



**Independent Review Consulting, Inc.**

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## **HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT “HIPAA”**

The issue of privacy is excellent.  
The concept of regulating it is ok  
The complexity of HIPAA is astounding.

My privacy counts  
You should guard it for me.  
HIPAA

We wish we could offer you a single solution, one grand Authorization Form.  
We can't. Information is used in so many ways out there.  
This is our offering to you.

Please remember  
your institutional committee,  
your own HIPAA expert and  
all the courses you can take.

Erica Heath, MBA, CIP  
President, IRC  
April 3, 2003



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## From IRC's View Point Our "HIPPA-TOME" 4/3/03

IRBs – at least this one – have always taken confidentiality very seriously. Some clients have alleged we have taken it too seriously. In our conceptualization, if a subject has a right to -- or an expectation of -- privacy, one of the risks of being in a study is a risk of loss of that privacy. As an IRB we have been interested in how records are stored, whether identifiers are on case report forms, what is told to the subject about confidences, and whether medical and research records are combined or separate.

The information we have to work with is from several sources:

- 1) The protocol generally has a section on confidentiality
- 2) The consent form should have a section regarding privacy.
- 3) IRC's investigator application form requests information about information handling.
- 4) When requested, we have occasionally received site policies.

These basic concepts and requirements will not lessen. We expect that our clients will soon be able to answer our questions with far more assurance than previously.

What is the position and duty of an IRB in the HIPAA world? Very little, we think. The reach of HIPAA is far broader than research. The IRBs role is small.

- HIPAA requires that a waiver of authorization be granted by an IRB or a Privacy Board.
- IRB rules require that alteration of a research consent form to include authorization information is a modification needing approval.

Beyond this, institutional IRBs are assuming duties as assigned them by the institution.

HIPAA sets the requirements for an authorization form but it does not require it to be approved by any entity. In many institutions, the Authorization forms are being generated and approved by a Forms Committee or a HIPAA Working Group or the institutional counsel.

This packet of information is intended to share our thoughts, to assist and to tell our policies. IT IS NOT AUTHORITATIVE. PLEASE DO NOT FORSAKE YOUR OWN COUNSEL.

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**HIPAA  
IRC Policy  
4/3/03**

- **HIPAA COMPLIANCE IS THE COVERED ENTITY 'S RESPONSIBILITY.**
- **AUTHORIZATIONS DO NOT REQUIRE IRB APPROVAL.**

### **Minimum Necessary Standard**

IRC has a reputation for being protective of subject privacy; we have reviewed demographics in case report forms and questioned items that were not necessary. HIPAA asks that the minimum necessary amount of data be collected and disseminated.

### **IRC wants to see HIPAA information and authorizations from sites.**

Authorization is a part of health care. Although the form may be used in a research context, it may be dictated by the site and is not necessarily an IRB issue. This is an effort to assure that sites are aware of HIPAA rules. If, for instance, they are a CE and they don't know what a privacy notice is, it is evidence of a need to get them practice related information.

New studies and sites will be asked about their HIPAA status, that is; if they are a CE, if they have a privacy notice they are using, if they are creating, using or disseminating PHI and, if yes, under what rubric.

### **For separate authorization forms: (preferred by IRC and required in California)**

When covered entities and PHI are involved, the consent form should cross-reference the authorization. A good place for this is at the end of the paragraph on privacy and/or just above the signature. If there are problems, we will *inform* the site/sponsor. We will not *approve* the authorization form.

- **Authorization is approved by an institutional authority**
  - We will review to determine presence of all elements
  - We will complete an evaluation form. If there are problems, we will *inform* the site/sponsor. We will not *approve* the authorization form.
- **Authorization is not approved by any institutional authority**
  - Applicant should complete HIPAA checklist.
  - IRC will double check for:
    - Elements
    - Plain language
    -

### **For integrated consent + authorization forms:**

- The IRB is required to review under both consent and authorization rules.
- All elements will be necessary and
- We will be firm about plain language.
- We urge setting the Authorization information apart by using a sidebar box.

### **CHARGES**

- \$250 Modification of a current consent form to integrate HIPAA language (call for multisite studies)
- \$250 Review a separate authorization form, if IRB is asked for approval. (This is the charge for a minor modification)
- \$ 50 Review a separate authorization form (for elements only) plus alteration of already approved consent document solely to cross-reference the forms.
- \$400 Waiver of authorization approval by the Privacy Board or IRB



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## HIPAA GUIDELINES

(A work in progress, as are the regulations)

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**We are all striving to implement HIPAA.** IRC is available to assist you with HIPAA compliance related to research issues. However, these new regulations could profoundly affect your business and research activity in many ways that are none of an IRB's affair. *The information in this Guide is not intended to be a complete HIPAA compliance package. If you think you need more help, there are HIPAA consultants springing up faster than Y2K consultants did a few years ago!*

### OVERVIEW AND A THOUGHT

Privacy is important to all of us in our own financial, legal and health affairs. *Private health information* should be protected. This was easier when gossip in the elevator was the core concern. With the spread of research and with new methods of sorting and sending data, it becomes more critical to corral. HIPAA is an attempt to do so from a civil rights aspect. *Identifiable private information about health that is governed by HIPAA is called Protected Health information or PHI.*

Covered entities (CEs) are responsible for PHI. Information that is de-identified is not *identifiable private information*. It was only polite to ask the patient for permission to send information outside the immediate circle of healthcare providers; now it is required for a covered entity. This is authorization. Authorization can be waived only if some of the risk to an individual's privacy is minimal. In between authorization and waiver of authorization, there are intermediate levels of access.

The effects of these new regulations will be extensive; they will drastically alter the way data is handled which, ultimately, will be with much more care. As much of the regulation is subject to interpretation, it is expected that the courts will have an impact. It is safe to say that anyone who performs research and/or collects data on human subjects should understand how HIPAA might affect their research activities.

