Research Repositories, Databases, and the HIPAA Privacy Rule

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Overview

Researchers in medical and health-related disciplines require access to many sources of health information, from archived medical records and epidemiological databases to disease registries, tissue repositories, hospital discharge records, and government compilations of vital and health records. As the Privacy Rule is implemented, researchers are asking how these rules might affect research that uses records within databases and repositories.

As of April 14, 2003, the Privacy Rule requires many health care providers and health insurers to obtain additional documentation from researchers before disclosing health information to them, and to scrutinize researchers' requests for access to health information more closely. Although the Privacy Rule introduces new rules for the use and disclosure of health information by covered entities for research, researchers can help to enable their continued access to health data by understanding the Privacy Rule and assisting health care entities covered by the Privacy Rule in meeting its requirements.

This fact sheet discusses the Privacy Rule and its potential to affect the creation of research databases and repositories, and research that uses identifiable health information in repositories and databases. Additional information about the Privacy Rule's potential impact on other research activities, such as clinical research, health services research, institutional review boards (IRBs) and Privacy Boards can be found in related publications, including:

- *Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule*
- *Health Services Research and the HIPAA Privacy Rule*
- *Clinical Research and the HIPAA Privacy Rule*
- *Institutional Review Boards and the HIPAA Privacy Rule*
- *Privacy Boards and the HIPAA Privacy Rule*

Introduction to the Privacy Rule

In response to a congressional mandate in the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Department of Health and Human Services (HHS) issued regulations entitled, *Standards for Privacy of Individually Identifiable Health Information*. For most covered entities, compliance with these regulations, known as the Privacy Rule, was required as of April 14, 2003.

The Privacy Rule is a response to public concern over potential abuses of the privacy of health information. The Privacy Rule establishes a category of health information, referred to as protected health information (PHI), which may be used or disclosed to others only in certain circumstances or under certain conditions. PHI is a subset of what is termed *individually identifiable health information*. With certain exceptions, the Privacy Rule applies to individually identifiable health information created or maintained by a covered entity. Covered entities are health plans, health care clearinghouses, and health care providers that transmit health information electronically in connection with certain defined HIPAA transactions, such as claims or eligibility inquiries. Researchers are not themselves covered entities, unless they are also health care providers and engage in any of the covered electronic transactions. If, however, researchers are employees or other workforce members of a covered entity (e.g., a covered hospital or health insurer), they may have to comply with that entity's HIPAA privacy policies and procedures. Researchers who are not themselves covered entities, or who are not workforce members of covered entities, may be indirectly affected by the Privacy Rule if covered entities supply their data. The HHS and the Food and Drug Administration's (FDA) Protection of Human Subjects Regulations (45 CFR part 46 and 21 CFR parts 50 and 56, respectively) may also apply to research involving the development or use of research repositories and associated data.

Overview of the Privacy Rule's Impact on Repositories and Databases

The Privacy Rule was not intended to impede research using records within databases and repositories that include individuals' health information, but the Privacy Rule does place new conditions on the use and disclosure of PHI by covered entities for research. The creation of a research database or repository, and the use or disclosure of PHI from a database or repository for research, may each be considered a research activity under the Privacy Rule. For more specific information about how the Privacy Rule could affect health services research, refer to the related publication, *Health Services Research and the HIPAA Privacy Rule*.

It is important to know that the Privacy Rule permits covered entities, such as hospitals, clinics, and other health care providers to continue amassing information on their patients for treatment, payment, and health care operations purposes, and to enter this information into their own databases without Authorization. The Privacy Rule also allows the disclosure of PHI to government-authorized public health authorities for disease surveillance, disease prevention, and other public health purposes, such as reporting disease and injury. When required by law, other disclosures are permitted, for example, state-mandated reporting to cancer registries. Covered entities may also continue to disclose PHI for adverse event and related reports to FDA and others for public health purposes (see section 164.512 of the Privacy Rule and additional information at *http://www.cdc.gov/mmwr/early_release.html*). Thus, many databases that are now used for records research continue to be maintained and updated, and will remain available to records researchers, although in some cases, under new terms.

The Privacy Rule permits a covered entity to use or disclose PHI for research under the following circumstances and conditions:

- For reviews preparatory to research if certain representations are obtained from the researcher
- For research solely on decedents' information if certain representations are obtained from the researcher
- If the subject of the PHI has granted specific written permission through an Authorization
- If the covered entity receives appropriate documentation that an IRB or Privacy Board has granted a waiver or an alteration of the Authorization requirement
- If the PHI has been de-identified in accordance with the standards set by the Privacy Rule (in which case, the health information is no longer PHI)
- If the information is released in the form of a limited data set, with certain identifiers removed, and with a data use agreement between the researcher and the covered entity
- If informed consent of the individual to participate in the research, an IRB waiver of such informed consent, or other express legal permission to use or disclose the information for the research is grandfathered by the transition provisions

For some records and database research, Authorization may not be needed. Some of the most important exceptions to the Authorization requirement that pertain to research using repositories and databases are the waiver of Authorization and the limited data set.

Waiver or Alteration of the Authorization Requirement by an IRB or Privacy Board

For some types of research, it may be impracticable for researchers to obtain written Authorization from research participants, for example, for some research conducted on existing databases or repositories where no contact information is available. To address these situations, the Privacy Rule contains criteria for the waiver or alteration of the Authorization requirement by an IRB or another review body called a Privacy Board. The Privacy Rule permits a covered entity to use or disclose PHI for research purposes without Authorization (or with an altered Authorization), if the covered entity received proper documentation that an IRB or Privacy Board has granted a waiver (or an alteration) of the Authorization

requirement for the research use or disclosure of PHI. The Privacy Rule establishes criteria to be evaluated by an IRB or Privacy Board in approving an Authorization waiver or alteration. For a covered entity to use or disclose PHI under a waiver or alteration of the Authorization requirement, it must receive documentation of, among other things, the IRB or Privacy Board's determination that the following criteria have been met:

- The PHI use or disclosure involves no more than a minimal risk to the privacy of individuals based on at least the presence of (1) An adequate plan presented to the IRB or Privacy Board to protect PHI identifiers from improper use and disclosure; (2) an adequate plan to destroy those identifiers at the earliest opportunity, consistent with the research, absent a health or research justification for retaining the identifiers or if retention is otherwise required by law; and (3) adequate written assurances that the PHI will not be reused or disclosed to any other person or entity except (a) as required by law, (b) for authorized oversight of the research study, or (c) for other research for which the use or disclosure of the PHI is permitted by the Privacy Rule.
- The research could not practicably be conducted without the requested waiver or alteration.
- The research could not practicably be conducted without access to and use of the PHI.

Additional information about waivers and alterations of Authorization can be found in the publications: *Institutional Review Boards and the HIPAA Privacy Rule* and *Privacy Boards and the HIPAA Privacy Rule*.

De-identified Data Sets

The Privacy Rule permits covered entities to release data that have been de-identified without obtaining an Authorization and without further restrictions upon use or disclosure because de-identified data is not PHI and, therefore, not subject to the Privacy Rule. A covered entity may de-identify PHI in one of two ways. The first way, the "safe-harbor" method, is to remove all 18 identifiers enumerated at section 164.514(b)(2) of the regulations.[1] Data that are stripped of these 18 identifiers are regarded as de-identified, unless the covered entity has actual knowledge that it would be possible to use the remaining information alone or in combination with other information to identify the subject.

The second way is to have a qualified statistician[2] determine, using generally accepted statistical and scientific principles and methods, that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by the anticipated recipient to identify the subject of the information. The qualified statistician must document the methods and results of the analysis that justify such a determination.

It is important to know that the Privacy Rule permits a covered entity to assign to, and retain with, the de-identified health information, a code or other means of record re-identification if that code is not derived from or related to the information about the individual and is not otherwise capable of being translated to identify the individual. For example, an encrypted individual identifier (e.g., a social security number) would not meet the conditions for use as a re-identification code for de-identified health information because it is derived from individually identified information. (See 67 *Federal Register* 53233, August 14, 2002.) In addition, the covered entity may not (1) use or disclose the code or other means of record identification for any purposes other than as a re-identification code for the de-identified data, and (2) disclose its method of re-identifying the information.

Limited Data Sets

Where only certain identifiers are needed, it may be permissible for a covered entity to provide a researcher with a limited data set. Limited data sets are data sets stripped of certain direct identifiers that are specified in the Privacy Rule. Limited data sets may be used or disclosed only for public health, research, or health care operations purposes. They are not de-identified information under the Privacy Rule. Importantly, unlike de-identified data, protected health information in limited data sets may include the following: Addresses other than street name or street address

or post office boxes, all elements of dates (such as admission and discharge dates) and unique codes or identifiers not listed as direct identifiers.[3]

Before disclosing a limited data set to a researcher, a covered entity must enter into a data use agreement with the researcher, identifying the researcher as the recipient of the limited data set, establishing how the data may be used and disclosed by the recipient, and providing assurances that the data will be protected, among other requirements. If the covered entity learns that the researcher has violated this agreement, the entity must take reasonable steps to end or repair the violation and, if such steps are unsuccessful, stop disclosing PHI to the researcher and report the problem to the HHS Office for Civil Rights. Additional information on limited data sets and data use agreements can be found in the booklet, *Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule*.

Activities Preparatory to Research

Covered entities may permit researchers to review PHI in medical records or elsewhere to prepare a research protocol, or for similar purposes preparatory to research. This review allows the researcher to determine, for example, whether a sufficient number or type of records exists to conduct the research. Importantly, the covered entity may not permit the researcher to remove any PHI from the covered entity. To permit the researcher to conduct a review preparatory to research, the covered entity must receive from the researcher representations that:

- The use or disclosure is sought solely to review PHI as necessary to prepare the research protocol or other similar preparatory purposes.
- No PHI will be removed from the covered entity during the review.
- The PHI the researcher seeks to use or access is necessary for the research purposes.

Additional information on activities preparatory to research can be found in the publications, *Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule* and *Clinical Research and the HIPAA Privacy Rule*.

Research Involving Decedents' PHI

A covered entity may provide access to decedents' records for research purposes if the covered entity receives from the researcher: Representations that the decedents' PHI is necessary for the research and is being sought solely for research on the PHI of decedents (not, for example, living relatives of decedents); and, upon request of the covered entity, documentation of the deaths of the study subjects. No Authorization or alteration or waiver of Authorization by an IRB or Privacy Board is needed for use or disclosure of PHI for research only on the PHI of deceased persons, if these conditions are met.

Other Privacy Rule Requirements

Minimum Necessary Standard

When using or disclosing PHI for research without an Authorization, a covered entity must make reasonable efforts to limit the PHI used or disclosed to the minimum necessary amount to accomplish the research purpose. If an IRB or Privacy Board has granted the researcher a waiver or an alteration of Authorization, a covered entity may reasonably rely upon the researcher's request consistent with the description of PHI in documentation from the IRB or Privacy Board as the minimum necessary amount of PHI for the research. Additional information on the minimum necessary standard can be found in the booklet, *Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule*.

Right to an Accounting of Disclosures

The Privacy Rule grants individuals new rights, including the right to receive an accounting of disclosures made for research by a covered entity without the individual's Authorization (e.g., under a waiver of Authorization), except for disclosures of a limited data set. The individual has a right to such an accounting of disclosures made by a covered entity in the 6 years prior to the date on which the accounting is requested, not including the period prior to the compliance date. For such

disclosures, in general, individuals who request an accounting must be told what PHI was disclosed, to whom it was disclosed, and the date and purpose of the disclosure. Covered entities must provide the address of the recipient, if known.

