

A USER'S GUIDE TO THE RASCAL HIPAA MODULE



COLUMBIA UNIVERSITY
MEDICAL CENTER

 **NewYork-Presbyterian**
 The University Hospital of Columbia and Cornell

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**This manual was originally developed by John Ennever, M.D., Ph.D, Medical Director; Clinical Trials
A special thanks to John for all of his work in the development of the Manual.*

A new module in the RASCAL system was introduced on November 30, 2005. This manual describes the use of this functionality – the ability to electronically create and submit HIPAA Forms for research protocols.

In April 2008 the IRB assumed primary responsibility for the review of IRB submitted protocols to evaluate the HIPAA requirements for research protocols with pre-review by the Office of HIPAA Compliance.

When a new protocol is submitted for the first time and there are no HIPAA forms attached (described within), a dialogue box pops up in RASCAL with a warning that all IRB protocols should have at least one HIPAA form attached. However, a HIPAA Form is not a requirement for submitting a protocol.

In addition, when you click to submit your protocol (initial submission, renewal or modification); the RASCAL system does a check to make sure certain elements are included. If any of the required elements are missing, RASCAL will give you a prompt that states at the top:

You cannot submit protocol IRB-AAABXXXX until the following information is completed:

This is followed by a list of missing elements, all of which are REQUIRED before the system lets you submit the protocol.

If you choose not to use the HIPAA module for example in a renewal or modification for a study for which you have an already approved HIPAA form, this prompt will remind users to verify that the correct HIPAA form is attached:

Investigators are required to use this system to generate and submit HIPAA forms even if you have an already approved HIPAA form for your study. Changes to protocols may require additional HIPAA forms.

SUGGESTED USE OF THE MANUAL

The manual is designed to be used as an electronic document. There are imbedded links throughout that allow you to quickly jump to a referenced section. These links are present everywhere in the text where “see page” and “see Figure” is followed by a number. The cursor will change from an open hand to a pointing finger when you are on a link. By clicking your left mouse button you will be taken to the referenced section. You can quickly move back to your original position by using the combination of ALT key and the left arrow (←) key. (These links only work within this document, so references to the RASCAL IRB manual are not linked).

Questions about this manual or HIPAA Compliance for research protocols can be directed to the Office of HIPAA Compliance at HIPAA@columbia.edu or (212) 342-0059

INTRODUCTION

In 1996, Congress passed a law called the Health Insurance Portability and Accountability Act (HIPAA). One of the major purposes of this legislation was to render health insurance more portable by protecting health insurance coverage for workers and their families when they change or lose their jobs. A part of this law also included a mandate to the Department of Health and Human Services (HHS) to develop national standards for electronic healthcare transactions. The goal of the part of HIPAA was to standardize the way health care entities speak electronically to Medicare and Medicaid across the U.S. – a necessary first step in moving towards a fully electronic medical record.

At the same time, Congress recognized that advances in electronic technology could erode the privacy health information. Consequently, Congress incorporated into HIPAA provisions a mandate for the adoption of Federal privacy protections for individually identifiable health information. In response to this mandate, HHS published a final regulation in the form of the Privacy Rule with an effective date of April 14, 2003.

This Privacy Rule set national standards for the protection of health information, as applied to the three types of “covered entities”: health plans, health care clearinghouses, and health care providers who conduct certain health care transactions electronically. By the compliance date of April 14, 2003, “covered entities” were required to implement standards to protect and guard against the misuse of individually identifiable health information or protected health information (PHI). Failure to comply with these standards may, under certain circumstances, trigger the imposition of civil or criminal penalties.

HIPAA regulations apply to research at Columbia University Medical Center (CUMC) because faculty submit healthcare claims electronically and, as the employing entity, CUMC is thereby considered the “covered entity” required to protect PHI from unauthorized use or disclosure. Because virtually all clinical research involves the collection and use of PHI, the use and disclosure of this information falls under the HIPAA regulations. Even to the extent patient information is de-identified, HIPAA applies and requires certification that the de-identification is done properly (further discussed below).

HIPAA does not forbid the use of PHI in clinical studies, but does require subjects to be asked for their explicit authorization for its use. Therefore, in all clinical studies where identified health information will be used to conduct research, a research subject will have to sign an authorization permitting such use and any further disclosure (e.g., to the Sponsor) of their PHI. This authorization is granted by use of a form that the subject reads, understands and then signs – it is titled Form A Clinical Research Authorization.

The administrative responsibility for assuring compliance with the HIPAA regulations for research comes under the function of the IRB. The Office of HIPAA Compliance provides guidance and review of the HIPAA elements of a research protocol.

The HIPAA module within RASCAL allows you to generate the appropriate HIPAA authorization form and submit it along with your RASCAL IRB submission. Essentially all protocols submitted to the IRB should have at least one (and many will have more than one) HIPAA form.

HIPAA FORMS USED FOR RESEARCH AT CUMC

At CUMC there are 7 different HIPAA Research forms, Form A through Form G. There is one authorization (Form A), two waivers (Form B and C), three certifications (Forms D, E, and G) and one agreement (Form F).

FORM A – HIPAA Research Authorization

If the researcher is obtaining written informed consent, you will almost always need a HIPAA Form A.

This is the only HIPAA form that is signed by study participants. It provides permission from the study participant to their providers and to the investigator to disclose and use PHI for research purposes. This form is available in the HIPAA module in two versions, one for research that has an external sponsor who will be receiving PHI, labeled:

Form A: Clinical Research Authorization – Sponsored.

The other is for studies with no external sponsored labeled:

Form A: Clinical Research Authorization – Non-Sponsored.

The term “sponsor” refers to the entity sponsoring the study – the obvious sponsors would be the NIH, CDC or a pharmaceutical company. A less obvious “sponsor” could be a colleague at another institution who initiated a multi-centered study in which you are participating. In this case, the colleague is the “sponsor” (even if he/she is not giving you any money to do the study). In addition, because these two Form A’s are signed by participants, the HIPAA module has both English and Spanish versions.