Generally speaking, researchers need to do the following steps to deal with HIPAA:  
(See our IRC Flow Sheets, the rest of this Guide, and the regulations for help)

1. Determine if your institution is a *Covered Entity* under the privacy rule  
(If you're not a *Covered Entity*, HIPAA does not apply.)
2. Determine how *Protected Health Information* will be accessed and disseminated in your studies. (Even if you are not a Covered Entity, your access to PHI will be conditioned on HIPAA requirements.)
3. Make sure you have a Privacy Notice for patients.
4. Develop forms and processes for HIPAA compliance.
5. Educate, educate, educate.

### WHAT IS HIPAA?

HIPAA stands for the Health Insurance Portability & Accountability Act of 1996. HIPAA is also known as the Kennedy-Kassebaum Act. There are three segments.

- Administrative Simplification sets standards for electronic administrative transactions (billing and payment functions.)
- The Privacy Rule sets standards to protect a person's health information.
- The Security Standards set standards for safeguarding the confidentiality, integrity and availability of a person's health information.

For purposes of this document, we are concerned solely with the Privacy Rule.

## IMPORTANT DEFINITIONS

HIPAA has created a whole new set of research acronyms and vocabulary (as if we needed any more). New words and phrases are *italicized* in this Guide. Their definitions can be found in the rule or the HIPAA Glossary. Many concepts include subjective words. An often heard clarification is that their definition, “will be decided by the courts.”

## HIPAA PRIVACY STANDARDS:

- Limits the use and release of health information;
- Gives patients the right to access their medical and billing records
- Gives patients the right to know who accessed their health information;
- Restricts most disclosures of health information to the minimum necessary;
- Establishes new requirements for access to records by researchers
- Establishes criminal and civil penalties for improper use or disclosure.

## WHEN DOES THE PRIVACY RULE BECOME EFFECTIVE?

Compliance is required as of April 14, 2003.

## DETERMINING THE EFFECTS OF HIPAA ON YOUR RESEARCH

### IS YOUR GROUP, PRACTICE, OR INSTITUTION A *COVERED ENTITY*?

This is HIPAA’s way of saying, “Yes, the Privacy Rule applies to you, and you’d better do something about it by April 14, 2003.”

There is a useful, self-guided set of decision tools at the web site of the Centers for Medicare & Medicaid Services:

<http://www.cms.hhs.gov/hipaa/hipaa2/support/tools/decisionsupport>

The questions you need to ask are: (See the IRC HIPAA Flow Sheet)

1. Am I a *health care provider* under the definitions of the Rule? (21 CFR 160.103)
2. Do I or does my organization furnish, bill, or receive payment for *health care* in the normal course of business?
3. Do I or does my organization conduct *covered transactions*?

NOTE: If you determine that you are a *Covered Entity* under the Privacy Rule, you have a lot of work to do that isn’t any of IRC’s business. We suggest you seek HIPAA help. If you are not a *Covered Entity*, the new regulations will not apply to you, but will impact the requirements you must meet in order to obtain access to the health information held by covered entities.

### WHICH OF YOUR STUDIES WILL BE AFFECTED BY HIPAA?

If your study will be open for enrollment after April 14, 2003, and if any information collected for the study is classifiable as *Protected Health Information*, you will be affected.

Protected Health Information is any information created, received or maintained by a covered entity in which the individual is identifiable. PHI includes all medical records, billing records, and demographic information about the patient, family and household members, and employers.

The typical compliance response will be to expand (or append) the protocol descriptions of what *Protected Health Information* is used and how that *PHI* is created, transmitted, and protected, and who has access. Researchers will need to ensure that the research subject signs a HIPAA Authorization Form before they may use or disclose any Protected Health Information.

The HIPAA Authorization Form must contain very specific information. We recommend that the researcher request a copy of this form from their institution.

### DO HIPAA REQUIREMENTS APPLY TO SPECIMENS AND TISSUE SAMPLES THAT INCLUDE IDENTIFIERS?

Yes, it does apply if the samples/specimens include identifying information, and/or if a code key (link) is retained.

### DOES HIPAA OVERRIDE IRB HUMAN PROTECTION REGULATIONS?

No, HIPAA does not override human research subject IRB requirements. Each regulation is

applied independently. When HIPAA and human subject protection regulations apply, both sets of requirements (45 CFR 160-164 & IRB Rules) must be followed.

### DOES THE PRIVACY RULE OR STATE LAW TAKE PRECEDENCE?

The more restrictive rules should be followed. Several states have much stricter standards than HIPAA. (California: a separate authorization form is required)

## THE BASICS – GETTING OR GIVING INFORMATION

### HOW CAN RESEARCHERS ACCESS PATIENT INFORMATION UNDER HIPAA?

Researchers who want access to *Protected Health Information* must request the information from and meet the requirements of the *Covered Entity* responsible for the information. The Privacy Rule allows information to be released to you – or by you – based on any one of the following:

- ⇒ *De-identification* of a person's health information,
- ⇒ A patient *authorization*,
- ⇒ Preparatory work for research purposes,
- ⇒ Use of a *Limited Data Set*,
- ⇒ Decedents,
- ⇒ An approved *waiver* of patient *authorization*.

**NOTE: Subjects who signed a consent form before April 14, 2003 are exempt from having to provide any of the above authorizations, unless re-consent is required.**

Researchers obtaining information from other health care providers should expect them to be applying HIPAA as well.

#### 1. Accessing Information through De-identification ([Section 164.514](#))

To state the obvious; de-identified information is not identifiable private information. This category is listed first as it deals with information that is not PHI.

