

NEW IRB PROCEDURES:

Separate HawkIRB applications for
IRB-01 and IRB-03



A little history

- ▣ 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 of 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.

Why the “NEW” IRB-03

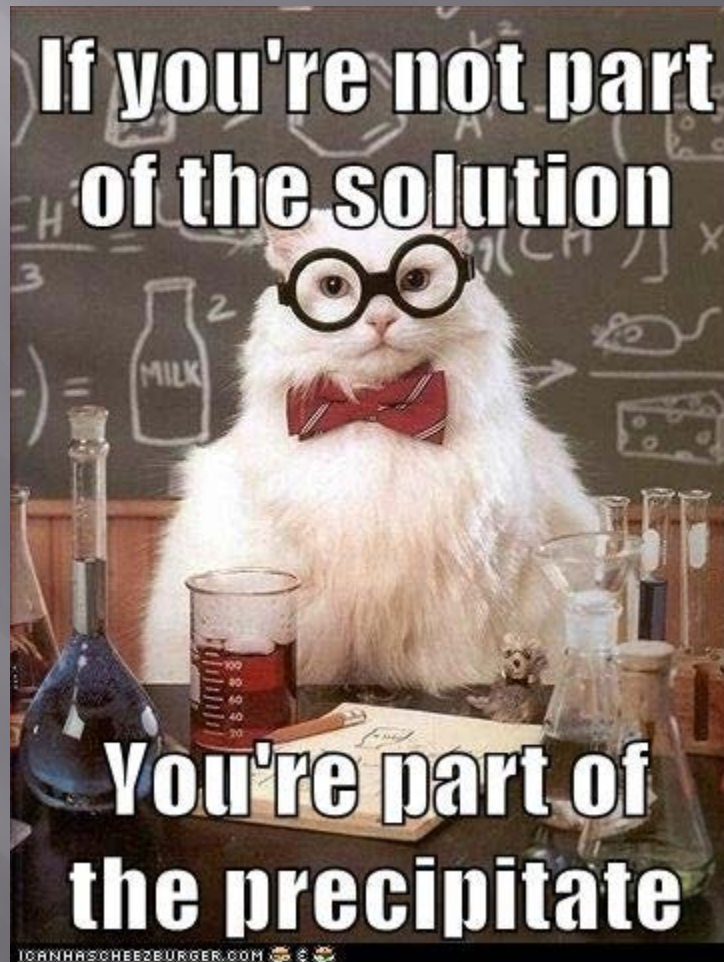
- ▣ August 2014, ORO conducted a site visit of the Iowa City VAHCS Human Research Protection Office (including IRB-03)
 - ▣ Final ORO visit report cited the VA HRPP:
“ICVAHCS must revise local SOPs and review tools to ensure that VA research is clearly separated from non-VA research.”
- ▣ Hence the split



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

- ▣ Email
- ▣ Children
- ▣ Keeping or destroying data.
- ▣ HIPAA
- ▣ Enrolling non veterans

What to do?



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

m	Funding	REFs	Approval	Monit
	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			
nt Risk Device	N/A			
se	N/A			

Duplicate Project

[HawkIRB](#) > Duplicate Project

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 created.

Select Principal Investigator:

To search on a name, start typing the name of your selection. Type a **space after the complete name**.

Duplicate

Cancel

Link back to project

Prisoners	No	Emergency
Review		Other
Next Approval Due By		Certificate
Closed to Accrual	N/A	IRB Authority
		Unaffiliated

History

Form	Received	Agenda Date	Type	Status
New	02/08/16			Pe

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

Multi center clinical trial

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

Multi center clinical trial

VII.A Project Description (A) - Collaborating Sites

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:

Using a VA/UI resource

- ▣ 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

Using a VA/UI resource

- 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 you 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

VA funding

II	III	IV	V	VI	VII.A	VII.B	V				
. Funding/Other Support											
III.1		<i>Funding Sources</i>									
		<table border="1"><thead><tr><th>Type</th><th>Source</th></tr></thead><tbody><tr><td>Federal Agency</td><td>US Department of Veterans Affairs, Iowa City Veterans Affairs Medical Center</td></tr></tbody></table>						Type	Source	Federal Agency	US Department of Veterans Affairs, Iowa City Veterans Affairs Medical Center
Type	Source										
Federal Agency	US Department of Veterans Affairs, Iowa City Veterans Affairs Medical Center										
		* new source name									
III.2		<i>Which office will process the agreement for this project</i> Sponsored Programs - <input type="text" value="Federal/State/Local Agency Funded"/>									
III.3		<i>Does any member of the research team have a financial conflict of interest which members below.</i>									
		<table border="1"><thead><tr><th>Name</th></tr></thead></table>						Name			
Name											

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>