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 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.

Why the "NEW" IRB-03

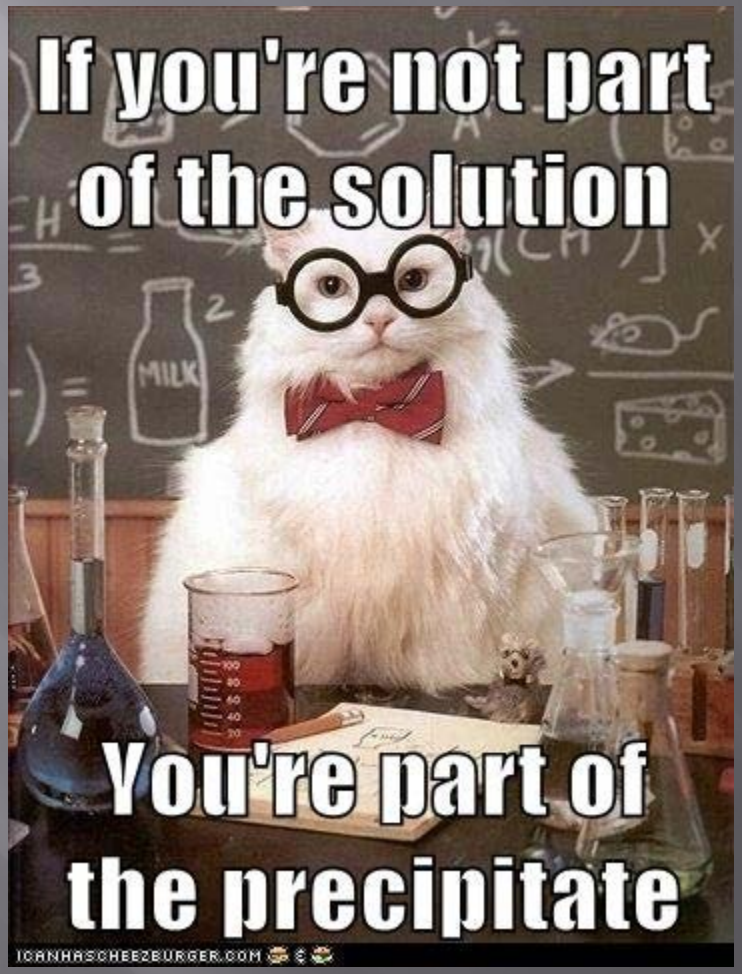
- August 2014, ORO conducted a site visit of the Iowa City VAHCS Human Research Protection Office (including IRB-03)
  - Final ORO visit report cited the VA HRPP: "ICVAHCS must revise local SOPs and review tools to ensure that VA research is clearly separated from non-VA research."
- Hence the split

The University of Iowa

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
MILK
ICANHASCHEEZBURGER.COM

Separate IRB applications for VA and UI research.

- IRB 01 will describe University of Iowa components
- IRB 03 will describe VAMC components.