A *Covered Entity* can release de-identified health information without patient *authorization*. *Protected Health Information* can be de-identified through deletion of 18 specific identifiers or through certification by a statistician. Information in any medium that contains any one or more of the following 18 identifiers:

- |   |                                      |   |
|---|--------------------------------------|---|
| 1. Names  | 4. Telephone numbers                 | 10. Account numbers   |
| 2. All geographic subdivisions smaller than a state   | 5. Fax numbers                       | 11. Certificate/license numbers   |
| 3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death, etc. | 6. Electronic mail addresses (email) | 12. Vehicle identifiers and serial numbers, including license plate numbers |
|   | 7. Social security numbers           | 13. Device identifiers and serial numbers                                   |
|   | 8. Medical record numbers            |   |
|   | 9. Health plan beneficiary numbers   |   |

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14. Web Universal Resource Locators (URLs)	16. Biometric identifiers, including finger and voice prints	18. Any other unique identifying number, characteristic, or code
15. Internet Protocol (IP) address numbers	17. Full face photographic images and any comparable images	or Anything else-alone or in combination - that might reasonably allow identification

Can you keep a code? Yes. Keeping a code will not render the data identified. The code number used should not allow re-identification except within the covered entity. (An example might include tissue sent to a repository with a sequential number and no identifiers.)

**BEWARE:** Although data may be de-identified for HIPAA purposes, research with the data may still need IRB review. The IRB (Common Rule) definition is that the link is completely, totally, and forever anonymized. (<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/decisioncharts.htm>)

## 2. Accessing Information through Patient *Authorization* (Section 164.508)

A *Covered Entity* may use or disclose *Protected Health Information* for research purposes with a valid *authorization*. A valid *authorization* must have the following elements:

- |   |  |  |
|---|--|--|
| <ul style="list-style-type: none"><li>• A description that identifies the information in a specific and meaningful fashion;</li><li>• The name of the person(s) authorized to make the requested use or disclosure;</li><li>• The name of the person(s) to whom the <i>Covered Entity</i> may make the requested use or disclosure;</li><li>• An expiration date / expiration event that relates to the purpose of the use or disclosure;</li></ul> | <ul style="list-style-type: none"><li>• A statement of the individual's right to revoke the <i>authorization</i> in writing and the effect of revocation, together with a description of how the individual may revoke the <i>authorization</i>;</li><li>• A statement that information used may be subject to re-disclosure by the recipient and no longer be protected by this rule;</li><li>• Signature of the individual and date;</li></ul> | <ul style="list-style-type: none"><li>• If the <i>authorization</i> is signed by a personal representative of the individual, a description of such representative's authority to act for the individual;</li><li>• The <i>authorization</i> must be written in plain language</li></ul> <p>Several states have additional requirements to consider.</p> |
|---|--|--|

Authorization documents can stand-alone or can be combined with an IRB approved research consent form. Combination is allowed IF treatment is involved. If treatment is not involved, a separate HIPAA Authorization Form would be required.

Authorization can be revoked by the individual. Information that has been relied upon in analysis can be retained, but can only be as necessary to maintain the integrity of the research study. For example, PHI may be used to account for the patient's withdrawal from the study, to incorporate information into a FDA marketing application, to conduct scientific misconduct investigations, or to report adverse events.

## 3. Accessing Information for Preparatory Work for Research (Section 164.512)

At a site qualification visit, the site may claim plenty of potential subjects and the sponsor may wish to double-check this claim by looking at some information. For preparatory work, the researcher must submit a request to the *Covered Entity* documenting that:

- reviewing *Protected Health Information* is necessary to prepare a research protocol;
- information will not be removed by the researcher during the review;
- information for which access is sought is necessary for research purposes.

The *Covered Entity* can determine the appropriate mechanism for reviewing the request. This is a records policy decision for each *Covered Entity* to make. The request for preparatory work does not require *Privacy Board* approval, and probably not IRB approval, either.

#### 4. Accessing PHI Through a Limited Data Set (Section 164.512)

Although this is a more complicated option, it may be useful. We strongly suggest you consult a HIPAA expert before you commit to using this method. Basically, it means the following:

- A *Covered Entity* may use or disclose a “*Limited Data Set*” of *Protected Health Information* without an *authorization* from an individual, for purposes of research, public health, or health care operations, if they enter into a *Data Use Agreement* with the recipient of the data (e.g. the sponsor or the researcher).
- A *Limited Data Set* is *Protected Health Information* that excludes 16 specified direct identifiers of the individual or of relatives, employers, or household members of the individual.
- A *Data Use Agreement* specifies for what the *Protected Health Information* will be used, and who is permitted to access it. It also limits further disclosure or use, and requires the recipient of the *Protected Health Information* to enter into a similar agreement with agents or subcontractors.

#### 5. Accessing Information of Decedents for Research (Section 164.512)

A researcher may also review *Protected Health Information* from deceased persons. For this, the researcher must submit to the *Covered Entity* a request stating that:

- the review is for research purposes;
- information is about decedents only;
- information for which access is sought is necessary for research purposes.

The researcher may also have to provide documentation that the person is deceased.

Remember that HIPAA and IRB requirements are different. Even if one can access decedent information, IRB review may be required.

#### 6. Accessing Information Through Authorization Waiver (Section 164.512 (i) (2) (ii) (A, B, & C))

A *Covered Entity* may use or disclose *Protected Health Information* without written *authorization* and without an opportunity for the person to agree or object – but not easily. Waiving authorization is the opposite end of the spectrum from authorization; it should not be easy to do and it demands added obligations. Disclosures must be tracked and records maintained for six years. (Note this requirement applies regardless of the method of authorization.) Waiver is possible if an IRB or a Privacy Board finds that:

- a. The use or disclosure involves no more than a minimal risk to the privacy of individuals based on:
  - 1) an adequate plan to protect confidentiality
  - 2) a plan to destroy identifiers, and
  - 3) assurances that *Protected Health Information* will not be reused, and
- b. The research could not practicably be conducted without the *waiver* or alteration, and
- c. The research could not practicably be conducted without access to and use of the *Protected Health Information*.

A *Privacy Board* has members with varying backgrounds including one non-affiliated member and no member with a conflict of interest. Either a Privacy Board or an IRB may approve the waiver.

