

Developing Language to Communicate Privacy and Confidentiality Protections to Potential Clinical Trial Subjects: Meshing Requirements under Six Applicable Regulations, Laws, Guidelines and Funding Policies

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Abstract: *Clinical trials must address a number of laws, regulations, and other sources of requirements when communicating privacy and confidentiality protections to potential participants. This article outlines relevant requirements from Common Rule regulations, Food and Drug Administration regulations, Health Insurance Portability and Accountability Act regulations, International Council for Harmonisation guidelines, the Confidentiality of Substance Use Disorder Patient Records statute, and Certificates of Confidentiality provisions under the 21st Century Cures Act. A consent form template is presented as one example of language that incorporates all of these requirements in an integrated manner that addresses some of the tensions among the various requirements.*

Keywords: *Informed Consent, Confidentiality, Privacy, Common Rule, Certificate of Confidentiality, HIPAA*

Introduction

An effective process for satisfying the ethical obligation to obtain informed consent for participation in clinical research requires that potential subjects be informed about the consequences of agreeing to be part of the research (Lentz, Kennett, Perlmutter, & Forrest, 2016). Consent processes and forms must include a description of privacy and confidentiality protections and need to disclose the possibility that private information collected for the research

will become known outside the research context. The confidentiality section of consent forms generally must adhere to requirements from at least six different sources: from the Federal Policy for the Protection of Human Subjects (“Common Rule” [HHS, 2005; 2017]; including changes with a general compliance date of January 21, 2019), from the Food and Drug Administration (“FDA”) regulations for the Protection of Human Subjects (FDA, 1981), from the International Council for Harmonisation (“ICH” [ICH, 1996, 2016]), from regulations under the Health Insurance Portability and Accountability Act (“HIPAA” [HHS 2000a, 2000b]), from regulations concerning Confidentiality of Substance Use Disorder Patient Records (“Part 2” [HHS, 2018a]), and from the 21st Century Cures Act (“Cures Act” [Cures Act, 2016]) and associated National Institutes of Health (“NIH”) funding policy on Certificates of Confidentiality (NIH, 2017a). In addition, many states have laws and regulations concerning the privacy or confidentiality of specific types of health information (Mello, Adler-Milstein, Ding, & Savage, 2018).

The precipitating event for addressing the harmonization of the confidentiality requirements was NIH’s implementation of the Cures Act requirement to provide Certificates of Confidentiality for all NIH funded research (NIH, 2017b). The language suggested by NIH for consent forms (2017c) has a Flesch-Kincaid Grade Level score of 19 (post-graduate level; Wolf & Beskow, 2018), and is presented in isolation, without guidance or a model for integration with other privacy or confidentiality requirements.

At Boston Medical Center (“BMC”) and Boston University (“BU”) Medical Campus, which share a Human Research Protection Program (“HRPP”), our previous consent forms addressed each requirement in a separate section. In considering how to incorporate the Cures Act language much more frequently, some examples were found of templates that combine the Common Rule and Cures Act language (NIH, 2018) or the Common Rule and HIPAA language (Boston Children’s Hospital IRB, 2018), or that simplify the Cures Act language (Wolf & Beskow, 2018). However, none that we found integrated the presentation of confidentiality and privacy requirements in a manner that reduced redundancy and addressed inconsistencies among the requirements.

An overall requirement for consent forms is that they are “in language understandable to the subject or legally authorized representative” (HHS, 2005, §46.116; HHS, 2018b, §46.116[a] [3]), “written in plain language” (HHS, 2000b, §164.508[c][3]), “and organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject’s or legally authorized representative’s understanding of the reasons why one might or might not want to participate” (HHS, 2018b, §46.116[a][5][ii]). We felt that simply adding Certificate of Confidentiality language to our existing template would not be consistent with these requirements. This article describes the revision of our consent template to mesh the applicable requirements into an integrated explanation of how subjects’ identifiable information will be handled.

Methods

The process of revising the existing consent form privacy and confidentiality language to incorporate all requirements started with the realization that merely adding NIH's suggested Certificate of Confidentiality language (NIH, 2017c), or using a simplified version (we considered using the same simplified language as University of Nevada, Reno; Wolf & Beskow, 2018, p. 355), would not meet our goal of being understandable to subjects. Three of the authors of this article (FKE, PAB, LOH) were the main individuals involved in the development of the template, with consultation during the process by ECF and review of the completed template by SN. The development process also involved review by our HRPP Advisory Committee, and the final version was approved by our Institutional Review Board ("IRB") Executive Board.

