

Federal Regulations

Before a Nursing Home Study Begins: Description of potential regulatory requirements for research participation

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Table of Contents

1	Purpose	3
2	Scope	3
3	Description	3
4	Sharing Resident Information - the HIPAA Privacy Rule.....	4
5	Nursing Home Engagement in Research - the Common Rule	9
6	Research Agreements	11
7	Scenario-Based Decision Guide	13
	Appendix 1: Resources.....	16
	Appendix 2: List of identifiers that must be removed from a HIPAA-protected datafile under the Safe Harbor Method to create a de-identified file	18
	Appendix 3: HIPAA Accounting Requirements for the Disclosure of Identifiable PHI	20
	Appendix 4: Definitions	23

1 Purpose

The purpose of this guide is to give you, a nursing home industry (NH) leader, a better understanding of your roles and responsibilities in collaborative research. Your research partner should be able to detail what agreements are necessary for the specific project or relationship under discussion. To provide you with background and context for these discussions, the guide includes:

- A review of the HIPAA Privacy Rule (45 CFR § 164) as it relates to the use and disclosure of protected health information (i.e., resident information/data) for **research** purposes
- An introduction to federal rules for research called “The Common Rule” (45 CFR § 46) and how it might apply to a project
- Examples of the nursing home partner responsibilities depending on the type of research
- Appendices that offer more detailed information about the specific rules, regulations, and terms discussed

Use of this guide, along with [NEXT STEPs “Norms of Engagement for Nursing Home Research.”](#) will equip you, as a nursing home partner, to collaborate on research studies with confidence.

2 Scope

This document is intended for all NH leaders considering research collaboration. It focuses on the HIPAA Privacy Rule and the Common Rule but **excludes** any additional requirements under FDA regulations specific to drug or device trials (21 CFR § 50 & 56).

3 Description

Research in the NH setting has the potential to improve the quality of life of residents, the workflow of staff, operational efficiency, and more. It can take many forms and might be conducted exclusively by a research team or involve your clinical and administrative staff. Some research might be conducted entirely outside of the walls of your NH (e.g., use of EMR data only; telephone surveys) while other research may take place onsite. The focus of the research may be on residents, family members of residents, staff, clinicians, care practices, or other topics. No matter the scenario, it is important to follow federal guidelines that are designed to help ensure the ethical conduct of research. It is also beneficial for you, the nursing home partner, and the research team to agree on the terms of cooperation

including roles, responsibilities, intellectual property rights, and data sharing before a study begins.

Below, we address common questions posed by NH leaders who are considering participation in a research project.

4 Sharing Resident Information - the HIPAA Privacy Rule

How does our organization's role as a covered entity under HIPAA come into play when it comes to research using **identifiable** resident information (a.k.a., identifiable protected health information (PHI))?

The HIPAA Privacy Rule governs the storage, use, and disclosure of PHI for both operational/healthcare purposes AND for research purposes (Appendix 1). Researchers may ask to use information (a.k.a., data) that you maintain on your residents for their study. Under the HIPAA Privacy Rule, you are allowed to use and disclose resident data, *even fully identifiable resident data*, for research purposes so long as certain conditions are met.

Permission to access data (HIPAA Authorization)

In many cases, researchers are required to obtain permission to use a resident's data directly from either the resident or the resident's legally authorized representative (LAR). This "HIPAA Authorization" is generally done during the informed consent process when enrolling residents into a study. Once the resident or LAR signs the authorization, you may share the identifiable data described in that authorization with the study team.

There are situations, however, for which getting direct authorization from residents or LARs can be waived. In this case, researchers must request permission to waive HIPAA authorization requirements from a HIPAA Privacy Board or IRB serving as a HIPAA Privacy Board, and demonstrate that the situation meets specific criteria described in the federal guidelines. These "waivers of HIPAA authorization" fall into two categories – partial and full.

