Before a Study Begins: A Roadmap to Regulatory Requirements for Developing Research in Nursing Homes

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1 Purpose

The purpose of this guide is to provide investigators a roadmap to the regulatory requirements that may be necessary for conducting nursing home (NH) research to comply with Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and the Common Rule protections for research subjects within the code of federal regulations. Specifically, this guide describes appropriate use of various agreements such as Business Associate Agreements (BAAs), Data Use Agreements (DUAs), and other binding and non-binding agreements, and discusses when a Federal Wide Assurance (FWA) and Institutional Review Board (IRB) approval is needed by NH partners. See Appendix 1 for a list of Resources relevant to these topics.

2 Scope

This document is intended for all investigators planning research with NH partners, regardless of funding source. It covers requirements pertaining to the HIPAA Privacy Rule (45 CFR § 164) and the Common Rule (45 CFR § 46), but **excludes** additional requirements under FDA regulations pertaining to drug or device trials (21 CFR § 50 & 56).

3 Definitions (in alphabetical order)

Business Associate: a person or entity who performs activities that use or involve disclosure of protected health information (PHI) *on behalf of a covered entity* [see definition below], most commonly for healthcare operations. Like a covered entity, a business associate must adhere to the HIPAA Privacy Rule (see 45 CFR § 160.103 for full definition).

Business Associate Agreement (BAA): an agreement between a covered entity and a business associate 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.

Covered Entity: a health plan, health care clearinghouse, or health care provider who transmits any health information electronically in connection with a transaction covered by 45 CFR 160 Subpart C. This usually refers to the NH, but in some cases particular researchers (e.g., physicians) are also covered entities. (45 CFR § 160.103)

Data Use Agreement (DUA): in the context of the HIPAA Privacy Rule, it is a required agreement between the covered entity and the researcher's institution when there is disclosure of a limited dataset for research purposes (45 CFR § 164.514(e)).

De-identified Data: in the context of the HIPAA Privacy Rule, a datafile in which all identifying information has been removed, making it impossible to link the data back to a specific individual (see Appendix 2).

Engagement in Research: an "engaged" institution is one whose agents (i.e., staff) for the purposes of a research study 1) secure consent from subjects, 2) collect information about subjects through interaction or observation, 3) receive identifiable, private information about research subjects, or 4) are the primary awardees of a grant that engages in any of the above.

Exempt Human Subjects Research: minimal risk human subjects research that falls under one or more exemption categories as defined by the Common Rule (see Appendix 4). Only an IRB can determine whether a study qualifies for an exemption.

Federal Wide Assurance (FWA): a document that confirms an institution's commitment to following federal regulations that protect human research participants (45 CFR § 164).

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

HIPAA Privacy Board: A review body that can be established to act on requests for waivers or alterations of the authorization requirement under the HIPAA Privacy Rule for research studies involving the use or disclosure of Protected Health Information (PHI). In some organizations, the IRB 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 covered entity. Waivers or alterations of authorization can be granted if the disclosure of PHI involves no more than minimal risk to the privacy of the individual; the research could not practicably be completed without the waiver; and the research could not be practicably carried out without access to or use of the PHI.

Human Subjects: a living individual about whom an investigator conducting research obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. (45 CFR § 46.102(e)).

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. It 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.

Limited Dataset: In the context of the HIPAA Privacy Rule, a HIPAA protected dataset that excludes the 16 identifiers asterisked in Appendix 2.

Memorandum of Understanding (MOU): a non-binding agreement outlining the terms of cooperation between two or more parties 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).

Minimal Risk Research: the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 C.F.R. § 46.102(i)).

Non-exempt Human Subjects Research: all human subjects research that does not qualify for exemption and therefore must adhere to the Common Rule, 45 CFR §46.

Nursing Homes: The use of 'nursing home' throughout this document is inclusive of post-acute skilled nursing and long-term care facilities.

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: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR §46.102(i)).

Research Collaboration Agreement: a legally binding contract outlining the terms of cooperation between two or more parties 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., Research Services Agreement.).

Single IRB (sIRB): the requirement to use a single IRB of Record when conducting collaborative research. All US-based institutions must agree to rely on a chosen IRB when conducting non-exempt human subjects research funded by the federal government.