FORM B Application for a Waiver of Authorization.

This is the form you need to submit if you are doing a type of research in which you will not have any direct contact with the study subject, for example, many types of medical records research. You need this waiver approved by the IRB before you can have access to medical records that are not part of your own practice. This applies to both the paper and electronic medical records.

Studies that use a Form B do not have a form A, and vice versa.

FORM C Request for Recruitment Waiver of Authorization.

This is similar to, but very different from, Form B. It is a request to use a patients’ contact information from medical records that were obtained under Form D to directly contact potential subjects. You are asking the IRB to give you permission to directly approach the potential subjects that you identified under Form D without having their physician serve as an intermediary. The IRB will usually not allow such a recruitment strategy – and generally requires recruitment to be done only after the subject has had an opportunity to discuss the research with their provider with whom they have a treatment relationship.

Permission for a recruitment waiver is granted by the IRB only under rare occasions – e.g., public health research using PHI from patients with many different providers who cannot all be contacted to speak to

patients about the study. Before you submit one of these forms the researchers should discuss the situation with the Privacy Officer at 212-305-7315.

FORM D Investigator's Certification for Reviews Preparatory to Research.

This form has two distinct purposes:

1. To determine whether or not there are sufficient potential subjects for a research project you are developing. For example, if you are thinking about a study of men between the age of 45 and 50 who have had a stroke and have anemia and a creatinine above 4, you could query the Clinical Data Warehouse (see: <http://healthsciences.columbia.edu/research/equip/eq-minex.htm>) to determine how many subjects seen at the medical center in the last year meet these criteria. Before you can do this database search, you would have to file a Form D and have it approved by the IRB. In this case, where you have not yet developed an IRB protocol, you would use the "Stand Alone" version.
2. After you have developed a protocol, you can use the same database tool to help you identify potential subjects for study. In this case you would use the Form D that is not "stand alone" but is linked to a protocol.

"How is this different from Form C?" The answer is that you are not going to use the PHI you obtained through this process to directly contact the potential subject. Rather, what you would do is contact the potential subject's physician and ask him/her to make the initial contact with his/her patient about the study.

Even if you identify potential subjects the old fashioned way, by going on the inpatient floors and reviewing charts or talking to treating physicians, you need to have filed a HIPAA Form D in order to be compliant with the Federal regulations.

A clinical study for which you are requesting use of PHI to identify study subjects would have both a HIPAA Form D and a Form A.

FORM E Investigator Certification for Research with Decedent Information.

Decedent is a term used principally in law. It means people who are no longer alive. HIPAA protections extend to the PHI of people who have died. HIPAA permits research using decedent PHI if the investigator files a certification (Form E).

This form is not linked to a human subject protocol (the IRB does not regulate research on non-living people), thus the designation "stand alone."

This form does not apply for subjects from whom you obtained a signed Form A (when they entered your study) and they subsequently died. The disclosure of their PHI for the study falls under the original authorization.

FORM F Data Use Agreement for Disclosure of a Limited Data Set.

This form is used if you need to share data with an outside group for some collaborative research purpose, but the information cannot be totally de-identified, the limited data use agreement would permit

disclosure of limited demographics and dates if an agreement between CUMC and the other entity was put in place. Review by the Privacy Officer is required along with signatures by the Principal Investigator, the recipient of the limited data set and Research Administration (SPA).

FORM G Investigator Certification for Research with De-Identified Data.

This is a form where the researcher attests that the data collected for your research is completely de-identified. The form contains the list of things you cannot have in your data set and still have it qualify as de-identified. In other words, if any of the items on this list are in your data set, you are not using “de-identified data” (according to HIPAA). This form may be used in medical record research where you are generally conducting retrospective reviews that don’t require the patient’s identity to do the research. This form may also be used in addition to questionnaires or surveys where PHI is not collected. It is extremely helpful exception since it removes this type of research from the restrictions of HIPAA.

This form cannot be used when a code or link back to the source where the records is maintained. This form maybe used for International research where direct identifiers will not be brought back to CUMC.

USING THE RASCAL HIPAA MODULE

LIST OF FIGURES

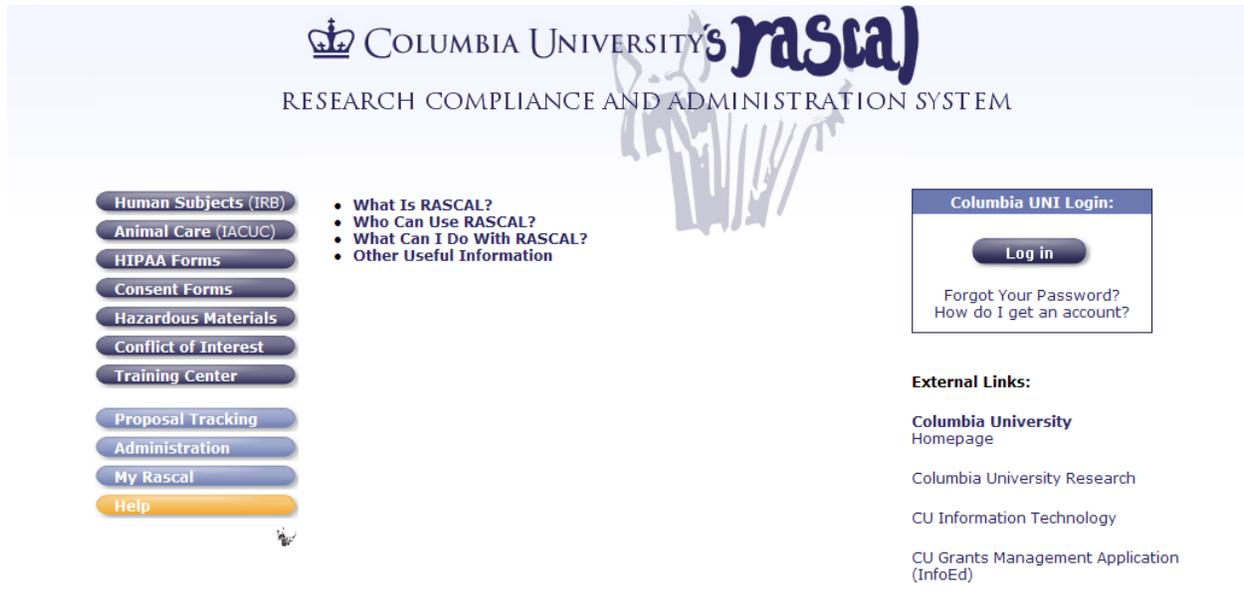
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The structure of the HIPAA module within RASCAL is analogous to the Consent Form Module. That is, a document is produced in the HIPAA module and then “attached” to the appropriate RASCAL protocol, prior to submission. This process allows certain information (e.g., the study title and the Principal Investigator’s name) to be pulled from the Protocol and automatically entered into the HIPAA form. The HIPAA module is structured in a way that is parallel to that used in the Consent Form module.