For certain research disclosures made by a covered entity, two other options exist for providing an accounting. When multiple disclosures of PHI are made to the same person or entity for a single purpose, the accounting for such disclosures may consist of the information described above for the first disclosure, plus the number or frequency of disclosures, and the date of the last disclosure during the time period covered by the request.

If, during the period covered by the accounting, the covered entity has disclosed the records of 50 or more individuals for a particular research purpose, the covered entity may provide a more general accounting to the requestor. The covered entity would provide the following information in the general accounting:

- The name and description of the protocols for which their PHI may have been disclosed
- A brief description of the type of PHI disclosed
- The date or period of time of the disclosures
- The contact information of the researcher and the research sponsor
- A statement that the PHI of the individual may or may not have been disclosed for a particular protocol or research activity

Section 164.528(b)(4)(ii) of the Privacy Rule requires that, upon request, the covered entity must help the individual contact the sponsor and researcher when it is reasonably likely that the individual's PHI was disclosed for a particular protocol. Additional information on accounting of disclosures can be found in the booklet, *Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule*.

Frequently Asked Questions and Answers

Q: Are tissue repositories covered entities?

A: Not unless the organization maintaining the tissue repository conducts some other activity that makes it a covered entity. For example, tissue repositories that conduct testing of specimens for the benefit of transplant recipients based on another health care provider's orders would be covered providers under HIPAA if they conduct electronic transactions for which the HHS has adopted standards.

Q: A researcher does not receive names, addresses, social security or medical record numbers, or other obvious identifiers from data sources. If the IRB has not considered this data to be individually identifiable in the past, and thus, determined that the research was not human subjects research under 45 CFR part 46, or that the research was exempt under 45 CFR 46.101(b), will this change under the Privacy Rule?

A: No. The Privacy Rule does not change the applicability or the requirements of the HHS and FDA Protection of Human Subjects Regulations. However, where the information sought by the researcher is held by a covered entity, the covered entity's use or disclosure of that information is subject to the Privacy Rule, unless the information is de-identified by the Privacy Rule's standards. The Privacy Rule's de-identification safe-harbor method is likely more stringent than what has been applied in the past to render information no longer identifiable for research purposes. De-identification under the Privacy Rule's safe-harbor standard may be accomplished through the removal of all 18 identifiers (section 164.514(b)(2) of the Privacy Rule).

Alternatively, fewer identifiers may need to be removed for health information to be de-identified if a qualified statistician determines that the risk of re-identification is very small (section 164.514(b)(1) of the Privacy Rule).

The Privacy Rule also permits a covered entity to retain, with the de-identified health information, a code for re-identification as long as the code is not related to or derived from information about the individual and is not otherwise capable of being translated to identify the individual, and as long as the covered entity does not disclose its method of re-identification or use or disclose its code for other purposes (section 164.514(c) of the Privacy Rule). For example, a randomly assigned re-identification code would not make the de-identified information to which it is assigned PHI, because a random code would not be derived from or related to information about the individual.

Where a researcher needs data elements that would render the information identifiable under the Privacy Rule, but where certain direct identifiers (set forth in section 164.514(e)) are not needed, a limited data set may be sufficient for the research. A limited data set is information stripped of only the direct identifiers listed at section 164.514(e), which include, but are not limited to, the name and street address of the individual. To use or disclose a limited data set, the covered entity must enter into a data use agreement with the recipient of the information.

In practice, this means that records research that may not require IRB approval under the HHS Protection of Human Subjects Regulations, still may require an Authorization or a waiver of Authorization under the Privacy Rule, or be subject to a data use agreement if a limited data set is used or disclosed.

Q: How may a covered entity use or disclose PHI for the creation of a research repository or database when it is unknown at the time of collection what specific protocols will make use of the repository or database in the future?

A: There are two separate activities to consider: (1) The use or disclosure of PHI for creating a research database or repository and (2) The subsequent use or disclosure of PHI in the database for a particular research protocol.

A covered entity's use or disclosure of PHI to create a research database or repository, and use or disclosure of PHI from the database or repository for a future research purpose, are each considered a separate research activity under the Privacy Rule. In general, the Privacy Rule requires Authorization for each activity, unless, for example, an IRB or Privacy Board waives or alters the Authorization requirement. (See **Overview of Privacy Rule's Impact on Repositories and Databases**.) Documentation of a waiver or an alteration of Authorization to use or disclose PHI to create a research database requires, among other things, a statement that an IRB or Privacy Board has determined that the researcher has provided adequate written assurances that PHI in the database will not be further used or disclosed except as permitted by the Privacy Rule (e.g., for research uses and disclosures with an Authorization or waiver). A covered entity also could use or disclose a limited data set to create a research repository or database under conditions set forth in a data use agreement.

For subsequent use or disclosure of PHI for research purposes from a repository or database maintained by the covered entity, the covered entity may:

- Obtain the individual's Authorization for the research use or disclosure of PHI as specified under section 164.508
- Obtain documentation of an IRB or Privacy Board's waiver of the Authorization requirement that satisfies section 164.512(i)
- Obtain satisfactory documentation of an IRB or Privacy Board's alteration of the Authorization requirement as well as the altered Authorization from the individual
- Use or disclose PHI for reviews preparatory to research with representations that satisfy

section 164.512(i)(1)(ii) of the Privacy Rule
- Use or disclose PHI for research on decedents' PHI with representations that satisfy section 164.512(i)(1)(iii) of the Privacy Rule
- Provide a limited data set and enter into a data use agreement with the recipient as specified under section 164.514(e)
- Use or disclose PHI based on permission obtained prior to the compliance date of the Privacy Rule—informed consent of the individual to participate in the research, an IRB waiver of such informed consent, or Authorization or other express legal permission to use or disclose the information for the research as specified under section 164.532(c) of the Privacy Rule

A covered entity may also use or disclose PHI from databases and repositories for other purposes without Authorization as permitted by the Privacy Rule, such as if required by law or to a public health authority for a public health activity (e.g., disclosures to cancer registries). Covered entities may also de-identify PHI according to standards set forth in the Privacy Rule so that its use and disclosure are not protected by the Privacy Rule.

Q: May a single Authorization permit a covered entity to use or disclose PHI for multiple activities of a specific research study, including the collection and storage of tissues for only that study? Does the option for using a single Authorization differ if a research study also collects and stores PHI as part of a central repository for future research?

A: A single Authorization may cover uses and disclosures of PHI for multiple activities of a specific research study, including the collection and storage of tissues for that study. In addition, where two different research studies are involved, such as where a research study collects information for the study itself, and collects and stores PHI in a central repository for future research, the Privacy Rule generally would permit them to be combined into a single, compound Authorization form.

However, a compound Authorization is not allowed where the provision of research-related treatment, payment, or eligibility for benefits is conditioned on only one of the Authorizations, and not the other. See section 164.508(b)(3)(iii) of the Privacy Rule. For example, a covered entity that conducts an interventional clinical trial that also involves collecting tissues and associated PHI for storage in a central repository for future research would not be permitted to obtain a compound Authorization for both research purposes if research-related treatment is conditioned upon signing the Authorization for the clinical trial. Any compound Authorization must clearly specify the different research studies covered by the Authorization so the individual is adequately informed.

Q: How could the Privacy Rule affect research involving data from repositories or databases that were created prior to the Privacy Rule's compliance date (April 14, 2003)?

A: The Privacy Rule contains a transition provision that, under certain conditions, allows covered entities to continue to use or disclose PHI without an Authorization, or waiver or alteration of the Authorization requirement, in connection with ongoing research, including research involving repositories or databases. For many such uses and disclosures of PHI in connection with ongoing research, a covered entity may rely on any one of the following that was obtained prior to the compliance date:

- An Authorization or other express legal permission from an individual to use or disclose PHI for research
- The informed consent of the individual to participate in the research
- A waiver by an IRB of informed consent in accordance with applicable laws and regulations governing informed consent, unless informed consent is sought after the compliance date

If the transition provisions do not apply and the information is not de-identified, subse-

quent uses and disclosures of PHI from databases and repositories held by covered entities generally require an individual's Authorization unless otherwise permitted by the Privacy Rule (e.g., with a waiver of Authorization or as a limited data set).

In addition, if the database or repository, which is held or maintained by a covered entity, contains only de-identified health information (which may include a re-identification code) meeting the Privacy Rule's requirements at section 164.514(a)-(c), the Privacy Rule does not apply.

Q: Does the Privacy Rule apply if a covered entity maintains and conducts research on a database of pre-existing specimens and data that are considered exempt from the HHS Protection of Human Subjects Regulations?

A. Yes, if the database contains PHI, the Privacy Rule applies. The covered entity, however, may de-identify the data by either: (1) Removing the 18 identifiable data elements listed at section 164.514(b)(2) of the Privacy Rule and having no actual knowledge that the information could be used, alone or in combination with other information, to identify the subject; or (2) having a qualified statistician's certification, with appropriate documentation, that there is a very small risk of identification by an anticipated recipient. If the information is not de-identified, subsequent uses and disclosures of PHI from databases and repositories held by covered entities generally require an individual's Authorization unless otherwise permitted by the Privacy Rule (e.g., with a waiver of Authorization or as a limited data set).

Q: A covered entity has a research repository and database of individually identifiable data for which the IRB waived informed consent for its creation and subsequent uses and disclosures of identifiable data prior to April 14, 2003. Is the covered entity required to obtain Authorization for research use and disclosure of PHI from the repository or database after April 14, 2003?

A: No, because the waiver, as described, meets the transition provisions of the Privacy Rule at 164.532(c). However, if informed consent is being sought from specimen donors after the compliance date, Authorization by the donors will be needed unless an IRB approves a waiver of the Authorization requirement, or another permitted use or disclosure applies.

Q: Does the Privacy Rule apply to databases held by covered entities that only receive de-identified participant data?

A: No, so long as the health information is de-identified according to the Privacy Rule, the Privacy Rule does not apply to the database or to future uses and disclosures of de-identified data from the database.

Q: May ongoing longitudinal studies continue after April 14, 2003?

A: Yes. Permissions or waivers obtained prior to the Privacy Rule's compliance date of April 14, 2003, for ongoing longitudinal studies are grandfathered by the Privacy Rule if they meet the transition provisions at 164.532(c). For many such uses and disclosures of PHI in connection with ongoing research, a covered entity may rely on any one of the following that was obtained prior to the compliance date:

- An Authorization or other express legal permission from an individual to use or disclose PHI for research
- The informed consent of the individual to participate in the research
- A waiver by an IRB of informed consent in accordance with applicable laws and regulations governing informed consent, unless informed consent is sought after the compliance date

Q: A researcher requests data that assigns a code derived from the last four digits of the social security number. This code is necessary to link individual records from different data sources. The data contain none of the other listed HIPAA identifiers at section 164.514(b)(2). Are the data de-identified under the Privacy Rule?

A: No. Under the Privacy Rule, a de-identified data set may not contain unique identifying codes, except for codes that have not been derived from or do not relate to information about the individual and that cannot be translated so as to identify the individual. A code derived from part of a social security number, medical record number, or other identifier does not meet this test.

Q: Does the Privacy Rule permit a covered entity to de-identify health information or create a limited data set without obtaining Authorization, waiver of the Authorization requirement from an IRB or Privacy Board, or representations for reviews preparatory to research?

A: Yes. In the Privacy Rule, creating de-identified health information or a limited data set is a health care operation of the covered entity, and thus, does not require the covered entity to obtain an individual's Authorization, a waiver of the Authorization requirement, or representations for reviews preparatory to research. If a business associate is hired by a covered entity to de-identify health information or create a limited data set, such activity must be conducted in accordance with the business associate requirements at sections 164.502(e) and 164.504(e).