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## CLOSING COMMENTS

We hope that this guide has been helpful. As always, it is best to read the regulations for yourself, and decide how best to achieve compliance. At IRC, we are ready to help you with all aspects of the Privacy Rule *as it applies to* IRB review and jurisdiction. However, the new regulations are sweeping in scope, and will profoundly affect the business operations of any organization that qualifies as a *Covered Entity*.

Once you determine if you are in a Covered Entity and if you are working with Protected Health Information, the fun work will begin.

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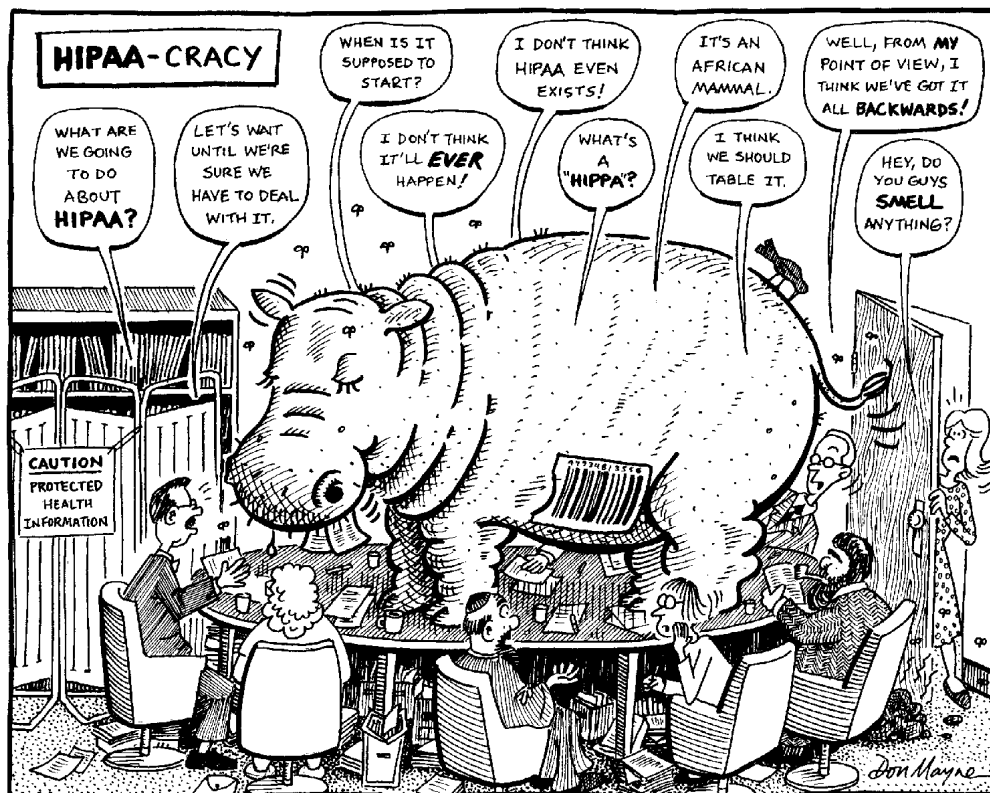
## REFERENCES

DHHS Office of Civil Rights <http://dhhs.gov/ocr/>

As OCR is responsible for HIPAA, this site has the most up to date information. Other sites have more explanatory information

Final Privacy Rule (<http://aspe.hhs.gov/admsimp/final/PvcTxt01.htm>)

Search for HIPAA and find a multitude of sites. Many courses are offered at conferences, through medical groups, and on the web.





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## HIPAA GLOSSARY

(adapted from the HIPAA Advisory web site, and other sources)

### Authorization:

See HIPAA Authorization Form.

### Business Associate:

A person or organization that uses protected health information to perform a function or activity on behalf of a covered entity, but is not part of the covered entity's workforce. A business associate can also be a covered entity in its own right. Also see Part II, 45 CFR 160.103.

### Code Set:

Under HIPAA, this is any set of codes used to encode data elements, such as tables of terms, medical concepts, medical diagnostic codes, or medical procedure codes. This includes both the codes and their descriptions. Also see Part II, 45 CFR 162.103. HIPAA has standardized billing codes used in the administrative transactions.

### Covered Entity (CE):

Under HIPAA, this is a health plan, a health care clearinghouse, or a health care provider who transmits any health information in electronic form in connection with a HIPAA transaction. Also see Part II, 45 CFR 160.103.

### Covered Function:

Functions that make an entity a health plan, a health care provider, or a health care clearinghouse. Also see Part II, 45 CFR 164.501.

### Covered Transaction:

Transactions for which the Secretary has adopted standards. The definitions are very detailed, and can be found at 45 CFR, Part 162. Most common is a health care claim or equivalent encounter information from a health care provider to a health care plan, for health care.

### Data Use Agreement:

A written agreement for research, public health, or health care operations between two entities that share Protected Health Information, specifying for what it will be used, and who will be permitted to access it. Further disclosure or use must be limited by the terms of the Agreement. This agreement must establish the permitted uses and disclosures of the information, establish who is permitted to use or receive the limited data set; and provide that the limited data set recipient will:

- Not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law;
- Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the data use agreement;
- Report to the covered entity any use or disclosure of the information not provided for by its data use agreement of which it becomes aware;
- Ensure that any agents, including a subcontractor, to whom it provides the limited data set agrees to the same restrictions and conditions that apply to the limited data set recipient with respect to such information; and
- Not identify the information or contact the individuals.
- See Part II, 45 CFR 164.514.e.4

### De-Identification:

Removal of all 18 elements that make data individually identifiable (see Individually Identifiable Health Information). (De-linked under the Common Rule is quite different)

### Disclosure:

Release or divulgence of information by an entity to persons or organizations outside of that entity. Also see Part II, 45 CFR 164.501.