You begin from the RASCAL Home page (Figure 1).

Figure 1. The Rascal Home Page.

From the home page, you select HIPAA Forms and after logging in you are brought to the main HIPAA page.



Note:

- Do not open more than one RASCAL browser window at the same time.
- Please disable any [Pop-up Blockers](#) and enable [JavaScript](#) & [Cookies](#).
- This system will log you out after approximately one hour of [inactivity](#). Please save your work often.

Figure 2. HIPAA Page

From this menu, select “Create HIPAA Authorization / Waiver Form.” This brings up the HIPAA Form General Information Page shown in Figure 3.

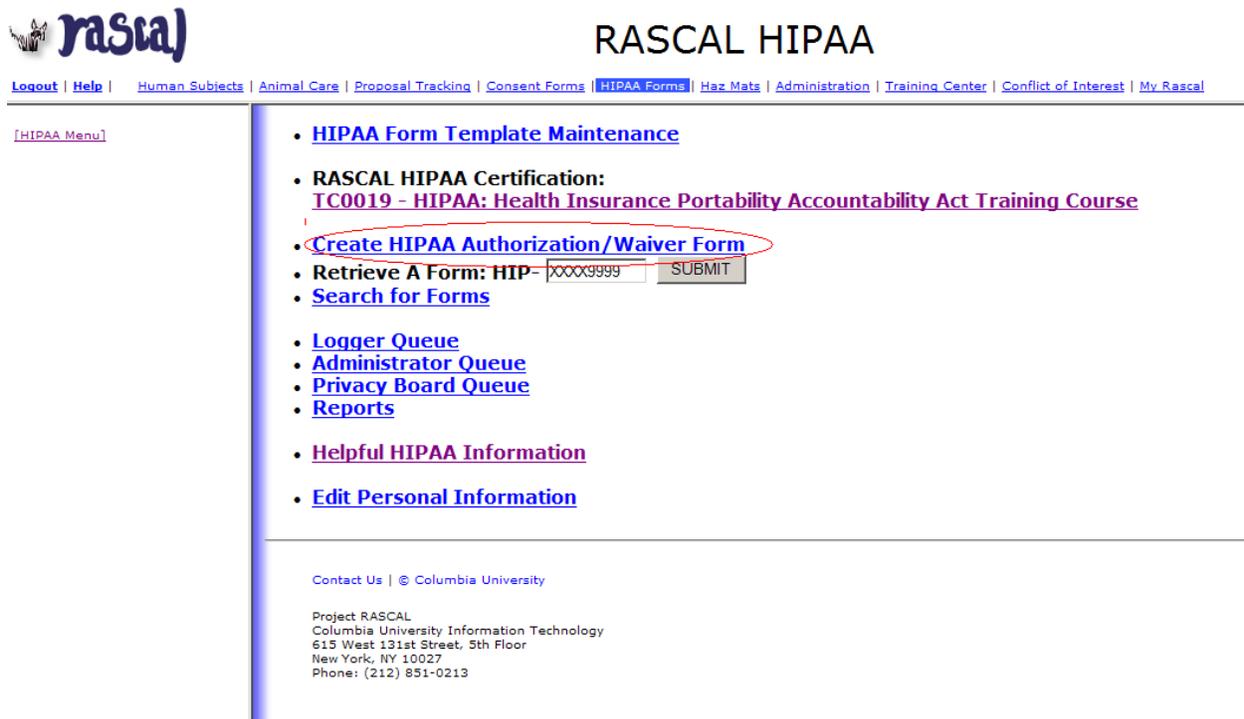


Figure 3. HIPAA Form General Information page (prior to hitting “save” button).

RASCAL HIPAA

Logout | Help | Human Subjects | Animal Care | Proposal Tracking | Consent Forms | **HIPAA Forms** | Haz Mats | Administration | Training Center | Conflict of Interest | My Rascal

HIP-AAAAF0456
Status: Creating

General
[Authorize Access](#)
[Answer Questions](#)

[Copy Form](#)
[Delete Form](#)

[View Form](#)
[View History](#)

[Add/Edit Form Text](#)
[Form Layout](#)

[\[Previous List\]](#)
[\[HIPAA Menu\]](#)

Authorization/Waiver Number	HIP-	Initiator	
Form Template		Identifier	
Date Created	10/12/2010 at 16:06	Attached to IRB protocol	not attached
You are			

GENERAL INSTRUCTIONS

Form Title: _____

Select Form Template:

Form Identifier (not displayed on form):

Select Form Template

From this drop-down menu you choose which form you want to create. The types of forms are explained in detailed starting on page 5.