Q: What is a limited data set, and what are its advantages?

A: A limited data set is PHI that does not include a specified list of direct identifiers. The limited data set is not considered to be de-identified information, and unlike de-identified information, a limited data set may include identifiers such as ZIP codes, elements of dates, and unique identifiers not listed as direct identifiers at section 164.514(e). The advantage of a limited data set is that even though it is not de-identified, it can still be used or disclosed for research purposes without an Authorization or a waiver of the Authorization requirement. A covered entity must, however, enter into a data use agreement with the recipient of the limited data set before using or disclosing it. (See section 164.514(e) of the Privacy Rule.)

Q: What types of information (direct identifiers) must be omitted from PHI in order to qualify the information as a limited data set?

A: All the following direct identifiers of the individual or of relatives, employers, or household members of the individual must be removed:

- Name
- Street name or street address or post office box (i.e., not including city, state, or ZIP code)
- Telephone and fax numbers
- Email address
- Social security number
- Certificate/license numbers
- Vehicle identifiers and serial numbers
- URLs and IP addresses
- Full-face photos and other comparable images
- Medical record numbers, health plan beneficiary numbers, and other account numbers
- Device identifiers and serial numbers.
- Biometric identifiers, including finger and voice prints

Q: What is the difference between a de-identified data set and a limited data set?

A: A de-identified data set is one in which either: (1) The 18 identifiers specified in 164.514(b)(2)(i) have been removed and the covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify the individual (safe harbor method); or (2) a person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable, determines the risk is very small that the information could be used by the recipient, alone or in combination with other reasonably available information, to identify an individual (section 164.514(b)(1)), and documents the basis for such determination. A de-identified data set is not protected by the Privacy Rule and may be used and disclosed without restriction.

A limited data set is one that excludes the direct identifiers in 164.514(e)(2). Unlike a de-identified data set, a limited data set is PHI because it may include dates, city, state, and ZIP codes, and other unique identifying codes or characteristics not listed as direct identifiers. A limited data set may be used or disclosed, without Authorization, for research, public health, or health care operations purposes, in accordance with section 164.512(e), only if the covered entity and limited data set recipient enter into a data use agreement. However, if the use or disclosure could be made under another provision of the Privacy Rule, such as for public health purposes in accordance with section 164.512(b), such agreement is not required.

Q: Are an individual's initials considered to be identifiers under the Privacy Rule?

A: Yes, because an individual's name is an identifier and initials are derived from the individual's name, initials are considered identifiers under the Privacy Rule. Thus, for information to be de-identified using the safe harbor method of the Privacy Rule, an individual's initials must be stripped from the information. However, it may be possible for initials to remain as part of de-identified information if the statistical method for de-identification at section 164.514(b)(1) allows it.

Q: May a limited data set include the geographic subdivision code with the five-digit ZIP code (or a nine-digit ZIP code)?

A: Yes, the limited data set may include the five-digit or nine-digit ZIP code plus any other geographic subdivision, such as state, county, city, precinct, and their equivalent geocodes, except for street name or street address or post office box.

Q: May a covered entity use or disclose PHI to locate or identify the whereabouts of a research participant (e.g., subjects who are "lost to follow-up")?

A: A covered entity is permitted to use or disclose PHI to identify or locate the whereabouts of a research participant during the study as long as the use or disclosure is not limited in the individual's Authorization (or grandfathered prior permission, if relevant) or waiver or alteration of Authorization. In addition, such use or disclosure is permissible if, for example, it is necessary for treatment of the individual or for a permissible public health purpose.

Q: What special requirements apply to research involving PHI from mental health providers?

A: The Privacy Rule provides individuals special protection for psychotherapy notes, which are notes recorded by a mental health provider that document or analyze counseling session conversations, and are maintained separately from the medical record. Unless the covered provider obtained, prior to the compliance date, the individual's informed consent or other express legal permission for the research or an IRB waiver of informed consent for the research, a covered entity may not use or disclose these notes for research without the individual's written Authorization. Information in the medical record and certain types of information, even if maintained separately from the medical record (e.g., information about test results, length and frequency of treatment, diagnosis, symptoms, or progress), is excluded from the definition of psychotherapy notes and may be released to researchers who obtain an Authorization or a waiver of Authorization from an IRB or Privacy Board, as part of a limited data set, or if appropriate, for reviews preparatory to research or for research involving decedent's information where required representations are obtained. Special requirements also apply to compound authorizations involving the use or disclosure of psychotherapy notes. (See section 164.508(b)(3)(ii) of the Privacy Rule.) Various state laws governing the use or disclosure of mental health records, including psychotherapy notes, which are more stringent than the Privacy Rule provisions, may also apply.

Q: How does the Privacy Rule apply to research involving blood or tissue samples?

A: Under the Privacy Rule, neither blood nor tissue, in and of itself, is considered individually identifiable health information; therefore, research involving only the collection of blood or tissue would not be subject to the Privacy Rule's requirements. Remember, however, blood and tissue are often labeled with information (e.g., admission date or medical record number) that the Privacy Rule considers individually identifiable and thus, PHI. A covered entity's use or disclosure of this information for research is subject to the Privacy Rule. In addition, the results from an analysis of blood and tissue, if containing or associated with individually identifiable information, would be PHI.

Q: Do the transition provisions apply to a surgical consent obtained by a covered provider that was signed or agreed to prior to the removal of tissues that were later added to a repository?

A: Yes, the transition provisions would apply in this case if, in the surgical consent or other express legal permission, the individual specifically agreed to the use and disclosure of PHI for research.

Q: Do the transition provisions at section 164.532(c) of the Privacy Rule apply to informed consent or waiver of informed consent to store and use PHI in a repository or database that was obtained before the compliance date?

A: Yes. HHS has stated, "…some express legal permissions and informed consents have not been study-specific and sometimes authorize the use or disclosure of information for future unspecified research. Furthermore, some IRB-approved waivers of informed consent have been for future unspecified research. Therefore, the final Rule at [section] 164.532 permits covered entities to rely on an express legal permission, informed consent, or IRB-approved waiver of informed consent for future unspecified research, provided the legal permission, informed consent or IRB-approved waiver was obtained prior to the compliance date." (See 67 *Federal Register* 53226, August 14, 2002.)

Q: Does the Privacy Rule limit, to specific types of research studies, disclosures permitted as preparatory to research or for research on decedents' information?

A: No. The Privacy Rule does not limit the types of research studies that may rely upon the provisions for reviews preparatory to research or for research on decedents' information set forth at section 164.512(i). However, representations made to satisfy these provisions must include, among other requirements at sections 164.512(i)(1)(ii) and 164.512(i)(1)(iii), a statement that the use or disclosure of protected health information is "necessary for the research purposes."

Q: Does the Privacy Rule restrict access for research purposes to information held by the Medicaid or SCHIP programs?

A: Yes. Local and state Medicaid authorities are covered entities under HIPAA, as are the State Children's Health Insurance Program (SCHIP) programs. These agencies or programs are covered under the Privacy Rule because they are listed in the Privacy Rule's definition of a "health plan." All SCHIP programs and state Medicaid agencies must consequently comply with the Privacy Rule; if they are hybrid entities, they must ensure that their designated health care components comply with the Privacy Rule. These government units will have some mechanism (a privacy officer, a Privacy Board, and/or an IRB) for controlling access to PHI for research purposes. A researcher will need to identify the responsible party and discuss with that office or official the ways in which access to PHI may be granted for research.

Q: In conducting records research, will a researcher who is a covered entity still be required to comply with state laws relating to medical records privacy, such as state HIV/AIDS confidentiality laws?

A: Probably. If the state law does not conflict with the Privacy Rule, the state law is not preempted by HIPAA, and the covered entity will be required to comply with both the state law and the Privacy Rule. If the state law conflicts with a provision of the Privacy Rule, the Privacy Rule has a preemption provision that allows state medical privacy laws to remain in place, if they are more stringent than the federal privacy standards. The Privacy Rule does not prohibit states from adopting privacy protections that are more stringent than the federal privacy standards.

Q: I am a researcher, and my research data source is asking me to sign a business associate agreement. Is this necessary?

A: Business associates are persons who perform certain services for, or functions or activities on behalf of, the covered entity that require access to PHI, but who are not part of the workforce of the covered entity. If the data source is not a covered entity, no business associate contract is required because the Privacy Rule only applies to covered entities.

If the data source is a covered entity, whether a business associate contract is required depends on the services, functions, or activities that the researcher is providing to or performing for the covered entity. Researchers are not business associates solely by virtue of their own research activities (although they may become business associates in some other capacity, e.g., if de-identifying PHI on behalf of a covered entity). A business associate agreement will typically be a legally enforceable contract, so a researcher may wish to consult legal counsel before signing one.

Q: Does a covered entity need to account for disclosures of PHI contained in a limited data set?

A. No. The accounting requirement does not apply to limited data set disclosures.

[1] The following identifiers of the individual or of relatives, employers, or household members of the individual must be removed: (1) Names; (2) all geographic subdivisions smaller than a state, except for the initial three digits of the ZIP code if the geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; (3) all elements of dates except year, and all ages over 89 or elements indicative of such age; (4) telephone numbers; (5) fax numbers; (6) email addresses; (7) social security numbers; (8) medical record numbers; (9) health plan beneficiary numbers; (10) account numbers; (11) certificate or license numbers; (12) vehicle identifiers and license plate numbers; (13) device identifiers and serial numbers; (14) URLs; (15) IP addresses; (16) biometric identifiers; (17) full-face photographs and any comparable images; (18) any other unique, identifying characteristic or code, except as permitted for re-identification in the Privacy Rule.

[2] A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable.

[3] The following direct identifiers must be removed for PHI to qualify as a limited data set: (1) Names; (2) postal address information, other than town or city, state, and ZIP code; (3) telephone numbers; (4) fax numbers; (5) email addresses; (6) social security numbers; (7) medical record numbers; (8) health plan beneficiary numbers; (9) account numbers; (10) certificate or license numbers; (11) vehicle identifiers and license plate numbers; (12) device identifiers and serial numbers; (13) URLs; (14) IP addresses; (15) biometric identifiers; and (16) full-face photographs and any comparable images.