4 Description

NH administrators are well-versed in the rules and regulations governing their responsibilities to residents and residents' protected health information (PHI) for operational and clinical purposes, but many have little to no experience with the research process, and how tasks may be regulated differently under the research umbrella. For example, while the HIPAA Privacy Rule governs the use and disclosure of PHI in both clinical and research settings, compliance requirements differ. Additionally, whether NHs must comply with the Common Rule depends on their level of research engagement, something largely determined by the investigator's (your) study design.
Those engaged in research must undergo appropriate training. It is critical, therefore, for you to understand not only your own regulatory requirements, but those of your NH partners when planning a study in the NH setting. Be prepared to support NHs in navigating these requirements and minimizing burden in order to effectively partner in research.

The remainder of this document describes some requirements to meet federal regulations provided in the HIPAA Privacy Rule and the Common Rule as well as some best practices. It also points out things that might be required by your institution or the NH beyond the federal regulations.

5 The HIPAA Privacy Rule

The HIPAA Privacy Rule sets national standards for the storage, use, and disclosure of data collected by a covered entity (Appendix 1). It is not a research-specific rule, but does cover the use of the data for research purposes. NHs (and, collectively, their business associates like data vendors that manage their data) are considered covered entities under the HIPAA Privacy Rule and the data they maintain on their residents is considered HIPAA-protected health information (PHI). This includes information like MDS assessments, health and medical records, and insurance claims.

The HIPAA Privacy Rule is applied in a NH on a daily basis when accessing data for non-research purposes such as administration and clinical care. You may want to access the data for your research study. When a study involves direct contact and informed consent from NH residents or their legally authorized representatives (LARs), obtaining direct authorization to access a resident's PHI should be included in the consent process. There are many types of minimal risk studies, however, that do not require direct contact with residents. Under the HIPAA Privacy Rule, NHs are also allowed to use and disclose resident data, including identifiable PHI, for research purposes without direct authorization so long as certain conditions are met. They may not be familiar with these conditions if they do not regularly partner with

investigators for research. So, while meeting the regulatory requirements of the HIPAA Privacy Rule is ultimately the responsibility of the NH, you, as the investigator partnering with them, should familiarize yourself with the Rule to help the NH understand their responsibilities.

When considering disclosing data without direct authorization from the resident, one key requirement related to privacy is that only the minimum data ***reasonably necessary*** to conduct the study be disclosed. One way NHs can meet this requirement is by considering the level of identifiability of the data.

5a. Data Identifiability

5.a.1. **De-identified data** – data that have little to no risk of being re-associated with a specific individual -- are no longer HIPAA-protected and can be freely shared. The data must be de-identified using either of two methods described in the HIPAA Privacy Rule.

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 covered entity.

De-Identified Data

NH Requirements for sharing de-identified data: Other than documentation needed for the Expert Determination method, NONE. No resident authorizations or data use agreements between institutions are required.

Example: a researcher needs patient age ranges, diagnoses, and number of days between events rather than exact dates.

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 (variable removal, collapsing of data elements, file restructuring) that the NH is not equipped to handle
- Not possible to link primary data collected during study to dataset

5.a.2 **Limited dataset** – a HIPAA-protected dataset that contains some indirect identifiers but excludes 16 HIPAA-defined direct identifiers such as names, addresses, and full SSNs. See Appendix 2 for a full list.

- Examples of elements 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 including city/town, state, and zip code

Limited Dataset

NH Requirements for sharing the data:

- Data Use Agreement (DUA) with HIPAA-mandated provisions
  - NOTE: This differs from a Business Associate Agreement (BAA). See information about BAAs in the *General* section below.
- 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 dataset

5.a.3 **Identifiable PHI** – HIPAA-protected data that contains one or more direct identifiers (e.g., names, SSNs, full addresses, contact information).

- Under HIPAA, NHs may disclose PHI only if:
  - The researcher obtains individual patient authorization, OR
  - An IRB or Privacy Board grants a HIPAA waiver of authorization.

Identifiable PHI

NH Requirement for sharing data:

- Must ensure principal investigator has gotten either direct authorization from residents or else a waiver for the use of identifiable resident data from a HIPAA Privacy Board or IRB.
- A data use agreement (DUA) is not required but it is best practice to have one that documents how the data will be used and protected, for what purpose the data will be used, who will access the data, and more.

Example: A researcher will be linking facility level data as well as person level data collected during the study to PHI received from the NH.