The choices are:

- Form A: Clinical Research Authorization – Non-Sponsored (English version)
- Form A: Clinical Research Authorization – Non-Sponsored (Spanish version)
- Form A: Clinical Research Authorization – Sponsored (English version)
- Form A: Clinical Research Authorization – Sponsored (Spanish version)
- Form B: Application for Waiver of Authorization
- Form C: Request for Recruitment Waiver of Authorization
- Form D: Investigator Certification for Reviews Preparatory to Research
- Form D: Investigator Certification for Reviews Preparatory to Research (stand alone)
- Form E: Investigator Certification for Research with Decedent Information
- Form E: Investigator Certification for Research with Decedent Information (stand alone)
- Form F: Data Use Agreement for Disclosure of a Limited Data Set
- Form G: Investigator Certification for Research with De-Identified Data

Selection of the correct HIPAA Form:

Most protocols at the Medical Center will have at least one HIPAA form attached. Many will have both English and Spanish versions of a Clinical Research Authorization. You will not have both a Non-Sponsored and Sponsored version for the same protocol. If you have a Form A, and want to use any clinical information (Protected Health Information or PHI) that is not from your own practice in order to recruit subjects, you will also need to create a Form D.

If you are thinking about identifying potential subjects from a search of PHI (authorized by form D) and directly contacting the potential subject without going through the potential subject's healthcare provider, you will need approval of a Form C (as well as approval by the IRB for this recruitment strategy). In this scenario, you would have one or two Form A's (English and Spanish), one Form D and one Form C.

Studies for which Form B is used do not usually have additional forms. These are typically medical records research. These are studies in which you are not going to have any direct contact with any subjects; therefore you have no need for any Form A.

Similarly, Forms F and G are usually submitted with a protocol without any additional HIPAA forms

Form Identifier (not displayed on form)

You must enter a name in the text box. It is important to give this form a name which has meaning to you so that you know which form is which.

The reason that you need a meaningful name as the Form Identifier is so that when you need to "Attach" the form to a Rascal IRB submission you can quickly find it among your myriad of HIPAA Forms. The type of Form (e.g., Form A sponsored English, Form B, etc) is automatically added. At the very least, you should include the name of (or abbreviation for) the study to which you are going to attach this HIPAA form.

After entering the name you must hit the SAVE button.

Hitting the save button, brings up the next screen (Figure 4)

Figure 4. HIPAA Form General Information page. (after hitting “save” button)

The screenshot shows the RASCAL HIPAA Form General Information page. At the top left is the RASCAL logo. The main header is 'RASCAL HIPAA'. Below the header is a navigation bar with links: Logout | Help | Human Subjects | Animal Care | Proposal Tracking | Consent Forms | HIPAA Forms | Haz Mats | Administration | Training Center | Conflict of Interest | My Rascal. The left sidebar contains the following links: General, Authorize Access, Answer Questions, Copy Form, Delete Form, View Form, View History, Add/Edit Form Text, Form Layout, [Previous List], and [HIPAA Menu]. The main content area is titled 'HIPAA Form General Information' and contains a table with the following data:

Authorization/Waiver Number	HIP-AAAF0456	Initiator	
Form Template	Form A: Clinical Research Authorization - Non-Sponsored (English version)	Identifier	Test Form A
Date Created	10/12/2010 at 15:51	Attached to IRB protocol	not attached
You are			

Below the table is a section titled 'GENERAL INSTRUCTIONS' with a help icon. It contains the following text: 'Form Title: Form A: HIPAA Clinical Research Authorization for Non-Sponsored Research' and 'Form Identifier (not displayed on form):' followed by a text input field containing 'TestForm A'. A 'Save' button is located below the input field.

As with both the Human Subjects and the Consent Form modules, this initial saving brings up additional menu items on the left side of the page. It also gives your form a unique number, with the prefix HIP– followed by the familiar RASCAL numbering system.

The menu items on the left include:

Authorize Access:

This is the same as with the consent form (see Rascal IRB Manual) where you add people using their UNI and give them edit or view only privileges.

Answer Questions:

This is a unique feature of the HIPAA module. Depending upon the particular form (see below) there may be one or more items to fill in to complete the form.

All of the forms with the exception of the Form G have questions that need to be answered. The answers to these questions will be incorporated into the HIPAA forms that RASCAL will generate. The questions are identical to the questions that needed to be answered in the HIPAA forms that were in use in the paper-based system. The only difference is now they are entered into RASCAL.

Form A questions:

The Form A for sponsored studies has two questions to fill out:

1. The name of the Sponsor of the research

Enter the name of the Sponsor of the study, e.g., Pfizer, National Heart, Lung and Blood Institute.

2. List of any medical history of a potentially sensitive matter that you will be collecting and potentially sharing with others. The instructions state:

If your study will be collecting medical history that may include sensitive information, such as HIV status, history of drug or alcohol abuse, list these items in this box. If none, enter “Not Applicable.” in the box.

The Form A for non-sponsored research has only the second question about sensitive information.

Form B questions:

Please note that next to each question there is a text box where your answers should be added and remember to click on the “save” button after each response. In addition this page also has a blue and white (?) next to each question with sample text.

1. If applicable describe the plan to protect subject identifiers from improper use and disclosure.

For example: we will maintain appropriate security measures for the subject identifiers, including: (a) storing physical files in a locked cabinet to which only study staff can access with a key or combination lock; and / or (b) maintaining a secure database to which only the PI or key study staff can access with a password.) Alternatively: The data in this study will contain no identifiers.

2. If applicable describe the plan to destroy the subject identifiers or justify their retention.

For example, the identifiers are listed on a sheet that matches the identifier with the patient name. This sheet will be destroyed at the conclusion of the research. Alternatively: The identifiers will not be destroyed at the earliest opportunity because there is a health justification for retaining the identifier. The lab test may produce information that should be reported to the patient. Alternatively: The data in this study will contain no identifiers.