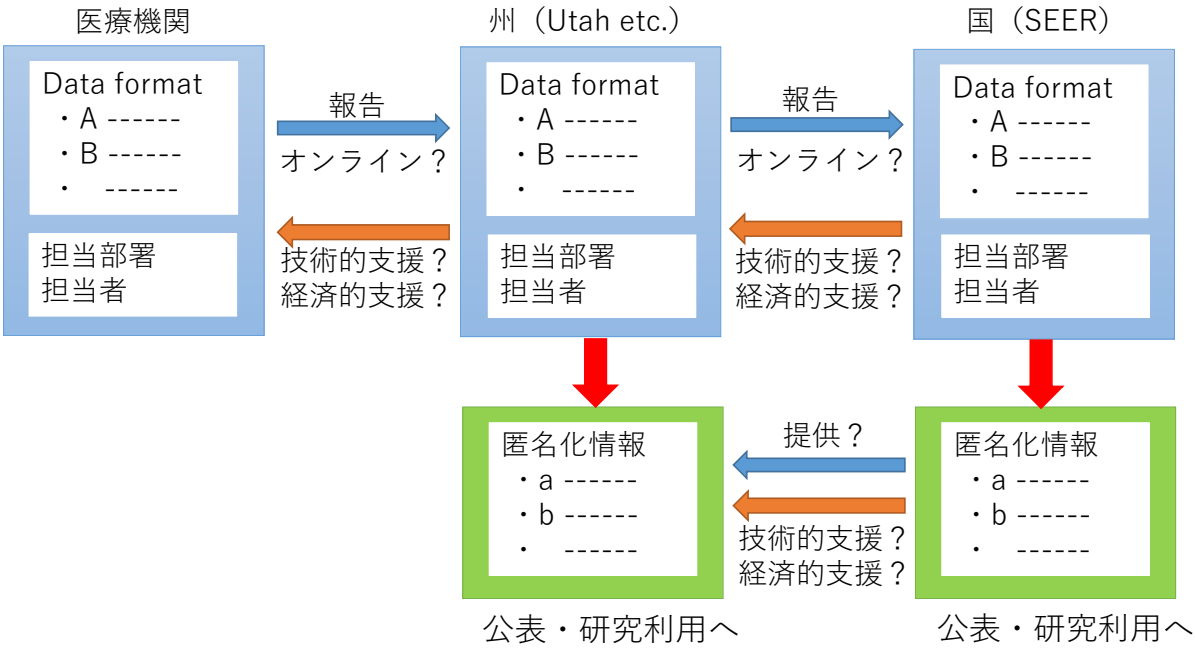
NIH Publication Number 04-5489 January 2004

長期記述疫研究用特定匿名化情報の整備に関する研究

宮城県立がんセンター
宮城県対がん協会
金村　政輝

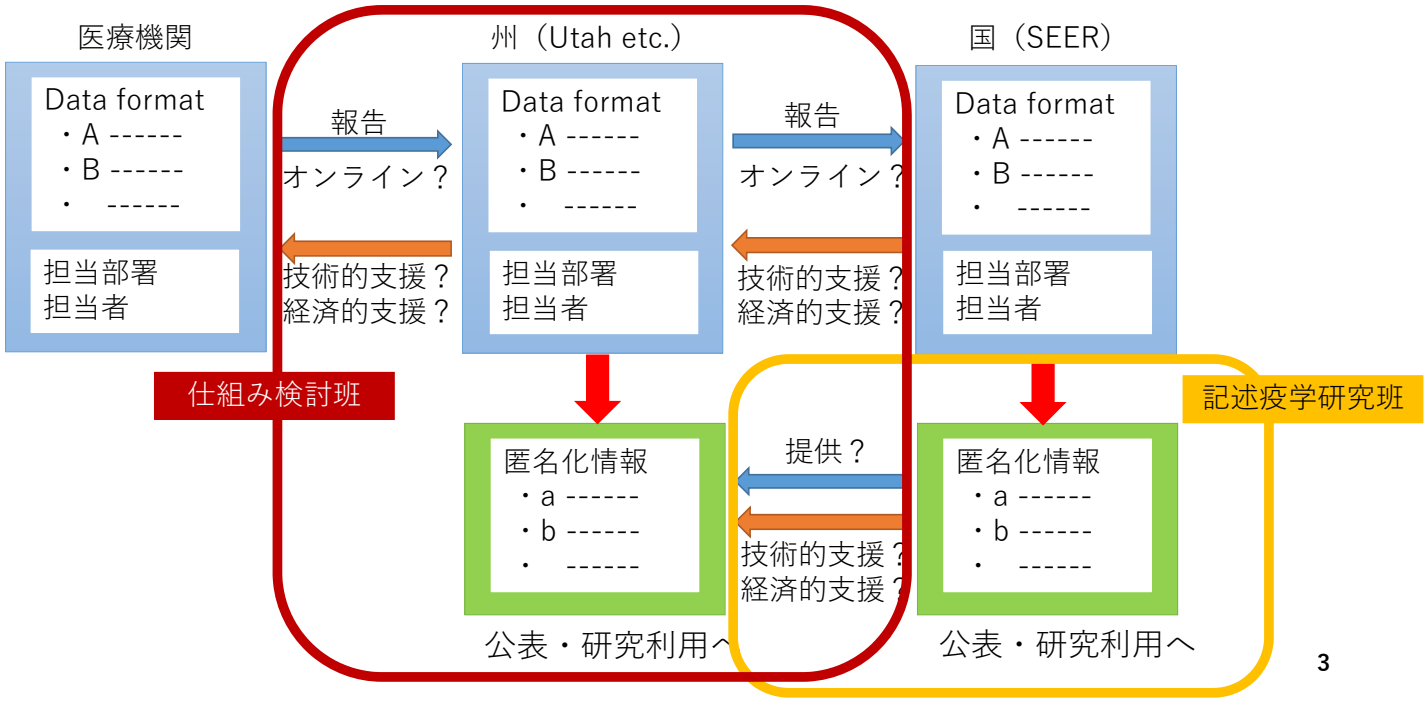
1

がん登録情報・がん診療情報とその基盤



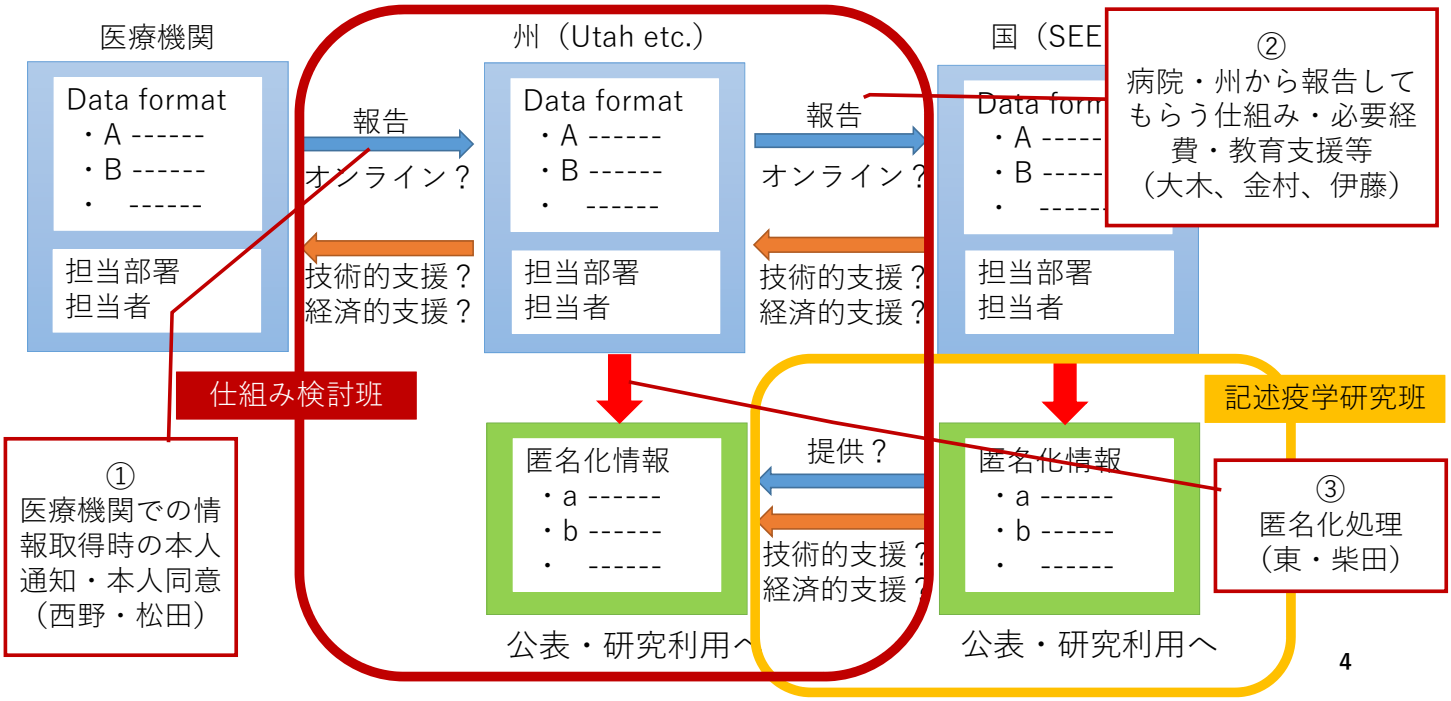
2

がん登録情報・がん診療情報とその基盤



3

がん登録情報・がん診療情報とその基盤



4

病院・州から報告してもらう仕組み・必要経費・教育支援等

- 仕組み
  - ➢法的な枠組みの有無と内容（国、ユタ州）
  - ➢資金的援助を伴うプログラムとしての枠組み（SEER、ユタ州）
  - ➢その他
- 必要経費
  - ➢経費の総額・内訳
  - ➢資金的援助（SEER）
  - ➢資金的援助（ユタ州）
  - ➢資金的援助（他機関等）
- 教育支援
  - ➢教育プログラム
  - ➢技術的支援
  - ➢その他

疑問
- 前述の図が正しいのか？
- 図の中の「？」はどうなのか？

確認
- 2つの検討班での分担、検討班内での分担は？
- 内容によっては、2つの検討班で重複して確認することになる・確認したほうがいい項目があるのでは？

5

病院・州から報告してもらう仕組み

- 法的な枠組みの有無と内容（p1,別紙1）
  - ➢国：不明➡要調査
  - ➢ユタ州：Utah Administrative Code, Rule R384-100, the Cancer Reporting Rule（p3-5,別紙2 ）➡詳細の読み込み・日本との比較必要
    - https://rules.utah.gov/publicat/code/r384/r384-100.htm#/T1
    - ✓“For Providers: How to Report a Cancer Case”（p6-7,別紙3 ）
      - http://healthsciences.utah.edu/utah-cancer-registry/reporting-cancer-in-utah/providers-how-to-report-a-cancer-case.php
- 資金的援助を伴うプログラムとしての枠組み（p1,別紙1）
  - ➢国（SEER）：不明➡要調査
  - ➢ユタ州： funded under Contract No. HHSN261201300017I(NCI)
    ➡要調査

6

病院・州から報告してもらう仕組み(2)

- その他
  - ➢報告のルール（p8-9,別紙4）➡詳細の読み込み、必要があれば日本との比較
    - ① SEER Program Coding and Staging Manual 2016
      https://seer.cancer.gov/tools/codingmanuals/
    - ② NACCR: Data Standards & Data Dictionary, Volume II
      https://www.naaccr.org/data-standards-data-dictionary/
  - ➢様式（Case form/Report form）➡詳細の読み込み、日本との比較
    - ① Urologists: Report a Cancer Case Form（p10,別紙5）
      http://healthsciences.utah.edu/utah-cancer-registry/docs/urologist-report-form-20161108.pdf
    - ② Dermatologists: Report a Cancer Case Form（p11,別紙6）
      http://healthsciences.utah.edu/utah-cancer-registry/docs/melanoma-report-form.20161108.pdf
    - ③ All other : General Report Form（p12,別紙7）
      http://healthsciences.utah.edu/utah-cancer-registry/docs/general-report-form-20161108.pdf

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病院・州から報告してもらう仕組み(3)

- その他
  - ➢報告の方法（p6-7,別紙3）➡詳細の読み込み、要調査
    - ① 郵送: 650 Komas Drive, Suite 106B, Salt Lake City, UT 84108
    - ② FAX: 801-851-4560
    - ③ Electronic Reporting: electronically through the Centers for Medicare and Medicaid Electronic Health Record (EHR) Incentive Program, also known as Meaningful Use or Advancing Care Information.
      - ✓“Cancer Reporting For Meaningful Use”（p13-14,別紙8）
        http://healthsciences.utah.edu/utah-cancer-registry/reporting-cancer-in-utah/cancer-reporting-for-meaningful-use.php
        1. Provider Checklist（p15-16,別紙9）
        2. Onboarding Process（p17,別紙10）
        3. Frequently Asked Questions（p18-19,別紙11）
        4. Quality Assurance Guide（p20-21,別紙12）

