



**Nutrition
Incentive Hub**

CREATED BY GUSNIP NTAE CENTER



HIPAA, Program Evaluation, and Research

HIPAA Issue Brief 3 of 5

Resource Created by: Center for Health Law and Policy
Innovation of Harvard Law School

January 2022

This work is supported by Gus Schumacher Nutrition Incentive Program grant no. 2019-70030-30415/project accession no. 1020863 from the USDA National Institute of Food and Agriculture.



About this Brief and the Series

This resource was created for the GusNIP Nutrition Incentive Program Training, Technical Assistance, Evaluation, and Information Center (NTAE) by the Center for Health Law and Policy Innovation of Harvard Law School. It is part of a series of briefs intended to educate GusNIP Produce Prescription grantees on patient privacy laws; these briefs should not be considered legal advice. For specific legal questions, consult an attorney.

This third brief of the series discusses approaches to navigating HIPAA for program evaluation and research activities.

The other briefs in this series cover the following foundational HIPAA compliance topics relevant to Produce Prescription grantees:

- **Introduction to Patient Privacy Laws for Produce Prescription Grantees (Issue Brief 1)**
This brief discusses patient privacy laws for Produce Prescription grantees.
- **Developing HIPAA-Compliant Approaches to Information Sharing (Issue Brief 2)**
This brief discusses different approaches to structuring the collection and dissemination of participant information in a manner compliant with HIPAA.
- **Business Associate Arrangements (Issue Brief 4)**
This brief provides additional information on Business Associates and Business Associate Arrangements—a common but resource intensive approach to structuring information sharing from health care providers to third parties.
- **Developing a Privacy Program (Issue Brief 5)**
This brief reviews key technological and other considerations for developing a privacy program.



Under the U.S. Department of Agriculture 2018 Farm Bill, which funds the Gus Schumacher Nutrition Incentive Program (GusNIP), Produce Prescription grantees are required to evaluate the impact of their project. Grantees must collect core participant-level metrics, which include individual fruit and vegetable consumption and household-level food insecurity. Produce Prescription grantees may also collect metrics evaluating the impact of these programs on a participant's health outcomes, health care utilization, and costs.¹

This brief reviews several different approaches to collecting participant information for program evaluation and research, and implications for compliance with HIPAA.

Independent Data Collection

Some grantees collect their own metrics via the direct administration of surveys to program participants. When participants relay their personal and health information directly to the grantee through, for example, a survey, this is NOT subject to HIPAA. Additionally, this information is not protected by HIPAA unless the grantee itself is otherwise subject to HIPAA. *For additional information on whether a grantee is subject to HIPAA, see Issue Brief 1.*

Grantees must still:

- review state privacy law;
- apply for and receive approval from an Institutional Review Board (IRB) (*for more information on IRB requirements and assistance, please visit the Nutrition Incentive Hub resources on this topic at: <https://www.nutritionincentivehub.org/resources-and-support/resources/reporting-evaluation/institutional-review-board/general-irb-resources>*); and
- consider developing privacy standards as discussed in *Issue Brief 5* of this series.

Receiving Metrics from a Health Care Provider

Other GusNIP Produce Prescription grantees want to use information collected by their health care provider partners, either directly or indirectly, through a third-party evaluator.

Under the HIPAA Privacy Rule, a health care provider is prohibited from sharing patient information unless the disclosure meets requirements for a permitted disclosure. In order for a health care provider to share patient information for program evaluation and/or research purposes, one of the requirements below must be met.

1. The patient has signed a written Authorization containing all the elements specified in the Privacy Rule.

Written patient authorizations are described in more detail in Issue Brief 2: Developing HIPAA-Compliant Approaches to Information Sharing.

Distinguishing HIPAA Authorizations from IRB Informed Consent

IRB informed consent and HIPAA Authorizations serve different purposes. IRB informed consent ensures that subjects consent to participate in the research being conducted. HIPAA Authorizations ensure that participants consent to sharing protected health information. IRB informed consent and a HIPAA Authorization can be combined into one form for participants to sign, and it is common for template HIPAA Authorization language and related procedures to be included as part of an IRB approval process. *See [Guide to the Health Information Portability and Accountability Act \(HIPAA\)](#) for more information about HIPAA Authorizations as part of the IRB approval process.*



2. The health care provider has “de-identified” the data prior to disclosing it.²

De-identified data refers to data that has been scrubbed of personally identifiable information— information that can be used to determine an individual’s identity.³ De-identified data is **not** protected by the Privacy Rule because it does not fall within the definition of PHI.

Table 1. below contains several elements of PHI, linking names, dates of birth, and diagnoses. In Table 2., the data has been de-identified— specific identifiers have been removed.

