRL)

❑Cardiology Diagnostic Services

- oAbout Cardiology Diagnostic Service
- oBest Practices for Using Cardiology Diagnostic Services
- oKey UWMC Contacts
- oKey HMC Contacts
- oTimeline

3. Office of Sponsored Programs (contracts, financial disclosure, and the eGC-1 process)

❑Flow Chart Illustrating the Office of Sponsored Programs Process

❑The Research Agreement

❑The Concurrent Review Process

- oWhat it is
- oHow it works
  - •At CRBB
  - •At OSP

❑Best Practices

- oFor Using the Concurrent Review Process
- oFor Streamlining the OSP Review Process
- oFor Completing the eGC-1 Form for Industry-Sponsored Clinical Trials

❑Significant Financial Interest Disclosure

❑The Budget Number

❑Advance Budget Numbers

K31

APPENDIX K

❑Appendix: Outline of Existing Handbook (continued)

- ❑Key OSP Contacts
- ❑Timeline

4. UW Institutional Review Boards
   - ❑Flow Chart - UW IRB
   - ❑Flow Chart - Western Institutional Review Board (WIRB)
   - ❑Flow Chart - UW-WIRB Process
   - ❑Flow Chart - Cancer Consortium IRB
   - ❑General Information about Institutional Review Board (IRB) Review
   - ❑Determining Where Your Trial Needs to be Reviewed
     - oIf Your Trial is Reviewed by the UW IRB
     - oIf Your Trial is Reviewed by Western Institutional Review Board (WIRB)
     - oIf Your Trial is Reviewed by the Cancer Consortium IRB (CC-IRB)

5. Radiation Safety Committee
   - ❑Flow Chart Illustrating the Radiation Safety Committee Process
   - ❑Quick Access to Forms Referenced in this Section
   - ❑Review Requirements
   - ❑Radiation and Pregnancy
   - ❑RSC Application Forms for New Studies
   - ❑Best Practices for Completing the Application Forms
     - oConsent Form Radiation Risk Statements
     - oForm 32 (for annual renewals)
   - ❑Administrative Start-up Checklist
   - ❑Key Contact

K32

APPENDIX K

❑Appendix: Outline of Existing Handbook (continued)

- ❑Timeline

6. Institute for Translational Health Sciences
   - ❑Flow Chart Illustrating the Clinical Research Center Process
   - ❑General Information
   - ❑Best Practices for Developing the CRCN Budget
   - ❑Best Practices for Completing the ITHS Application
   - ❑Best Practices for Using the ITHS Facilities
   - ❑Key Contacts
   - ❑Timeline

7. Human Gene Transfer Review
   - ❑The National and Local Review Process
   - ❑Best Practices for Expediting the Committee Review
   - ❑Administrative Start-Up Checklist
   - ❑Key Contact
   - ❑Timeline

8. Biosafety Review
   - ❑The Review Process
   - ❑Best Practices for Expediting the Biosafety Committee Review
   - ❑Administrative Start-Up Checklist
   - ❑Key Contact
   - ❑Timeline

❑Appendix: Outline of Existing Handbook (continued)

9. Implant & Investigational Device Committee
    - ❑Flow Chart Illustrating the Implant and Investigational Device Review Process
    - ❑General Information
        - oCategory A Devices
        - oCategory B Devices
    - ❑Review at UWMC and HMC
        - oUWMC New Implant and Investigational Device Form
        - oHMC New Implant and Investigational Device Request Form
    - ❑Best Practices for Expediting the Review
    - ❑Key Contacts
    - ❑Timeline

10. Preparing for FDA Inspections
    - ❑Why are FDA inspections done?
    - ❑What is the regulatory basis of FDA inspections?
    - ❑Does the FDA publish advice about its own inspections?
    - ❑What types of inspections does the FDA conduct?
    - ❑How does the FDA notify clinical investigators about impending inspections?
    - ❑How long do FDA inspections last?
    - ❑How do I prepare for an FDA inspection?
    - ❑What happens after the inspection?
    - ❑General advice for study staff