8

病院・州から報告してもらう必要経費

- 経費の総額・内訳
  - ➢不明➡要調査
- 資金的援助（SEER)
  - ➢不明➡要調査
- 資金的援助（ユタ州）（p1,別紙1）
  - ➢funded under Contract No. HHSN261201300017I(NCI)➡要調査
- 資金的援助（他機関等）（p2,別紙1）
  - ➢Additional Support➡要調査
    - ① Utah Department of Health cancer programs
    - ② University of Utah Health
    - ③ Huntsman Cancer Institute at the University of Utah

9

病院・州から報告してもらう教育支援等

- “Resources for Registrars”（p22-23,別紙13）
  http://healthsciences.utah.edu/utah-cancer-registry/reporting-cancer-in-utah/resources-registrars.php
  - ➢教育プログラム（p23）➡詳細の読み込み、要調査
    - “Cancer Registrar Training Programs & Workshops”（p23）
    - ✓National Cancer Registrars Association
    - ✓National Program for Cancer Registries
    - ✓NCI SEER Registrar Training
    - ✓NAACCR Registrar Education and Training
  - ➢技術的支援➡詳細の読み込み、要調査
    - “Resources for Registrars”（p22）
    - ✓Data Quality and Completeness
    - ✓Resources for Reporting Facilities

10

その他

- ユタ州では研究協力として患者調査も行っている模様（p24-25,別紙14）
  ” Information for the Public”
  -” Utah Cancer Registry Contacted Me. What Should I Do?”
  http://healthsciences.utah.edu/utah-cancer-registry/reporting-cancer-in-utah/info-for-public.php
- 市民が利用可能な教育資源（p25,別紙14, p26,別紙15）
  G. Mitchell Morris Cancer Learning Center (Health University of Utah)
  http://healthcare.utah.edu/huntsmancancerinstitute/cancer-information/cancer-learning-center/our-services.php

11

Authorizations & Institutional Affiliations

In the Utah Administrative Code, Rule R384-100, the Cancer Reporting Rule (https://rules.utah.gov/publicat/code/r384/r384-100.htm#T1) directs the Utah Cancer Registry to collect and manage cancer incidence and mortality data on behalf of the Utah Department of Health (http://health.utah.gov/).

The Cancer Reporting Rule states that:

> "Cancers constitute a leading cause of morbidity and mortality in Utah and, therefore, pose an important risk to the public health. Through the routine reporting of cancer cases, trends in cancer incidence and mortality can be monitored and prevention and control measures evaluated."

The rule further states that the cancer data collected by the registry are owned by the Utah Department of Health (UDOH) and that the authority for the registry is within the Utah Code under Title 26, Utah Health Code, Chapter 5, Chronic Disease Control, Section 3 (https://le.utah.gov/xcode/Title26/Chapter5/26-5-S3.html?v=C26-5-S3_1800010118000101), System for detecting and monitoring diseases established by department.

In addition to the registry's fundamental role of providing cancer data to the Utah Department of Health, Utah Cancer Registry staff support the Utah Department of Health Cancer Programs by participating in:

- the Utah Cancer Action Network (http://www.ucan.cc/)
- Genomics program (http://cancerutah.org/genomics/)
- and other activities

SEER Affiliation

The Utah Cancer Registry is affiliated with the US National Cancer Institute's Surveillance, Epidemiology and End Results (SEER) program (https://seer.cancer.gov/), funded under Contract No. HHSN261201300017I.

Our registry contributes de-identified data to the SEER research data set (https://seer.cancer.gov/data/).

資料1

Additional Support

We obtain additional financial support for our surveillance and research activities from the:

- Utah Department of Health cancer programs (http://cancerutah.org/)
- University of Utah Health (../../index.php)
- and Huntsman Cancer Institute at the University of Utah (http://www.huntsmancancer.org/)

Security & Confidentiality

The security and confidentiality measures that protect Utah Cancer Registry data are guided by the state through the Utah Cancer Reporting Rule and a Memorandum of Agreement between the University of Utah and the Utah Department of Health.

The Memorandum of Agreement outlines appropriate disclosure of data by the Utah Cancer Registry and states that an advisory committee (../docs/arc-members-may-2016.pdf) will oversee registry policies and data disclosures.

In addition, under the contract with the US National Cancer Institute's SEER program, our registry must comply with federal guidelines on data security and human subjects' research referenced therein.

The University of Utah's data security and confidentiality policies (http://regulations.utah.edu/it/rules/index.php) also apply to our registry.

CONTACT US

Utah Cancer Registry

650 Komas Drive, Suite 106B
Salt Lake City, UT 84108

Phone: 801-581-8407
Fax: 801-851-4560
Email: ucr.info@hsc.utah.edu (mailto:ucr.info@hsc.utah.edu)

R384. Health, Disease Control and Prevention, Health Promotion.
R384-100. Cancer Reporting Rule.
R384-100-1. Purpose Statement.

(1) The Cancer Reporting Rule is adopted under authority of sections 26-1-30 and 26-5-3.

(2) Cancers constitute a leading cause of morbidity and mortality in Utah and, therefore, pose an important risk to the public health. Through the routine reporting of cancer cases, trends in cancer incidence and mortality can be monitored and prevention and control measures evaluated.

(3) Cancer records are managed by the Utah Cancer Registry (Registry) on behalf of the Utah Department of Health. This Cancer Reporting Rule is adopted to specify the reporting requirements for cases of cancer to the Registry. The Utah Department of Health retains ownership and all rights to the records.

R384-100-2. Definitions.

As used in this rule:

(1) "Cancer" means all in-situ (with the exception of in-situ cervical cancers) or malignant neoplasms diagnosed by histology, radiology, laboratory testing, clinical observation, autopsy or suggestible by cytology, but excluding basal cell and squamous cell carcinoma of the skin unless occurring in genital sites such as the vagina, clitoris, vulva, prepuce, penis and scrotum.

(2) "Follow-up data" includes date last seen or date of death, status of disease, date of first recurrence, type of recurrence, distant site(s) of first recurrence, and the name of the physician who is following the case.

(3) "Health care provider" includes any person who renders health care or professional services such as a physician, physician assistant, nurse practitioner, registered nurse, licensed practical nurse, dentist, optometrist, podiatric physician, osteopathic physician, osteopathic physician and surgeon, or others rendering patient care.

(4) "Registrar" means a person who:

(a) is employed as a registrar and who has attended a cancer registrar training program;

(b) has two years of experience in medical record discharge analysis, coding, and abstracting, and has successfully completed a course in anatomy, physiology, and medical terminology; or

(c) has successfully passed the Certified Tumor Registrar examination offered by the National Cancer Registrars' Association.

(5) "Reportable benign tumor" means any noncancerous neoplasm occurring in the brain.

R384-100-3. Reportable Cases.

Each case of cancer or reportable benign tumor, as described in R384-100-2, that is diagnosed or treated in Utah shall be reported to the Utah Cancer Registry, 546 Chipeta Way; Suite 2100; Salt Lake City, Utah 84108, telephone number 801-581-8407, FAX number 801-581-4560.

R384-100-4. Case Report Contents.

Each report of cancer or reportable benign tumor shall include information on report forms provided by the Registry. These reports

shall be made in the format prescribed by the Registry and shall include items such as the name and address of the patient, medical history, environmental factors, date and method of diagnosis, primary site, stage of disease, tissue diagnosis, laboratory data, methods of treatment, recurrence and follow-up data, and physician names.

R384-100-5. Agencies or Individuals Required to Report Cases.

(1) All hospitals, radiation therapy centers, pathology laboratories licensed to provide services in the state, nursing homes, and other facilities and health care providers involved in the diagnosis or treatment of cancer patients shall report or provide information related to a cancer or reportable benign tumor to the Registry.

(2) Procedures for reporting:

(a) Hospital employed registrars shall report hospital cases.

(b) Registrars employed by radiation therapy centers shall report center cases.

(c) Pending implementation of electronic reporting by pathology laboratories, pathology laboratories shall allow the Registry to identify reportable cases and extract the required information during routine visits to pathology laboratories.

(d) If a health care provider diagnoses a reportable case but does not send a tissue specimen to a pathology laboratory or arrange for treatment of the case at a hospital or radiation therapy center, then the health care provider must report the case to the Registry.

(e) If the Registry has not received complete information on a reportable case from routine reporting sources (hospitals, radiation therapy centers, pathology laboratories), the Registry may contact health care providers and require them to complete a report form.

R384-100-6. Time Requirements.

(1) New Cases:

(a) Hospitals and radiation therapy facilities shall submit reports to the Registry within six months of the date of diagnosis.

(b) Other facilities and health care providers shall submit reportable data to the Registry upon request.

(2) Follow-up Data:

(a) Hospitals and radiation therapy centers shall submit annual follow-up data to the Registry within 13 months of the date the patient was last contacted by hospital or facility personnel.

(b) Physicians shall submit follow-up data to the Registry upon request.

R384-100-7. Reporting Format.

Reports shall be submitted in the standard format designated by the Registry. Report forms can be obtained by contacting the Registry.

R384-100-8. Data Quality Assurance.

Records maintained by hospitals, pathology laboratories, cancer clinics, and physicians are subject to review by Registry personnel acting on behalf of the Department of Health to assure the completeness and accuracy of reported data.

R384-100-9. Confidentiality of Reports.

All reports required by this rule are confidential under the

provisions of Title 26, Chapter 3 and are not open to inspection except as allowed by Title 26, Chapter 3. The Registry shall maintain all reports according to the provisions of Title 26, Chapter 3.

R384-100-10. Penalties.

Enforcement provisions and penalties for the violation or for the enforcement of public health rules, including this Cancer Reporting Rule, are prescribed under Section 26-23-6 and are punishable.

KEY: cancer, reporting requirements and procedures
Date of Enactment or Last Substantive Amendment: March 15, 2010
Notice of Continuation: March 18, 2014
Authorizing, and Implemented or Interpreted Law: 26-1-30; 26-5-3

Utah Cancer Registry (../index.php) **Reporting Cancer in Utah** (index.php)

Utah Cancer Registry Navigation

For Providers: How to Report a Cancer Case

Cancer is designated as a reportable disease in the state of Utah (Cancer Reporting Rule, R384-100) (https://rules.utah.gov/publicat/code/r384/r384-100.htm#T1).

Reporting Cancer Cases to the Utah Cancer Registry

Health care providers are required to report cases to the Utah Cancer Registry (index.php) when they diagnose a reportable (http://healthsciences.utah.edu/utah-cancer-registry/reporting-cancer-in-utah/index.php#reportable)case but do not send a tissue specimen to a lab or refer the patient to a hospital for treatment.

Additionally, UCR may request a report form when other reporting sources do not provide adequate information about the cancer case.

What Form Should I Use to Report a Cancer Case?

UCR provides a one-page report form for health care providers to complete about their reportable cancer cases.

Urologists and dermatologists have forms that are specific to those specialties:

- Urologists: Report a Cancer Case Form (../docs/urologist-report-form-20161108.pdf)
- Dermatologists: Report a Cancer Case Form (../docs/melanoma-report-form.20161108.pdf)

All other providers can use the General Report Form (../docs/general-report-form-20161108.pdf).