Pros:

- A rich dataset linkable to other files
- Least time consuming for the NH - minimal cleaning of the dataset needed prior to disclosure to the research team

Cons:

- Higher privacy and confidentiality risks
- The NH has specific disclosure tracking requirements per the HIPAA Privacy Rule (see Appendix 3)

NOTE: While the goal is to receive the least identifiable data necessary for your research study, in practice that might mean receiving fully identifiable data if the NH is unable to provide it in any other way. This may be due to a lack of IT expertise, time, resources, or other constraint that would prevent the NH staff from extracting a study-specific dataset from their larger database. In this case, the disclosure of the identifiable data will still likely meet the 'reasonably necessary' criteria of the HIPAA Privacy Rule.

- It should be noted that a NH resident has the right to know each instance, up to 6 years prior to the inquiry, that their identifiable PHI has been disclosed for research purposes if they did not provide direct authorization for its release. You can help the NH be prepared in the event that a resident or family member asks about this. If the NH agrees to release identifiable data to you, alert them to their accounting responsibilities under the HIPAA Privacy Rule (Appendix 3), provide them with your study-specific information, and encourage them to track disclosures.

6 Common Rule

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 the Common Rule. Institutions that are subject to the Common Rule must obtain a Federal Wide Assurance (FWA) number (see *Definitions* above), affiliate with an IRB, and maintain IRB compliance to include human subjects research training for all engaged staff. If your institution regularly receives research grants, it will already have an FWA, IRB, and training in place. Academic institutions that receive any federal grant funding often require *all* research studies, regardless of funding, to comply with the Common Rule. If your study is not federally funded and you are unsure of your institution's requirements, consult with your IRB office.

Your NH partners will also have to adhere to the Common Rule requirements if they are considered engaged in your research study. See the specific definition of engagement in *Definitions* above.

For example, a NH is engaged in research when

- NH staff consent participants into a study
- NH staff collect data beyond standard clinical care

A NH is not engaged in research when

- The study falls under an exempt category of the Common Rule (Appendix 4)
- NH staff introduce the investigator to the resident but do not directly obtain consent from or interact with residents for research purposes
- The NH is only providing space or data (to include creating de-identified or limited datafiles) but has no active research role

NOTE: Pragmatic clinical trials – those that study the effectiveness of an intervention in a real-life setting as opposed to those that study the efficacy of an intervention under a strict research protocol – may blur the lines between what activities are considered research, quality improvement, and standard of care by the clinical staff. It may be beneficial for you to consult with your IRB office during the design phase to clearly understand the nuances.

There will be added responsibilities and time commitments needed on the part of both the NH administrator and participating NH staff to meet regulatory compliance if they are considered engaged in research. Consider whether there are any changes that could reasonably be made to your study design to eliminate a NH's engagement. For example, rather than having NH staff consent residents for study participation, could the NH staff refer residents to a research staff to conduct the consenting process?

If the NH *is* engaged in your study, help them meet their requirements.

- Look up the NH in the FWA database (Appendix 1) to see whether they already have an active FWA on file. FWAs must be renewed every 5 years and so even if a NH participated in research in the past, they may need to re-file.
- Share the link found in Appendix 1 for filing an FWA with the NH and be prepared to assist.
- The FWA application requires that an IRB be named. If the NH does not have one that they typically use, or have never used one before, ask your IRB office whether it can be listed in the FWA application. If not, work with them to come up with possible solutions for the NH. There are several commercial, fee-based, IRBs that could be used (e.g., Advarra or WCG).
- Keep in mind any study-related single IRB requirements. As you write your sIRB plan, consider the obligations of all engaged institutions and assist the NH in meeting theirs.
- Determine what your funder and IRB of record for the study require in terms of research training for your particular study and assist the NHs in getting it, as needed. This might mean asking whether the funder or IRB offer free training, whether the NH staff can access the CITI program offered by your institution, or otherwise budgeting for any required training that must be purchased.

7 Research Agreements

The intent of this section is to provide you with some of the basic terminology and concepts that can be associated with research agreements between your institution and your NH partners. The only agreement that is required by the HIPAA Privacy Rule or Common Rule is a data use agreement (DUA) for the use of a HIPAA-protected limited dataset when direct permission is not sought from the residents or their LARs. 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 you do get direct permission from NH residents to use their data, you will still need to work with the NH to get the data 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. Below are some binding and non-binding options, with a special note about Business Associate Agreements, which are often the most familiar type of agreement to NH providers, but not generally appropriate for research purposes.

Keep in mind that your institution or 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 NH partners and execute any such agreements. It is unlikely that you should ever be the one signing a binding agreement.

