Responsible Use of Health Data Certification

Review Process Guide

2025

Issue Date: June 16, 2024

What's New in 2025

New or revised content for 2025 is identified by underlined text in the activities noted below.

Changes effective July 1, 2025

No changes for July 2025.

Responsible Use of Health Data Certification Review Process Guide

Responsible Use of Health Data Certification

Organization Review Preparation

This guide is intended to prepare your organization for a review of compliance with the Responsible Use of Health Data (RUHD) certification standards. It is important that you read this guide and follow the instructions, as well as access the recommended resources so that your organization is prepared for participating in the certification review process. In this activity guide your organization will find guidance on how to prepare for a Responsible Use of Health Data certification review.

There are three possible configurations for a Responsible Use of Health Data review:

1. **Single healthcare organization (HCO) certification** – the certification is awarded to one organization.
2. **Corporate centralized system with RUHD activities at individual HCO level**- the certification is awarded to the corporate entity. The review process will include a sample of the organizations (HCOs) that have been listed in the e-application. While a sample of individual organizations' RUHD activities will be accessed, the review will be conducted with the corporate entity.
3. **Corporate centralized system with *NO* RUHD activities at individual HCO level-** A corporation applies for the certification and is reviewed. The management of data as outlined in RUHD requirements (i.e., policies and procedures, deidentification, transfer of data, etc.) is managed, governed, and performed at the corporate level. There are no HCO-level activities therefore there is no sampling.

The *Certification Review Process Guide* describes each activity of a Joint Commission certification review. Organizations should become familiar with the review activities which include:

- The purpose of the activity.
- Descriptions of what will happen during the activity.
- Discussion topics, when applicable.
- Recommended participants.
- Any materials needed for the activity.

These activity descriptions can be shared organization-wide as appropriate.

Introductory Phone Call

A Joint Commission Account Executive will be in touch with your organization by phone soon after your application is received. The purpose of this call is to:

- Conduct initial introductions
- Confirm information reported in your application for certification
- Confirm computer hardware and internet connectivity (recommend hardwire internet connection)

- Confirm your hours of operation; if these change at any time, please call and inform your Account Executive
- Confirm your mailing address, internet website address, if applicable
- Confirm that your organization knows how to access your secure Joint Commission *Connect* extranet site to view communications and certification-related information
- Answer any of your questions.

Responsible Use of Health Data Certification

Certification Review Notification and Postponement Policies

Notice of Initial Certification Onsite Review

If this is your organization's first time through the certification process you will receive a thirty (30) day advance notice of your onsite review date(s). Notice will be provided via e-mail to the individuals identified on your account as the Primary Certification Contact and CEO. Also thirty (30) days prior to your review, the Notification of Scheduled Events section on your organization's extranet site, The *Joint Commission Connect*, is populated with the event along with a link to the reviewer name, biographical sketch and photograph. Approximately 7 days prior to the event, the reviewer will send a TEAMS meeting appointment link to the certification contact. The certification contact should share that appointment will all required parties.

Notice of Re-Certification Onsite Review

Your organization will receive notice from The Joint Commission seven (7) business days prior to the first day of the scheduled review date(s) for Responsible Use of Health Data re-certification. The notice will be emailed to the individuals identified on your account as the Primary Certification Contact and CEO and will include the specific review date(s) and the program(s) being reviewed. Following the notification, the reviewer will send a TEAMS meeting appointment link to the certification contact. The certification contact should share that appointment with all required parties.

Once the reviewer connects with an organization staff member via Teams on the morning of the review, they will activate the Notification of Scheduled Events section on your organization's extranet site, The *Joint Commission Connect*, which is populated with the review event including a link to the reviewer's name, biographical sketch, and photograph.

Review Postponement Policy

The Joint Commission may not certify a program if the organization does not allow The Joint Commission to conduct a review. In rare circumstances, it may be appropriate to request a review postponement. An organization should direct a request for postponement to its Account Executive. A request to postpone a review may be granted if a major, unforeseen event has occurred that has totally or substantially disrupted operations, such as the following:

- A natural disaster or major disruption of service due to a facility failure.
- The organization's involvement in an employment strike.
- The organization's cessation of admitting or treating patients.
- The organization's inability to treat and care for patients and its transference of patients to other facilities.

