

Accounting of Disclosures of Individually Identifiable Information (III)

- **Background:** The **Privacy Act** (5 USC §552a(c)) requires VHA to track certain disclosures of covered information from VHA records and to provide an accounting of these disclosures to individual subjects of the records upon request. The Health Insurance Portability and Accountability Act (HIPAA) **Privacy Rule** contains a similar accounting requirement though not all disclosures requiring tracking under the Privacy Act are mandated to be tracked under the Privacy Rule. To meet these requirements, VHA must maintain a cumulative accounting or list of what information VHA discloses, to whom VHA discloses the information, for what purpose and when, for each patient or veteran. This is called an “**Accounting of Disclosures**”. In addition, VA Central Office requires that the [VAMHCS] Privacy Office conduct quarterly audits of all disclosures, including research disclosures.
- **Instances when an accounting of disclosures is needed:** An accounting is needed anytime individually-identifiable information (III), including protected health information, contained in a system of records (*including research records!*) is disclosed to an outside entity.
 - This applies to research records as well as clinical records (CPRS, etc.).
 - It applies to information disclosed to the research participant as well as to other parties.
 - Therefore, investigators are required to track disclosures of any III whenever they release information to their research participants or to third parties (personal physicians, etc.).
- **Steps for disclosures:**
 - Obtain authorization from the participant.
 - Disclose the requested information.
 - Document & track the disclosure.

See “What Investigators need to do” (below) for specific steps. The information is very long and may look complicated. There are three ‘scenarios’ and two methods of tracking the disclosures. Before you get bogged down in the details, first skim through the main points of this Hot Topic, and then choose the **scenario** that best fits your study. After that, read the details that apply to your study.

What Investigators need to do

- Release of Information (ROI) Forms:

- Have your participants sign a ‘release of information’ (ROI) form, either VA Form [10-5345](#) or [10-5345a](#):
 - VA Form **10-5345**, “*Request for and Authorization to Release Medical Records or Health Information*”, is used when information is released to a third party (primary medical doctor, specialist, employer, etc.).
 - VA Form 10-5345a, “*Individuals’ Request for a Copy of Their Own Health Information*”, is used when information is released to the participant/patient him/herself.
 - You can have the participant complete the form at any time to prospectively cover disclosures; or the participant completes the ROI form prior to a specific disclosure.
 - See these guidelines for completing the ROI forms: “[Guidance on the Completion of VA Form 10-5345](#)”, “[Expiration Date Guidance for VA Form 10-5345](#)”, “[HIPAA Privacy Rule Defective Authorization Guidance](#)”. Form 10-5345a requires less information, but the guidances for 10-5345 can still be useful guidelines for how to answer the questions.
 - i You can be somewhat general in your description of the items to be disclosed. For example, instead of listing individual laboratory reports, you can say “all laboratory reports from 1/1/2010 – 12/31/2012”. You can give date ranges in the “Information Requested” box (10-5345) or the “date of treatment” box (10-5345a).
 - ii In the description of the disclosure, **specify that the disclosures are from research records**.
 - iii Be sure to specify an ‘expiration’ in the “Authorization” section of the 10-5345.
- A ROI authorization (VA Form 10-5345a or 10-5345) must be on record, ***even if the information released is listed in the signed HIPAA authorization!!!***
 - File the ROI with your study documents. In some instances (see scenarios below) the original will be sent with the participant to the ROI office. In others, the investigator will keep the original.
 - Log the release of information (disclosure) into the VAMHCS tracking system by following one of the scenarios described below.
- Releasing the information:
 - There are three scenarios for the release of research information:
 - **Scenario A:** the participant has a CPRS chart and the information requested is contained in CPRS. For example, a radiology report for a chest x-ray performed at the VAMHCS for the research study.
 - **Scenario B:** the participant has a CPRS chart but the information requested is NOT contained in CPRS. For example, a laboratory report for blood work sent to an external central laboratory for the research study (that lab report would be in the research file but would not be in CPRS).

- **Scenario C:** the participant DOES NOT have a CPRS chart. For example, a non-veteran is enrolled in a study that does not require VAMHCS services (such as an exercise study that does not require lab work, radiology services, etc.). (all the participant's data would be contained in the research file and not in CPRS).

Based on the scenarios above, the method for releasing and tracking the information is different.

