Responsibilities of the IRBs of the Cooper Health System and Rowan University for Research Conducted by Investigators from a Combination of the Following Institutions: the Cooper Health System, Rowan University, and Cooper Medical School of Rowan University

Revised Version: June 16, 2014

Purpose:

The purpose of this policy is to eliminate redundancies in the education requirements for investigators and in IRB review of projects that are conducted by investigators who are affiliated with a combination of the following institutions: the Cooper Health System (Cooper), Rowan University (Rowan) and Cooper Medical School of Rowan University (CMSRU).

Policy:

Cooper and Rowan have agreed that projects that involve employees of both institutions and/or involve CMSRU faculty or medical students will be reviewed by only one of the IRBs. (CMSRU will not have its own IRB.) The Rowan IRB Chair and/or the Cooper IRB Director or Manager will decide which IRB should review any given project using the guidelines described below.

Cooper and Rowan have also agreed on the education requirements that will be accepted by each IRB for investigators affiliated with the other institution or CMSRU. See the information below.

Notification of the Other IRB:

For those projects that involve employees from the other institution(s), the reviewing IRB will inform the IRB at the other institution of the project by sending their IRB approval letter to the IRB at the other institution within 30 days of the IRB approval of the project.

Cooper IRB
The Cooper IRB will list the title and principal investigator of projects approved by the Rowan IRB on the next available agenda after receipt of the Rowan IRB approval letter.

Rowan IRB
The Rowan IRB will list the title and principal investigator of projects approved by Cooper IRB on the next available agenda after receipt of the Cooper IRB approval letter.

Determining who the investigators are and who the principal investigator is:

Cooper IRB Requirements

The Cooper IRB requires that any individual who will look at records (medical records, school records, or any other records) of subjects for research purposes, collect data for research purposes, interact with subjects for research purposes (e.g. talk to potential subjects about the research, obtain informed consent, interview subjects, perform any procedures for research purposes), or analyze data for research purposes be named as key study personnel (KSP) on the application to the IRB.
The Cooper IRB requires that a Cooper investigator be named as one of the (KSP) if access to Cooper patients or to medical records of Cooper patients is required for the research.

If the project will be reviewed by the Cooper IRB, the individual initiating the project should be named as the principal investigator if the project involves research in a field in which s/he has expertise, regardless of the individual’s institution (Cooper, Rowan, or CMSRU). For example, a Rowan employee who is a psychologist doing research that involves Cooper patients could be named as the principal investigator if the research involves only social and behavioral manipulations and measures. (A Cooper employee who has access to the patients who are potential subjects would need to be named as a co-investigator, however.) But a Rowan employee who is a psychologist who wants to conduct a research project with Cooper patients that involves medical treatments, e.g. prescription of medications, is required to have a physician who is a Cooper employee named as the principal investigator.

If the Rowan employee who initiates the project wants to examine the medical records of Cooper patients, the Rowan employee could be named as the principal investigator, but a Cooper employee who would have clinical access to the records of those patients should participate in the research and be named as a co-investigator on the application.

**Rowan IRB Requirements**

For non-medical research reviewed by Rowan University’s IRB, Rowan’s IRB requires that a Rowan investigator be named as the principal investigator or one of the key personnel in the study if the study includes human subjects that are CMSRU or Rowan students and/or Rowan employees. Additionally, Rowan IRB requires that a Rowan investigator be named as one of the key personnel in the study, if investigators are Rowan employees or CMSRU students and the subjects are external, or when the subjects are all CMSRU faculty who are not Rowan or Cooper employees.

For medical research reviewed by Rowan University’s IRB, where the investigator is any Rowan employee, the Rowan IRB requires that a Rowan investigator be named as either the principal investigator or one of the key personnel in the study, if the study includes human subjects that are Rowan employees, CMSRU faculty that are neither Rowan or Cooper employees, or/and external human subjects. The aforementioned criteria are not applicable if the principal investigator on the project is CMSRU faculty.

**Determining the education requirements for the investigators:**

Rowan University employees or students doing research reviewed by the Rowan IRB Rowan employees or students conducting research to be reviewed by the Rowan IRB must adhere to Rowan University’s training requirements. Rowan University utilizes the CITI program to administer training in human subject research. Human subject training requirements may be tailored depending on the investigator’s field of study or purpose of the research project. Training requirements can be found on the Rowan Office of Research, Institutional Review Board webpage.