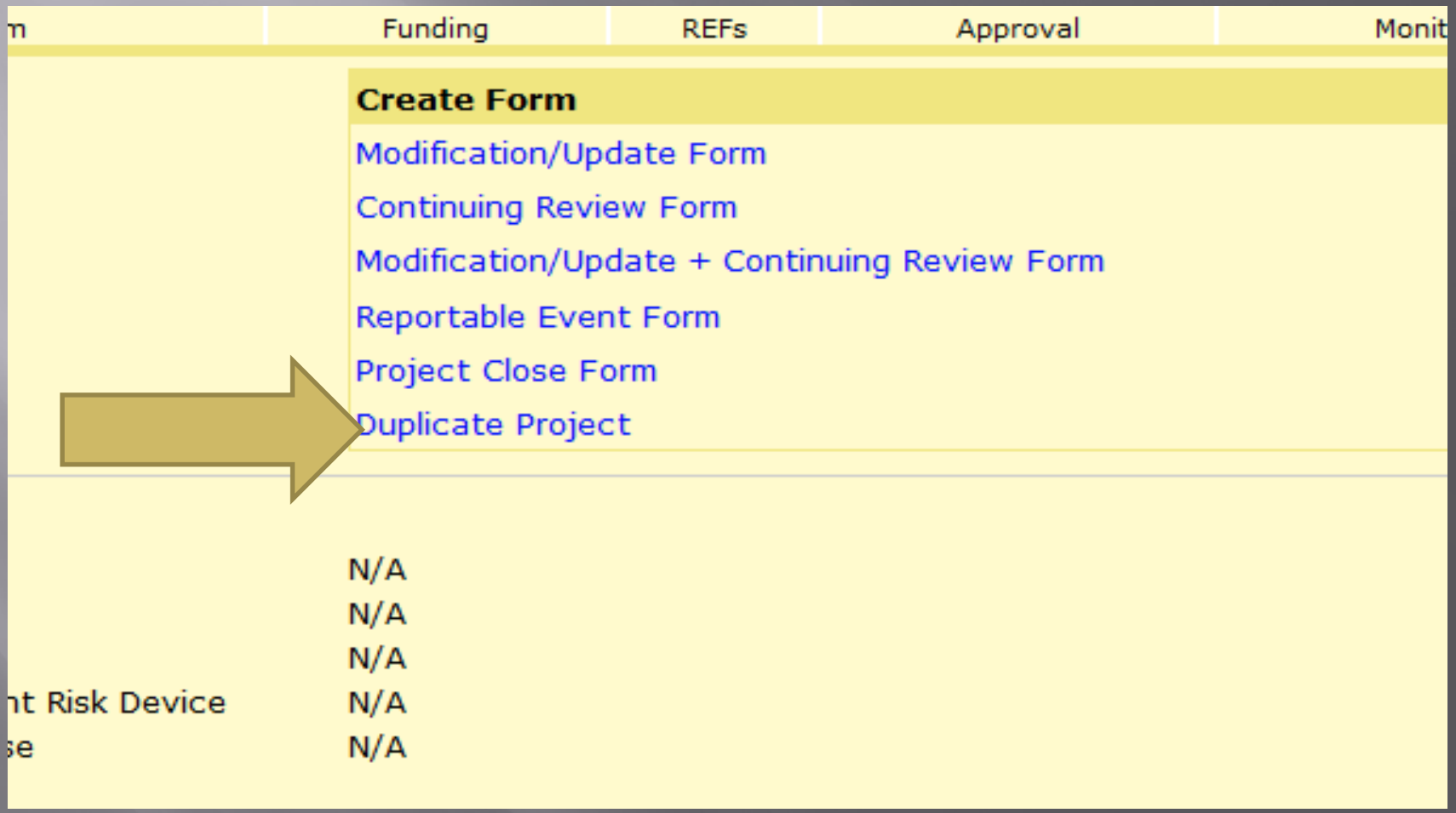
This is good news!

- 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.