### Electronic Form, or Electronic Transaction:

Using electronic media, as described in 45 CFR 162.103 to transmit covered information. This includes Internet, Extranet, Telephone lines (e.g. facsimile), private networks, and electronic

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media moved physically from one location to another (e.g. magnetic tape, disk, CD, etc.).

### Health Care

Care, services, or supplies related to the health of an individual. See also 45 CFR 160.103

### Health Care Provider:

Any person, business, or agency that furnishes, or bills or receives payment for health care in the normal course of business. See also Part II, 45 CFR 160.103.

### Health Insurance Portability and Accountability Act of 1996 (HIPAA):

HIPAA stands for the Health Insurance Portability & Accountability Act of 1996. HIPAA is known as the Kennedy-Kassebaum Bill, the Kassebaum-Kennedy Bill, K2, or Public Law 104-191. There are two major segments:

The Privacy Rule has been published and it does affect the research community. It sets up standards to protect a person's health information.

The Security Standards was released in February 2003 and will take effect April 2005.

### HIPAA Authorization Form:

An entity may not use or disclose protected health information without a valid authorization. A valid authorization may be part of the consent form, or a separate document presented as an attachment to the consent form. A valid authorization must have the following elements:

1. A description that identifies the information in a specific and meaningful fashion;
2. The name of the person(s) authorized to make the requested use or disclosure;
3. The name of the person(s) to whom the covered entity may make the requested use or disclosure;
4. An expiration date / expiration event that relates to the purpose of the use or disclosure;
5. A statement of the individual's right to revoke the authorization in writing and the exceptions to the right to revoke, together with a description of how the individual may revoke the authorization;
6. A statement that information used may be subject to re-disclosure by the recipient and no longer be protected by this rule;
7. Signature of the individual and date;
8. If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual;
9. The authorization must be written in plain language.

### Individually Identifiable Health Information:

Information in any medium that contains any one or more of the following 18 identifiers:

- |   |   |  |
|---|---|--|
| 1. Names  | 7. Social security numbers  | 15. Internet Protocol (IP) address numbers                       |
| 2. All geographic subdivisions smaller than a state   | 8. Medical record numbers   | 16. Biometric identifiers, including finger and voice prints     |
| 3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death, etc. | 9. Health plan beneficiary numbers  | 17. Full face photographic images and any comparable images      |
| 4. Telephone numbers  | 10. Account numbers   | 18. Any other unique identifying number, characteristic, or code |
| 5. Fax numbers  | 11. Certificate/license numbers   | or Anything else that might reasonably provide identification    |
| 6. Electronic mail addresses (email)  | 12. Vehicle identifiers and serial numbers, including license plate numbers |  |
|   | 13. Device identifiers and serial numbers                                   |  |
|   | 14. Web Universal Resource Locators (URLs)                                  |  |

### Limited Data Set:

A covered entity may use or disclose a "limited data set" without an authorization, for purposes of research, public health, or health

care operations, if they enter into a data use agreement with the recipient of the data. A limited data set is Protected Health Information that excludes 16 direct identifiers of the

individual or relatives, employers, or household members of the individual.

**Minimum Scope of Disclosure (aka Minimum Use Disclosure):**

The principle that, to the extent practical, individually identifiable health information should only be disclosed to the extent needed to support the purpose of the disclosure.

**Privacy Board:**

A board that considers application for a waiver of patient authorization for research purposes. Like an IRB, Privacy Board has members with varying backgrounds including one non-affiliated member and no member with a conflict of interest. Either an IRB or a Privacy Board may issue a waiver of authorization for research.

**Privacy Notice:**

Notice given to a patient no later than the first day of service concerning the uses and disclosures of protected health information that may be made by the covered entity and of the individual's rights and the covered entity's legal duties with respect to protected health information. This is not a document that requires review by an IRB or a Privacy Board, but all covered entities should have a Privacy Notice, and know how to use it. (See 45 CFR 160.520 for more information.)

**Protected Health Information (PHI):**

Individually identifiable health information, including demographic information, created or received by a Covered Entity in any medium, and relating to:

- past, present, or future physical or mental health or condition
- provision of health care
- past, present, or future payment for health care
- See also Part II, 45 CFR 164.501.

**Research:**

Research is best defined in 45 CFR 46 as a systematic investigation designed to yield generalizable knowledge.

There is not much information in the Privacy Rule about how research activity relates to the regulations.

See Part II, 45 CFR 164.501 for the official regulation, but OCR's December 2002 Guidance is more helpful [www.hhs.gov/ocr/hipaa/privacy.html] IRC can be even more helpful in interpreting how your research situation may be affected by HIPAA. Give us a call!

**TPO:**

Treatment, Payment, and Operations. Covered Entities may use or disclose Protected Health Information without the patient's authorization for treatment, payment or healthcare operations purposes.

**Waiver of Authorization:**

A waiver of the requirement to obtain patient authorization prior to the use or disclosure of Protected Health Information for research purposes. A waiver may be granted by either a Privacy Board or an IRB. There are 3 criteria that must be met for a waiver to be granted:

1. The use or disclosure of Protected Health Information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
  - a. An adequate plan exists to protect the identifiers from improper use and disclosure;
  - b. An adequate plan exists to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law, and
  - c. Adequate written assurances exist that the Protected Health Information will not be used or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of Protected Health Information would be permitted by the regulations.
2. The research could not practically be conducted without the waiver or alteration; and
3. The research could not practically be conducted without access to and use of the Protected Health Information.

[See also 45 CFR 164.512(i)(2)(ii)]



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**HIPAA  
Compliance Information**

Form 4-41A (4/3/03)

IRC is not a Covered Entity and is not a consultant to you on HIPAA matters. However, your knowledge of HIPAA and the manner in which your site implements it impacts on your research duties and an Authorization, if used, is a part of the consent process. IRC requires submission of form 4-15 to assess the extent of compliance. A glossary and guidance are available on our web site.