Table 1. Example of PHI		
Patient Name	Date of Birth	Diagnosis
Alison Apple	9-29-1987	Diabetes
Betty Bettman	5-4-1979	Diabetes
Jane Doe	11-18-1983	Hypertension

Table 2. Example with Generalized Values		
Participant #	Age Range	Diagnosis
1	< 35 years	Diabetes
2	35-45 years	Diabetes
3	35-45 years	Hypertension

3. The data are in the form of a “limited data set” containing no HIPAA “direct identifiers,” and the parties have signed a HIPAA Data Use Agreement (DUA).⁴

Health care providers use DUAs to share a “limited data set” with third parties for certain specific, limited purposes, including research.

Is program evaluation research under HIPAA?

HIPAA defines research as, “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”⁵

Grantees should work with their health care partners to determine whether and to what extent program evaluation activities under the grant are included within this definition. Different health care organizations may take different positions on this matter depending, for example, on organizational policies and procedures, and how the results of the evaluation will be used.

Through a Data Use Agreement, a health care provider can share PHI that has been partially de-identified. Most identifiers must be removed from the data, but the data set **can** include the following: city, state, and zip code, ages under 90 years, and dates that relate to an individual, such as a birthday or important dates in a medical history.⁶

Important features to note about this approach to sharing PHI for research purposes include that a DUA must: (1) contain certain required content; (2) be in place (signed and effective) before the limited data set is shared; and (3) be study specific.⁷

Required Components of a DUA

A DUA must:

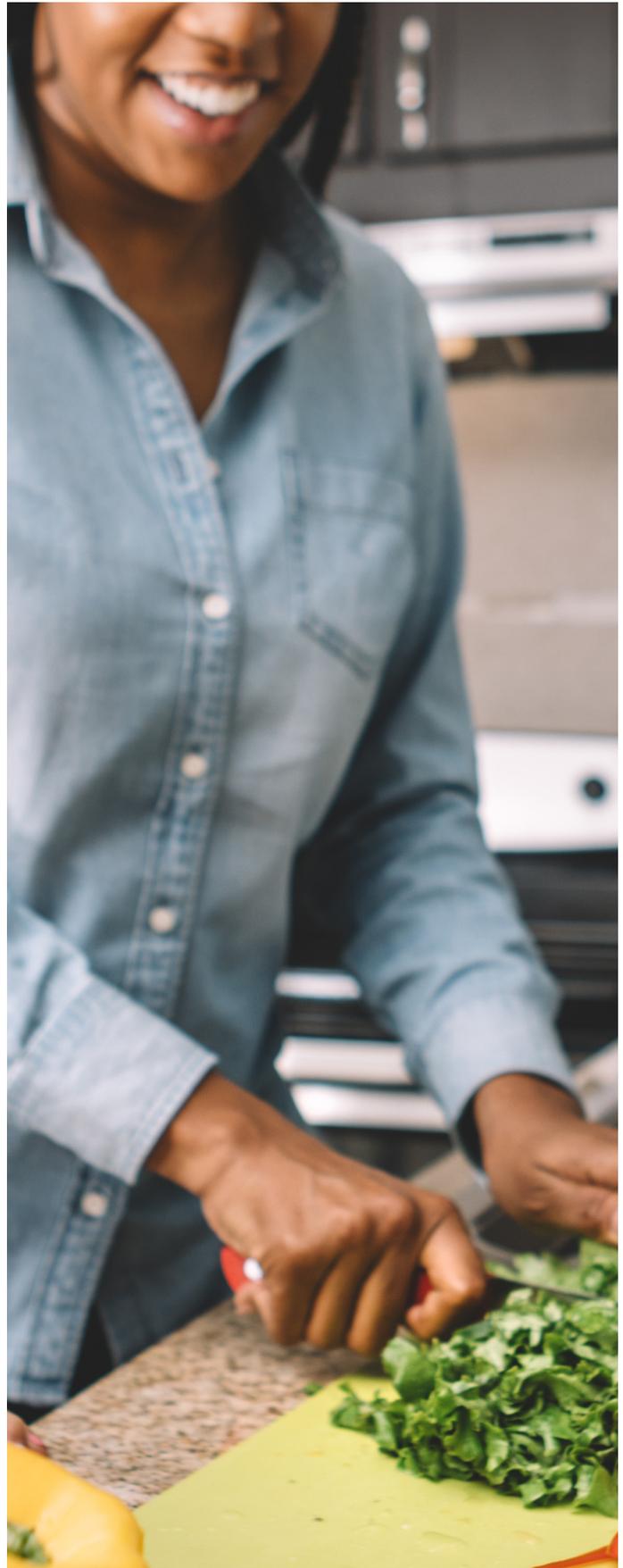
- establish who is permitted to use and receive the limited data set (e.g., the grantee, a third-party evaluator), and permitted uses/disclosures by the recipient;
- prohibit the recipient(s) from using/disclosing the information other than as permitted by the DUA or as otherwise required by law;
- require the recipient(s) to use “appropriate safeguards to prevent uses or disclosures of the information that are inconsistent with the DUA;”
- require the recipient(s) to report to the health care entity if it becomes aware of uses or disclosures that are in violation of the DUA;
- require the recipient(s) to ensure that anyone else who receives the data set will agree to the same restrictions and conditions; and
- prohibit the recipient(s) from using the data set to identify and/or contact individuals to whom the information in the data set relates.