- A Partial Waiver of HIPAA authorization may be granted when a researcher wants to access a NH's database for recruitment purposes (e.g., reviewing your EHR). A researcher may record information about the resident to support recruitment, but the data will remain on your system.
- A Full Waiver of HIPAA authorization may be granted when a researcher conducting a minimal risk study wants to use resident data for purposes beyond recruitment – for example, to characterize their health or measure outcomes.

With a full waiver of authorization, you can release a copy of identifiable data to the study team.

Typically, a researcher will use their own IRB/HIPAA Privacy Board to make the determination about whether a waiver of authorization is permissible. However, it is ultimately the NH's responsibility, as the covered entity, to comply with the HIPAA Privacy Rule. You have the right to use your own HIPAA Privacy Board to make the waiver of authorization determinations if you so choose. It is recommended that you ask for, review, and maintain a copy of the board's determination in your files.

How does my role as a covered entity come into play under this rule when it comes to research using **de-identified or limited** resident data?

Sometimes researchers only need data that has removed some or all of a set of HIPAA-defined identifiers. These identifiers are listed in Appendix 2. Depending on how many are removed, the data will be classified as '**de-identified**' or a '**limited dataset**.' When that happens, your obligations under the HIPAA Privacy Rule change and the research team can help you meet them. In the boxes below, we lay out your responsibilities by level of data identifiability.

De-identified data – De-identified data is information that has little to no risk of re-identifiability. This kind of data does not require HIPAA-protections as it does not include PHI. The data must be de-identified using one of two methods described in the HIPAA Privacy Rule before you can share it:

- 1 Safe Harbor method: Removal of 18 specific identifiers including names, dates, and geographic information (see Appendix 2).
- 2 Expert Determination method: A qualified statistician determines that data poses minimal risk of re-identification. This method must be certified, documented, and the documentation must be kept for at least 6 years by the NH.

NH Requirements for sharing de-identified data

Documentation verifying that the data has been de-identified.
No resident authorization or data use agreement between institutions is required.

Example: a researcher needs patient age ranges, diagnoses, and number of days between events rather than exact dates. The NH is able to create a dataset that meets their needs without any of the 18 specific HIPAA identifiers.

Pros:

- Minimal/no risk of re-identifiability
- No resident authorization needed
- No data use agreement required per federal regulations

Cons:

- Data are often of limited utility to researchers
- May require extensive data management to create (variable removal, collapsing of data elements, file restructuring) that the NH is not equipped to handle
- Not possible to link other data collected during study to this de-identified dataset

Limited dataset – a HIPAA-protected dataset that removes 16 of the 18 HIPAA-defined identifiers (Appendix 2)

- Identifiers allowed in a limited dataset that are not allowed in de-identified data:
 - Exact dates such as admission, discharge, birth, and death dates
 - Geographic information smaller than the state

NH Requirements for sharing a Limited Dataset

- Data Use Agreement (DUA) with the researcher's institution
 - NOTE: This differs from a Business Associate Agreement (BAA). See information about BAAs later in this guide.
- No direct authorization from residents is required

Example: A researcher needs admission and discharge dates but does not need patient names or full addresses.

Pros:

- No resident authorization needed
- More granularity in the data for the researcher
- Data use agreement that clearly lays out terms of use

Cons:

- May require some data management (e.g., variable removal) that the NH is not equipped to handle
- Not possible to link primary data collected during study to this limited dataset

What else do I need to know before I am ready to share data?

Per the HIPAA Privacy Rule, your residents have the right to know each instance, up to 6 years prior to the date of the inquiry, that their **identifiable** PHI has been disclosed for research purposes under a HIPAA waiver of authorization. Be prepared in the event that a resident or family member asks about this. Your specific accounting responsibilities can be found in Appendix 3. Note, this does NOT apply to de-identified or limited datasets, or when there is direct permission provided by the resident or LAR during a research study to access their data.

I want to support the research, but I don't have the resources to create the dataset, or deal with the accounting requirements of releasing an identifiable dataset to the research team. What are my options?