Study Title	
Sponsor	
PI	
IRC ID Number	

**A. IS THE SITE A COVERED ENTITY?**

<input type="checkbox"/> Yes <input type="checkbox"/> No	If no, sign here and submit. If yes, continue
<input type="checkbox"/> No idea	

**B. ARE YOU COLLECTING, CREATING OR DISTRIBUTING PHI?**

<input type="checkbox"/> Yes <input type="checkbox"/> No	If no, sign here and submit. If yes, continue
<input type="checkbox"/> No idea	

**C. IS INFORMATION BEING OBTAINED FROM AN EXTERNAL SITE?**

<input type="checkbox"/> Yes <input type="checkbox"/> No	THE SITE IS RESPONSIBLE FOR RELEASE OF INFORMATION TO YOU.. The site may or should ask for the authorization of their patient.
<input type="checkbox"/> Perhaps	

**D. IS PHI BEING SENT TO OTHERS? WHY? HOW ARE HIPAA DISCLOSURE REQUIREMENTS BEING MET? (One study may use several avenues.)**

	Disclosure to: (Don't forget the consultants, CRO, DSMB, etc.)	Purpose	HIPAA compliance method (see code below table)						
			A	B	C	D	E	F	G
1	FDA	Audit,	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	IRB	Audit, AE reports,	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	Sponsor:	Audit,	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

<b>Compliance Method Code</b>	A. De-identified	D. Limited data set form	G. Waiver of Authorization
	B. Preparatory to research	E. Authorization on consent	
	C. Decedents	F. Separate Authorization	

**C. If De-Identified (A) is checked,**

Is there a code? <input type="checkbox"/> Yes <input type="checkbox"/> No	How is the code protected?  When are the 18 identifiers removed?
--	--

**D. If Preparatory to Research (B) is checked,**

<input type="checkbox"/> Yes <input type="checkbox"/> No	Did the P.I. submit a request to the C.E? Date:
--	---

**E. If Decedents (C) is checked,**

<input type="checkbox"/> Yes <input type="checkbox"/> No	Did the P.I. submit a request to the C.E? Date:
--	---

**F. If Limited Data Set (D) is checked,**

<input type="checkbox"/> Yes <input type="checkbox"/> No	Is there a Data Use Agreement? What data fields?
--	---

**G. If Authorization integrated within the Consent Form (E) is checked,**

Is the language <input type="checkbox"/> Modifiable <input type="checkbox"/> Untouchable	(NOTE: This is not an option within California.) Attach the authorization element checklist and an annotated Authorization/ Consent form Where did you get the language used?
--	--

**H. If Authorization on a Separate Form (F) is checked,**

Is the language <input type="checkbox"/> Modifiable <input type="checkbox"/> Untouchable	Attach the authorization element checklist and an annotated Authorization form Where did you get the language used?
--	--

**I. Waiver of authorization (G) is checked,**

	Call first.
--	-------------

**APPLICANT SIGATURES**

<ul style="list-style-type: none"><li>▪ I certify that this information is complete and is correct.</li><li>▪ I accept ultimate responsibility for the release of any information.</li><li>▪ I acknowledge that IRC's obligation is solely to review waivers of authorization. Authorization forms are generated by the Covered Entity and will be IRB reviewed for completeness and plain language but will not be granted "approval."</li><li>▪ I should seek expert HIPAA help</li></ul> Investigator _____ Printed _____ Date _____
--



**Independent Review Consulting, Inc.**

Phone: 415-485-0717 www.irb-irc.com Fax: 415-485-0328

**HIPAA  
Authorization Form Checklist**

Form 4-41B (3/10/03)

**This is the form IRC reviewers will use. You can help them by filling it in yourself.**

IRC will not "approve" an authorization form as it is the responsibility of the Covered Entity. However, as authorization must be integrated into the consent process, we will review to assure (a) all of the elements are clearly present and (b) are in plain language.

Study Title	
IRC Client	
PI name	

**A. Where did the authorization language originate? (eg., sponsor by name, CRO, site)**

--

**B. State(s) involved. (A few states have additional requirements.)**

--

**HIPAA AUTHORIZATION CHECKLIST**

All of this should be in PLAIN language

ELEMENTS	45 CFR 164.508(c)	Para- graph	Absent	
			<input type="checkbox"/>	OK, but ...
Description of information	(1)(i)		<input type="checkbox"/>	
Discloser/user identified	(1)(ii)		<input type="checkbox"/>	
Recipient (s) identified	(1)(iii)		<input type="checkbox"/>	
Purpose(s) of use/disclosure stated	(1)(iv)		<input type="checkbox"/>	
Expiration date or event or Statement there is no expiration	(1)(v)		<input type="checkbox"/>	
Signature	(1)(vi)		<input type="checkbox"/>	
If LAR –authority described	(1)(vi)		<input type="checkbox"/>	
Date	(1)(vi)		<input type="checkbox"/>	
Copy to individual	(4)		<input type="checkbox"/>	
<b>STATEMENTS</b>				
Can revoke authorization In writing	(2)(i) (2)(i)		<input type="checkbox"/>	
Revocation exceptions or ref to Privacy notice	(2)(i)(A)		<input type="checkbox"/>	
Consequence of refusal (can't be in study is ok)	(2)(ii)(A) (2)(ii)(B)		<input type="checkbox"/>	
Potential for re disclosure by recipient	(2)(iii)		<input type="checkbox"/>	

Site check \_\_\_\_\_ IRC Check \_\_\_\_\_

Date \_\_\_\_\_ Date \_\_\_\_\_



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**HIPAA  
Request – Waiver of Authorization**

Form 4-41C (4/3/03)

IRC is not a Covered Entity and is not a consultant to you on HIPAA matters. However, your knowledge of HIPAA and the manner in which your site implements it impacts on your research duties and an Authorization, if used, is a part of the consent process. IRC requires submission of form 4-15 to assess the extent of compliance. A glossary and guidance are available on our web site.