The Joint Commission may, at its discretion, approve a request to postpone a review for an organization not meeting any of the criteria listed above.

Your organization's Joint Commission Account Executive can answer questions about these policies or put you in contact with other Joint Commission staff that can assist you.

Responsible Use of Health Data Certification

Opening Conference

Organization Participants
Individual who leads Responsible Use of Health Data improvement efforts, senior leadership, key team members involved in implementing Responsible Use of Health Data initiatives, certification contact, individual or individuals that will provide the Safety Briefing to the reviewer, and other clinical and administrative leaders at the discretion of the organization.

Opening Conference Description
Approximately 15 minutes in duration and includes:

- Introduction of reviewer
- Introduction of Responsible Use of Health Data leader, other senior leaders, and key team members (Please note: other staff can be introduced as the reviewer encounters them throughout the review)
- Overview of Responsible Use of Health Data Certification program
- Agenda review with discussion of any needed changes
- Overview of the SAFER™ portion of the Summary of Certification Review Findings Report
- Explanation of the post-review process and required follow-up actions
- Questions and answers about the review process.

Planning Tips

- Inform the reviewer of any scheduling issues that could affect activities for the day.
- Inform the reviewer of your organization's expectations for the certification review.

Responsible Use of Health Data Certification

Orientation to Responsible Use of Health Data Initiatives

Organization Participants
Responsible Use of Health Data leader, certification contact, other team members at the discretion of the organization

Orientation to Responsible Use of Health Data Initiatives Description
This 30-minute (if corporate model with sampling is utilized may need additional time) activity should include a presentation by the organization about your approach to improving responsible use of health data. The reviewer will use the information presented to ask further questions.

An overview of the following topics should be presented during the Orientation to Responsible Use of Health Data Initiatives activity. A more detailed discussion of some of these areas may occur throughout the certification review (e.g., during the Policy & Process discussion, Performance Improvement, or Competence sessions).

Organization representatives participating in this session should be able to discuss topics such as:

- Identification of a leader and their role
- Organization's goals for improving the responsible use of health data to the program's leader, organization leaders, and other staff supporting the program.
- Organization collaboration with patients, families, and caregivers and external organizations in responsible use of health data initiatives. Brief discussion related to the process for evaluating the organization's performance improvement activities (e.g., identify what is being evaluated, who receives the evaluation data, who is identifying the need for improvement, what improvements have been made and why, who determines and sets the priorities for improvement, how often is the evaluation done, and is the scope of the initiatives provided)

Responsible Use of Health Data Certification

Reviewer Planning Session

During this activity, the reviewer, in conjunction with organization representatives, will review all requested documentation to ensure completeness.

Organization Participants

- Organization representative(s) that will facilitate policy and process discussion activity

Materials Needed for this Activity

- Organizational chart for leaders in the organization including Responsible Use of Health Data leader
- Responsible Use of Health data governance structure
- Policies and procedures:
    - Addressing De-Identification of Data
    - Addressing Data Controls
    - Addressing Limitations of Data Use
    - Data Use Agreement
    - Addressing Algorithm Validation
    - Addressing Patient Transparency
- Minutes from Patient and Family Advisory Council or similar mechanism including discussion about responsible use of health data
- List of external organizations collaborating with the organization regarding responsible use of health data
- For the Performance Improvement Session-have slides available with the following data:
    - Security Monitoring data
    - Data involving the re-evaluation of data sets
    - Responsible use of health data action plans

Planning Guidelines – Competence Files Selection for Review

A minimum of (3) files will be selected.

- At least one file of the staff who implement the Expert Determination method (if this method is utilized by the organization) will be reviewed
- Other files for this review activity will be selected by the reviewer based on the individuals encountered during policy and process review and discussion.

The reviewer will inquire about how much time is needed to obtain human resources files. If necessary, the reviewer will identify the files they would like to see at this time to facilitate the organization's retrieval efforts.