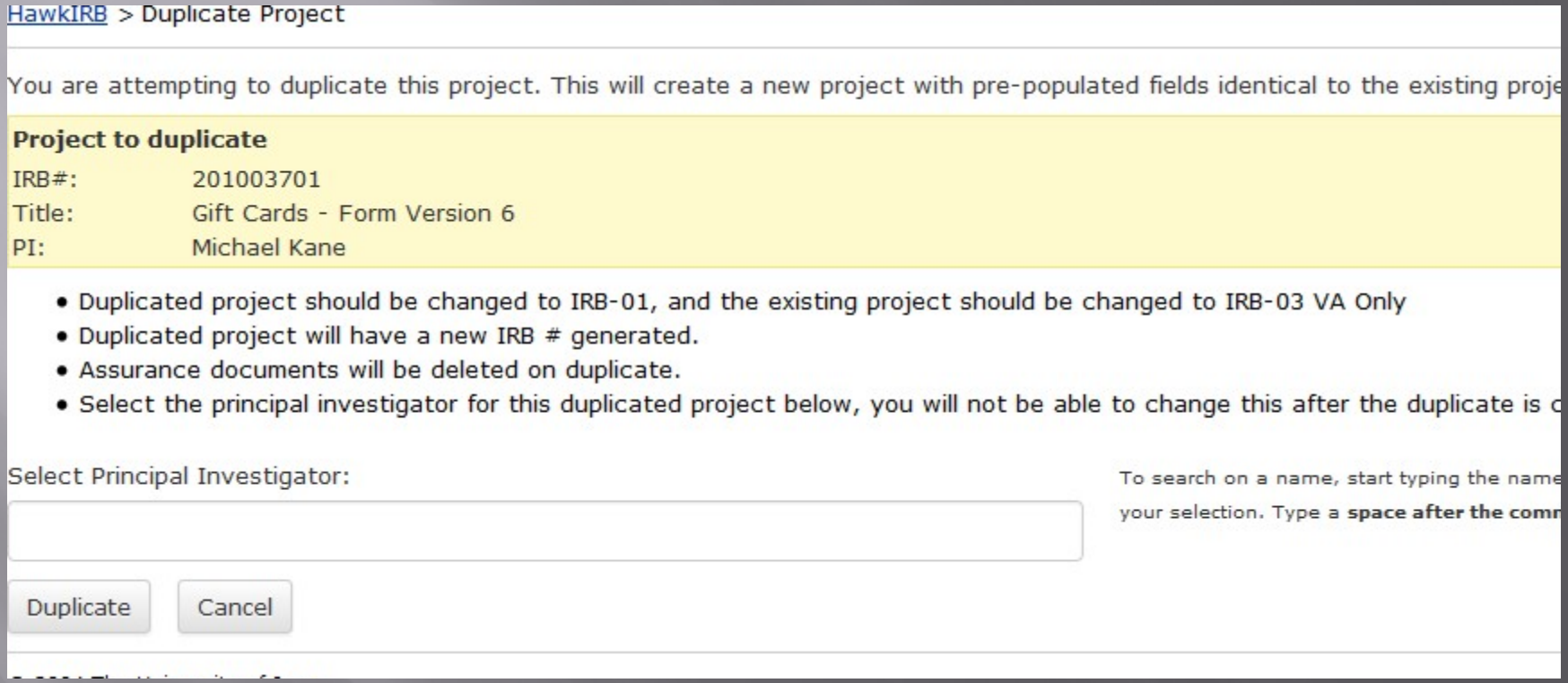
Process for open studies

- 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



Duplicate Project



Link back to project

Prisoners	No	Emergenc
Review		**Other**
Next Approval Due By		Certificat
Closed to Accrual	N/A	IRB Autho
		Unaffiliate

History

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

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

Clinical trial at both sites

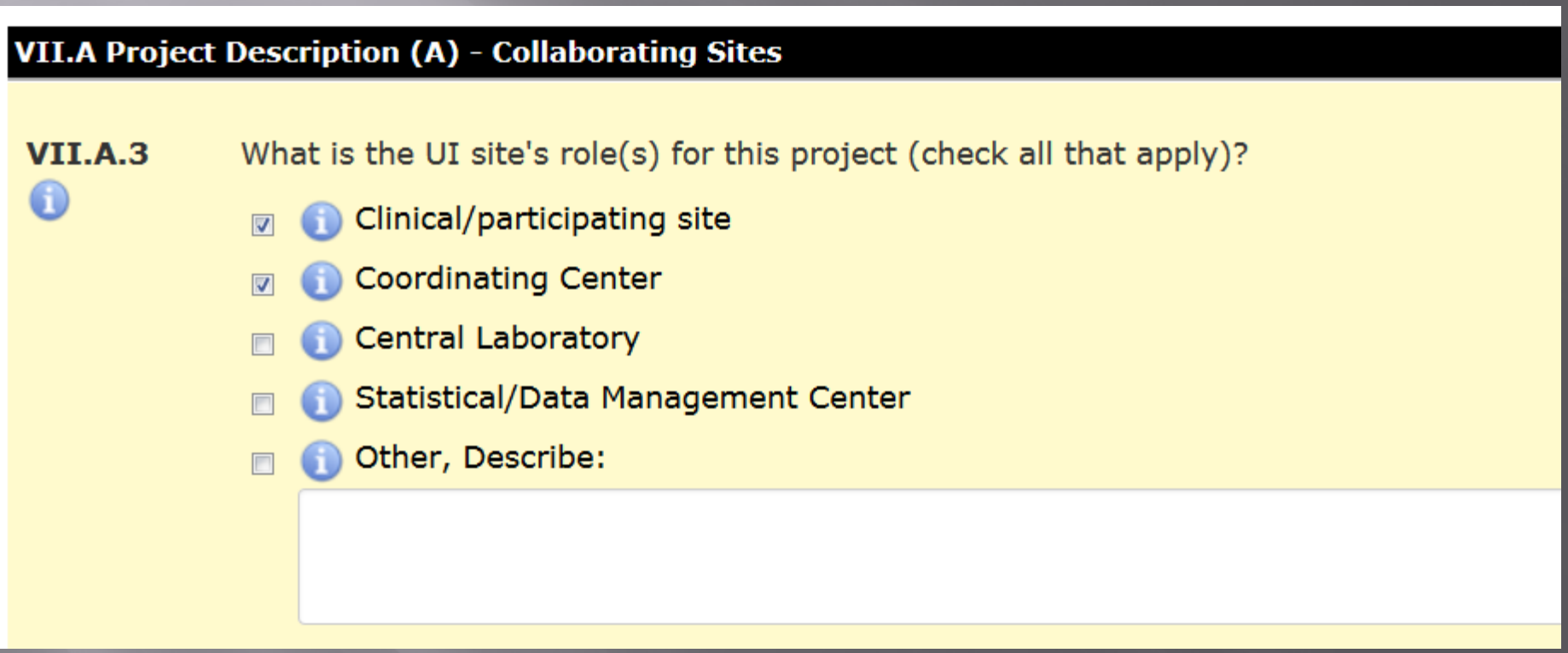
- Two applications, IRB 01 and IRB 03
- Multi center study
- Both will be participating sites

