

# VAMHCS RESEARCH SERVICE HOT TOPIC

Vol. 2 No. 7  
September 16, 2008

## CONFIDENTIALITY AND PRIVACY: What to do when you submit protocols for R&D approval

- Many of you have recently received contingency letters from the IRB or the R&D Committee (R&DC) regarding VA information security and/or privacy issues. Many of you will probably become familiar with these contingencies if you have recently submitted protocols with the VAMHCS as a site to the IRB or R&DC.
- The VA Central Office has issued very specific requirements for privacy and for information/data security. Privacy Officers and Information Security Officers are now required to sit on the R&DC and must approve all new protocols, renewals and some amendments. The IRB and R&DC must also document that criteria have been met.
- Our VAMHCS Privacy Officer (Janice Crosby) and our VAMHCS Information Security Officer (Lucy Fleming) and the IRB have noticed some common problems. Following the tips below will help your protocol move smoothly through the IRB and R&DC review processes.
- PRIVACY: In BRAAN (Section K) or CICERO, specify a plan for destruction of data and a time point when destruction will happen.

- The following paragraph is ~~an example of~~ recommended language that will meet the requirement:

The data will be destroyed ~~5 years after completion of the study OR~~ once the maximum retention period is reached, as defined by the Department of Veteran Affairs Records Control Schedule 10-1. Data will be destroyed using the most current electronic data destruction methodologies which are available at the time of data destruction. All destruction techniques will be in compliance with approved national disposal policies and procedures.

[You must accurately describe your actual plans for destruction of data, but this gives an idea of what to think about when you write your description in BRAAN/CICERO]

- ~~Your plan must also include a time point for destruction of data. Stating that identifiers will be destroyed at the earliest opportunity at the ‘end of research study’ is acceptable if you do not have a specific date/benchmark for when data will be destroyed. (This is currently covered in the HIPAA Authorization).~~

- Acceptable methods of destruction at this point of time: shredding of paper, incineration, or any method that renders the media permanently unreadable.

- In the “**THIS AUTHORIZATION WILL NOT EXPIRE...**” paragraph of of the HIPAA authorization template, enter the following statement:

“Your records will be kept indefinitely.”

■ INFORMATION SECURITY:

- There is a new required Data Security Checklist for the R&DC. THIS CHECKLIST REPLACES “APPENDIX C” AND “APPENDIX D”. Please remove copies of the old checklists from your files and folders!!
- The new checklist has been attached to this Hot Topic but will shortly be available on the Research Service website ([www.maryland.research.va.gov](http://www.maryland.research.va.gov)).
- You must also explain your data security plan in BRAAN/CICERO (Section K Confidentiality in BRAAN).
- In your description of your data security plan, please support your answers to the 12 questions on the Data Security Checklist.
- VA sensitive and/or identifiable information MUST either be behind the VA firewall OR stored on encrypted devices at UM.
- For questions about privacy or information security issues, please contact the VAMHCS Privacy Officer or Information Security Officer directly:

VAMHCS PRIVACY OFFICER

Janice Crosby

410-605-7328 (office)

410-447-4912 (pager)

VAMHCS INFORMATION SECURITY OFFICER

Lucy Fleming

410-605-7140, 410-605-7141 or 410-642-1881

**For questions concerning this or other Research Service Hot Topics OR for adding staff or colleagues to the Hot Topics mailing list, contact:**

Jessica Mendoza, RN, BSN, CCRC  
Research Compliance Specialist  
Rm 6-B-135  
(410) 605-7000 x5591  
[jmend001@umaryland.edu](mailto:jmend001@umaryland.edu)

**Can't put your finger on a past Hot Topic you know would solve your problem? No problem. Check the Hot Topics archive on the Research Service website:**

[http://www.maryland.research.va.gov/hot\\_topics.asp](http://www.maryland.research.va.gov/hot_topics.asp)

**For comments, complaints or suggestions regarding the Research Service or Office of Research**

**Compliance, contact:**

Melody Higgins, RN, MSN, CCRC  
Research Compliance Officer  
Rm 3-A-125  
(410) 605-7000 x6512  
[melody.higgins2@va.gov](mailto:melody.higgins2@va.gov)