The report forms are editable pdfs that can be completed on the computer or printed. These forms can be mailed or faxed to UCR:

Mailing Address: 650 Komas Drive, Suite 106B, Salt Lake City, UT 84108
Fax Number: 801-851-4560

Electronic Reporting Through Centers for Medicare & Medicaid Electronic Health Record (EHR) Incentive Program

Health care providers can opt to report their cases electronically through the Centers for Medicare and Medicaid Electronic Health Record (EHR) Incentive Program, also known as Meaningful Use or Advancing Care Information (cancer-reporting-for-meaningful-use.php).

This program provides incentives for health care providers to use an EHR to document their patient care and requires that providers meet specific measures to get the incentives.

Cancer case reporting is one of the measures providers can use to get incentives.

CONTACT US

Utah Cancer Registry

650 Komas Drive, Suite 106B
Salt Lake City, UT 84108

Phone: 801-581-8407
Fax: 801-581-4560
Email: ucr.info@hsc.utah.edu (mailto:ucr.info@hsc.utah.edu)

(cancer-reporting-for-meaningful-use.php)

Utah Cancer Registry (../index.php) **Reporting Cancer in Utah** (index.php)

Utah Cancer Registry Navigation

Cancer As a Reportable Disease

Cancer is designated as a reportable disease in the state of Utah (Cancer Reporting Rule, R384-100 (https://rules.utah.gov/publicat/code/r384/r384-100.htm)).

Cases reportable to the registry follow the SEER Program Coding and Staging Manual 2016 (https://seer.cancer.gov/tools/codingmanuals/) which includes:

- in situ and invasive neoplasms (with certain exceptions)
- benign brain tumors
- and central nervous system tumors.

For detailed reportability requirements see below or review the SEER Program Coding and Staging Manual 2016 (https://seer.cancer.gov/tools/codingmanuals/) beginning on page 5.

Cancer registrars at hospitals and other health care facilities across the state, as well as Utah Cancer Registry staff members, work to identify cases of cancer through systematic review of:

- pathology reports
- medical records
- hospital discharge lists
- and vital records

The Utah Cancer Registry collects diagnostic information, treatment, and follow-up in accordance with data standards of the National Cancer Institute SEER Program (https://seer.cancer.gov/tools/codingmanuals/index.html) and the North American Association of Central Cancer Registries (http://www.naaccr.org/StandardsandRegistryOperations/VolumeII.aspx).

How to Report Cancer Cases If You Are a Health Care Provider

Health care providers can learn how to report cancer cases in Utah (providers-how-to-report-a-cancer-case.php).

Which Conditions Are Reportable?

資料1

All in situ and malignant/invasive histologies (Behavior code /2, /3, see ICD-O-3) are reportable including:

- Intraepithelial neoplasia, grade III (examples: AIN III C210 & C211; VAIN III & VIN III)
- Carcinoid, NOS of the appendix is reportable. As of January 1, 2015, the ICD-O-3 behavior code changed from /1 to /3
- Urine cytology positive for malignancy is reportable for diagnoses in 2013 and later (exception: When a subsequent biopsy of a urinary site is negative, do not report)
- Non-invasive mucinous cystic neoplasm (MCN) of the pancreas with high grade dysplasia
- Mature teratoma of the testes in adults is malignant and reportable as 9080/3

Benign and borderline primary intracranial and central nervous system (CNS) tumors (behavior code /0 or /1 as of January 1, 2004):

- Pilocytic Juvenile astrocytoma is reportable and should be coded as 9421 with behavior /3 (9421/3)

Reporting Exceptions

Reportability Exceptions: Malignant and invasive histologies **not required:**

- Skin primaries (C440-C449) with any of the following histologies:
  - Malignant neoplasm (8000-8005)
  - Epithelial carcinoma (8010-8046)
  - Papillary and squamous cell carcinoma (8050-8084)
  - Basal cell carcinoma (8090-8110)
  - AIN III (8077) arising in perianal skin (C445)
- Carcinoma in situ of cervix (/2) or cervical intraepithelial neoplasia (CIN III or SIN III) of the cervix (as of January 1, 1996)
- Prostatic intraepithelial neoplasia (PIN III) of the prostate (C619) (as of January 1, 2001)

See the reportability section of the SEER Program Coding and Staging Manual 2016 (https://seer.cancer.gov/tools/codingmanuals/) beginning on page 5 for a more descriptive list of reportable diagnoses and exceptions. This resources also shows a table of required sites for benign and borderline primary intracranial and CNS tumors.

CONTACT US

Utah Cancer Registry

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Fax: 801-851-4560
Email: ucr.info@hsc.utah.edu (mailto:ucr.info@hsc.utah.edu)

UNIVERSITY OF UTAH HEALTH SCIENCES | Utah Cancer Registry

Dear Doctor:

In compliance with Utah state law, please use this form to report prostate cancer cases. Should you have any questions, you may call us at 801-581-8407. Completed forms may be faxed or mailed to the address or phone number below. Please attach a copy of the appropriate pathology report if available.

Patient Name: _____ Race: _____

Date of Birth: _____ SSN: _____ Phone: _____

Address at diagnosis: _____City_____State_____Zip_____

When was this malignancy first diagnosed? _____

Was the patient ever hospitalized for the malignancy mentioned on the Pathology Report? ☐Yes ☐No

If YES, please indicate the name of the hospital: _____

If NO, please complete the following:

DRE Findings: _____ PSA: _____

Clinical TNM/Stage: _____

TREATMENT (please circle):

SURGERY RADIATION CHEMOTHERAPY HORMONE OTHER

_____ _____
procedure / type date

_____ _____
procedure / type date

Date last seen: _____ ☐ Alive ☐ Dead

Physician at diagnosis: _____

Physician patient was referred to (if different than above): _____

Thank you for your help.

SuAnn McFadden, CTR

SuAnn McFadden
Operations Manager

650 Komas Drive Suite 106B
Salt Lake City, Utah 84108
Phone (801) 581-8407
Fax (801) 581-4560

UNIVERSITY OF UTAH HEALTH SCIENCES | Utah Cancer Registry

Dear doctor:

In compliance with Utah state law, please use this form to report skin cancer cases (with the exception of basal and squamous cell carcinomas)*. Should you have any questions, you may call us at 801-581-8407. Completed forms may be faxed or mailed to the address or phone number below. Please attach a copy of the appropriate pathology report if available.

Patient name: _____ Race: _____

Date of birth: _____ SSN: _____ Phone: _____

Address at diagnosis: _____City_____State_____Zip_____

When was this malignancy first diagnosed? _____

Was the patient ever hospitalized for the malignancy mentioned on the Pathology Report? ☐Yes ☐No

If YES, please indicate the name of the hospital: _____
If NO, please complete the following:

Site & laterality of lesion: _____

Please describe the type(s) of bx, or excision(s) done:
_____ Date: _____

_____ Date: _____

Specific histology type: _____

Breslow's depth (if applicable): _____ Clark's level (if applicable): _____

Ulceration present? ☐Yes ☐No Size of lesion: _____

Any other treatment (radiation, chemo, etc.):
_____ Date: _____

Date last seen: _____ ☐ Alive ☐ Dead

Physician at diagnosis: _____

Physician patient was referred to (if different than above): _____
Thank you for your help.

SuAnn McFadden, CTR

SuAnn McFadden
Operations Manager

*reportable diagnoses: kaposis sarcoma, melanomas (including lentigo maligna and insitu), mycosis fungoides, dermatofibrosarcoma protuberans, malignant fibrous histiocytoma, cutaneous t-cell lymphoma, queyrat's erythroplasia, merkel cell carcinoma, sweat gland adenocarcinoma, sebaceous adenocarcinoma, eccrine adneocarcinoma, cerumionous adenocarcinoma, and skin mets from other primary cancers.

650 Komas Drive Suite 106B
Salt Lake City, Utah 84108
Phone (801) 581-8407
Fax (801) 581-4560

UNIVERSITY OF UTAH HEALTH SCIENCES | Utah Cancer Registry

Dear Doctor:

In compliance with Utah state law, please use this form to report cancer cases. Should you have any questions, you may call us at 801-581-8407. Completed forms may be faxed or mailed to the address or phone number below. Please attach a copy of the appropriate pathology report if available.

Patient Name: _____ Race: _____

Date of Birth: _____ SSN: _____ Phone: _____

Address at diagnosis: _____City_____State_____Zip_____

When was this malignancy first diagnosed? _____

Site & laterality of lesion: _____

Was the patient ever hospitalized for the malignancy mentioned on the Pathology Report? ☐Yes ☐No

If YES, please indicate the name of the hospital: _____

If NO, please complete the following:

TREATMENT (please circle):

SURGERY RADIATION CHEMOTHERAPY HORMONE OTHER

_____ _____
procedure / type date

_____ _____
procedure / type date

Date last seen: _____ ☐ Alive ☐ Dead

Physician at diagnosis: _____

Physician patient was referred to (if different than above): _____

Thank you for your help.

SuAnn McFadden, CTR

SuAnn McFadden
Operations Manager

650 Komas Drive Suite 106B
Salt Lake City, Utah 84108
Phone (801) 581-8407
Fax (801) 581-4560

Utah Cancer Registry (../index.php) **Reporting Cancer in Utah** (index.php)

Utah Cancer Registry Navigation

Cancer Reporting For Meaningful Use

Providers can meet the Medicare and Medicaid EHR Incentive Program, Meaningful Use for 2015-2017 specialized registry reporting requirement.

Is Utah Cancer Registry Currently Receiving Cancer Data?

- Since January 5, 2015 we have received electronic cancer data.
- We will be ready for active engagement and will be accepting optional stage 3 data beginning **January 1, 2017**.

How Do I Send Electronic Cancer Data?

If you are an eligible provider and would like to register your intent to send electronic cancer data to UCR, please read our resources below for instructions on how to proceed.

1. Provider Checklist (docs/ucr-provider-checklist.pdf)
2. Onboarding Process (docs/ucr-onboarding-process.pdf)
3. Frequently Asked Questions (docs/ucr-mu-faqs.pdf)
4. Quality Assurance Guide (docs/ucr-quality-assurance.pdf)

Questions About Reporting Cancer Cases?

If you have any additional questions, please feel free to contact us at: UCR_MeaningfulUse@Utah.edu (mailto:UCR_MeaningfulUse@Utah.edu)

CONTACT US

Utah Cancer Registry

650 Komas Drive, Suite 106B
Salt Lake City, UT 84108

Phone: 801-581-8407
Fax: 801-581-4560
Email: ucr.info@hsc.utah.edu (mailto:ucr.info@hsc.utah.edu)

MEANINGFUL USE RESOURCES

資料1

UTAH DEPARTMENT OF HEALTH MEANINGFUL USE WEBSITE (HTTP://HEALTH.UTAH.GOV/MEANINGFULUSE/)

CENTER FOR MEDICARE & MEDICAID SERVICES (CMS) (HTTPS://WWW.CMS.GOV/REGULATIONS-AND-GUIDANCE/LEGISLATION/EHRINCENTIVEPROGRAMS/INDEX.HTML?REDIRECT=/EHRINCENTIVEPROGRAMS)

CMS MEANINGFUL USE MODIFIED STAGE 2 (HTTPS://WWW.CMS.GOV/REGULATIONS-AND-GUIDANCE/LEGISLATION/EHRINCENTIVEPROGRAMS/FAQ.HTML)

NATIONAL COORDINATOR FOR HEALTH IT MEANINGFUL USE (HTTPS://WWW.HEALTHIT.GOV/PROVIDERS-PROFESSIONALS/EHR-INCENTIVES-CERTIFICATION)

OFFICE OF NATIONAL COORDINATOR FOR HEALTH CERTIFIED EHR SOFTWARE (HTTPS://CHPL.HEALTHIT.GOV/#/SEARCH)

CENTERS FOR DISEASE CONTROL & PREVENTION MEANINGFUL USE (HTTPS://WWW.CDC.GOV/CANCER/NPCR/MEANINGFUL_USE.HTM)

HEALTHINSIGHT (HTTP://HEALTHINSIGHT.ORG/MEANINGFUL-USE-HEALTH-IT)

Utah Cancer Registry
650 Komas Drive, Suite 106B
Salt Lake City, UT 84108
801-581-8407

Provider Checklist for Achieving Meaningful Use (MU) for Cancer Reporting to Utah Cancer Registry (UCR)

Eligibility

- ☐ Are you a provider that diagnoses or treats cancer patients? If not, you do not need to test with (UCR).