7.a. **Data Use Agreement (DUA)**

Required for limited data set disclosure and use, but recommended for *any* type of data sharing, if direct authorization from the NH resident or their LAR is not sought. Since the requirement falls on the HIPAA-protected covered entity, it is the responsibility of the NH partner to offer the initial terms of the agreement. If a NH is inexperienced and does not have a standard template, your institution may offer a data use agreement template, or else the NH can choose one available from the Federal Demonstration Partnership (Appendix 1).

7.b. **Business Associate Agreement (BAA)**

This is a specific type of agreement with which NHs are likely familiar because they often work with business associates in their normal operations and regularly enter into BAAs for the purposes of handling resident PHI (e.g., an independent hospice organization providing palliative care services in the facility, or a vendor that manages medical records). NHs may confuse this type of agreement with a DUA needed for research purposes and may offer it in lieu of a DUA. In most cases this is not appropriate, as a BAA adds specific

security and privacy requirements beyond those necessary for research. It may just take a simple explanation of the difference between BAAs and DUAs to get the NH to use the correct agreement.

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

- if a NH wants to hire a member of your research team to access their data in order to prepare the limited or de-identified dataset that will then be disclosed to your team for purposes of carrying out the research.
- if, in exchange for accessing the data for research purposes, your team agrees to prepare some NH metrics unrelated to the study for the NH to assess its operational and clinical efficiency.

In these two instances, a member of your team would be providing operational services to the NH as opposed to carrying out research activities and, as such, would be acting as a business associate. In these instances, entering into BOTH a BAA (for the bulleted activities) AND a DUA (in the case of a limited dataset) for the subsequent use of the data for the research itself, would be appropriate.
However, since a BAA adds specific and privacy requirements beyond that of research, your institution's legal or contracting team should advise on the feasibility of this arrangement. Not all academic institutions are equipped or willing to take on the responsibilities of a business associate.

7.c. **Research Collaboration Agreement (RCA)**
This agreement may go by other names in your institution. The key characteristics of this type of agreement is that it is a binding agreement between institutions. It is broader than a data use agreement. It can include as much information as is desired between the parties and can also incorporate any HIPAA-required DUA terms (e.g., through a Rider) so as to minimize the number of overall agreements needed between institutions.

7.d. **Memorandum of Understanding (MOU)**
These are sometimes labelled 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. If a DUA is required for use of the data, it should be separate from this non-binding document.

The content of an 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
- representations and warranties
- payment
- indemnification and insurance
- governing law and dispute resolution
- confidentiality
- termination
- permitted uses and disclosure of data
- responsibilities of data provider
- responsibilities of data recipient
- HIPAA-required language and terms

Agreements are meant to benefit both parties. Take care to consider the type(s) of agreements you may need/want for your research study. They can often take months to negotiate and this should be factored into your study's timeline.

8 Scenario-Based Decision Guide

The intent of this section is to provide some specific examples of when BAAs, DUAs, and NH FWAs are regulatorily required. They are for illustrative purposes only and are not exhaustive. More than one scenario may apply in a single study. There are other binding and non-binding agreements (see section 7) that the NH or your institution may require for some or all of the below activities. For example, while the NH will not need a BAA, DUA, or NH FWA to allow a study to take place within its walls, it may want a written document 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] (full)
Aside from gaining access to the data for research purposes, the researcher agrees 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 in order to screen for study recruitment purposes	No	No	No	Yes (partial)

[1] Though not regulatorily required, a NH may require a DUA. It is their purview as the covered entity.
[2] Unless direct permission is obtained from the study participants.

Appendices

Appendix 1: Resources

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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/fwas/index.html

5. FWA lookup
   https://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc

6. NIH website on Research Engagement
   https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html

7. 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%2 0research%2C%20and%20other%20endeavors.

8. 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

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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 rule in Appendix 1 for timeframes and other requirements for compliance.

Appendix 4: Human Subjects Research Exemption Categories

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As laid out by the Common Rule, the following types of studies may be determined to be exempt by an IRB office, and therefore not subject to the remaining federal regulations found within the Common Rule. For additional details, see the link to the full Common Rule in Appendix 1. The following text is taken directly from the federal regulations.

(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. ….

(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 46.111(a)(7).

(3)

(i) **Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:**

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the

identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

(ii) [Reserved]

(6) Taste and food quality evaluation and consumer acceptance studies:

(i) If wholesome foods without additives are consumed, or

(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by § 46.111(a)(8).

(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with § 46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with § 46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by § 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and

(iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.