It might be possible to enter into a **Business Associate Agreement (BAA)** with the researcher's institution to allow a member of the research team to access your data directly and create the dataset needed for the study. You are likely familiar with this type of agreement if you work with business associates to handle resident PHI for normal business operations (e.g., an independent hospice organization providing palliative care services in the NH, or a vendor that manages medical records). A BAA is different from the DUA mentioned above. A BAA only covers the operational services a research team member would be doing on your behalf outside of the research itself – in this case, creating a dataset from your larger database that could be disclosed to the larger research team for use in their study. It does not cover the use of the data for research purposes.

It is important to note, however, that a BAA adds specific HIPAA responsibilities to the researcher's institution beyond those required in a DUA for research. Not all academic institutions are equipped or willing to take on those added responsibilities.

I am supportive of research in general, but I do not want to deal with individual research requests for the use of our data, even when permission to use the data is given by the resident or LAR during a study. Is there any other option?

Yes, your organization can join the Long-Term Care (LTC) Data Cooperative, which assembles clinical data from electronic health records (EHR) from skilled nursing facilities and assisted living communities nationwide for use by researchers. The LTC Data Cooperative does not include any billing or financial data from EHR systems, and the EHR vendors share your EHR data on your behalf – there is no extra work required from your IT personnel. This is an option open to all long-term care organizations nationally. Governed by the American Health Care Association and National Center for Assisted Living (AHCA/NCAL) and funded by the National Institute on Aging, the LTC Data Cooperative's mission is to improve the quality of care within post-acute and long-term care facilities. To learn more, visit <https://www.ltcdatacooperative.org/pages/default.aspx>.

Now that I understand what types of authorizations and agreements are needed for sharing resident information, how do I get these data into the hands of the research team?

This is a discussion you will begin before any agreements are signed as the details are often important to that process. Important considerations include the level of identifiability of the data to be shared and whether the researcher is approved to access the data only on your server or can obtain a physical copy of the data to be stored at the researcher's institution. Several other details should be worked out as well:

- In what format will the data be provided?
- What kind of information about the data, if any, will be provided?
- What is the method of access and transport for the data? (Potential options include direct access to the system, secure electronic file transfer, encrypted physical media shipped by mail, and others.)
- How often will the data be pulled and sent?
- What kind of assistance, if any, will the NH provide to explain the data?
- Will data be resent if errors are found by the research team?

It is important that the methods of access/data transfer/recipient storage align with the requirements of the HIPAA Privacy Rule.

5 Nursing Home Engagement in Research - the Common Rule

Participating in a research project is not necessarily considered being “engaged” in the context of the formal definition. The Common Rule is the code of federal regulations that governs human subjects research (45 CFR § 46) (Appendix 1). Any institution that is “engaged” in federally funded non-exempt human subjects research must adhere to it. Because adhering to the Common Rule imposes additional training and regulatory requirements for your NH, it is critical to understand whether your participation meets the definition of “engaged” in research as defined by the Common Rule. The researcher’s IRB will make the determination of engagement.

Is my NH considered “engaged” in all research that takes place within its walls or involves its residents or staff?

No, there are many types of research studies that are either not considered *human subjects* research studies, or else are *minimal risk studies* that fall into an exemption category defined within the Common Rule. The researcher’s IRB will make this determination. If the proposed study is granted an exemption by the IRB, your NH can participate without being considered “engaged” in research.

Even if the study does include human subjects and is not exempt from Common Rule requirements, in many cases, the NH is not itself considered engaged in the research.

For example, your NH is NOT engaged when

- NH staff answer questions about whether a resident is appropriate to approach for a research study
- NH staff introduce the investigator to the resident
- The NH provides space or data (to include creating de-identified or limited datafiles for the research team) but has no active role specific to the research itself

Your NH IS engaged when

- NH staff consent participants into a study
- NH staff collect research data or specimens beyond what they would do in standard clinical care

There are some research designs that are meant to study the effectiveness of a proven intervention in a NH setting under real-world conditions that may blur the lines between what activities are considered research, quality improvement, and standard of care by the

clinical staff. The researcher's IRB will review all study activities and make the determination of whether your NH is considered engaged in research or not.