11. Investigator Responsibilities
    - ❑General Information

K34

APPENDIX K

❑Appendix: Outline of Existing Handbook (continued)

- ❑Investigator Responsibilities - A Brief Outline
- ❑Useful Web Resources
- ❑Useful Self-Assessment Checklists
- ❑Responsibilities of the Sponsor-Investigator

12. Useful Tools and Checklists
    - ❑Completing Case Report Forms - Rules of Thumb
    - ❑Concomitant Medication Log
    - ❑Data and Safety Monitoring Board Charter
    - ❑Drug Inventory and Accountability Log
    - ❑Feasibility Checklist
    - ❑Study Coordinator Time Tracking Log
    - ❑Study Site Signature and Delegation of Responsibility Form
    - ❑Subject Enrollment Log
    - ❑Telephone Communication Record
    - ❑Virtual Regulatory Binder - Partners HealthCare, Boston

    <u>Staff Task Lists</u>
    - ❑Pre-study tasks
    - ❑On-study tasks
    - ❑Post-study tasks

    <u>Other Resources</u>
    - ❑Clinical Research Toolbox (NIH/National Institute on Aging)

Tell Me What You Need?

Where is it?

- *When did it get there?*
- *What is the expected turnaround?*
- *Who has it?*
- *When will they begin working on it?*
- *When did they finish with it?*

What is happening to it?

- *If they have questions or issues will they contact me?*
- *If they are done with it and/or it results in an approval, will they let me know right away, or do I have to wait for some other process to be completed (e.g. copies mailed)?*
- *How much time will it take to notify me of any decisions or changes that are made?*
- *Can I be notified of important milestone/approvals that happen while it is there that may allow me to proceed with other steps, even if it hasn't been finalized?*

What are the delays between stops

- *Where is it when it is stalled?*
- *Why is it stalled?*

L1

APPENDIX L

Where are we now?

PIRO/DORA:

- *PIRO: (Protocol Institutional Review Office)database used by Institutional Review Office and the Protocol Office at Fred Hutchinson Cancer Research Center*
- *DORA: (Database of Research Activity)used by the Human Subjects Division and the Office of Sponsored Programs at University of Washington*
- *Both systems share a common framework, but contain different data*

SAGE/ SPAERC/Status Tracker

- *SPAERC: (Sponsored Programs Administration Electronic Research) used by the Office of Sponsored Programs at University of Washington*
  - *The "backend" system used in OSP which holds the data used in SAGE*
- *SAGE: (System to Administer Grants Electronically) used by thousands of users across the University of Washington*
  - *eGC1 is the submittal form used by SAGE which routes electronically*
- *Status Tracker: used by departmental administrators to check the status of their contracts*
  - *Pulls data from SPAERC*

L2

APPENDIX L

Challenges

Functional Challenges

- *Much of the data that will be useful for tracking purposes is dependent on manual input*
- *Must be adopted by all contributors of data, otherwise the data won't be complete*
- *Will need to develop some form of common tracking number for reference*
- *Cannot require duplicate (or more) entry into multiple systems, making the new system more labor intensive and/or slower than current systems is a guarantee of failure*

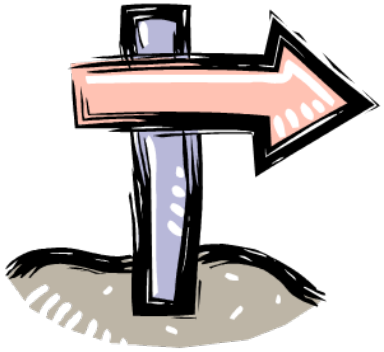
Technical Challenges

- *Is questionable if current source systems have the "technical backbone" to support this endeavor*
- *Needs to stay in sync with the source systems, nightly updates may not be frequent enough*
- *It is not clear how existing systems will talk to each other.*
- *May be difficult to "normalize" the data - relate information from different system that share a common proposal*

L3

APPENDIX L

Where could we go?