- **Releasing information under Scenario A** (participant has a CPRS chart; requested info is in CPRS; ROI Office performs the release of information and tracking of the disclosure):
 - Participant signs a 'release of information' (ROI) form, either VA Form 10-5345 or 10-5345a, completed as above.
 - Send the original form with the participant to the ROI office (3D-121); keep a copy for the research chart.
 - Participant obtains the requested information from the ROI office.
 - ROI staff will document the disclosure in VAMHCS ROI Manager. The investigator does NOT need to do anything to track the disclosure.
- **Releasing information under Scenario B** (participant has a CPRS chart; requested info is not in CPRS because it is obtained through the research & outside of CPRS):
 - Participant signs a 'release of information' (ROI) form, either VA Form 10-5345 or 10-5345a, completed as above.
 - The investigator CHOOSES to proceed with either "Option 1" or "Option 2".
 - OPTION 1 (similar to Scenario A above):
 - i The investigator **writes a "RESEARCH Progress Note"** that states or summarizes the requested information. **Please ensure that this is a historical note and that an encounter/office visit is not created to link the note to an encounter.**
 - ii Send the participant to the ROI office (3D-151) with the original ROI form and keep a copy for the research chart.
 - iii The participant obtains the information (the RESEARCH Progress Note) from the ROI office.
 - iv ROI staff will document the disclosure in VAMHCS ROI Manager. The investigator does NOT need to do anything to track the disclosure.
 - OPTION 2 (similar to Scenario C below: In this case, the investigator/staff releases the information according to the specifications in the ROI form and investigator/staff then tracks the disclosure.)
 - i Keep the original form for the research chart; give a copy to the participant.
 - ii Give the participant a copy of the requested information.
 - iii Enter the disclosure information into one of the "Accounting of Disclosures Spreadsheets".

iv Send the spreadsheet to ROI and R&D Service monthly as described below.

- **Releasing information under Scenario C** (participant does not have a CPRS chart; investigator/staff releases the information according to the specifications in the ROI form and investigator/staff then tracks the disclosure):
 - Participant signs a 'release of information' (ROI) form, either VA Form 10-5345 or 10-5345a, completed as above.
 - Keep the original form for the research chart; give a copy to the participant.
 - Give the participant a copy of the requested information.
 - Enter the disclosure information into one of the "Accounting of Disclosures Spreadsheets".
 - Send the spreadsheet to ROI and R&D Service monthly as described below.
- Some investigators may prefer to create a CPRS chart for the purpose of releasing information to a participant (Scenario B, Option 1). As long as the participant does not object to being registered in CPRS, there is not a problem with this method.

■ Track (account for) the disclosures:

- If you follow the processes in "Scenario A" or "Scenario B, Option 1" above, then you do not have to take any additional steps to track the disclosures. The ROI staff will log the disclosures into ROI Manager (VAMHCS tracking system) when they release the information from CPRS.
- If you follow the processes in "Scenario C" or "Scenario B, Option 2" above, then you follow these steps:
 - Enter the disclosures on one of the sample spreadsheets, "**Accounting of Disclosures Spreadsheet**".
 - i There are two versions of the spreadsheet: one is for a "unit based" organization where more than one investigator or study might be listed on one disclosure spreadsheet; the other is for an individual investigator/study (See "Release of Information" in the list of forms on the "Forms" webpage).
 - ii It is OK to make your own minor adaptations to the spreadsheets (for example, for a single investigator who has several studies, you may wish put the investigator's name once in the top portion, and only list individual studies in the left column).
 - iii The columns should fit on one page.
 - Accounting of disclosures **must be done electronically**.
 - Submit your spreadsheets to HIMS and the Research Service:
 - i Send the spreadsheets on a **monthly** basis. Do not send blank spreadsheets if no disclosures occurred during the month.
 - ii Send the spreadsheets **via encrypted email** to yvonne.copeland2@va.gov (HIMS) with cc's to

leslie.wilson4@va.gov (ROI) and jessica.mendoza@va.gov (Research Service).

iii In the Subject line of the email, identify your research unit/area/study. For example: “*Subject: GRECC Accounting of Disclosures*”.

- ROI staff will use the spreadsheet to document the disclosure in VAMHCS ROI Manager.

■ Bottom Line:

- HIPAA authorizations allow you to disclose some types of information, BUT
- When you do disclose (release), you MUST
 - Obtain a signed ‘release of information’ (ROI) form (VA Form 10-5345 or 10-5345a) from the participant, AND
 - Account for the disclosure in a tracking system and periodically (monthly, only for months when disclosures have occurred) send the spreadsheet to HIMS, ROI and the Research Service via encrypted email.

Think in terms of this scenario:

Your research participant asks for a copy of his lab results obtained through his participation in your research study. You have him sign a ‘release of information’ form (VHA Form 10-5345a) and then give him a copy of his lab report. Later, the lab report (containing the participant’s name, SSN and medical information) is found on the sidewalk in front of the Medical Center. Someone finds it there and brings it to the Privacy Officer (PO) to file a complaint.

If you (the VAMHCS) have documentation that the report was in the possession of the participant (the signed 10-5345a plus the accounting of the disclosure) and therefore was not lost/dropped by the research team, then the VAMHCS would avoid a significant penalty.

The attachments to this Hot Topic will be posted on the Forms page of the Research Service website:

http://www.maryland.research.va.gov/research/human/human_subject_forms.asp

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

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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

For comments, complaints or suggestions regarding the Research Service,
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