What can I expect if the IRB considers my NH to be engaged?

There will be added responsibilities and time commitments needed on the part of both you and participating NH staff to meet regulatory compliance if anyone from your NH is considered engaged in the research study. You may want to ask the researcher to consider whether there are any changes that could reasonably be made to the study design to eliminate the NH's engagement and lessen your regulatory responsibilities. For example, rather than having NH staff consent residents for study participation, could the NH staff refer residents to research staff to conduct the consenting process either by phone or in person?

If no changes can be made to the research design and you still want to participate in the study, you will have to review and understand your responsibilities under the Common Rule. This will include obtaining a Federal Wide Assurance (FWA) number, affiliating with an IRB, and maintaining IRB compliance to include human subjects research training for all engaged staff. Do not be afraid to ask the research team for help in meeting your institution's requirements.

An FWA is an agreement filed with the federal Office of Human Research Protections (OHRP) certifying that your staff who are engaged in research have been trained in research ethics and that you will follow federal regulations related to the conduct of research. You can:

- Look up the NH in the FWA database (Appendix 1) to see whether you already have an active FWA on file. FWAs must be renewed every 5 years and so even if your facility has participated in research in the past, you may need to re-file.
- Follow the instructions in Appendix 1 for filing an FWA
- Ask the research team to explain ongoing IRB requirements.
- Ask the research team to determine what the funder and IRB of Record for the study require in terms of research training and ask for their help in obtaining it, as needed. Training can take many forms including, but not limited to, free online training offered by the funder or IRB of Record, access to the Collaborative Institutional Training Initiative (CITI) training program offered by the researcher's institution, or a training session offered by the researcher him/herself. You can also ask the research team to compensate you for any required training that must be purchased.

6 Research Agreements

This section provides some basic terminology and concepts that can be associated with research agreements between your NH/corporation and your research partners. The only agreements that are required by the HIPAA Privacy Rule or Common Rule are the data use agreement (DUA) for the use of a HIPAA-protected limited dataset or the Business Associate Agreement (BAA), when applicable. Regardless, it is considered best practice to lay out the terms of cooperation between two or more parties for a joint research project, including roles, responsibilities, intellectual property rights, and data sharing. After all, even if the study team gets direct permission from NH residents to use their protected health information maintained by the NH, for example, you will still need to work out details with the research team to get that data to the team in a manner and timeframe that works for both parties. There are also likely a number of other aspects of the study that need to be agreed upon.

This agreement can be formal or informal. Keep in mind that the NH/corporation, the research institution, or the funding agency may require specific types of agreements and note that any binding agreement entered into is between institutions and not individuals. Work with your appropriate institutional signing authority to negotiate terms with your research partners and execute any such agreements.

Data Use Agreement (DUA)

A DUA is required for limited data set disclosure and use, and is recommended for *any* type of data sharing if direct authorization from the NH resident or their LAR is not obtained. Since the DUA requirement falls on the HIPAA-protected covered entity, it is your responsibility to offer the initial terms of the agreement. If you are unfamiliar with DUAs and do not have a standard template, you can ask your research collaborator's institution to offer a data use agreement template, or else you can choose one available from the Federal Demonstration Partnership (Appendix 1).

Business Associate Agreement (BAA)

As mentioned earlier, the BAA is a specific type of agreement with which you are likely familiar and use in your normal operations. It is not usually needed for research purposes, but can have limited utility in certain situations.

Two instances where a BAA *would* be appropriate are:

- If you want to hire a member of the research team to prepare a limited or de-identified dataset that will then be disclosed to the larger research team for purposes of carrying out the research.

- if, in exchange for accessing the data for research purposes, the research team offers to prepare some NH metrics unrelated to the study for your use – e.g., to assess your facility's operational and clinical efficiency.

Keep in mind that since a BAA adds specific regulatory requirements beyond that of research to the researcher's institution, not all academic institutions are equipped or willing to take on the responsibilities of a business associate.