MS Sharepoint:

- *HR at UW has made use of Sharepoint for tracking*
- *Sharepoint has a pre-built add-in for tracking and also one for workflow*
- *Supports web service calls and can be pushed to a portal*
- *Netid supported for user authentication*
- *Integrates easily with other MicroSoft products*

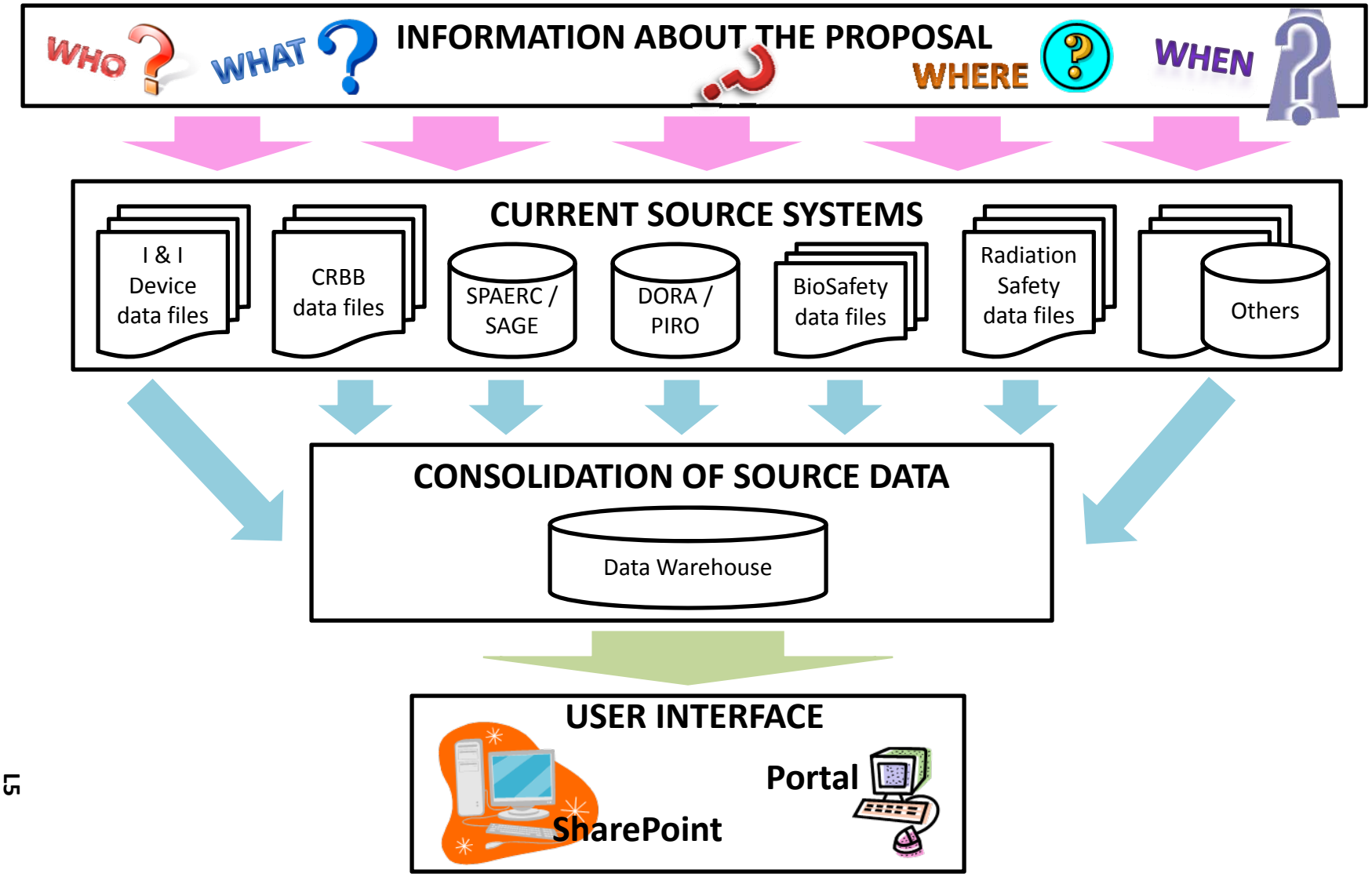
Campus EAI (new campus portal project)