3. Describe your plan regarding reuse of Protected Health Information.

For example, only study staff will have access to the PHI. Appropriate security measures will be maintained for the subject identifiers, including storing physical files in a locked cabinet and / or maintaining a secure database to which only the PI or key study staff can access with a password. Alternatively: This research study may require reporting of PHI to the following public health authorities, e.g., New York State Department of Health,

4. Explain why your research could not practicably be conducted with the waiver or alteration.

For example, the number of charts may be too numerous – this retrospective medical chart research involves reviewing 2000 charts of patients some of whom were seen many years ago.

5. Explain why your research could not practicably be conducted without access to and use of Protected Health Information.

For example, the study requires the use of identifiable patient information in order to be a scientifically valid study.

Form C questions:

1. Describe the nature and scope of the patient information to which access is sought.

This should be as complete as is feasible.

2a. Why would it be impractical to rely on Columbia University, or on a Columbia University-affiliated clinician with whom the potential participants have a treatment relationship, to contact the potential participants on your behalf?

This is the key argument you need to make as to why you need this waiver: that you cannot practically contact a health care provider that has a treatment relationship with the patient in order to have him / her either talk to the subject or give you permission to contact the subject.

2b. Describe your plan to safeguard the patient information from improper use and disclosure while it is in your possession.

See Form B, item number 1.

2c. Describe your plan to destroy or return the patient information at the conclusion of the record review / recruitment activity.

See Form B, item number 2.

3. As a condition of accessing patient information for the purpose(s) indicated in (1), I agree not to use or to disclose to a third party any of the information for any other purpose.

This is answered by checking the box to affirm this statement.

Form D questions:

1. Purpose(s) for which access to records maintained by or on behalf of Columbia University Medical Center is (are) sought (check all that apply):

The choices are: Access sought for Protocol Development and / or
 Access sought for Identification of potential Research Participants

You check one or both.

2. Describe the nature and scope of the patient information to which access is sought.

If this form is to be attached to a Protocol (in other words, not the “stand alone” version, an example of what you could enter here is:

“The hospital charts on the Medicine floors of the Milstein Hospital will be reviewed to determine whether or not a patient meets the eligibility requirements of this study”

Instead of hospital charts, you could be reviewing the logs in the Emergency Department, or querying the Clinical Data Warehouse.

Form D Stand Alone

If you are submitting a “stand alone” version (not attached to a protocol), then you need to describe as completely as possible, the nature and scope of information to which you are requesting access. (You can’t refer to a protocol, because there isn’t one, yet)

In addition the “stand alone” version of Form D requires that you enter the Principal Investigator’s name and the title of the study. (In the “non stand alone” version, this information is pulled from the Rascal IRB protocol when it is attached) and then submit form for approval.

RASCAL HIPAA

Logout | Help | Human Subjects | Animal Care | Proposal Tracking | Consent Forms | **HIPAA Forms** | Haz Mats | Administration | Training Center | Conflict of Interest | My Rascal

HIP-AAA9210
Status: Creating

General
[Authorize Access](#)
[Answer Questions](#)
[Submit Form](#)
[Copy Form](#)
[View Form](#)
[View History](#)
[Add/Edit Form Text](#)
[Form Layout](#)
[\[Previous List\]](#)
[\[HIPAA Menu\]](#)

HIPAA Form General Information			
Authorization/Waiver Number	HIP-AAA9210	Initiator	Irina Mera
Form Template	Form D: Investigator Certification for Reviews Preparatory to Research (stand-alone)	Identifier	The Cookie Research
Date Created	10/04/2011 at 14:37	Attached to IRB protocol	not attached
You are	Irina Mera (im2119)		

GENERAL INSTRUCTIONS ?

Form Title: Form D: Investigators Certification for Reviews Preparatory to Research (stand-alone)

Form Identifier (not displayed on form):

Form E questions:

Describe the nature and scope of the deceased patients’ information to which access is sought.

Form F questions:

Please note that you must answer the two questions on the form and click on the “save” button after each response. The HIPAA Form should be printed and forwarded to the Office of HIPAA Compliance for review and approval.

1. Recipient

This is the name of the person, or organization with whom you are proposing to share a “limited data set”.

2. Effective Date

This is the start date for this agreement

Form G questions:

This is even easier than Form F, there are no questions.

This is the end of the answer question section.

The item below are found on the left side of the HIPAA Module after the form has been created.

View Form:

This generates a pdf version of your HIPAA form.

For all the forms with the exception of the “stand alone” forms, when you view the form, there will be three items that remain unfilled on top of form until you “attach” this form to a RASCAL protocol. Protocol Number, Name of the Study, and Principal Investigator. All three are taken from the RASCAL protocol to which the form is attached and entered at the top of the form. In addition, the name of the Principal Investigator is added in the first paragraph in place of “[Principal Investigator]”.

The next two menu items (Add / Edit Form Text and Form Layout) are only necessary if you have a sponsor that requires specific language in the HIPAA authorization form that is not included in the RASCAL templates.

Add / Edit Form Text:

Changes to the form(s) will have to be reviewed and approved by the IRB / HIPAA Compliance.

STOP: YOUR FORM IS NOW DONE

Once you have filled in the required questions for your form, you are done. RASCAL will automatically generate the final HIPAA form(s). The next step is submitting the form. How this is done is described in the next section.

SUBMITTING THE FORM(S)

Stand Alone Form

Form D: Investigator Certification for Reviews Preparatory to Research (stand alone), and
Form E: Investigator Certification for Research with Decedent Information (stand alone)

These two forms have a menu item “submit form” in the left hand menu. The other forms which require being “attached” to a RASCAL Protocol do not have this menu item (see figure 4). To submit these “stand alone” forms to the Privacy Office simply click the Submit menu item in the left hand menu.

Non-Stand Alone (Attached) Forms

The other forms are all associated with a specific IRB protocol and need to be linked (“attached”) to the protocol in order to submit them.