Research Collaboration Agreement (RCA)

The RCA agreement may go by other names. The key characteristics of this type of agreement is that it is a binding agreement between institutions. It is broader than a DUA. It can include as much information as is desired between the parties and can also incorporate any HIPAA-required DUA terms to minimize the number of overall agreements needed between institutions. Typically, the researcher's institution will draft the RCA for you and your legal team to review and sign.

Memorandum of Understanding (MOU)

A MOU may also be known as a letter of understanding, memorandum of agreement, and similar. The key characteristic of this type of agreement is that it is non-binding. It is meant to lay out roles and responsibilities less formally than a binding document like a RCA or DUA. If a DUA is required for use of the data, it should be separate from this non-binding document.

The content of a MOU agreement will depend on the nature of the study and the type of agreement used. Among other things, it may include one or more of the following:

- study description or title
- services provided by the researcher team and the NH
- representations and warranties
- payment
- indemnification and insurance
- governing law and dispute resolution
- confidentiality
- termination

Agreements are meant to benefit both parties. Take care to consider the type(s) of agreements you may need/want for your research study.

7 Scenario-Based Decision Guide

This section provides some specific examples of when BAAs, DUAs, and NH FWAs are required. They are for illustrative purposes only and are not exhaustive. More than one scenario may apply in a single study. As described in section 7, there are other binding and non-binding agreements that you or the research institution may require for some or all of the below activities. For example, while you will not need a BAA, DUA, or NH FWA to allow a study to take place within your NH, you may want a MOU that outlines the expectations, time frames, allowable uses of the facility, and other agreed-upon terms and conditions.

Scenario	BAA	DUA	NH FWA	HIPAA Waiver
NH staff is directly involved in consenting residents into a study.	No	No	Yes	No
NH staff collects daily pain measures from residents as a study outcome in addition to the screening done in routine clinical care.	No	No	Yes	No
The NH staff is not equipped to create a de-identified dataset from its EHR, but will allow a member of the research team to do it.	Yes	No ¹	No	No
The NH staff is not equipped to create a limited dataset from its EHR, but will allow a member of the research team to do it for use in a study.	Yes	Yes	No	No
NH creates a de-identified dataset for the research team but has no other role in the study.	No	No ¹	No	No
NH creates a limited dataset for the research team but has no other role in the study.	No	Yes	No	No
NH provides an identifiable dataset to the research team but has no other role in the study.	No	Best Practice ¹	No	Yes ²
Aside from gaining access to the data for research purposes, the researcher offers to analyze NH PHI for the NH's operational purposes.	Yes	No	No	No
NH staff share a flyer with the residents advertising a research study and ask them if the research team can contact them about participating.	No	No	No	No
NH allows the research team to use the resident lounge to interview residents for a study.	No	No	No	No
NH allows researcher to access the EHR directly to screen for study recruitment purposes.	No	No	No	Yes

¹ Though not regulatorily required, a NH may require a DUA. It is your purview as the covered entity.

² Unless direct permission is obtained from the study participants.

BAA = Business Associate Agreement

DUA = Data Use Agreement

NH FWA = Nursing home Federal Wide Assurance

HIPAA Waiver = HIPAA Waiver of Authorization

Appendices

Appendix 1: Resources

Appendix 2: Safe Harbor Method of De-identification Under the
HIPAA Privacy Rule

Appendix 3: HIPAA Accounting Requirements for the Disclosure
of Identifiable PHI

Appendix 4: Definitions



NEXT STEPS Best Practices:
Conducting Research in Nursing Homes
(Information for Nursing Home Administrators)