In developing the integrated template, we identified all pertinent requirements, including both the definitions of what made information identifiable, and the elements, information, and statements that should be included in the consent form. Table 1 lists the definitions of what makes information identifiable from the six different sources, ranging from what is arguably the narrowest definition, in the Common Rule, to the broadest definition, in the Cures Act. Table 2 lists the relevant requirements for the content of consent forms from these six sources.

Revisions to the existing consent template required numerous drafts, trying out different simplifications and rearrangements, with particular attention to removing redundancies and reconciling potential contradictions among the requirements (the Discussion section addresses the four major issues we confronted). Each draft was checked for reading level (using the Flesch-Kincaid grade level scoring tool that is embedded in Microsoft Word) and for compliance with the requirements in Tables 1 and 2, and assessed for overall readability and understandability in the judgement of the authors and additional reviewers. Our consent form template is structured to be useable in a variety of circumstances depending on the details of a particular study (whether biospecimens are obtained, whether information will be placed in the subject's medical record, whether information subject to mandated reporting is gathered, etc.). Extending this structure to incorporate the variables needed for the discussion of privacy and confidentiality was an additional challenge of this project, which was addressed by grouping variable sections and making extensive use of parenthetical directions to users of the template.

Table 1. Definitions of Identifiability

Source	Definition
Common Rule	Identifiable information means that the identity of the subject is or may readily be ascertained by the investigator (HHS, 2005, §46.102[f]; HHS, 2017, §46.102[e] [5]). This definition will be reexamined within one year of the effective date of the revised Common Rule and at least every 4 years thereafter (HHS, 2018b, §46.102[e][7][i]).
FDA	Identifiability is not defined in the human subjects protections regulations.
HIPAA	Identifiable information is information that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual (HHS, 2000b, §160.103).
ICH	Identifiability is not defined in the human subjects protections guidelines.
Part 2	Identifying information means the name, address, social security number, fingerprints, photograph, or similar information by which the identity of a patient can be determined with reasonable accuracy either directly or by reference to other information (HHS, 2018a, §2.11).
Cures Act	Identifiable information is defined as information for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual. All identifiable research information is considered identifiable sensitive information (Cures Act, 2016, HHS, 1944, §241[d][4]).

Table 2. Consent Form Requirements

Source	Requirements (numbered for reference in the Results section)
Common Rule	CR-(1) Informed consent must include a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained (HHS, 2005, §46.116[a][5]; HHS, 2018b, §46.116[b][5]).
	CR-(2) Informed consent must include a statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility (HHS, 2018b, §46.116[b][9][i]).
FDA	FDA-(1) Informed consent must include a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records (FDA, 1981, §50.25[a][5]).
	FDA-(2) For applicable clinical trials, as defined in 42 U.S.C. 282(j)(1)(A), the following statement must be provided to each clinical trial subject in informed consent documents and processes: "A description of this clinical trial will be available on http://www.ClinicalTrials.gov , as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time" (FDA, 1981, §50.25[c]).
HIPAA*	HIP-(1) Authorizations must include a description of the PHI to be used or disclosed that identifies the information in a specific and meaningful fashion (HHS, 2000b, §164.508[c][1][i]).
	HIP-(2) Authorizations must include the name or other specific identification of the person(s), or class of persons, who will make the requested use or disclosure (HHS, 2000b, §164.508[c][1][ii]).
	HIP-(3) Authorizations must include the name or other specific identification of the person(s), or class of persons, to whom the Covered Entity may make the requested use or disclosure (HHS, 2000b, §164.508[c][1][iii]).