- ☐ Do you have a certified Electronic Health Record (EHR)? To look up your Centers for Medicare and Medicaid Services (CMS) EHR Certification identification number, see the Certified Health IT Product List.

Registration to Test with UCR

- ☐ Complete the registration at http://health.utah.gov/meaningfuluse/. Testing is prioritized by your site's reporting period and the order in which registration requests are received.

- ☐ After your registration request has been validated, you will receive confirmation and instructions on how to begin testing and validation.

Testing and Validation

- ☐ Identify the people on your vendor support team or practice staff who will be responsible for testing, validation, and ensuring active engagement.

- ☐ Work with your vendor to ensure your CDA documents use correct codes and sections as outlined in the implementation guide.

- ☐ Work with your vendor to receive proper training in using the EHR to ensure the information required for cancer reporting is captured. For information about these fields, refer to the implementation guide.

- ☐ Work with your vendor to ensure your CDA documents are formatted correctly and the required fields are filled in with valid data.

- ☐ Receive an e-mail with instructions on how to submit your first test CDA documents and work with UCR to connect to their SFTP site to transmit both test and real data.

- ☐ Work with UCR's MU Coordinator to review your test data to ensure CDA documents will contain valid values.

- ☐ If the validation fails, you will receive a summary of the errors.

- ☐ Generate and submit CDA documents from your EHR.

- UCR will validate the documents' content and format and perform a quality assurance review.

Confirmation of Production Status

- After the data have been transmitted and validated, you will receive confirmation from UCR and instructions for continuing active engagement.

Onboarding Process for Cancer Data Submission

To meet the Meaningful Use (MU) cancer reporting objective, Eligible Professionals (EP) must register and complete all steps in the on-boarding process. Providers registered using the Utah Department of Health website will receive acknowledgement of the Utah Cancer Registry (UCR) MU status they have achieved. Statuses include Registered, Invited to Onboard, Testing and Validation, and Production.

Registration and Connection:

Eligible Professional (EP) registers intent to submit cancer data for MU.

1. Register using on the Utah Department of Health website at http://health.utah.gov/meaningfuluse/
2. UCR will provide an email confirmation to designated recipients of successful registration with instructions for sending more information to UCR. Your MU status will be "Registered".

Invitation to Onboard

Clinics will be prioritized for onboarding by the UCR.

1. UCR will provide an email invitation indicating that the EP should begin the onboarding process. Your MU status will be "Invited to Onboard" and once you begin to submit messages it will change to "Testing and Validation."

Message Structure Validation:

EP submits cancer messages using defined structure for UCR staff to validate. The message contains test data.

1. Prepare a message conforming to the structure detailed in the implementation guide and that can be validated by the CDC NIST validator.
2. Submit sample messages to UCR by SFTP for structural validation.
3. Incorporate UCR feedback as necessary to refine message structure to meet MU and UCR message requirements.

Message Content Validation:

EP submits cancer messages using defined content standards for UCR staff to validate. Message contains actual patient data

1. Submit messages that contain actual (production) data.
2. Incorporate feedback from UCR to refine message content to meet MU and UCR requirements.

Production:

EP initiates ongoing submission of cancer data and participates in periodic quality assurance activities.

1. Initiate regular production transmission of cancer messages to UCR. Your MU status will be updated from "Testing and Validation" to "Active Engagement"
2. Incorporate UCR feedback as necessary to ensure quality of data.
3. UCR will provide an e-mail communication acknowledging active engagement when this step is completed.

Frequently Asked Questions

About Cancer Reporting for Meaningful Use

What is Meaningful Use?

Meaningful Use is a program offered by the Centers for Medicare and Medicaid Services (CMS) that provides incentives to eligible hospitals and professionals who demonstrate meaningful use of Certified Electronic Health Record Technology (CEHRT). More information can be found here: https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html?redirect=/ehrincentiveprograms.

Where can I find Clinical Document Architecture (CDA) specifications for cancer reporting?

They are published through the Centers for Disease Control and Prevention. Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries HL7 Clinical Document Architecture (CDA) Release 1.1 located at http://www.cdc.gov/phin/resources/guides/documents/implementation_guide_for_ambulatory_healthcare_provider_reporting_to_central_cancer_registries_march_2014.pdf.

What is an Eligible Professional?

An Eligible Professional (EP) is a term defined by CMS for individual practitioners who qualify for the Meaningful Use incentive program. The criteria are published on the CMS website, link below. The UCR reporting requirements apply to private physicians who diagnosis and/or treat cancer patients. Private physicians may qualify as an Eligible Professional, but this is determined by CMS and not UCR. https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html?redirect=/ehrincentiveprograms.

Can I begin cancer reporting for 2015-2017 if I have not successfully achieved MU1?

Please refer to the CMS website for details. https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html?redirect=/ehrincentiveprograms.

How do I register intent to submit cancer data for MU?

Visit the Utah Department of Health's website at http://health.utah.gov/meaningfuluse/ and complete the registration form.

How does MU registration apply to individual physicians not a part of a group practice?

If you are an individual physician who is not coordinating MU reporting with a larger group practice, you will need to register through the Utah Department of Health website and indicate that you are the primary contact for whom all MU2 cancer registry communications should be directed. You will not be required to enter a group National Provider Identifier (NPI) number, but you will be required

to enter your individual NPI number as assigned from the National Plan & Provider Enumeration System (NPPES).

How does MU registration apply to group practices?

For physicians who belong to a single group practice, under which all MU2 activities are coordinated, it is recommended that a single person from the practice serve as the primary MU2 administrator and contact representative. This administrator will register all EPs under the practice name in a single registration session and will provide a single group NPI during the registration process. If your practice has more than one group NPI, please enter just one group NPI during registration.

What if I am a hospital-based physician and I want to report my cases via CDA messages?

CMS publishes strict guidelines on the MU incentive qualifications for physicians who practice in a hospital setting. While you may not qualify for CMS incentives under MU EP guidelines, the UCR will still accept CDA messages from any private physician who elects to report using this method. Please note that if you are a hospital-based physician who diagnosis and/or treats cancer patients, the hospital facility is already reporting these cases to the cancer registry.

If multiple eligible professionals (EPs) are using the same certified EHR technology across several physical locations, can a single test or onboarding effort serve to meet the measures of these objectives?

Yes. Providers that are registered under the same practice/organization from which the same EHR technology is shared can conduct on test that covers all providers registered. For example, if a large group of EPs with multiple physical locations use the same EHR technology and those locations are connected using a network that the group has either operational control of or license to use, then a single test would cover all EPs in that group.

What are the reporting periods for an EP to begin the onboarding and reporting process?

Please refer to the 2015-2017 modification rule for at https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html?redirect=/ehrincentiveprograms. .

UCR Meaningful Use Quality Assurance Testing Guide

This guide is intended for:

1. Eligible professionals who meet the requirements for Meaningful Use (MU).
2. Providers who diagnose or treat cancer patients and want to begin reporting their patient cancer data to UCR using the Clinical Document Architecture (CDA) format.

This document outlines the data quality standards required for reporting data to the UCR using the HL7 CDA format, which is required for MU. Certain fields are required in the CDA document to pass the quality assurance review. Providers should configure the Electronic Health Record (EHR) so that valid data is entered in the required fields before testing with UCR.

Quality Assurance Testing Requirement

Following the successful submission of a test CDA document for MU, eligible providers must pass quality assurance testing before production status is achieved. It is important to note that EHR certification does not guarantee that EHR software meets your business needs or the UCR requirements. Furthermore, to ensure complete and correct data are recorded, UCR has set high standards for data completeness, quality, and timeliness.

Compliance with follow-up submission requires eligible professionals to adhere to the quality assurance testing process. Eligible professionals must demonstrate active engagement in quality assurance testing by following the steps listed below. After providers have passed the quality assurance testing process, production submission can occur.

Quality Assurance Testing Steps

Providers must complete the following six steps to meet the quality assurance testing requirements. Along with the six steps, tips are listed for providers to achieve each step.

Step 1 - Document transport

- Connectivity to UCR for submission is enabled through an SFTP site.
- Review UCR's connectivity requirements.
- Work with your vendor to make sure your CDA documents are formatted correctly.

Step 2 - Validate that the certified EHR captures the required fields

- Review the required fields in the implementation guide located in the implementation guide.

Step 3 - Validate that the certified EHR contains the correct codes and sections

- Review codes and sections as outlined in the implementation guide in the implementation guide

Step 4 - Message format validation

- Send sample CDA documents to UCR. Documents must comply with the CDA specification in the implementation guide.

Step 5 - Content validation

- UCR will conduct a data quality analysis and provide feedback on the content of the cancer data.

Step 6 – Production

- Regularly send UCR electronic cancer data and respond to requests from UCR concerning data quality.

Quality Assurance Criteria

Required Fields – All required fields should be included in the CDA document. It is a production requirement to include all of the required fields. The required fields should not contain filler or "dummy" data. If there is no value in a required field because it was not entered or because the value is unknown, the appropriate "flavor of null" should be provided.

Fields that cannot be left empty are identified in the CDA Validation Plus software and are subject to change pending the outcome of the CDC-NPCR Workgroup's decision on standardized required fields for all states.

Utah Cancer Registry (../index.php) **Reporting Cancer in Utah** (index.php)

Utah Cancer Registry Navigation

Resources for Registrars

Hospital-based cancer registrars and off-site abstractors perform a critical function for the Utah Cancer Registry. We depend on the information we receive from registrars to be timely and high quality.

Data Quality and Completeness

The Utah Cancer Registry (UCR) participates in the National Cancer Institute's Surveillance, Epidemiology and End Results (SEER) program and must meet SEER requirements (https://seer.cancer.gov/registrars/) for reportable cases and data collection.

- Information for Reporting Facilities (docs/information-for-reporting-facilities.pdf)
- Edits Metafile - UCR_V16D.zip (../docs/ucr_v16d.zip)

Resources for Reporting Facilities

- National Cancer Registrars Association (NCRA) (http://www.ncra-usa.org/i4a/pages/index.cfm?pageid=1)
- National Cancer Institute SEER Program (SEER) (https://seer.cancer.gov/)
- North American Association of Central Cancer Registries (NAACCR) (https://www.naaccr.org/)
- American College of Surgeons Commission on Cancer (COC) (https://www.facs.org/quality-programs/cancer)
- National Cancer Data Base (NCDB) (https://www.facs.org/quality-programs/cancer/ncdb)
- SEER Coding & Staging Manuals (https://seer.cancer.gov/tools/codingmanuals/)
- NAACCR Datadictionary (http://datadictionary.naaccr.org/)
- Collaborative Stage Data Collection System (CS) (https://cancerstaging.org/cstage/schema/Pages/version0205.aspx)
- SEER Required CS Site Specific Factors (https://seer.cancer.gov/csreqstatus/application.html)
- International Classification of Diseases 10th Edition (ICD 10) (https://www.cdc.gov/nchs/icd/icd10cm.htm)

Cancer Registrar Training Programs & Workshops

- National Cancer Registrars Association (http://www.ncra-usa.org/i4a/pages/index.cfm?pageid=1)
- National Program for Cancer Registries (https://www.cdc.gov/cancer/npcr/training/ccr.htm)
- NCI SEER Registrar Training (https://seer.cancer.gov/training/)
- NAACCR Registrar Education and Training (http://www.naaccr.org/EducationandTraining/WebinarSeries.aspx)

Most health institutions and contract abstracting companies prefer or require Certified Tumor Registrars.