If a Produce Prescription grantee does decide to enter into a DUA, it should make sure that it is familiar with all of the terms of the agreement and that it can fulfill the obligations that the agreement assigns to it.

4. An IRB has waived or altered the requirement for HIPAA Authorization.

IRBs can (but are not required to) waive restrictions on the sharing of PHI for research purposes. In order to waive the requirement for patient-driven authorization, the IRB must determine that certain criteria are satisfied, including that there is an adequate plan in place to protect PHI from improper use and disclosure, and that the research could not practicably be conducted without both the data and the waiver.⁸

Researchers are responsible for presenting to the IRB, as part of the IRB approval process, a compelling argument as to why HIPAA requirements should be waived. It may be difficult for a Produce Prescription grantee to demonstrate to the IRB that a waiver from the requirement for HIPAA Authorization is necessary to be able to conduct the research (e.g., that the researchers could not practicably secure patient authorization).



References

¹ 7 U.S.C. § 7517(e).

² 45 C.F.R. § 164.514(a).

³ HIPAA recognizes 18 types of identifiers: names; geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code, and their equivalent geocodes; all elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death, etc.; telephone numbers; fax numbers; email addresses; Social Security Numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers; device identifiers and serial numbers; web URLs; IP addresses; biometric identifiers, including finger and voice prints; photographic images; and any other unique identifying number, characteristic, or code. 45 C.F.R. § 164.514(a).

⁴ 45 C.F.R. § 164.514(e).

⁵ 45 C.F.R. § 164.501.

⁶ 45 C.F.R. § 164.514(e).

⁷ 45 C.F.R. § 164.514(e).

⁸ 45 C.F.R. § 164.512(i). Factors for consideration by an Institutional Review Board in determining whether a waiver for research purposes would be appropriate are: the presence of an adequate plan to protect identifiers from improper use and disclosure; the presence of an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research; adequate written assurances that, subject to certain exceptions, the PHI will not be reused or redisclosed; whether the research could practicably be conducted without the waiver; and whether the research could practicably be conducted without access to the information. 45 C.F.R. § 164.512(i).

About

Acknowledgments

The Center for Health Law and Policy Innovation of Harvard Law School (CHLPI) advocates for health and food justice, with a focus on the needs of systemically marginalized individuals. CHLPI works with a range of stakeholders to expand access to high-quality health care and nutritious, affordable food; to reduce health and food-related disparities; and to promote more equitable and sustainable health care and food systems. CHLPI's Health Law Lab advances health care system efforts to address social determinants of health and health-related social needs, improve health equity, and mitigate health disparities.

GusNIP NTAE staff and University of California San Francisco consultants reviewed and edited the briefs for alignment with GusNIP goals and activities.

Suggested Citation

Landauer, R. and Downer, S. (2022, January). *HIPAA Issue Brief 3 - HIPAA, Program Evaluation, and Research*. GusNIP NTAE Center, Nutrition Incentive Hub. <https://www.nutritionincentivehub.org>

[nutritionincentivehub.org](https://www.nutritionincentivehub.org)
info@nutritionincentivehub.org

The Nutrition Incentive Hub

The Nutrition Incentive Program Training, Technical Assistance, Evaluation, and Information (NTAE) Center is led by the Gretchen Swanson Center for Nutrition. In partnership with Fair Food Network, they created the Nutrition Incentive Hub, a coalition of partners to support this work. These partners are practitioners, retail experts, researchers, and evaluators from across the country bringing decades of experience and leadership in technical assistance, training, reporting, and evaluation. The Nutrition Incentive Hub is dedicated to building a community of practice to maximize program impact and ensure that all Americans have access to the healthy foods they need.

This work is supported by Gus Schumacher Nutrition Incentive Grant Program (GusNIP) Nutrition Incentive Program Training, Technical Assistance, Evaluation, and Information Center (NTAE) [Grant no. 2019-70030-30415/project accession no. 1020863 from the United States Department of Agriculture (USDA) National Institute of Food and Agriculture]. Any opinions, findings, conclusions, or recommendations expressed in this publication are those of the author(s) and do not necessarily reflect the view of USDA.