The “attaching” of the form to a Rascal IRB Protocol is done within the Human Subjects module. How this is done depends on whether or not your protocol has been submitted to the IRB yet.

Forms for new protocols

For new protocols that have not yet been submitted to the IRB, the HIPAA forms are attached using the Attach HIPAA forms menu item on the Human Subjects module, (between Attach Hazmats and Attach Documents). See Figure 5 if your protocol has already been submitted to the IRB, even if it is still pending or has been returned to you, you need to follow the directions in the next section, Forms for Existing Protocols, see page below.

Clicking on this menu item brings up the following screen:

Figure 5. HIPAA Form Attachment Screen (in Human Subjects Module).

RASCAL Human Subjects

HIPAA Forms

Protocol Number: IRB-AAAI0387

Protocol Creation Date	10/15/2010 at 15:29	Department	Faculty Practice (594)
Principal Investigator	Karen Pagliaro-Meyer (kp155)	Initiator	Irina Mera (im2119)
You are	Irina Mera (im2119)	Year	1 Modification 00

GENERAL INSTRUCTIONS

Current HIPAA Forms	Attach	View Form	Detach	Status
Clinical Research Authorization - Non-Sponsored (English version) Form A	▶			
Clinical Research Authorization - Sponsored (English version) Form A	▶			
Clinical Research Authorization - Non-Sponsored (Spanish version) Form A	▶			
Clinical Research Authorization - Sponsored (Spanish version) Form A	▶			
Application for Waiver of Authorization Form B	▶			
Request for Recruitment Waiver of Authorization Form C	▶			
Investigator Certification for Reviews Preparatory to Research Form D	▶			
Investigator Certification for Research with Decedent Information Form E	▶			
Data Use Agreement for Disclosure of a Limited Data Set Form F	▶			
Investigator Certification for Research with De-Identified Data Form G	▶			

By clicking on the blue attach button (2nd column from the left), all of your unattached HIPAA forms of the particular type you selected are displayed. You select the one you want to be attached to this protocol and you are done with that form.

RASCAL TIP

Here is where a meaningful (at least to you) form identifier, is extremely useful. A meaningful identifier will help you when you are at the point of attaching the Form to the protocol, to select the correct form.

When the RASCAL IRB protocol is sent to the IRB, the “attached” HIPAA forms are routed to the Privacy Office.

Forms for Existing Protocols

If you need to add a HIPAA form after you have initially submitted the IRB protocol, you go to the Protocol Overview Page in the Human Subjects section (Figure 6). NOTE: It doesn't matter whether the protocol is approved or not, you submit HIPAA forms using this method once you have submitted the IRB protocol to the IRB for the first time.

Figure 6. Protocol Overview Page.

The last menu in the center panel is "Manage HIPAA Forms." This brings up a page (Figure 7) that is very similar to that shown in Figure 5, but has a new functionality that allows you to add new or remove already attached HIPAA forms.

RASCAL Human Subjects

Logout | Help | Human Subjects | Animal Care | Proposal Tracking | Consent Forms | HIPAA Forms | Haz Mats | Administration | Training Center | Conflict of Interest | My Rascal

IRB-AAAI0387
Status: Creating

General
Personnel
Research
Funding
Location
Subjects
Investigational Product
Approvals
Attach Hazmats
Attach HIPAA Forms
Attach Documents
Attach Consent Forms
Notify Approvers
Submit Protocol
Copy Protocol
Delete Protocol
Print Menu
View History
View Data Sheet
View Study Description
Protocol Overview
Meeting History
[IRB Menu]

HIPAA Forms

Protocol Number		IRB-AAAI0387	
Protocol Creation Date	10/15/2010 at 15:29	Department	Faculty Practice (594)
Principal Investigator	Karen Pagliaro-Meyer (kp155)	Initiator	Irina Mera (im2119)
You are	Irina Mera (im2119)	Year	1 Modification 00

GENERAL INSTRUCTIONS ?

Current HIPAA Forms	Attach	View Form	Detach	Status
Clinical Research Authorization - Non-Sponsored (English version) Form A	+			
Clinical Research Authorization - Sponsored (English version) Form A	+			
Clinical Research Authorization - Non-Sponsored (Spanish version) Form A	+			
Clinical Research Authorization - Sponsored (Spanish version) Form A	+			
Application for Waiver of Authorization Form B	+			
Request for Recruitment Waiver of Authorization Form C	+			
Investigator Certification for Reviews Preparatory to Research Form D	+			
Investigator Certification for Research with Decedent Information Form E	+			
Data Use Agreement for Disclosure of a Limited Data Set Form F	+			
Investigator Certification for Research with De-Identified Data Form G	+			

Figure 7. Attach HIPAA page after IRB submission.

RASCAL Human Subjects

Logout | Help | Human Subjects | Animal Care | Proposal Tracking | Consent Forms | HIPAA Forms | Haz Mats | Administration | Training Center | Conflict of Interest | My Rascal

IRB-AAAI0387
Status: Approved

General
Personnel
Research
Funding
Location
Subjects
Investigational Product
Approvals
Attach Hazmats
Attach HIPAA Forms
Attach Documents
Attach Consent Forms
Notify Approvers
Submit Protocol
Copy Protocol
Delete Protocol
Print Menu
View History
View Data Sheet
View Study Description
Protocol Overview
Meeting History
[IRB Menu]

HIPAA Forms

Protocol Number		IRB-AAAI0387	
Protocol Creation Date	10/15/2010 at 15:29	Department	Faculty Practice (594)
Principal Investigator	Karen Pagliaro-Meyer (kp155)	Initiator	Irina Mera (im2119)
You are	Irina Mera (im2119)	Year	1 Modification 00

GENERAL INSTRUCTIONS ?

