

# 2013

## COLORECTAL SURGERY GROUP

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# [A RESEARCH COORDINATOR'S GUIDE]

## Initiating Sponsored Studies

*The research coordinator will play an important role in starting up industry-sponsored studies. This section of the handbook will explain the steps that are taken to start up these studies, starting from initial contact with the sponsor to the Site Initiation Visit.*

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# Flowchart



## The Process

The following section will describe the general steps taken to initiate a sponsored research study that requires Clinical Trial Agreements:

### I. Confidentiality Agreement (CDA)

Before a Principal Investigator (PI) decides to review a proposal from a company, the company requires review and sign off of a Confidentiality Agreement (CDA). Please send the agreement to Esther Wu, Providence Healthcare Research Institute (PHCRI) Contracts Manager, for review and processing before the PI signs the agreement. The PI is not the legal entity of the Institution for signing. However, the PI

may sign and send the CDA to the company before you are notified and you will be required to send the CDA to Esther afterward.

## II. Site selection/Pre-site Visit

A representative from the company (may be from a third party company called a Contract Research Organization or CRO) may arrange a pre-site visit with the PI and you before selecting the site to ensure that the site has the proper facilities to carry out the study.

A pre-site visit may involve the following items:

- overview of the study
- inclusion/exclusion criteria
- tour of facilities - this is dependent on the departments required by the study (may include blood laboratory, pharmacy, outpatient department, operating room)

After the pre-site visit, a representative from the sponsor will contact you regarding site selection. If they have selected your site, they will send you a letter of acceptance and regulatory documents that you will be required to complete and send back.

## III. Ethics Submission

### Commitment Letter from Sponsor

Before you start the ethics application, please ask the sponsor representative to send a commitment letter addressed to the PI. This letter is to ensure that the sponsor will pay for the ethics board review fee and the research coordinator's time spent on writing the ethics application, in the event that the ethics submission falls through.

Fees:

1. REB review fee: \$3000 CAD
2. Research Coordinator's time\*: \$70/hr x 50 hrs = \$3500 CAD\*\*

\*Subject to additional 25% overhead.

\*\*This is a suggested amount.

### RISe

Once you receive the letter, you may start on the ethics application. The ethics submission is done on the UBC RISe (Research Information Services) site. This can be accessed on [www.rise.ubc.ca](http://www.rise.ubc.ca).

You will require a CWL (Campus-wide login) in order to access RISe.

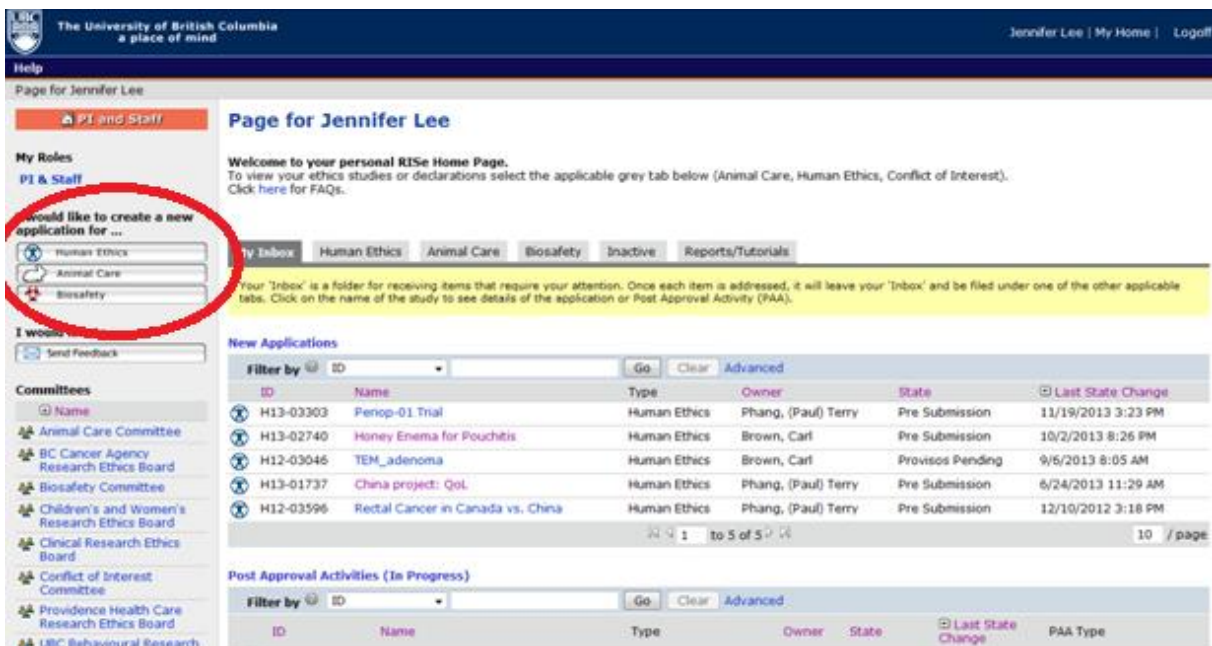
If you do not have a CWL, you must ask the PI to sponsor you as a guest. Please send the PI this link: <https://www.cwl.ubc.ca/SponsorGuest/guests/login.jsp>. The PI will create a username and password for you.