Appendix 1: Resources

Appendix 1: Resources

1. The Common Rule - Electronic Code of Federal Regulations (eCFR)
<https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46>
2. The HIPAA Privacy Rule - eCFR
<https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-C/part-164>
3. Federal Demonstration Partnership – available DUA templates
<https://thefdp.org/demonstrations-resources/dtuas/>
4. FWA filing
<https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwass/index.html>
5. FWA lookup
<https://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc>
6. Long-Term Care Data Cooperative
<https://www.ltcdatacooperative.org/pages/default.aspx>
7. NIH website on Research Engagement
<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html>
8. NIH website on HIPAA deidentification
<https://www.hhs.gov/hipaa/for-professionals/special-topics/de-identification/index.html#:~:text=The%20process%20of%20de%2Didentification,sciences%20research%2C%20and%20other%20endeavors.>
9. NIH website on human subjects research
<https://grants.nih.gov/policy-and-compliance/policy-topics/human-subjects/research>



Appendix 2: Safe Harbor Method of De-identification Under the HIPAA Privacy Rule

Appendix 2: List of identifiers that must be removed from a HIPAA-protected datafile under the Safe Harbor Method to create a de-identified file

Note: removal of only the 16 identifiers asterisked constitutes a HIPAA-protected Limited Dataset.

45 CFR § 164.514 b(2)

(i) The following identifiers of the individual or of relatives, employers, or household members of the individual, are removed:

- (A)* Names;
- (B) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:
 - (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
 - (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
- (C) All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
- (D)* Telephone numbers;
- (E)* Fax numbers;
- (F)* Electronic mail addresses;
- (G)* Social security numbers;
- (H)* Medical record numbers;
- (I)* Health plan beneficiary numbers;
- (J)* Account numbers;
- (K)* Certificate/license numbers;
- (L)* Vehicle identifiers and serial numbers, including license plate numbers;
- (M)* Device identifiers and serial numbers;
- (N)* Web Universal Resource Locators (URLs);
- (O)* Internet Protocol (IP) address numbers;
- (P)* Biometric identifiers, including finger and voice prints;
- (Q)* Full face photographic images and any comparable images; and
- (R)* Any other unique identifying number, characteristic, or code, except as permitted by [paragraph \(c\)](#) of this section; and

(ii) The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.



Appendix 3: HIPAA Accounting Requirements for the Disclosure of Identifiable PHI

Appendix 3: HIPAA Accounting Requirements for the Disclosure of Identifiable PHI

45 CFR § 164.528

(b) **Implementation specifications: Content of the accounting.** The covered entity must provide the individual with a written accounting that meets the following requirements.

(1) Except as otherwise provided by [paragraph \(a\)](#) of this section, the accounting must include disclosures of protected health information that occurred during the six years (or such shorter time period at the request of the individual as provided in [paragraph \(a\)\(3\)](#) of this section) prior to the date of the request for an accounting, including disclosures to or by business associates of the covered entity.

(2) Except as otherwise provided by [paragraphs \(b\)\(3\)](#) or [\(b\)\(4\)](#) of this section, the accounting must include for each disclosure:

(i) The date of the disclosure;

(ii) The name of the entity or person who received the protected health information and, if known, the address of such entity or person;

(iii) A brief description of the protected health information disclosed; and

(iv) A brief statement of the purpose of the disclosure that reasonably informs the individual of the basis for the disclosure or, in lieu of such statement, a copy of a written request for a disclosure under [§ 164.502\(a\)\(2\)\(ii\)](#) or [§ 164.512](#), if any.

(3) If, during the period covered by the accounting, the covered entity has made multiple disclosures of protected health information to the same person or entity for a single purpose under [§ 164.502\(a\)\(2\)\(ii\)](#) or [§ 164.512](#), the accounting may, with respect to such multiple disclosures, provide:

(i) The information required by [paragraph \(b\)\(2\)](#) of this section for the first disclosure during the accounting period;

(ii) The frequency, periodicity, or number of the disclosures made during the accounting period; and

(iii) The date of the last such disclosure during the accounting period.