Title	
Client	
PI	

	IRC or PB REVIEWER OK or comment
<b>A. Why is the PHI needed?</b>	
<b>B. What information is being disseminated? Is it the minimum necessary?</b>	
<b>C. Why is the PHI needed for this study?</b>	
<b>D. Describe the plan to protect identifiers?</b>	
<b>E. Describe the plan to destroy identifiers? Is it as early as possible?</b>	
<b>F. How do you assure the PHI will not be re-used by the recipient?</b>	
<b>G. What other HIPAA duties do you have to the patients if the waiver</b>	
<b>H. Why should this PHI use be considered no more than a minimal risk of harm to privacy?</b>	
<b>I. Are you also requesting a separate waiver of consent to be in research?</b>	
<b>J. SIGNATURE</b> <ul style="list-style-type: none"> <li>▪ I certify that this information is complete and is correct.</li> <li>▪ I accept ultimate responsibility for the release of any information.</li> </ul> Investigator _____ Printed _____ Date _____	<b>REVIEWER</b> Signature/Date

**COVERED ENTITY LETTERHEAD**

**NOTE:** This satisfies all the requirements in 164.508(c). This may be modified & used as a separate, one-page HIPAA Authorization Form or it may be inserted (in a sidebar) into the consent document.

**RESEARCH CONSENT FORM ADDENDUM  
DISCLOSURE OF YOUR PERSONAL HEALTH INFORMATION**

You are being invited to be in a research study. As part of that study lots of data will be generated. Some of it will be your personal health information. If you don't authorize use or disclosure of your health information, you cannot participate in the study as it would not contribute to the outcome.

1. **WHO** can give out the information?(1)(ii)  
 \_\_\_\_\_: (name the entity that may disclose, and list all types of information that apply)
2. **WHAT** information may be disclosed? (1)(i)
  - Study forms and surveys that you fill out
  - Results of lab tests done for the study
  - Medical history information collected for the study
  - Parts of your doctor's medical records about you, including \_\_\_\_\_.
  - Contact information (so the sponsor can mail you your payment).
  - *Other study information, specify so that the subject knows what the information is.*
3. **TO WHOM and WHY** will the information above will be disclosed (name each entity)? (Make a table or a list)

(1)(iii)	(1)(iv)
Sponsor: XYZ Corp	research and product development purposes
CRO ENABELERS	a research group helping the sponsor to analyze study data

- The sponsor, \_\_\_\_\_ (for research and product development purposes)
- \_\_\_\_\_, (a research group helping the sponsor to analyze study data)
- \_\_\_\_\_, (the laboratory that will process specimens for this study)

- The U.S. Food and Drug Administration (FDA), to audit.
- The Institutional Review Board (IRB) responsible for oversight of this research are entitled to inspect the above information.
- (other)

Your personal health information may no longer be protected by the Privacy Rule if any of these groups re-disclose it to somebody else. (2)(iii) (There could be other rules they must follow, however.)

4. **REVOCAATION:** You may cancel this authorization at any time, by notifying the following person in writing: (2)(i)  
 Name of Person  
 Address  
 City, State, Zip

If you cancel this authorization, your health information collected during the study will only be used to make administrative or safety reports required of us. You will also have to be withdrawn from the study. (2)(i)(A)

5. **EXPIRATION:** This authorization will expire automatically after (event) or (date). (v)

6. **REFUSAL:** If you decline to sign *this* authorization, it will not affect regular, non-research treatment by your doctor, payment from your insurance, enrollment in any health plan, or eligibility for their benefits. However, you cannot participate in the study if you do not sign. (2)(ii)(A)

**IRC Sample #1**

7. Access to Information: You may inspect and get a copy of the information disclosed under this Authorization.

Or You are agreeing that you will give up your right to view or obtain the information disclosed under this Authorization until (event, eg., breaking the blind, or date).

8. Compensation: The cost of understanding the privacy rules and preparing forms and records is hemongeous. (Black humor, Insert truthful disclosure. Aren't you glad you read to the end?) The (sponsor?) will compensate the (CE) per record which will be a teensy portion of our costs.

(vi)	Subject Signature	Investigator/Coordinator Signature
(4)	I am authorizing use of my health information in the way it is described above. After we sign this, I will get a copy	We will allow this subject's information to be used only as described above. After we sign this, we will keep the original.
Signature		
Printed name		
Date/Time		

<b>COVERED ENTITY LETTERHEAD</b>
----------------------------------

This sample illustrates how some of the elements may be distributed into other sections. If used, please produce a version with lines numbered so assist reviewers.

**CONSENT TO BE A RESEARCH SUBJECT and  
AUTHORIZATION FOR USE OF INFORMATION  
A Follow-up Study**

<b>Purpose</b>	The people in charge and making disclosures at the site can be inserted here.
<b>Procedures</b>	The kinds of information collected should be clear in this section.
<b>Risks</b>	<p><u>Physical:</u> There is no risk of physical harm from the study procedures.</p> <p><u>Privacy:</u> (Standard IRB type risk info) There could be family issues if your relatives learn about your condition.</p> <p><u>Disclosure Authorization:</u> When you consented to be in the first study, you also signed an Authorization form. This authorization is for the follow-up study</p> <p>You are being asked to authorize disclosure of your health information.</p> <ul style="list-style-type: none"> <li>* The Phone Follow-up Corp needs your name in order to call you and only you,</li> <li>* The FDA and the IRB (impartial board reviewing the study) to audit the study.</li> <li>* CAPs Inc, the sponsor needs information to analyze the results.</li> </ul> <p>The federal privacy rules don't control disclosure by the groups who receive the information though they may be controlled by other rules.</p>
<b>Benefits</b>	
<b>Alternatives</b>	
<b>Questions</b>	
<b>Money</b>	Regular IRB info and info about compensating the site for the cost of the access.
<b>Rights</b>	You can refuse the authorization. If you do you will not be called and it won't alter your current treatment. If you agree but want to revoke the authorization later, please write whomever Inc at the address above.