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- HIP-(4) Authorizations must include a description of each purpose of the requested use or disclosure (HHS, 2000b, §164.508[c][1][iv]).
- HIP-(5) Authorizations must include an expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. The statement “end of the research study,” “none,” or similar language is sufficient if the authorization is for a use or disclosure of PHI for research (HHS, 2000b, §164.508[c][1][v]).
- HIP-(6) Authorizations must include the signature of the individual and date. If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual must also be provided (HHS, 2000b, §164.508[c][1][vi]).
- HIP-(7) Authorizations must include a statement concerning the individual's right to revoke the authorization in writing and the exceptions to the right of revocation, including in particular the ability of the researchers to continue to use and disclose as necessary to preserve the integrity of the research and for institutional or governmental oversight (HHS, 2000b, §164.508[c][2][i]).
- HIP-(8) Authorizations must include a statement concerning whether providing the authorization is a condition for treatment, payment, enrollment, or eligibility for benefits. Research-related treatment may be conditioned on providing the authorization; however, the statement must inform the individual about the consequences of not signing the authorization (HHS, 2000b, §164.508[c][2][ii]; §164.508[b][4][i]).
- HIP-(9) Authorizations must include a statement concerning the potential for information disclosed pursuant to the authorization to be re-disclosed by the recipient and no longer be protected by HIPAA (HHS, 2000b, §164.508[c][2][iii]).
- ICH ICH-(1) The informed consent should include explanations that the monitor(s), the auditor(s), the IRB, and the regulatory authority(ies) will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject's legally acceptable representative is authorizing such access (ICH, 2016, 4.8.10[n]).
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	ICH-(2)	The informed consent should include explanations that records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential (ICH, 2016, 4.8.10[o]).
Part 2	Pt2-(1)	Consent for disclosures of identifiable information about substance use outside the Part 2 program must include essentially the same elements required for a HIPAA authorization. The consent requirement varies based on whether the recipient does or does not have a treating provider relationship with the patient (HHS, 2018a, §2.31).
	Pt2-(2)	Information necessary for the investigation of crimes and child abuse and neglect may be disclosed without consent (HHS, 2018a, §2.22[b]).
	Pt2-(3)	Identifiable Part 2 information may be used for research if confidentiality protections are adequate, including uses approved by an IRB and uses where the information is reported in such a way that patients cannot be re-identified (HHS, 2018a, §2.52).
Cures Act**	CA-(1)	With four exceptions (see CA-(2) below), any person or institution to whom a Certificate of Confidentiality is issued is prohibited from disclosing or providing to any other person not connected with the research a subject's name or any information, document, or biospecimen that contains identifiable, sensitive information and that was created or compiled for purposes of the research (HHS, 1944, §241[d][1][B]).
	CA-(2)	The four exceptions are for a disclosure or use that is: <ul style="list-style-type: none"> CA-(2)(a) Required by Federal, State, or local laws, with an exclusion to this exception for legal proceedings (see CA-(3) below) (HHS, 1944, §241[d][1][C][i]). CA-(2)(b) Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual (HHS, 1944, §241[d][1][C][ii]). CA-(2)(c) Made with the consent of the individual to whom the information, document, or biospecimen pertains (HHS, 1944, §241[d][1][C][iii]). CA-(2)(d) Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research (HHS, 1944, §241[d][1][C][iv]).

- CA-(3) The exclusion to exception CA-(2)(a) is that any person or institution to whom a certificate is issued is prohibited, except with the consent of the individual, from disclosing or providing the name or any information, document, or biospecimen that contains identifiable, sensitive information and that was created or compiled for purposes of the research, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding. Identifiable, sensitive information protected under a Certificate of Confidentiality, and all copies thereof, are immune from the legal process, and may not, without the consent of the individual to whom the information pertains, be admissible as evidence or used for any purpose in any action, suit, or other judicial, legislative, or administrative proceeding (HHS, 1944, §241[d][1][D]).
- CA-(4) Identifiable, sensitive information collected by a person or institution to whom a Certificate of Confidentiality has been issued, and all copies thereof, are subject to the protections afforded by the Certificate of Confidentiality in perpetuity (HHS, 1944, §241[d][1][F]).
- CA-(5) Having a certificate does not limit the access of an individual who is a subject of research to information about himself or herself collected during such individual's participation in the research (HHS, 1944, §241[d][3]).

*HIPAA requirements refer to authorization to use and disclose Protected Health Information ("PHI") by a Covered Entity, with elements and statements that may be incorporated into research consent forms (HHS, 2000b, §164.508[b][3][i]).