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



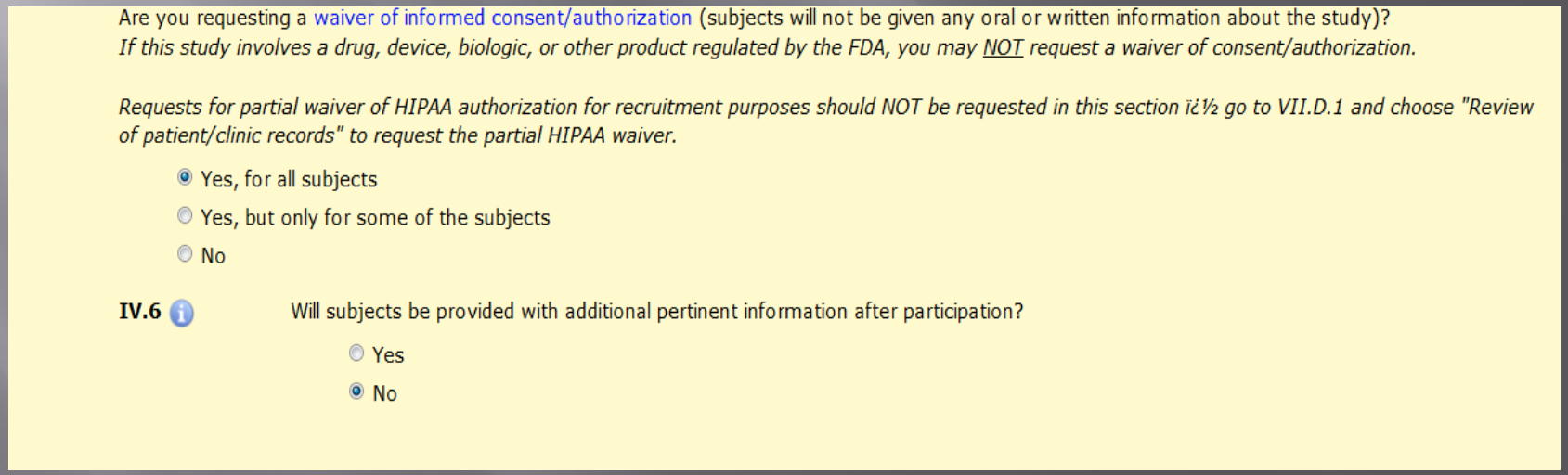
Using a VA/UI resource

- 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.