If you agree to participate in the follow-up and if you authorize use of your Protected Health Information, and if your questions have been answered, we will both sign the form. I will give you a copy to keep and to refer to as needed.

	Subject	Coordinator
Signature		
Printed Name		
Date/Time		

**COVERED ENTITY LETTERHEAD**

**CONSENT TO BE A RESEARCH SUBJECT**

**A Novel Widget Device – Does it work?**

**PART I - INFORMATION ABOUT BEING IN A STUDY**

Being in a study is different from being a patient. As a patient, the doctor’s focus is on you. As a subject, the investigator must also follow the rules of the study. Those rules and your individual needs may come into conflict. In the event of a conflict, the study doctor’s first responsibility is for your safety and welfare.

This consent form describes the research study and your role as a participant. Please read this form carefully. Do not hesitate to ask anything about the information provided; it should stimulate your questions. The doctor or nurse will describe the study and answer your questions.

**PART 2 – INFORMATION ABOUT THIS STUDY**

**1 Purpose**

**2 Procedures**

**3 Risks**

- A. *Physical risk of harm*
- B. *Economic risk*
- C. *Risks to your privacy*

Your identity will be maintained as confidentially as is possible within the limits of the law. No scientific reports by the investigator or the company will use any identities.

Pictures (side view with your eyes masked) will be taken which may be published in a later report. No identifiable pictures will be published without specific consent from you.

**AUTHORIZATION FOR USE OF INFORMATION**

Federal privacy rules require your authorization before your private health information can be given to anyone. Part of thinking about consenting to be in this study is considering an authorization.

FROM: Dr. Chapeau will gather and send information and may allow inspectors to see your file. (1)(ii)

ABOUT: The information is about you and your condition. (1)(i)

FORMAT: Codes will be used on everything leaving the office. Despite this, there might be enough information (e.g. a birth date) to identify you if someone really wanted. The key to the code will be kept at this office.

WHY: Information is needed to do the study. Studies are monitored and audited to make sure they are honest and accurate. (1)(iv)

TO WHOM: The receiving groups are: (1)(iii)

- \* the U.S. Food and Drug Administration and perhaps its sister agencies in other countries,
- \* the sponsoring company, Caps, Inc,
- \* the people conducting the study, CRO name
- \* the impartial review board that reviewed this study.

The federal privacy protections do not extend to disclosure by the groups who receive the information but they may be controlled by other rules, contracts or promises. (2)(iii)

YOUR RIGHTS: You have the right to refuse to authorize this use of information.

(2)(ii)(A) If you refuse, you cannot participate in the study since the data would not be usable.

You have the right to revoke your authorization. (2)(i) The request should be in writing to Dr. Chapeau who will assist you. This authorization expires (1)(v) when your data is used in the data analysis complete.

AGREEING - OR NOT: When you sign this consent document, you are also agreeing to this authorization.

**CAVEAT: This sample demonstrates use of plain language. IT MAY NOT satisfy everything needed for your study. Consult your HIPAA expert or counsel.**

### **5. Potential for Benefit**

### **6 Alternatives you might consider**

### **7. Where can you ask questions**

### **8 Your rights and those of the study**

#### **staff:**

Both you and the investigator have some rights.

### **Subject rights:**

- Participation should be voluntary. You should not feel compelled to agree.
- You should be told about the study and your questions should be answered to your satisfaction. You should have all the information you wish. Keep asking questions.
- If you refuse, there should be no penalty
- If you agree and wish to withdraw, you may. You should tell the investigator in case there is any safety issue.

In California, an Experimental Subjects Bill of Rights should be attached.

You should receive a copy of this form signed by both of us. (4)

### **Investigator rights:**

- It is the investigator's right to accept or not accept participants. Occasionally studies must be stopped or individuals dropped from a study. Investigators can do this.

## **PART 3 – GIVING CONSENT AND INFORMATION AUTHORIZATION**

### **THE SUBJECT**

I will be receiving three forms:

- The research consent form
- This authorization form
- The California Experimental Subjects Bill of Rights (if in California)

I have read this form and discussed it with the person who will co-sign it

I will receive a copy of all forms after I and the co-signer have both signed

I have had a chance to ask questions.

I can refuse now or withdraw later.

I authorize use and disclosure of my individually identifiable health information.

I agree to participate.

### **SIGNATURES(4) and (vi)**



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**HIPAA FLOW SHEET #1**  
**(to see if you need HIPAA help)**

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**NOTE: This is intended as a GUIDE only. It is not to be relied upon for determination of HIPAA-related liability.**

**①**  
**Are you a Covered Entity?**  
(See flow sheet #2)

**YES**



**③**  
**Is your current study with IRC still open to enrollment as of April 14, 2003?**

**YES**



**④**  
**Is any information collected for the study classifiable as PHI?**

**YES**



***Congratulations! Your work is to be HIPAA compliant. Read all you can and seek help.***

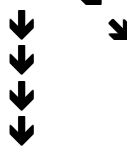
**②**  
**Do you receive PHI from any Covered Entity?**

**NO →**

**NO →**

*Thank your lucky stars, and STOP at this point.*

**YES**



*You will likely need to show the CE you are authorized to receive PHI. Although unlikely, you may be a "Business Associate" under the new privacy laws, and are strongly advised to seek more information from a HIPAA consultant.*

**NO →**

*You probably do not need IRB or Privacy Board review of HIPAA-related issues for this study. However, you are strongly advised to determine what your present or future obligations might be for other studies under the new privacy laws.*

**NO →**

*Are you sure? PHI is defined as "individually identifiable health information, created or received by a Covered Entity in any medium, and relating to:*

- past, present, or future physical or mental health or condition*
- provision of health care*
- past, present, or future payment for health care*

*(See the HIPAA Glossary for more information on what makes information identifiable)*