Cooper Health System employees doing research reviewed by the Cooper IRB
Follow Cooper education requirements. That is, take the NIH course or the Cooper CITI basic biomedical course for faculty and all investigators. Links to these courses can be found on the portal and in imedris.

Rowan University employees or students doing any kind of research reviewed by the Cooper IRB
Take the Rowan CITI biomedical course or the NIH course

Cooper Health System employees doing any kind of research reviewed by the Rowan IRB
Take the NIH course or the Cooper CITI basic biomedical course

CMSRU students doing any kind of research reviewed by either the Cooper or the Rowan IRB
Take the NIH course The Cooper IRB will also accept the Cooper CITI basic biomedical course or the Rowan CITI biomedical course if the student has already taken one of those. The student should consult with the Rowan IRB for projects to be reviewed by the Rowan IRB if the student has already taken another course to see if it is acceptable to the Rowan IRB.

Financial Conflicts of Interest

Projects to Be Reviewed by the Cooper IRB
According to the Cooper Financial Conflict of Interest Policy, all key study personnel (KSP) on a funded project to be reviewed by the Cooper IRB must submit financial disclosure forms to the Cooper Research Institute (CRI). The form is signed and submitted electronically through the imedris IRB on-line system if the investigator has an imedris account. Otherwise a paper form may be filled out and submitted to the CRI. If any of the KSP has a financial conflict with the sponsor of the project, the conflict must be reviewed by the Cooper Research Ethics Committee (REC) and their determination must be submitted to the Cooper IRBB at the time the research application is submitted to the IRB. The Cooper IRB will not review the research application until it receives the determination of the REC.

The Cooper IRB will also follow the Institutional Conflict of Interest Policy for funded projects that are reviewed by the Cooper IRB. Institutional conflicts of interest are reviewed by the Cooper Institutional Conflict of Interest Committee (ICOI Committee) and their determination must be submitted to the Cooper IRB at the time the research application is submitted to the IRB. The Cooper IRB will not review the research application until it receives the determination of the ICOI Committee.

If the funding for the project is going through Rowan, whether the Cooper IRB or the Rowan IRB reviews the project, any Cooper employees who are key study personnel on the project are subject to the Cooper financial conflict of interest policy as described above.

Projects to Be Reviewed by the Rowan IRB
All key personnel who are seeking research funding by DHHS/PHS or DHHS/PHS operational agencies will be subject to Rowan University’s Conflict of Interest policy. Key personnel include principal investigators, co-principal investigators, subrecipients, and consultants/other key personnel as it defined in the regulation.
When subject to the Conflict of Interest policy, significant financial disclosure forms are to be completed and signed by key personnel. Disclosure Review Committee or designated individual will review the disclosure forms and make a determination whether a conflict of interest exists. If applicable, a management plan will be created and implemented. The Disclosure Review Committee or its designee can provide a summary of the conflict of interest review and determination of any subsequent action to the Cooper IRB.

For Cooper employees who are identified on IRB protocols as either the principal investigator or key personnel and whose project is being reviewed by Rowan University's IRB, prior submission of financial disclosures at Cooper and a determination of a review of conflicts are allowable if conducted at Cooper, but upon request, Cooper must provide satisfactory evidence of the review and whether or not a conflict of interest exists and the subsequent management plan to mitigate the potential conflict of interest.

**Follow-up if the investigator does not comply with the IRB requirements:**

Each institution will follow its own policy regarding non-compliance of investigators, regardless of which institution the investigator is employed by. Each IRB may seek the assistance of the other IRB in obtaining compliance of an investigator who is employed by the other institution.

**Application Process**

Investigators should follow the application process prescribed by the IRB to which they are submitting the proposal. Verification of which IRB will review the project should be done before the application process is initiated because the application process is different for the two institutions. Applications to the Cooper IRB are submitted through imedris, the Cooper IRB on-line system. Applications to the Rowan IRB are submitted on paper.

It is the responsibility of the principal investigator to contact the Rowan IRB Chair and/or the Cooper IRB Director or Manager to verify which IRB should review the project.

