

ROWANSOM – INSTITUTIONAL REVIEW BOARD

WCG IRB PROCEDURES

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**SECTION 1: ELIGIBILITY OF PRINCIPAL INVESTIGATOR, CO-INVESTIGATORS**

**AND STUDY STAFF**

In order to be eligible to submit to WCG the Principal Investigator (P.I.) must meet current human subjects research policy requirement as to “Who May Be a Principal Investigator for Human Subjects Research” (Attachment A).

In, addition, all investigators and study staff must be RowanSOM paid faculty or employees. All investigators must be in good standing. The RowanSOM IRB Office will determine an investigator’s standing based on, but not limited to, the following criteria:

* Compliance issues
* Expired studies

**SECTION 2: WHICH PROTOCOLS MAY BE REVIEWED BY WCG**

Those studies which are both industry initiated and industry-sponsored and whose study activities are at only RowanSOM performance sites may be submitted to WCG.

* “Industry-initiated,” as opposed to investigator-initiated, means the project is not the original idea of the Principal Investigator.
* “Industry-sponsored” means that the funding company has the regulatory responsibility for the study in addition to funding the study.
* A “University performance site” is generally a location which is owned or operated or otherwise controlled by the University. All staff members are usually considered employees of the university. A private-practice not owned or controlled by the University, even though the site of practice of its faculty, is not a “University performance site.”

An industry-sponsored study that will be performed at a non-University site, whether exclusively, or as part of a multi-site study cannot be sent to WCG. RowanSOM IRB must review such a study.

**SECTION 3: SUBMISSIONS TO WCG**

The Principal Investigator must submit the following to the RowanSOM WCG Management Assistant. The WCG Management Assistant is located in the RowanSOM Clinical Trials Office:

* WCG Initial Review Submission Form
* FDA Form 1572, if any
* Protocol
* Investigator’s Brochure (if applicable)
* Current professional license for Principal Investigator (if already on file at WCG, only yearly updates needed)
* Curriculum Vitae for Principal Investigator and each Sub-Investigator (if already on file at WCG, only yearly updates needed)
* Investigator Financial & Other Personal Interests Disclosure Form signed by the Principal Investigator, Co-Investigator(s) and key personnel
* Sponsor’s consent form template (WCG will format consent using RowanSOM approved language)
* Department letterhead (1 sheet)
* Other materials to be provided to the subjects that are not included in the protocol, such as advertisements, questionnaires, subject diaries, etc.

RowanSOM IRB Pre-review Prior to Cayuse IRB WCG IRB Submission

The RowanSOM IRB Office should be consulted, prior to creating and submitting a Cayuse IRB Initial submission to the RowanSOM IRB, to complete a pre-review of all initial submissions to determine:

* the appropriateness of sending the study to WCG or to retain the study for review by the RowanSOM IRB due to significant local impact, and

RowanSOM IRB Review in Cayuse IRB

Once determined that the study is appropriate for WCG IRB submission, the contract is fully executed and the budget is final, the Principal Investigator or their designee must submit to the RowanSOM IRB an Initial Submission, identifying the submission type as WCG IRB, and include the following in the submission:

* Identify all researchers and assign to appropriate roles
  + WCG Management Assistant can be/may be named as Primary Contact in submission
* Investigator Financial & Other Personal Interests Disclosure Form signed by the Principal Investigator, Co-Investigator(s) and key personnel
* Completed Rowan IRB Protocol
* Investigator’s Brochure
* Advertisements, brochures, questionnaires, not included in the protocol and to be provided to subjects
* Completed Rowan IRB Consent form
* Clinical Trials Agreement and final, approved budget

The RowanSOM IRB Office will issue an approval letter. RowanSOM personnel, acting as the WCG Management Assistant, forwards the following documents to WCG Client Services @ clientservices@WCG.com. The Principal Investigator is required to ensure that the Rowan IRB approval letter is forwarded/provided to the RowanSOM Clinical Trials Office.

The WCG Management Assistant sends an email notification to the investigator and his/her study coordinator advising them that the submission has been forwarded to WCG.

WCG transmits a tracking number to the P.I. and to the WCG Management Assistant which is used to follow the status of the review. The WCG Management Assistant sends a monthly report of all active and closed studies to the IRB Office at RowanSOM.

The Principal Investigator or their designee must submit any modifications and/or incident and adverse events to the RowanSOM IRB via Cayuse IRB in addition to submitting to the WCG IRB. The RowanSOM IRB does not charge a fee for modification and incident and adverse events submissions.

**SUBMISSION OF MODIFICATIONS TO WCG**

All proposed changes to the study following initial approval must be submitted directly to WCG by the investigator. WCG transmits a status tracking number to the P.I. and to the WCG Management Assistant.