CONTACT US

Utah Cancer Registry

650 Komas Drive, Suite 106B
Salt Lake City, UT 84108

Phone: 801-581-8407
Fax: 801-581-4560
Email: ucr.info@hsc.utah.edu (mailto:ucr.info@hsc.utah.edu)

(../cancer-statistics.php)

Utah Cancer Registry (../index.php) **Reporting Cancer in Utah** (index.php)

Utah Cancer Registry Navigation

Information for the Public

Why Does Utah Collect Information About Cancer Diagnoses?

The state of Utah has designated cancer as a reportable disease (Cancer Reporting Rule, R384-100) (https://rules.utah.gov/publicat/code/r384/r384-100.htm#T1). This means that if you or a family member is diagnosed with a cancerous tumor, your doctor, lab technician, or hospital may report your tumor to the Utah Cancer Registry.

The state collects information about your diagnosis for population research only.

How do I request cancer information for a specific person?

If you are a cancer patient interested in obtaining your information from the cancer registry (or if you are a next of kin or legal guardian, or have power of attorney for an individual who had or has cancer), you may submit a notarized Request for Confidential Cancer Record Form (../docs/confidentialrecordrequestfillableform2017.pdf).

Downwinders

If you are a claimant or beneficiary for the Radiation Exposure Compensation Program (Downwinders) and you need a confidential cancer record, please visit the Radiation Exposure Compensation Program (https://www.justice.gov/civil/common/reca)'s website for more information.

You can also contact the Department of Justice at 1-800-729-7327.

Utah Cancer Registry Contacted Me. What Should I Do?

Utah Cancer Registry supports research to understand and reduce the burden of cancer, this includes contacting patients on behalf of researchers. Research studies that we are currently conducting are described here (../research/research-projects.php).

If you have received a letter from the Utah Cancer Registry about participating in a research study, be assured that this is legitimate research.

Utah Cancer Registry occasionally contacts members of the public to obtain information for our public health data. If you have received a letter from the Utah Cancer Registry requesting information about cancer treatment that you or a relative received, please know that this is a legitimate request in our effort to carry out our cancer reporting responsibilities.

The Utah Cancer Registry is authorized by the state of Utah to collect and maintain cancer information (https://rules.utah.gov/publicat/code/r384/r384-100.htm#T1).

If you have questions, please contact the registry at 801-581-8407 or ucr.info@hsc.utah.edu (mailto:ucr.info@hsc.utah.edu).

Where to Find Information About Cancer Rates In Your State

If you are a member of the public and are looking for information on cancer rates in your state, you can view reports from several sources, prepared by the UCR, the Utah Department of Health, and the Centers for Disease Control and Prevention:

- Cancer in Utah 2004 - 2013 (../docs/cancerinutah-2004-2013.pdf) prepared by the Utah Cancer Registry
- Cancer Indicator Reports (https://ibis.health.utah.gov/topic/Cancer.html) provided by the Utah Department of Health
- State Cancer Profiles (https://statecancerprofiles.cancer.gov/) reported jointly by the National Cancer Institute and Centers for Disease Control and Prevention

G. Mitchell Morris Cancer Learning Center

If you or a family member are affected by cancer and have questions about the disease, you can contact the:

G. Mitchell Morris Cancer Learning Center
(http://healthcare.utah.edu/huntsmancancerinstitute/cancer-information/cancer-learning-center/our-services.php)
801-581-6365
or toll free 1-888-424-2100,
Email: cancerinfo@hci.utah.edu (mailto:cancerinfo@hci.utah.edu).
The learning center services are available to all, regardless of whether you are a patient at the Huntsman Cancer Institute at the University of Utah.

CONTACT US

Utah Cancer Registry

650 Komas Drive, Suite 106B
Salt Lake City, UT 84108

資料1

Cancer Learning Center
About Us
Our Services
Frequently Asked Questions
Library Policies
Search Our Library
Contact the Cancer Learning Center
Centro de Información del Cáncer
Resource Guide
Publications

The G. Mitchell Morris Cancer Learning Center
Accurate information. Compassionate answers.

Our Services

Check out materials for free.

The G. Mitchell Morris Cancer Learning Center (CLC) is a free resource for cancer information. Anyone may visit our library located on the sixth floor of cancer hospital to get an information packet or to check out books, DVDs, and oth... materials.

If you are unable to pick up materials from our library in person, we will be happy to mail them to you, free of charge. If you are an HCI patient, we can deliver requested materials to your next clinic appointment, while you are receiving chemotherapy, or during a hospital stay.

Talk one-on-one and get answers to your cancer-related questions.

The CLC is staffed full-time by trained cancer information specialists, including specialists in health education and nursing, who can answer questions in person, over the phone, and via e-mail, text, and live chat. They may consult with physicians, nurses, and other health care professionals to ensure they provide the most accurate, up-to-date information available. Spanish-speaking information specialists are also available.

"They made me feel at ease and really went the extra mile in providing useful information and helping me understand it. I felt that the booklets and information were very accurate and helpful. Cancer is scary enough by itself. Your service definitely helps." -Randall, Bountiful, Utah

SCHEDULE AN APPOINTMENT

Cancer Questions?
Toll free 1-888-424-2100
cancerinfo@hci.utah.edu
Accurate Information. Compassionate Answers.

Contact Information

Huntsman Cancer Institute
2000 Circle of Hope
Salt Lake City, UT 84112

Cancer Hospital
801-585-0100

General
801-585-0303

Utah Cancer Registry について

愛知県がんセンター研究所　伊藤秀美

HP の情報によると・・・・

http://healthsciences.utah.edu/utah-cancer-registry/

収集データは、以下 2 種類

1. Utah 州法(R384-100 Cancer Reporting Rule)で定められている項目（参考資料 1)

→顕名データ（参考資料２）

(紙媒体を郵送あるいは FAX、または電子データ)

2. SEER program と NAACCR のデータ規格にあった診断、治療、フォローアップ情報を収集

疑問

どのように 1 と 2 を集めているのか？

それぞれ別々？

2 も顕名データで収集して、SEER に提出するときに不顕名データ(de-identified data)にする？

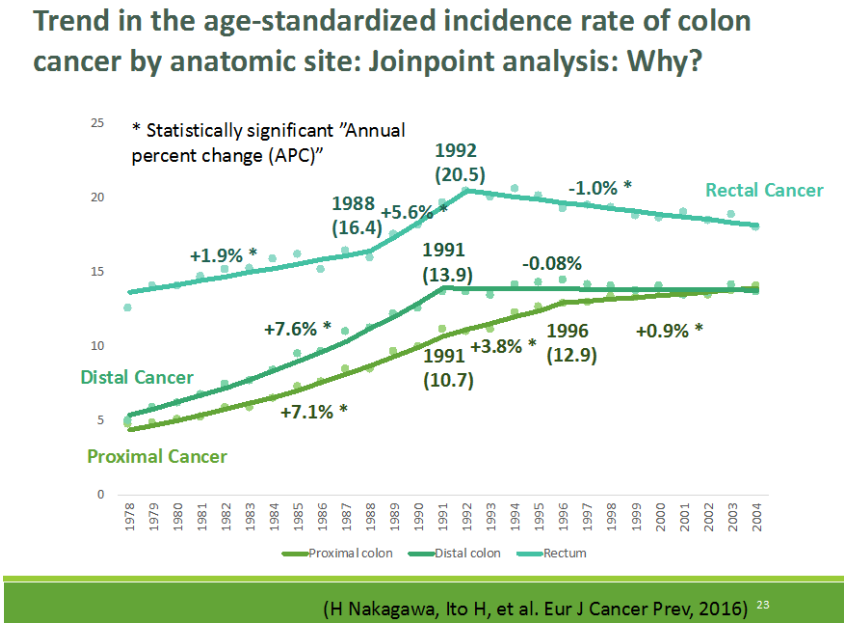
日本版 SEER 研究計画
愛知県がんセンター研究所　伊藤秀美

Trend in subsite-specific colorectal cancer incidence rates among Asians and Pacific Islanders in the United States, 1990-2014

【背景】我々は、地域がん登録データを利用し、日本人の大腸がん罹患の経年変化について部位別に joinpoint 解析を行った。大腸がん全体としての増加傾向は、1990 年代前半に横ばいに転じていた。近位、遠位結腸、直腸では、それぞれ上昇傾向、横ばい、減少傾向（図 1 参照）と、部位により経年変化のパターンが異なっていた。
【目的】1973-2014 年 SEER DATA 1973-2014 を利用し、米国における大腸がん罹患の部位別の経年変化について、1973-2014 年 SEER DATA 1973-2014 を利用して、人種別のパターンを記述し、日本人のパターンと比較し考察する。

層別化 1
1:　White (non-Hispanic), 2: Black, 3: Hispanic, 4: American Indian/ Alaska Native, 5: Asian or Pacific Islander, 6: Others, 9: Unknown
層別化 2　Asians or Pacific Islanders (East Asians/ South east Asians)
層別化 3　East Asians (Chinese Japanese, Koreans)

図 1　→



【参考】SEER DATA 1973-2008 における人種に関する変数

Race/ethnicity

01:White, 02:Black, 03:American Indian, Aleutian, Alaskan Native or Eskimo (includes all indigenous populations of the Western hemisphere), 04:Chinese, 05: Japanese, 06: Filipino, 07: Hawaiian, 08: Korean, 10: Vietnamese, 11: Laotian, 12: Hmong, 13: Kampuchean ,14: Thai, 15: Asian Indian or Pakistani, NOS, 16: Asian Indian, 17: Pakistani, 20: Micronesian, NOS, 21: Chamorran, 22: Guamanian, NOS, 25: Polynesian, NOS, 26: Tahitian, 27: Samoan, 28: Tongan,30: Melanesian, NOS, 31: Fiji Islander, 32: New Guinean, 96: Other Asian, including Asian, NOS and Oriental, NOS, 97: Pacific Islander, NOS, 98: Other, 99: Unknown

Spanish/Hispanic origin

0: Non-Spanish/Non-Hispanic, 1*: Mexican (includes Chicano), 2: Puerto Rican, 3: Cuban, 4: South or Central American (except Brazil), 5: Other specified Spanish/Hispanic origin (includes European; excludes Dominican Republic), 6 Spanish, NOS; Hispanic, NOS; Latino, NOS, 7: Spanish surname only, 8: Dominican Republic, 9: Unknown whether Spanish/Hispanic or not

Race recode (White, Black, Other)

1: White, 2: Black, 3: Other (American Indian/AK Native, Asian/Pacific Islander) , 4: Other unspecified, 9: Unknown

Race recode (W, B, AI, API)

1: White, 2: Black, 3: American Indian/ Alaska Native, 4: Asian or Pacific Islander, 7: Other unspecified, 9: Unknown

Origin Recode NHIA (Hispanic, Non-Hispanic)

0: Non-Spanish-Hispanic-Latino, 1: Spanish-Hispanic-Latino