**The Cures Act requirements for confidentiality (Cures Act, 2016) have been implemented by NIH through automatic issuance of Certificates of Confidentiality to all NIH-funded research (NIH, 2017a). In addition, Certificates of Confidentiality may be issued by other funding agencies within the Department of Health and Human Services for research that these agencies support, as well as by NIH for other health-related research that uses identifiable, sensitive information (NIH, 2017a; Wolf & Beskow, 2018).

Results

The consent form confidentiality and HIPAA sections that we developed are presented in Tables 3-5. The example used is for an NIH-funded clinical trial that obtains identifiable information and biospecimens, that will place study information in the subjects' medical records, that follows ICH-GCP guidelines, that plans to share information with other researchers, that gathers information that must be reported to external public health or public safety authorities, that may obtain consent from a legally authorized representative, and that will use and disclose PHI, including substance use disorder records from a federally-assisted program. Underlined, italicized words indicate study-specific details to be completed by the investigator. Bracketed sentences indicate directions to the person preparing the consent form about the inclusion of specific items. The full templates are available from the BMC and BU Medical Campus IRB (2018) website: <http://www.bumc.bu.edu/irb/inspir-ii/irb-templates/>.

Table 3. Consent Form Template Confidentiality Section

Paragraph	Requirements	Comments
We must use information that shows your identity to do this research. Information already collected about you will remain in the study record even if you later withdraw.	CR-(1) FDA-(1) ICH-(2) HIP-(7)	The first sentence introduces the Confidentiality section as the discussion of the use of identifiable information. The second sentence is always true for FDA-regulated research. For other research, if an investigator would like to give subjects the opportunity to withdraw already-collected data, the investigator may edit this second sentence.
We will store your information in ways we think are secure. We will store biological samples taken from your body (such as urine, blood, or tissue) <i>description of storage methods</i> . We will store paper files in locked filing cabinets. We will store electronic files in computer systems with password protection and encryption. However, we cannot guarantee complete confidentiality.	CR-(1) ICH-(2)	This paragraph describes the protections against unintentional disclosure outside the research context, with the caveat that confidentiality is not guaranteed. The remainder of the confidentiality and HIPAA discussion addresses intentional disclosures.
This study is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. All studies funded by the National Institutes of Health that involve identifiable information or biological samples are covered by a CoC.	CA-(1) CA-(2)(b) CA-(3) CA-(4) CA-(5)	This paragraph, complying with several of the requirements of the Cures Act, is placed early in the confidentiality section so the phrase “except as we describe below” can be used to communicate the exceptions to the general prohibition under the Cures Act against the disclosure of research information. Note that the subsequent paragraphs are included in the consent form even if there is no Certificate of Confidentiality.

The CoC provides how we can share research information or biological samples. Because we have a CoC, we cannot give out research information or biological samples that may identify you to anyone that is not involved in the research except as we describe below. Even if someone tries to get your information or biological samples in connection with a legal proceeding, we cannot give it to them. The CoC does not prevent you from sharing your own research information. We will record information from this study in your medical record, such as information related to your medical care. Please ask us if you have any questions about what information will be included in your medical records. You should know that once information has been put into your medical records, it is not covered by the CoC. However, information in your medical records is protected in other ways.

The sentences describing the Certificate of Confidentiality protections are written to apply whether or not the study gathers information that the subject might consider incriminating (see Results and Discussion). The last four sentences in this paragraph were added to convey that the Certificate of Confidentiality does not prevent research information from being placed in the subject's medical record (the first of these four sentences functions as the consent needed under the Certificate of Confidentiality—but not under HIPAA—to disclose information for treatment purposes) and to point out that although information in the medical record is not covered by the Certificate of Confidentiality, it is protected in other ways. These additional ways, such as HIPAA, Part 2 regulations, and state privacy laws, are referenced in general but not spelled out in the consent form for the sake of brevity.

If you agree to be in the study and sign this form, we will share information and biological samples that may show your identity with the following groups of people:

- People who do the research or help oversee the research, including safety monitoring.
- People from Federal and state agencies who audit or review the research, as required by law. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and the Massachusetts Department of Public Health.
- People who see your medical records.
- People who will get information and biological samples from us: name(s) and affiliation(s). These people are expected to protect your information and biological samples in the same way we protect it.
- Any people who you give us separate permission to share your information.