- *Campus EAI is a new portal product developed by a consortium of mid-size Colleges and Universities*
- *a user-centered application that provides users with their own personalized, customized, and adaptive collection of Web pages*
- *a web front-end to display data necessary for tracking the progress of a proposal*

L4

APPENDIX L

Conceptual System Structure



L5

APPENDIX L

Keys for Success

Functional Requirements

- *System must be well planned in advance with plenty of input from experienced users*
- *User interface is intuitive and does not require more than basic web skills*
- *Users need to know that the system exists and that it is a reliable source of information*
- *Roll-out must be done in a timely manner*
- *System ownership and ongoing support needs to be determined*
- *System development and support must be given high priority*

Technical Requirements

- *Source systems and tracking system must support a core of common fields*
- *Should be just as reliable as the source systems, in both data and technology aspects*
- *Needs to have role-based access*
- *Should support web services*
- *Must be accessible via the web and not require any individual desktop install)*

APPENDIX L

Appendix M
University of Washington
Clinical Research Proposal Process Improvement Project
Interim Tracking System – Options to Consider

What we know at this point:

- To track across the whole Clinical Research Proposal process requires that status points be extracted from multiple systems.
- The effort to extract and report status points from multiple systems is complex.
- The cost to build an Interim Tracking System may be significant.

OPTION 1	**OPTION 2**	**OPTION 3**
• Move ahead with pricing the project to build the Interim Tracking System. This will require identifying the resources to accomplish this task since the CTPIP project manager is focused on building the Clinical Research Handbook. • Determine how to fund the project to build the Interim Tracking System. For example, the units involved in the process could decide to share the cost.	• Encourage units (OSP, Radiation Safety, Institutional Biosafety, SCCA, etc.) to gather and publish their particular unit's status information. Some units already do, e.g. HSD. • Wait for a cross process solution from the Research Roadmap.	• Wait for a cross process solution from the Research Roadmap.
Pros: • Provides status information to customers. • Builds a baseline of data across the whole process that can be used to validate problem areas. **Cons:** • Costs to build the system may be significant.	**Pros:** • Status information for additional individual units becomes available. • No cost to build a system across the whole process in the interim. **Cons:** • No way to status across the whole process • No baseline data across the process. • May require effort on the part of some units to collect status information internally	**Pros:** • No cost to build a system across the whole process in the interim. • No effort required by units who are not already reporting. **Cons:** • No way to status across the whole process. • No baseline data across the process. • Status information is not available for individual units that do not currently collect status information internally.

University of Washington
Clinical Trials Proposal Process Improvement Project
Interim Tracking System - Key Status Points