Changes made to research personnel and performance site must be reported to the RowanSOM IRB Office by submitting:

* an updated RowanSOM application (or if study was submitted through the Cayuse IRB system, a modification request through Cayuse IRB)
* Investigator Financial & Other Personal Interests Disclosure Form
* FDA Form 1572, if any

**SUBMISSION OF CONTINUING REVIEW TO WCG**

The P.I. will be notified by WCG three (3) weeks prior to expiration of the study approval period. A Continuing Review Report Form (CRRF) is sent directly from WCG to the P.I. notifying him/her that the IRB approval is about to expire. The P.I. must send the CRRF back to WCG by the due date. A delinquency is considered a non-compliance issue which may take action to suspend the study. *Such a suspension may trigger required reporting by the University*

*to the federal Office for Human Research Protections (OHRP), and therefore should be avoided by investigators who are urged to be timely in submitting CRRFs to WCG.*

Upon receipt of the WCG Certification of Approval for the continuation of the study, the WCG Management Assistant, will file the approval in the appropriate study electronic folder, and will update the WCG database to indicate the new approval expiration date.

The WCG Management Assistant will contact the P.I. and request an updated RowanSOM

Investigator Financial & Other Personal Interests Disclosure Form to be signed by all research personnel.

**SECTION 4: BILLING FOR WCG SERVICES**

RowanSOM researchers submitting initial applications, continuing review applications and/or modifications of human subject’s research to WCG must indicate the name and address of the Sponsor in the “Billing Information” section of the WCG submission form, in accordance with the Clinical Trial Agreement or study contract. This information will make clear to WCG who will be responsible for paying the WCG fees and whom WCG should bill.

If the CTA or study contract indicates that the sponsor will reimburse the investigator for WCG reviews rather than paying WCG directly, the researcher must establish a purchase order (PO) payable to WCG. The investigator must provide the PO number and mailing address to RowanSOM-Accounts Payable in the “Billing Information” section of the WCG submission form. This ensures compliance with the RowanSOM accounting policy. The RowanSOM Institutional Review Board does not pay WCG fees.

In addition to the WCG charges, a one-time RowanSOM IRB administrative submission service fee of $750 is charged for initial applications. Sponsors will be billed separately for this charge by the Rowan SOM IRB staff. If the sponsor will reimburse the investigator for WCG-related expenses only, the researcher must identify who will receive the invoice in the “Billing Information” section of the RowanSOM Application for Review by WCG.

**SECTION 5: AUDITS OF WCG-APPROVED STUDIES**

**WCG Site Visits**

Upon completion of a WCG site visit of a WCG-approved study at a RowanSOM performance site, a copy of the On-Site Review Form will be forwarded to the WCG Management Assistant, who will scan and file it in the investigator’s study folder on a Rowan University secure drive. The Management Assistant will also send a copy to the Institutional Official, the Research Dean.

RowanSOM IRB Audits of WCG studies

The RowanSOM will conduct quality assurance assessments and audits of WCG approved studies according to the same standard practice as RowanSOM IRB approved studies.

**SECTION 6: UNANTICIPATED PROBLEMS/ADVERSE EVENTS/DEVIATIONS IN WCG-APPROVED STUDIES**

In addition to providing reports to WCG, the PI must submit all unanticipated problems/deaths to the RowanSOM IRB office via Cayuse IRB. The WCG Management Assistant will send the report electronically to the Research Dean. Reports will be scanned and the electronic documents filed in the investigator’s study folder located on a Rowan University secure drive.

Reports will be forwarded to the RowanSOM IRB for review and determination whether there should be any additional corrective actions taken. Quarterly deviation reports provided by WCG will also be forwarded to the RowanSOM IRB and review.

**SECTION 7: WCG-APPROVED STUDIES DATABASE**

The WCG Management Assistant will update the database when the following occurs:

1. Submission of new study to WCG

2. Notification from WCG that a study has been:

a. initially approved or disapproved

b. approved for continuation

c. suspended

d. closed

3. Change in study personnel

The WCG Management Assistant will send to the Research Dean at RowanSOM specific monthly status reports containing the following information:

1. Number of open studies

2. Number of closed studies

3. Number of protocol deviations submitted

4. Number of compliance issues

**SECTION 8: STUDY CLOSURE**

The Principal Investigator will notify WCG when a study concludes. WCG will notify the RowanSOM IRB office by sending a Confirmation of Closure and Conclusion of IRB Oversight letter to the IRB office. The Board’s letter will acknowledge receipt of closure notification by the principal investigator and will include the effective date of which WCG closed the study.

Upon receipt of the Confirmation of Closure and Conclusion of IRB Oversight letter from WCG, the WCG Management Assistant will verify that there are no outstanding fees connected to the study. If there are fees, the WCG Management Assistant will contact the P.I. to determine the best method to collect the outstanding fees.

The WCG Management Assistant will convert the closure notification into pdf document and save the file in the relevant protocol file. The WCG database must be updated to indicate the date WCG closed the study.