Current HIPAA Forms	Attach	View Form	Detach	Status
Clinical Research Authorization - Non-Sponsored (English version) Form A	+			
Clinical Research Authorization - Sponsored (English version) Form A	+	HIP-AAAF1467	+	Approved
Clinical Research Authorization - Non-Sponsored (Spanish version) Form A	+			
Clinical Research Authorization - Sponsored (Spanish version) Form A	+			
Application for Waiver of Authorization Form B	+			
Request for Recruitment Waiver of Authorization Form C	+			
Investigator Certification for Reviews Preparatory to Research Form D	+	HIP-AAAFB305	+	Creating
Investigator Certification for Research with Decedent Information Form E	+			
Data Use Agreement for Disclosure of a Limited Data Set Form F	+			
Investigator Certification for Research with De-Identified Data Form G	+			

Using this page, “you attach” the new HIPAA form to your already submitted (or approved or returned) IRB protocol. As shown in Figure 7, the Form A has been approved, and the Form D has just been added. If you needed to change a approved form A, you could “Detach” it and “Attach” a new (revised) Form A.

Pressing the button labeled “Submit HIPAA Forms” sends your newly attached forms to the Privacy Office.

Once the form is approved by the Privacy Office, the status will change to “approved” a watermark stating:

Privacy Office Approved MM DD YYYY

will be added to the bottom of each page.

The approved HIPAA form(s) can be printed from the Rascal along with the approved consent forms.

Modifying HIPAA Forms

Add/Edit Form Text

Selecting this menu from the left hand menu in Figure 4, bring up the following page (for a Form A for Sponsored Research):

Figure 8. HIPAA Form Text page.

[Logout](#) | [Help](#) | [Human Subjects](#) | [Animal Care](#) | [Proposal Tracking](#) | [Consent Forms](#) | [HIPAA Forms](#) | [Haz Mats](#) | [Administration](#) | [Training Center](#) | [Conflict of Interest](#) | [My Rascal](#)

HIP-AAAF1467
Status: Creating

[General](#)
[Authorize Access](#)
[Answer Questions](#)

[Copy Form](#)
[Delete Form](#)

[View Form](#)
[View History](#)

[Add/Edit Form Text](#)
[Form Layout](#)

[\[Previous List\]](#)
[\[HIPAA Menu\]](#)

HIPAA Form Text

Authorization/Waiver Number	HIP-AAAF1467	Initiator	Irina Mera
Form Template	Form A: Clinical Research Authorization - Sponsored (English version)	Identifier	March 4, 2011
Date Created	03/04/2011 at 12:15	Attached to IRB protocol	not attached
You are	Irina Mera (im2119)		

GENERAL INSTRUCTIONS ?

Add Text ? ➔

Add Signature Line ? ➔

Item Text	Edit/View	Add Subtext	Delete
[Blank Line]	➔	➔	🗑
[Blank Line]	➔	➔	🗑
[Sponsor's Name]	➔		
For the purpose of the conduct of the above name study, I agree to permit Columbia University Medical Center, my doctors, and my other health care providers (together "Providers"), and [Principal Investigator] and his/her staff (together "Researchers"); to use and disclose health information about me as described below.	➔	➔	🗑
1. The health information that may be used and disclosed includes:	➔		
all information collected during the research described in the Informed Consent Form for the above-named study ("the Research"); and	➔		
health information in my medical records that is relevant to the Research.	➔		🗑
This may include medical history information that may be considered sensitive, including:	➔		🗑
2. The providers may disclose health information in my medical records to:	➔	➔	🗑
the Researchers;	➔		
the sponsor of the Research, [Sponsor's Name], and its agents and contractors (together "Sponsor"); and	➔		🗑
representatives of government agencies, review boards, and other persons who watch over the safety, effectiveness, and conduct of the research.	➔		🗑
3. The researchers may use and share my health information:	➔	➔	🗑
among themselves and with other participating researchers to conduct the Research;	➔		🗑
representatives of government agencies, review boards, and other persons who watch over the safety, effectiveness, and conduct of research; and	➔		🗑
as permitted by the Informed Consent Form.	➔		
4. The Sponsor may use and share my health information as permitted by the Informed Consent Form.	➔	➔	🗑
5. Once my health information has been disclosed to a third party (e.g., a pharmaceutical company participating in this Study), federal privacy laws may no longer protect it from further disclosure.	➔	➔	🗑
6. Please note that:	➔	➔	🗑

Each block of text or question in each form has a unique ID. This number has no significance; the order in which the lines appear in the form is set in the Form Layout section (see below). Some lines have a parent ID to which they are associated. These “children” move when their parent is moved. A parent can have zero, one or more children. (These are all single parent households).

Some lines can be edited or deleted and others cannot. Only those lines that have a trash can icon in the right hand column can be deleted (obviously). In addition, only those with a trash can icon can be edited (less obviously).

As indicated in the menu item you can add new text or you can edit existing text. The general help states:

Added items will display in a table on this page. To edit or view an existing item, click the blue button in the “Edit” column of the item. If you wish to delete the item, click on the trash can icon (if the icon is present) for that item. The template from which this form was created determines whether paragraphs or questions can be edited or deleted.

As you add or edit items you may display the form in PDF format at any time by clicking the “View Form” link on the left.

The order of the items on the page may be changed on the Form Layout page.

Again, only those items that have a trash can icon associated with them can be edited or deleted. All the other items are unchangeable and cannot be deleted.

Selecting one of the editable items brings up the text box shown in the next figure.

Figure 9. Text Edit box.