Responsible Use of Health Data Certification

Policy and Process Discussion

This is an interactive review of policies with discussion focused on the processes guiding the organization's responsible use of health data.

Organization Participants

Organization staff and management who are involved in processes related to the responsible use of health data.

Materials Needed for this Activity

The following policies and procedures:

- De-Identification of Data
- Data Controls
- Limitations of Data Use
- Data Use Agreement
- Algorithm Validation
- Patient Transparency

Policy and Process Discussion Description

During this activity the reviewer, together with participants, will:

- Review and verify the policies and processes involved in responsible use of health data.
- Discuss the organization's oversight structure that monitors implementation of policies and processes for the responsible use of health data.
- Validate how providers communicate with patients in relation to responsible use of health data.

At the conclusion of the session, the reviewer communicates to the organization leaders any:

- Specific observations
- Issues that have the potential to result in requirements for improvement.

Responsible Use of Health Data Certification

System Tracer – Performance Improvement

This activity is focused on the organization's performance improvement process in relation to responsible use of health data. The reviewer and organization representatives will:

- Identify strengths and areas for improvement, compliance with performance improvement expectations, and any actions taken or planned to improve responsible use of health data.
- Identify specific data use topics requiring further exploration.

Organization Participants

- Responsible Use of Health Data leader(s)
- Administrative and clinical leaders involved in the Responsible Use of Health Data performance improvement process.
- Others at the discretion of the organization

Materials Needed for this Activity

- Responsible Use of Health Data performance improvement plan
- Action plans demonstrating the organization's use of and response to data.
- Slides available with the following data:
  - Security Monitoring data
  - Data involving the re-evaluation of data sets
  - Responsible Use of Health Data action plans

System Tracer – Performance Improvement Description

During this activity, the reviewer and organization will discuss:

- Individuals involved in improving Responsible Use of Health Data and their responsibilities.
- Responsible Use of Health Data performance improvement plan
- Data gathering and preparation.
- Data analysis and interpretation
- Dissemination and communication to leaders and staff
- Data use and actions taken on opportunities for improvement.
- Monitoring performance and evaluating improvements

- How data is used in decision-making and in improving the organization's process for responsible use of health data
- Strengths and opportunities for improvement in the processes used to obtain data and meet internal and external information needs.
- Techniques used to protect confidentiality and security of all types of patient data.
- Future planned initiatives.

The reviewer will want to know about the organization's priorities for performance improvement activities related to Responsible Use of Health Data and how these fit into the organization's overall performance improvement processes. This discussion may include a review of:

- Selection and prioritization of performance improvement activities
- Data reporting – when it occurs and who receives the information.
- Type of analyses being conducted – approach to trending data over time, comparing data to an expected level of performance, and looking at data in combination for potential cause and effect relationships.

Responsible Use of Health Data Certification

Competence Assessment Process

The purpose of this activity is to discuss how the organization meets the need for qualified and competent staff.

Organization Participants

- Staff responsible for:
  - Aspects of the organization's human resources processes that support Responsible Use of Health Data initiatives.
  - Orientation and education of staff the rationale for improving responsible use of health data.
  - Education and training of staff
- Individual(s) with authority to access information contained in personnel files.

Materials Needed for this Activity

Personnel files for individuals identified by the reviewer:

- A minimum of five (3) files will be selected.
- Responsible Use of Health Data leader
- Staff involved in the responsible use of health data process.

Note: The reviewer will select these files based on the individuals encountered during policy & process discussion. Please let the reviewer know if there could be a delay in getting files for review.

Competence Assessment Process Activity Description

During the session, the reviewer and organization representatives will:

- Participate in a facilitated review of selected files for:
  - Relevant education, experience and training or certification
  - Orientation
  - Competence
- Discuss the following competence assessment topics as they relate to the organization seeking certification:
  - Rationale for improving responsible use of health data
  - Process to assess the qualifications of individuals involved in responsible use of health data.

Individuals attending this session should be prepared to explain the organization's approach to competency assessment.

Responsible Use of Health Data Certification

Summary Discussion

This time will be utilized for a final discussion prior to the reviewer's report preparation and the exit conference.

