NEW IRB PROCEDURES:

Separate HawkIRB applications for IRB-01 and IRB-03
Previous to 2007, the VA was just another study location.

In 2008 IRB-03 became a separate distinct UI IRB

- Enforcement of 1200.5 resulted in pressure to demonstrate compliance with the additional VA-specific policies in the conduct or human subjects research
UI IRB-03 & VA Research Office

- IRB 03 collaborative effort with the VA Research Office
- IRB members and staff trained to understand additional VA regulations.
- Allowed research occurring at the University of Iowa and the Iowa City VAMC to be reviewed on one (IRB 03) form.
August 2014, ORO conducted a site visit of the Iowa City VAHCS Human Research Protection Office (including IRB-03)

- Final ORO visit report cited the VA HRPP: “ICVAHCS must revise local SOPs and review tools to ensure that VA research is clearly separated from non-VA research.”

Hence the split
Not just that the rules are stricter, they are different.

- Email
- Children
- Keeping or destroying data.
- HIPAA
- Enrolling non veterans
What to do?

If you're not part of the solution, you're part of the precipitate.
Separate IRB applications for VA and UI research.

- IRB 01 will describe University of Iowa components
- IRB 03 will describe VAMC components.
This is good news!

- Research mainly at UI, could expedite VA portion.
- Application designed for the study site-less confusion
- A delay for another committee will only hold up review of research at one site.
Process for open studies

- For open studies- don’t let coverage lapse.
- Submit an IRB 01 application and wait for approval before removing study procedures from your 03 form.
- Use the duplicate tool
## Duplicate tool

<table>
<thead>
<tr>
<th>Data</th>
<th>Funding</th>
<th>REFs</th>
<th>Approval</th>
<th>Monitor</th>
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### Create Form
- Modification/Update Form
- Continuing Review Form
- Modification/Update + Continuing Review Form
- Reportable Event Form
- Project Close Form
- Duplicate Project

| N/A  | N/A     | N/A  | N/A  | N/A    |
You are attempting to duplicate this project. This will create a new project with pre-populated fields identical to the existing project.

**Project to duplicate**

**IRB #:** 201003701  
**Title:** Gift Cards - Form Version 6  
**PI:** Michael Kane

- Duplicated project should be changed to IRB-01, and the existing project should be changed to IRB-03 VA Only  
- Duplicated project will have a new IRB # generated.  
- Assurance documents will be deleted on duplicate.  
- Select the principal investigator for this duplicated project below, you will not be able to change this after the duplicate is done.

Select Principal Investigator:

[Duplicate]  [Cancel]
The table contains the following data:

**Prisoners**: No

**Review**
- **Next Approval Due By**: N/A
- **Closed to Accrual**: N/A

**History**
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**This project was previously approved under IRB 03. Previous project history can be found here.**

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15.22, funding-question-select-seq 0.11, Survey Form 1.2, Project Form 16 0.1
Clinical trial at both sites

- Two applications, IRB 01 and IRB 03
- Multi center study
- Both will be participating sites
VII.A.2 Is this project also being conducted by other researchers at their own sites (e.g. a multi-site collaborative project)?

- Yes
- No
VII.A.3 What is the UI site's role(s) for this project (check all that apply)?

- Clinical/participating site
- Coordinating Center
- Central Laboratory
- Statistical/Data Management Center

Other, Describe:
A study is completed mostly at one site, however, a lab or computer server at another site must be used.

Still a multi center study
Consent obtained at only one site.

Waiver of consent for any data going to other site.

Are you requesting a waiver of informed consent/authorization (subjects will not be given any oral or written information about the study)? If this study involves a drug, device, biologic, or other product regulated by the FDA, you may NOT request a waiver of consent/authorization.

Requests for partial waiver of HIPAA authorization for recruitment purposes should NOT be requested in this section if it’s go to VII.D.1 and choose “Review of patient/clinic records” to request the partial HIPAA waiver.

- Yes, for all subjects
- Yes, but only for some of the subjects
- No

IV.6 Will subjects be provided with additional pertinent information after participation?

- Yes
- No
### III.1 Funding Sources

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<tr>
<td>Federal Agency</td>
<td>US Department of Veterans Affairs, Iowa City Veterans Affairs Medical Center</td>
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</table>

* new source name

### III.2 Which office will process the agreement for this project

Sponsored Programs - Federal/State/Local Agency Funded

### III.3 Does any member of the research team have a financial conflict of interest which members below.

<table>
<thead>
<tr>
<th>Name</th>
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Dual appointments

- Ensure you have the type of appointment needed to work at the VA or University of Iowa

- 8/8 appointments- Kari Steinkamp
  Kari.Steinkamp2@va.gov
Resources

- Tony Quinlan, Senior IRB Application Analyst
  335-9848 tony-quinlan@uiowa.edu

- Iowa City VA Research Compliance Officer - Sara Miller
  Sara.Miller@va.gov

- Nadine Miller (credentialing)- Nadine-miller@uiowa.edu

- HSO Website for VA research:
  http://hso.research.uiowa.edu/research-vahcs