After creating your CWL, you will be prompted to add your researcher ID number to create your account. If you don't know whether a Researcher account exists for you, email [risupport@ors.ubc.ca](mailto:risupport@ors.ubc.ca) and provide the administrator with the following information:

- First/Middle/Surname
- Email address
- Business Telephone Number
- UBC Department of Affiliation (if none, provide the name of your Institution and Department)
- UBC Rank
- UBC Employee ID (if applicable)

The RISE administrator will email you the researcher number upon receiving your request.

To start the ethics application, click on “Human Ethics” button on the left-hand side of your home page under “I would like to create a new application for...”. You will be prompted to the application page.



This is a print screen shot of what the RISE site looks like. Select “Human Ethics”, as demonstrated in the following picture.

The screenshot shows a user interface for 'PI and Staff'. At the top is a red header with a home icon and the text 'PI and Staff'. Below this is a section titled 'My Roles' with a sub-link 'PI & Staff'. A message reads 'I would like to create a new application for ...'. Underneath are three buttons: 'Human Ethics' (with a globe icon), 'Animal Care' (with a dog icon), and 'Biosafety' (with a biohazard icon). A red arrow points to the 'Human Ethics' button. Below this is another section 'I would like to ...' with a 'Send Feedback' button (with an envelope icon). The bottom section is titled 'Committees' and lists three committees: 'Animal Care Committee', 'BC Cancer Agency Research Ethics Board', and 'Biosafety Committee', each with a group of people icon.

Please use the protocol provided to complete the application. There are guidance notes on the right-hand side of the page. Please remember to save your work after each page.

### Consent Form

You will be required to create and attach a consent form to the Page 9. The following documents will help you write the consent form:

- REB Consent Form Guide and Template (See PHC REB website, under “Forms & Guidance”)
- Sponsor consent form template
- Previous studies’ consent form as template

After you have completed the ethics application, you should ask the PI to review and submit. Only the PI or a designated investigator will have the submit function on the application.

### Deadlines and Meeting Dates

The UBC-PHC Research Ethics Board (REB) is normally scheduled to meet on the last Friday of the month. Applications must be submitted 3 weeks prior. This is applicable for applications requiring full board review. The deadlines and meeting dates are found on the PHC REB website, under “Deadlines & Meeting Dates”.

## **Provisos**

After the REB has reviewed your application, they may give you feedback before releasing the ethics certificate. You may be asked to clarify sections of your application. Please remember to track changes on attached documents (i.e. consent form and letter of contact). It is suggested to submit a word document of your changes made to the application.

## **Ethics Tutorials and Training**

It is recommended that all research coordinators complete the Tri-Council Policy Statement (TCPS2) Online tutorial prior to starting your application. This interactive online tutorial can be completed in approximately two hours and provides an essential orientation to the [Tri Council Policy Statement](http://tcps2core.ca/welcome). This tutorial can be access with this link: <http://tcps2core.ca/welcome>

## **IV. Contracts review**

The main contact for contracts is Esther Wu, the PHCRI Contracts Manager.

Once a study is submitted through the ethics board, Esther will know a study is coming through for Sponsored Research. Gwen Sin, the contracts coordinator, would require you to send her a filled out Proprietary Interest/Intellectual Property (PI-IP) form (see *Appendix A*) and an electronic version of the Clinical Trial Agreement.

## **V. Budget**

The budget has to be reviewed by yourself and the PI. It is recommended that you ask the sponsor representative to send you a template of the budget. The fees can be estimated by requesting quotes from all departments involved. Please note that there is 25% overhead on all costs. The budget can be reviewed along side of Esther's review of the contract.

Please send the draft budget to Esther, as she will confirm the budget has the required overhead before she finalizes the contract. You will send the budget draft to your sponsor representative and negotiate the items.

A sample budget draft and notes are attached in *Appendix B*.

## **VI. Department Approvals**

Department approvals can be done along side of the ethics approval. Please contact the department contacts of all involved departments. It is recommended that you provide the department's involvement, the study protocol, and inquire about department fees. You may be required to complete an application for the approval. Once you receive approval from the department, forward the approval document or email to Nesa Kruse, the Pre-/Post- Ethics Manager.

## **VII. Research Account**

To set up a research account, you will need to submit a Research Trust Account Form to Cindy Paddon, Bookkeeper (see *Appendix C*). You are required to receive signatures from the Co-Investigator as the

Designate and from the Head of Department. In order to receive the Department Head's signature, contact his/her secretary regarding dropping off the form for his/her signature.

The funds for the study are normally sent to the PI and under the care of the Coordinator. You would then track receipt of the funds and send the cheque to the research office here to the attention of our PHCRI Bookkeeper, Harina Kang. An account will be set up once Finance receives the required paper work.

Please note that Joan Schembri, the Senior Administrative Assistant, would normally send the cheque deposits and requests. Please provide her a copy the cheque or invoice and provide the following information:

- description of cheque or invoice
- research account number
- PI of study

### **VIII. Final Institutional Approval**

After you have ethics and department approvals and paid the ethics review fee, a final institutional approval certificate will be sent to you and the PI.

### **IX. Site Initiation Visit**

The site initiation visit (SIV) is the official "handing off" of the study to the site. The sponsor representative will visit the hospital to take a tour of the facilities and talk to you and PI about details about the study. Please notify the departments before showing the representative around.

Congratulations on starting up the study!

You are now ready to execute the study.