ICH-(1)
 FDA-(1)
 Pt2-(3)
 CA-(2)(b)
 CA-(2)(c)
 CA-(2)(d)
 CA-(4)

This paragraph lists instances where identifiable information will be disclosed outside the research team, in conformance with the Cures Act requirement for the subject to consent to such disclosures. Because this discussion would be of interest to all potential subjects, it is also required for studies without a Certificate of Confidentiality. It gives specific examples of disclosures required by law (safety monitoring, auditing). The statement about FDA (and other regulatory bodies) being able to see the records was moved out of the HIPAA section in an earlier version of the template to avoid the implication that authorization was required for FDA to see identifiable data. The introductory phrase “If you agree to be in the study and sign this form” and the last bullet “Any people who you give us separate permission to share your information” communicate the idea that disclosures are allowed if made with the subject’s consent. Calling out the fact that people who see the subjects’ medical records will have access to the research information helps the subjects understand that they are providing consent for the research information to be disclosed to treating providers and others with medical record access, as required under the Cures Act. The investigator is expected to list anyone else in the fourth bullet who will get identifiable information. This is of interest to all potential subjects, and in addition, if substance abuse information is obtained, will disclose that identifiable information may be used for research purposes under PT2-(3). The Cures Act requirement CA-(4) that the protections apply to “all copies” of the information is communicated by the statement “These

<p>You should know that we are required to report information about: <u><i>list of information requiring mandatory reporting such as child abuse or neglect; elder abuse; specific reportable diseases; harm to self or others.</i></u></p>	<p>CR-(1) Pt2-(2) CA-(2)(a)</p>	<p>people are expected to protect your information and biological samples in the same way we protect it,” which tempers a later sentence in the HIPAA section required by HIP-(9) about HIPAA not applying to PHI after it is released.</p> <p>This paragraph is included if any of the information that is gathered is subject to mandatory reporting under state or local laws. This is another specific example of the exception CA-(2)(a) under the Cures Act for disclosures required by law. It is placed in a separate paragraph to emphasize this potential exception to confidentiality, because it could be critical to a prospective subject’s decision about whether or not to participate.</p>
<p>We will share research data where we have removed anything that we think would show your identity. There still may be a small chance that someone could figure out that the information is about you. Such sharing includes:</p> <ul style="list-style-type: none"> • Publishing results in a medical book or journal. • Adding results to a Federal government database. • Using research data in future studies, done by us or by other scientists. • Using biological samples in future studies, done by us or by other scientists. 	<p>CR-(1) CR-(2) ICH-(2) Pt2-(3) CA-(2)(c)</p>	<p>This paragraph is written to take into account the varying interpretations of “identifiability.” The first bullet, to reassure subjects that the reporting of the research will not identify them, complies with the ICH-(2) as well as the Common Rule requirement CR-(1) to describe confidentiality. Similarly, the second bullet covers any future sharing of de-identified data, such as required under Federal grant or journal publication requirements. The third and fourth bullets comply with the Common Rule requirement CR-(2) to tell subjects that their de-identified data and biospecimens may be shared in the future. The second sentence in the introductory part “There still may be a small chance that someone could figure out that the information is about you” was added because under the Cures Act (2016), information is considered identifiable if there is “at least a very small risk” of deducing the identity of the individual and therefore under requirement CA-(2)(c), the subject who signs the consent form is</p>

<p>A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.</p>	<p>FDA-(2)</p>	<p>giving consent for these disclosures. The Part 2 regulations allow potentially identifiable data to be used without consent for research purposes, but it is appropriate to inform subjects that this might be a possibility.</p> <p>This paragraph is required verbatim by the FDA regulations (1981, §50.25[c]). There is no option to reword to make the connection with the previous paragraphs clearer.</p>
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Table 4. Consent Form Template Use and Disclosure of Your Health Information (HIPAA) Section

Paragraph	Requirements	Comments
<p>The research team has to use and share your health information to do this study, including information that may identify you. By agreeing to be in this study and signing this form, you are giving us your permission where needed to use and share your health information as described in this form.</p>	<p>HIP-(2) HIP-(6) HIP-(8) Pt2-(1)</p>	<p>This paragraph provides the reason for the use and disclosure (using the phrase “to do this study” to refer to descriptions in other parts of the consent form) and clearly states that the subject is authorizing the study team to use and disclose their PHI by signing the consent form.</p>