**Cooper Process for investigators who are not Cooper employees**

Rowan employees and CMSRU faculty and medical students on projects that will be reviewed by the Cooper IRB must obtain an imedris account. To obtain this account, these individuals must submit documentation of education in protection of human subjects and a signed certificate of confidentiality (a Cooper IT requirement) to the Cooper IRB office. These investigators should be listed in the External Investigator section of the application and should be listed as key study personnel (KSP) on the application. The IRB application should be routed to these investigators for sign off on the application as for any other investigator. The sign-off statements of principal and co-investigators say that the investigator will comply with the Belmont Report, the relevant federal regulations, and Cooper policies. If investigators who are Rowan employees or CMSRU faculty or medical students are added after the project is approved, they should be added with an amendment form. They must obtain an imedris account and the study application must be revised to add them to the External Investigator section. (They will be added as KSP by the IRB staff after the amendment is approved.)
Determining Which IRB Reviews a Project

The Rowan IRB Chair and/or the Cooper IRB Director will decide which IRB should review any given project using the guidelines described below. Investigators should follow these guidelines but check with the Rowan IRB Chair or the Cooper IRB Director or Manager if they have any doubt about which IRB will review the project. The application process is different for the two IRBs so investigators should be sure which IRB will review the project before they begin the application.

Definitions

- Medical research involves medical procedures and/or interventions that involve greater than minimal risk and/or that are not included in the expedited review categories, i.e. cannot be given expedited review.
- Nonmedical projects are those that do not involve medical procedures and/or interventions that are greater than minimal risk. (These studies may involve looking at medical records but there can be no medical interventions or procedures conducted for purposes of the study.)
- External subjects and external investigators are those who are not Cooper employees, not Rowan employees, and are not CMSRU faculty or students.
- CMSRU faculty may be employees of Cooper, Rowan, Coriell, or the University of the Sciences (aka Philadelphia College of Pharmacy).
- CMSRU medical students may be affiliated with Rowan or with the University of the Sciences.
### NON-MEDICAL PROJECTS

<table>
<thead>
<tr>
<th>Investigator</th>
<th>Subjects</th>
<th>Cooper</th>
<th>Cooper employees</th>
<th>CMSRU students (Rowan &amp; nonRowan)</th>
<th>Rowan employee (any but CMSRU student)</th>
<th>External</th>
<th>CMSRU faculty not Rowan or Cooper employee</th>
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<tbody>
<tr>
<td>Cooper employee</td>
<td>Cooper patients</td>
<td>Cooper</td>
<td>Cooper employees</td>
<td>CMSRU students (Rowan &amp; nonRowan)</td>
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<td>CMSRU employees</td>
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Another way to express the table above:

**Cooper IRB reviews**
- If the subjects include Cooper patients
- If the subjects include Cooper employees unless
  - The PI is a Rowan employee (CMSRU faculty or not), or
  - The PI is a CMSRU student
- If the investigators include Cooper employees (CMSRU faculty or not) and the subjects are external

**Rowan IRB reviews**
- If the subjects are all CMSRU students
- If the subjects are all Rowan employees
- If the investigators are Rowan employees or CMSRU students and the subjects are external
- If the subjects are all CMSRU faculty who are not Rowan or Cooper employees

**Neither IRB reviews**
- If the PI is CMSRU faculty but not a Cooper or Rowan employee and the subjects are the same or are external. The Cooper IRB should be notified if the project involves medical research and the Rowan IRB should be notified if the project involves nonmedical research since these activities may reflect on CMSRU.
**MEDICAL RESEARCH PROJECTS**

<table>
<thead>
<tr>
<th>Subjects</th>
<th>Cooper patients</th>
<th>Cooper employees</th>
<th>CMSRU students (Rowan &amp; nonRowan)</th>
<th>Rowan employee (any but CMSRU student)</th>
<th>External</th>
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<td>CMSRU faculty not Rowan or Cooper employee</td>
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Another way to express the table above:

**Cooper IRB reviews**

- All projects unless
  - The subjects are Rowan employees and the PI is a Rowan employee unless the PI is a also CMSRU faculty
  - The subjects are external and the PI is a Rowan employee unless the PI is also a CMSRU faculty
  - The subjects are CMSRU faculty who are not Cooper or Rowan employees and the PI is a Rowan employee unless the PI is a also CMSRU faculty