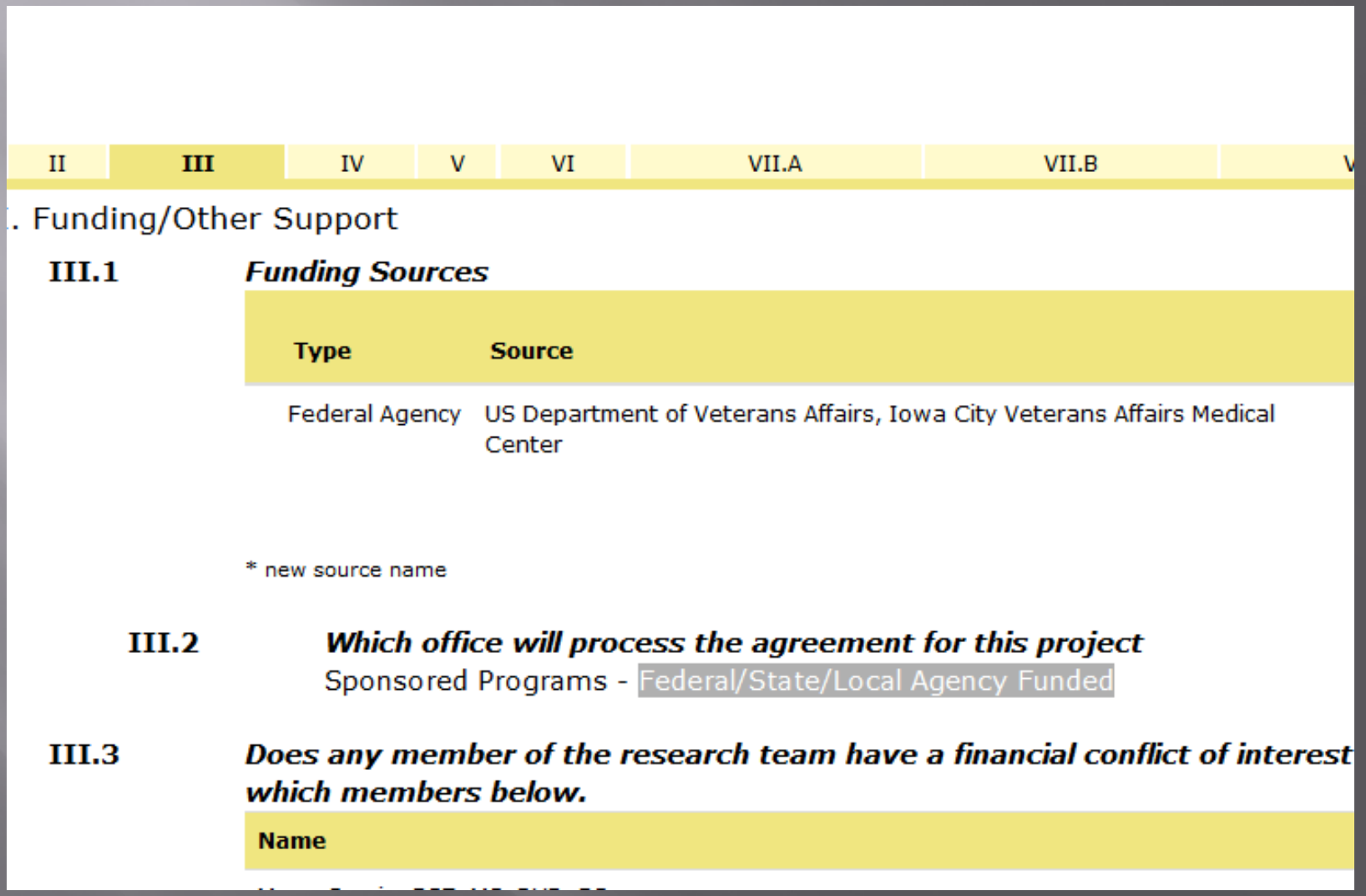
Requests for partial waiver of HIPAA authorization for recruitment purposes should NOT be requested in this section ï¿½ go to VII.D.1 and choose "Review of patient/clinic records" to request the partial HIPAA waiver.

- (•) 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 ***Funding Sources***

Type	Source
Federal Agency	US Department of Veterans Affairs, Iowa City Veterans Affairs Medical Center

* 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.***

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