<p>Health information that might be used or given out during this research includes:</p> <ul style="list-style-type: none"> • Information that is in your hospital or office health records. The records we will use or give out are those related to the aims, conduct, and monitoring of the research study. • Health information from tests, procedures, visits, interviews, or forms filled out as part of this research study. • [Note to investigator: Include this closed bullet and all applicable open bullet(s) if the study involves any of the following types of information.] The health information specifically includes: <ul style="list-style-type: none"> • Mental health communications (with a psychiatrist, psychologist, clinical nurse specialist, marriage-, family-, rehabilitation-, or mental-health-counselor, or educational psychologist) • Domestic violence counseling • Social work communications • Rape victim counseling • HIV/AIDS information 	<p>CR-(1) HIP-(1) Pt2-(1) Pt2-(2)</p>	<p>This paragraph provides the description of the information to be used or disclosed. The third bullet is included if certain sensitive types of information are involved, to provide the potential subject with information that might affect their decision about participating in the study. Besides the Part 2 requirements for alcohol or drug use (HHS, 2018a, §2.22), this template includes additional categories of sensitive information for which specific written permission must be obtained to disclose under Massachusetts laws (Commonwealth of Mass., n.d.).</p>
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- Sexually transmitted disease information
- Communicable disease information
- [IMPORTANT NOTE: Specific written consent is required if the study intends to further disclose alcohol or drug use information.] Alcohol or drug use disorder treatment records about: list of specific data to be used and shared
- Genetic testing

The reasons that your health information might be used or given out to others are:

- To do the research described here.
- To make sure we do the research according to certain standards set by ethics, law, and quality groups.
- To comply with laws and regulations. This includes safety-related information. As we explained above, we also have to give out any information from you about: list of information requiring mandatory reporting such as child abuse or neglect; elder abuse; specific reportable diseases; harm to self or others.

HIP-(4)
Pt2-(2)
CA-(2)(a)

This paragraph provides more detail about the reasons for the use and disclosure in addition to the introductory paragraph, and repeats the important information about mandatory reporting, if applicable.

<p>The people and groups that may use or give out your health information are:</p> <ul style="list-style-type: none"> • Researchers involved in this research study from Boston Medical Center, Boston University, and/or other organizations. • Other people within Boston Medical Center and Boston University who may need to access your health information to do their jobs such as for treatment, research administration, payment, billing, or health care operations • People or groups that the researchers use to help conduct the study or to provide oversight for the study • The Institutional Review Board that oversees the research and other people or groups that are part of the Human Research Protection Program that oversees the research • Research monitors, reviewers, or accreditation agencies and other people or groups that oversee research information and the safety of the study • The sponsor(s) of the research study, listed on the first page, and people or groups they hire to help them do the research 	<p>HIP-(2) HIP-(3) Pt2-(2) CA-(2)(a)</p>	<p>This paragraph identifies the class of persons to whom PHI may be disclosed, and again mentions mandatory reporting, if applicable. The statement in the second bullet about using the information for treatment, billing, or operations is not required because such use is allowed under HIPAA without consent or authorization. The statement is included here for consistency with the reference to placing the research information in the medical record in the Confidentiality section to meet the requirement under the Cures Act for obtaining consent for the use or disclosure of research information for treatment of the individual. Any of the last four bullets may be omitted by the investigator if not relevant to the particular study.</p>
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- Public health and safety authorities who receive our reports about: list information such as child abuse or neglect; elder abuse; specific reportable diseases; harm to self or others
- [Note to investigator: Include if applicable; otherwise delete bullet:] A list of other group(s) that will have access to the subject's health information

We ask anyone who gets your health information from us to protect the privacy of your information. However, we cannot control how they may use or share your health information. We cannot promise that they will keep it completely private.

HIP-(9)
CA-(4)

This paragraph complies with the HIPAA requirement HIP-(9) to communicate that PHI may not be covered by HIPAA after being disclosed, but also indicates that the recipients will be asked to protect the information, as is also described in the fourth paragraph of the Confidentiality section.

The time period for using or giving out your health information:

HIP-(5)

This paragraph takes advantage of the ability to have an indefinite expiration date for authorizations for research.

- Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information
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Your privacy rights are:

- You have the right not to sign this form that allows us to use and give out your health information for research. If you do not sign this form, you cannot be in the research. This is because we need to use the health information to do the research. Your decision not to sign the form will not affect any treatment, health care, enrollment in health plans, or eligibility for benefits.
- You have the right to withdraw your permission to use or share your health information in this research study. If you want to withdraw your permission, you must write a letter to the Principal Investigator at the address listed on the first page of this form. If you withdraw your permission, you will not be able to take back information that has already been used or shared with others. This includes information used or shared to do the research study or to be sure the research is safe and of high quality. If you withdraw your permission, you cannot continue to be in the study.

HIP-(7)
HIP-(8)

This paragraph implements HIPAA requirements HIP-(7) (the right to revoke the authorization in writing) and HIP-(8) (the consequences of not providing authorization), as well as providing information about the individual's ability to see information from their medical records, after the study is over (to preserve blinding). The introductory wording connects signing the consent form to providing authorization.

- When the study has been completed for everyone, you have the right to request access to the health information that we used or shared to make your treatment or payment decisions. If you ask for research information that is not in your medical record, we might not give it to you, but we will explain why not. You may use the contact information on the first page of this form to find out how to get your health information. You may also contact the HIPAA Privacy Officer at Boston Medical Center at: DG-privacyofficer@bmc.org or at Boston University at HIPAA@BU.EDU.

Table 5. Consent Form Template Signature Section

Paragraph	Requirements	Comments
By signing this consent form, you are indicating that: <ul style="list-style-type: none"> • you have read this form (or it has been read to you) • your questions have been answered to your satisfaction • you voluntarily agree to participate in this research study • you permit the use and release of information that may identify you as described, including your health information 	HIP-(6) CA-(2)(c)	The last bullet in this paragraph again makes explicit that the subject or legally authorized representative is consenting to/authorizing certain disclosures of their research information. This bullet appears even on consent forms that do not include a HIPAA authorization or have a Certificate of Confidentiality, because it is appropriate to reinforce that participating in the study involves gathering and using personal information.

Discussion

This process of producing the template was considered complete when the IRB Executive Board approved the template. The input of the community member was particularly valuable in assessing the understandability of the language. The other Executive Board members, including highly experienced Chairs and the IRB Director, agreed that the template was in compliance with applicable requirements for describing privacy and confidentiality in consent forms, and that the integrated discussion was an improvement over the previous template's approach of having a separate section for each requirement.

Four issues were particularly challenging to address, three because of tension between the requirements, and the fourth because of the unfamiliar concept of Certificates of Confidentiality.

The first issue was the requirement under the Common Rule for a statement about future uses of deidentified data (HHS, 2018b, §46.116[b][9][i]) versus the Cures Act's very expansive definition of what makes data identifiable (Cures Act, 2016; Wolf & Beskow, 2018). The final template addressed this issue by the following language in the Confidentiality section: "We will share research data where we have removed anything that we think would show your identity. There still may be a small chance that someone could figure out that the information is about you." The first sentence contains the required Common Rule statement, and the second sentence has the effect of obtaining consent for sharing information that could be considered identifiable under the Cures Act.

The second issue was that the subject's consent for research information to be shared for medical treatment is required under the Cures Act but not under HIPAA. The final template addressed the requirement for consent by placing the following language in the Confidentiality section for studies with a Certificate of Confidentiality: "We will record information from this study in your medical record, such as information related to your medical care." In the HIPAA section, although authorization/consent is not required to use or disclose information for treatment, to maintain consistency with the Confidentiality section, the final template included the following bullet in the list of people who may use or disclose PHI: "Other people within Boston Medical Center and Boston University who may need to access your health information to do their jobs such as for treatment, research administration, payment, billing, or health care operations."