	Enter Process	Mid Points	Exit Process	System	Data Element
CRBB	PI/SC submits matls. To CRBB [**CB2.1**]		Summary Review distributed to stakeholders [**CB2.40**]	Access database	
RS	Submit completed form and Human Subjects Radiation Approval Committee (HSRAC) [R1.6]		Scientific Executor (SE) and HSRAC Chair sign approval document(s) [R1.25]		
UW-IBC	Submit RPHA to RBSO [**B1.4, B2.1, B2.15**]	(1) Submit for public RAC review [B3.3]; (2) Receive approval from public RAC [B3.4]	Notify PI, IRB of approval & changes to Consent Form [**B2.11**]		
SCCA-IBC	(1) Submit proposal to NIH/OBA [SB2.0]; (2) Submit IBC Clinical Trial Review Submission Form and IBC application to RiO [SB1.9]	(1) Submit for public RAC review [SB2.3]; (2) Receive approval from public RAC [SB2.4]	Notify PI of approval via IBC approval letter [SB1.17]		
I&ID	Receive IDE intake form/Medicare packets (if applicable)/NIIDR (if applicable) [D1.9]	Compliance submits Medicare packets to Noridian [D1.19]	(1) PI notified that device is authorized [D1.17]; (2) Receive approval letter from Noridian [D1.21]		
SFI	OSP receives SFI documents from PI [SF1.10]	RGE transmits memo to OR with supporting documents [SF1.21]	OR notifies stakeholders of SFI management plan & marks approval in SPAERC [1.25]	SPAERC?	
HSD/UW-IRB	Initial intake by HSD front desk staff [**H1.2**]	Administrator asigns to primary reviewer & assigns review date [**H1.7**]	(1) Approved, send approval documents to PI [**H1.19**]; (2) Disapproved, send letter to PI [**H1.21**]; (3) Deferral or conditional approval, send letter to PI [**H1.22**]	DORA	
HSD/WIRB	Initial intake by HSD front desk staff [W1.6]		Scan coversheet, consent form, HIPAA form & send to PI [W1.7]	DORA	
HSD/CC-IRB	Initial intake by HSD front desk staff [C1.2]		Scan coversheet, send to PI & Protocol Office [C1.6]	DORA	
Protocol Office	Protocol Office receives documents [PO1.4]		N/A	FYI	
IRO/CC-IRB	Initial IRO intake [**CC1.2**]		(1) Expedited, IRB staff stamps approval documents & ships back to PI [**CC1.10**]; (2) Approved, documents released [**CC1.32**]; (3) Modifications required, send leter to Protocol Office [**CC1.18**]	PIRO	
SRC	SRC receives documents [SR1.1]		SRC generates approval documents [SR1.8]		
OSP - Industry Sponsored	OSP receives eGC1 [**S1.1**]		OSP issues Electronic Funding Action [**S1.22**]	SPAERC	
OSP - Govt./ Foundation Sponsored	OSP receives eGC1 [**S2.1**]	(1) Administrator submits documents to Sponsor [**S2.5**]; (2) OSP receives award notice [**S2.11**]	OSP issues Electronic Funding Action [**S2.27**]	SPAERC	

APPENDIX N

University of Washington
Clinical Trials Process Improvement Project
End of Project Communications Planned

Who is the Stakeholder	When & What to Communicate	Who Does the Communication
Executive Sponsors	▪ Meeting scheduled for 10/16/09	▪ Dick, Laura, Ann
Steering Committee	▪ Meeting scheduled for 10/14/09	▪ Dick
Principal Investigators	▪ Draft article for OSP, HSD & CRBB newsletters that summarizes results and links to full end of project report ▪ Have "grand opening" for handbook after go-live in Jan. 2010	▪ Laura & Dick
MSEC (clinical chairs)	▪ Present full end of project report in Oct. or Nov.	▪ Dick & J. Slattery
Hospital Leadership	▪ Present full end of project report in Oct. or Nov.	▪ Dick, Laura, Ann
Health Sciences Associate Deans mtg.	▪ Present abridged end of project report in Oct. or Nov.	▪ Dick & J. Slattery
CTBB Oversight Committee	▪ Present abridged end of project report in Nov.	▪ Dick
Clinical Departmental Administrators	▪ Present full end of project report in Nov.	▪ Dick, Laura, Ann
Attorney General's Office (2 lawyers)	▪ Send end of project report. Discuss if requested	▪ Dick
MDRN (UW & Harborview)	• Present full end of project report in Nov.	▪ Dick
ITHS	• Present full end of project report at bi-weekly mtg. that John has that includes Nora D.	▪ J. Slattery
Research Advisory Board	• Present abridged end of project report	▪ Dick, D. Flores, J. Slattery
Dean Ramsey, B. Ferguson, R. Mahan, M.F. Joseph	• Will be covered in other mtgs.	▪