RASCAL HIPAA

Logout | Help | Human Subjects | Animal Care | Proposal Tracking | Consent Forms | **HIPAA Forms** | Haz Mats | Administration | Training Center | Conflict of Interest | My Rascal

HIP- AAAF1467
itatus: Creating

[General](#)
[Authorize Access](#)
[Answer Questions](#)
[Copy Form](#)

[View Form](#)
[View History](#)
[Add/Edit Form Text](#)
[Form Layout](#)

[\[Previous List\]](#)
[\[HIPAA Menu\]](#)

Authorization/Waiver Number	HIP-AAAF1467	Initiator	Irina Mera
Form Template	Form A: Clinical Research Authorization - Sponsored (English version)	Identifier	March 4, 2011
Date Created	03/04/2011 at 12:15	Attached to IRB protocol	not attached
You are	Irina Mera (im2119)		

HIPAA Form Text

GENERAL INSTRUCTIONS

Add Text (circled in red)

Add Signature Line

Item Text	Edit/View	Add Subtext	Delete
[Blank Line]	▶	▶	🗑️
[Blank Line]	▶	▶	🗑️
[Sponsor's Name]	▶		
For the purpose of the conduct of the above name study, I agree to permit Columbia University Medical Center, my doctors, and my other health care providers (together "Providers"), and [Principal Investigator] and his/her staff (together "Researchers"), to use and disclose health information about me as described below.	▶	▶	🗑️
1. The health information that may be used and disclosed includes:	▶		
all information collected during the research described in the Informed Consent Form for the above-named study ("the Research"); and	▶		
health information in my medical records that is relevant to the Research.	▶		🗑️
This may include medical history information that may be considered sensitive, including:	▶		🗑️
2. The providers may disclose health information in my medical records to:	▶	▶	🗑️
the Researchers;	▶		
the sponsor of the Research, [Sponsor's Name], and its agents and contractors (together "Sponsor"); and	▶		🗑️
representatives of government agencies, review boards, and other persons who watch over the safety, effectiveness, and conduct of the research.	▶		🗑️
3. The researchers may use and share my health information:	▶	▶	🗑️
among themselves and with other participating researchers to conduct the Research;	▶		🗑️
representatives of government agencies, review boards, and other persons who watch over the safety, effectiveness, and conduct of research; and	▶		🗑️
as permitted by the Informed Consent Form.	▶		



The screenshot shows a software window titled "HIPAA Form Text Add/Edit". On the left side of the window, there is a vertical blue bar. The main content area contains a text input field with the label "Item Text" positioned to its left. The text field is empty and has a vertical scrollbar on its right side. Below the text field, there are two buttons: "Reset" and "Add".

If you select Add Text from the top menu in Figure 8, you get the same text box as shown in Figure 9, however it is blank.

The RASCAL instructions are quite good but somewhat technical.

“Parent Item’s ID” – if this text or question is to be indented, bulleted and subordinate to another item, enter that item’s ID here. You can find the ID of the item to which the text is to be subordinated in the first column of the table displaying the text and questions.

“Item Text” – enter here the text as you want it to appear on the form. If this is an indented, subordinate item it will automatically be bulleted unless you begin the text with some other kind of enumerator such as “a.”, “1”)”, “1, etc. Rascal will automatically recognize the combination of any non-alphanumeric character (other than a comma or an asterisk) followed by the first space in the string as the terminator of an enumerator.

The phrase “terminator of an enumerator” could be the next Schwarzenegger movie.

Any items that you add, you can also edit or delete.

LAYOUT

The finale ordering of the text is done in the Layout menu. This is a functionality that is analogous to, but somewhat more advanced than, that found in the Layout function found in the Consent form builder (see RASCAL IRB manual).

Figure 10. HIPAA Form Layout page.

RASCAL HIPAA

IP-AAAF1467
atus: Creating

General
Authorize Access
Answer Questions
Copy Form
Delete Form
View Form
View History
Add/Edit Form Text
Form Layout
Previous List
HIPAA Menu

Authorization/Waiver Number: HIP-AAAF1467
Form Template: Form A: Clinical Research Authorization - Sponsored (English version)
Date Created: 03/04/2011 at 12:15
Initiator: Irina Mera
Identifier: March 4, 2011
Attached to IRB protocol: not attached
You are: Irina Mera (im2119)

HIPAA Form Layout

GENERAL INSTRUCTIONS

Rearrange the sections of your HIPAA Form

Sequence	Child Sequence	Question Text (displaying 200 characters)
0		[Blank Line]
0		[Blank Line]
1		For the purpose of the conduct of the above name study, I agree to permit Columbia University Medical Center, my doctors, and my other health care providers (together "Providers"), and [Principal Investigator] and his/her staff (together "Researchers"), to use and disclose health information about me as described below.
2		1. The health information that may be used and disclosed includes:
	1	all information collected during the research described in the Informed Consent Form for the above-named study ("the Research"); and
	2	health information in my medical records that is relevant to the Research.
	3	This may include medical history information that may be considered sensitive, including:
3		2. The providers may disclose health information in my medical records to:
	1	the Researchers;
	2	the sponsor of the Research, [Sponsor's Name], and its agents and contractors (together "Sponsor"); and
	3	representatives of government agencies, review boards, and other persons who watch over the safety, effectiveness, and conduct of the research.
4		3. The researchers may use and share my health information:
	1	among themselves and with other participating researchers to conduct the Research;
	2	representatives of government agencies, review boards, and other persons who watch over the safety, effectiveness, and conduct of research; and
	3	as permitted by the Informed Consent Form.
5		4. The Sponsor may use and share my health information as permitted by the Informed Consent Form.
6		5. Once my health information has been disclosed to a third party (e.g., a pharmaceutical company participating in this Study), federal privacy laws may no longer protect it from further disclosure.
7		6. Please note that:
	1	You do not have to sign this Authorization, but if you do not, you may not participate in the Research.

This is where the final ordering of form is established. Here the relationship between parent and child is more apparent. If you put a "0" in the sequence (first column) the item will not appear on the final form. (In this example, the two blank lines are not included).

Because certain elements are required (e.g., you could not delete them in the Add/Edit Text function), you cannot assign them a "0" in this functionality.

If at all possible, you should use the HIPAA templates as provided. If you are required (for example by the Sponsor) to add certain language to the HIPAA form, you will not be able to use the provided Spanish – language version of the Form. This will need to be translated as well.

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