The third issue was the requirement under HIPAA to state that HIPAA protections do not necessarily apply after information has been disclosed (HHS, 2000b, §164.508[c][2][iii]) versus the Cures Act requirement that the Certificate of Confidentiality protections apply to all copies of the research data disclosed for research purposes (but not for medical treatment; HHS, 1944, §241[d][1][F]). The protections for information that has been shared for research purposes were addressed by the following statement in the Confidentiality section in the final template (for all studies, whether or not they have a Certificate of Confidentiality): "If you agree to be in the study and sign this form, we will share information and biological samples that may show your identity with the following groups of people: ...People who will get information and biological samples from us: name(s) and affiliation(s). These people are expected to protect your information and biological samples in the same way we protect it." The non-protected status of information

disclosed for treatment purposes was addressed by the following statement in the Confidentiality section (for studies with Certificates of Confidentiality): “You should know that once information has been put into your medical records, it is not covered by the CoC. However, information in your medical records is protected in other ways.” The requirement to state that HIPAA may not apply when information is disclosed from the Covered Entity was addressed by the following statement in the HIPAA section: “We ask anyone who gets your health information from us to protect the privacy of your information. However, we cannot control how they may use or share your health information. We cannot promise that they will keep it completely private.” This statement in the HIPAA section brings forward the concept from the Confidentiality section that the recipients of the research data are expected to protect the data, before adding the caveat that confidentiality is not guaranteed.

The fourth issue was describing the protections afforded by a Certificate of Confidentiality in a way that avoided conveying the idea that a subpoena of research records was likely. In our and other’s experiences (Wolf & Beskow, 2018; Check, Wolf, Dame, & Beskow, 2014), potential subjects can be confused about why their research information might be incriminating enough to be subpoenaed when discussing a consent form that contains the standard NIH Certificate of Confidentiality consent language (NIH, 2017c). If the study does not collect data that a subject would consider sensitive, and has a Certificate of Confidentiality only because it is funded by NIH, as in the example discussed in this paper, the final template states: “All studies funded by the National Institutes of Health that involve identifiable information or biological samples are covered by a CoC. ... Even if someone tries to get your information or biological samples in connection with a legal proceeding, we cannot give it to them.” In order to minimize the discussion of legal proceedings, the exception that subjects can give permission for release in legal proceedings is not called out explicitly, but is conveyed by two other statements: “The CoC does not prevent you from sharing your own research information,” and “If you agree to be in the study and sign this form, we will share information and biological samples that may show your identity with the following groups of people: ... Any people who you give us separate permission to share your information.” One helpful change in the Cures Act (2016) is that we no longer have to consider mandatory reporting under state laws as “voluntary,” because “required by law” state reporting is an exclusion from the disclosure prohibitions of a Certificate of Confidentiality (Wolf & Beskow, 2018; HHS, 1944, §241[d][1][C][i]). In our experience, describing mandatory reporting as “voluntary” was confusing to our investigators, many of who are mandatory reporters under various state abuse and disease reporting laws (Commonwealth of Mass., n.d.).

Due to the inconsistent requirements and complex concepts required to be conveyed, writing these sections of the consent form in simple language was also challenging. The attempt to reduce the reading level of the template, a well-known concern for confidentiality language (Wolf, Dame, & Beskow, 2018; Check, 2014), was only partially successful: the paragraphs ranged from the 8th to the 10th grade Flesch-Kincaid reading level, compared to the 19th grade reading level of the suggested language on the NIH Certificate of Confidentiality website (Wolf & Beskow, 2018). In addition, some redundancy remained, especially in statements about who will see identifiable information and the exceptions to confidentiality if research information will be subject to mandatory reporting requirements.

Conclusions

Although we could have been compliant with the various requirements by simply adding the Certificate of Confidentiality language as another section of our consent form templates, we set a goal of providing an understandable discussion of the privacy and confidentiality provisions to our research subjects, which still met all regulatory requirements for a valid consent and authorization. We did not have the resources to undertake a study to assess research subjects' understanding of confidentiality protections after consent processes using this and other language. However, the individuals involved in the development and review of the language had extensive experience in human subjects protection, and the final approval was from the IRB Executive Board that included a community member.

Our process and the resulting language (available on our website: <http://www.bumc.bu.edu/irb/inspir-ii/irb-templates/>) is only one way to integrate the varying requirements, and other solutions are certainly possible. We hope that this example may encourage other IRBs to explore the possibility of improving the understandability of the privacy and consent sections of consent forms.

Acknowledgements

The consent form template language was developed with valuable input from members of the HRPP Advisory Committee and IRB Executive Board, particularly Joyce Samet and Lincoln Larmond. John Ennever and the peer reviewers provided helpful comments on the manuscript.

Funding

This project did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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