(4)

(i) If, during the period covered by the accounting, the covered entity has made disclosures of protected health information for a particular research purpose in accordance with [§ 164.512\(i\)](#) for 50 or more individuals, the accounting may, with respect to such disclosures for which the protected health information about the individual may have been included, provide:

- (A) The name of the protocol or other research activity;
 - (B) A description, in plain language, of the research protocol or other research activity, including the purpose of the research and the criteria for selecting particular records;
 - (C) A brief description of the type of protected health information that was disclosed;
 - (D) The date or period of time during which such disclosures occurred, or may have occurred, including the date of the last such disclosure during the accounting period;
 - (E) The name, address, and telephone number of the entity that sponsored the research and of the researcher to whom the information was disclosed; and
 - (F) A statement that the protected health information of the individual may or may not have been disclosed for a particular protocol or other research activity.
- (ii) If the covered entity provides an accounting for research disclosures, in accordance with [paragraph \(b\)\(4\)](#) of this section, and if it is reasonably likely that the protected health information of the individual was disclosed for such research protocol or activity, the covered entity shall, at the request of the individual, assist in contacting the entity that sponsored the research and the researcher.

See a link to the full HIPAA Privacy Rule rule in [Appendix 1](#) for timeframes and other requirements for compliance.



NEXT STEPS Best Practices:
Conducting Research in Nursing Homes
(Information for Nursing Home Administrators)

Appendix 4: Definitions

Appendix 4: Definitions

Business Associate Agreement (BAA): an agreement between a covered entity such as a NH and a person or entity who performs activities that use or involve disclosure of protected Health Information (PHI) on behalf of the NH. The purpose of a BAA is to establish their working relationship and provisions. It must include specific provisions per the HIPAA Privacy Rule (45 CFR § 164.504(e)).

(the) Common Rule: the code of federal regulations that covers human subjects research (45 CFR § 46). This does not include additional FDA regulations.

Data Use Agreement (DUA): a required agreement between the NH and the researcher's institution when there is disclosure of HIPAA-protected resident information for research purposes (45 CFR § 164.514(e)).

Engagement in Research: an "engaged" NH is generally one whose staff 1) secure consent from residents to participate in a research study, 2) collect information about residents for the purposes of a research study through interaction or observation outside of what is collected as part of normal clinical care.

Federal Wide Assurance (FWA): a document that confirms a NH's commitment to following federal regulations that protect human research participants when engaged in a research study (45 CFR § 164).

HIPAA Privacy Rule: a set of national standards for the protection of certain health information held by covered entities including NHs. They include provisions for the use and disclosure of health information for research purposes (45 CFR § 164).

HIPAA Privacy Board: a review body established to act on research-related requests for waivers or alterations of the authorization requirement under the HIPAA Privacy Rule. In some organizations, the Institutional Review Board (IRB) also serves as the HIPAA Privacy Board.

HIPAA Waiver of Authorization: direct permission (authorization) is typically required from the NH resident or their authorized representative for the NH resident's data to be disclosed to a third party by the NH. Waivers or alterations of authorization can be granted by a HIPAA Privacy Board to access data for recruitment purposes or for minimal risk studies that meet certain criteria.

Institutional Review Board (IRB): a formally designated group that reviews, approves, and conducts periodic review of human subjects research to ensure the protection of the rights

and welfare of study subjects. An IRB can also serve to approve HIPAA waivers of authorization for the use of identifiable protected health information (PHI). Academic institutions often have their own IRBs, but commercial IRBs are also available.

Memorandum of Understanding (MOU): a non-binding agreement outlining the terms of cooperation between a NH and a researcher for a joint research project, including roles, responsibilities, intellectual property rights, and data sharing. The name and format of these can vary by institution (e.g., letter of intent, memorandum of agreement).

Protected Health Information (PHI): individually identifiable health information that is created, received, maintained, or transmitted by covered entities (i.e., healthcare providers, health plans, healthcare clearinghouses, and their business associates).

Research Collaboration Agreement: a legally binding contract outlining the terms of cooperation between a NH and a researcher for a joint research project. It can address the scope of the partnership such as roles, responsibilities, intellectual property rights, and data sharing. The name and format of these can vary by institution (e.g., Research Services Agreement.)