Organization Participants
Will vary depending upon the issue

Materials Needed for this Activity
Will vary depending upon the issue

Preparation for Issue Resolution
None required

Summary Discussion Description
Topics that may be addressed include:

- Any issues not yet resolved.
- The identified Requirements for Improvement (RFIs)
- Sharing best practices to inspire quality improvement and/or outcomes.
- Determination if RFIs will be discussed in detail at closing.

The reviewer will work with the organization's certification contact to organize and conduct the summary discussion.

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Reviewer Report Preparation

The reviewer uses this time to compile, analyze and organize the data they have collected throughout the review into a preliminary report reflecting the organization's compliance with standards.

Organization Participants
None required, unless specifically requested by the reviewer.

Materials Needed for this Activity
None needed unless specifically requested by the reviewer.

Reviewer Report Preparation Description
The reviewer uses this time to analyze their observations and determine if there are any findings that reflect standards compliance issues.

Responsible Use of Health Data Certification

Exit Conference

The Exit Conference is the final activity when the organization receives a preliminary report of findings from the reviewer. In addition, reviewers will

- Review the Summary of Certification Review Findings report, including the new SAFER™ matrix feature if determined during the Summary Discussion Session.
- Discuss any standards compliance issues that resulted in Requirements for Improvement (RFIs)
- Allow the organization a final onsite opportunity to question the review findings and provide additional material regarding standards' compliance.
- Explain the post-review process and required follow-up actions, as applicable.

Organization Participants

- Organization leaders
- Other staff at the discretion of the organization

Materials Needed for this Activity

None

Preparation for the Exit Conference

None required

Exit Conference Description

This is a 30-minute activity that takes place at the completion of a review. Administrative and clinical leaders, and other organization staff, as invited, will hear a verbal report of review findings, requirements for improvement, and where these are appearing on the SAFER™ matrix. The preliminary certification review findings and printed report are shared with participants in the Exit Conference ONLY with the permission of the CEO. All reports are preliminary and subject to change upon review by Joint Commission central office staff.

Certification Review Template Agenda

The Joint Commission

Responsible Use of Healthcare Data Certification

One Reviewer for One Day Agenda (Virtual)

Note: For organizations that elect the **Corporate centralized system with RUHD activities at individual HCO level** system review, the activity times will be expanded based on the number of healthcare organizations to be sampled.

Time	Activity & Topics	Suggested Organization Participants
8:00 - 8:15 a.m.	**Opening Conference** • Introductions • Brief review of agenda	Data Use leader Organization's certification contact Others at organization's discretion
8:15 - 8:45 a.m.	**Orientation to Responsible Use Initiatives** Topics to be covered include an overview of: • Responsible Use leadership oversite structure • Organization's goals to protect data. • Process to evaluate Responsible Use of Healthcare Data initiatives. Q & A discussion	
8:45 - 9:15 a.m.	**Reviewer Planning Session** Please have the following information available for the Reviewer Planning Session: See *Responsible Use of Healthcare Data – Information Request*	Organization representative(s) who can facilitate secondary data use discussion.

Time	Activity & Topics	Suggested Organization Participants
9:15 -12:30 p.m.	**Policy & Process Discussion** Topics to be covered include: **De-Identification Process** • Verify Policies & Procedures for data de-identification. • Verify the HIPAA method utilized for de-identification. • Verify the evaluation method the organization utilizes for each data set and intended use case to identify and implement appropriate HIPAA method? • Identify staff who are involved in the de-identification of data? Verify how the organization determines that the staff are qualified? **Data Controls** • Verify the security infrastructure. • Verify the recognized security standards or best practices the organization utilizes? • Verify the security infrastructure monitoring process. • Verify the policies & procedures the organization utilizes to address security breaches of de-identified data. • Verify the process for receiving evidence of a security certification or independent audit from recipients of data prior to disclosure. • Verify the process to ensure prior to being released, the recipients of the data have policies and procedures in place to monitor compliance with security standards, conduct risk assessments and mitigation and receive and act on notification of security incidents. **Limitations on Use** • Verify the Data Use Agreement (DUA). Ensure the agreement: o Prohibits reidentification of data	Organization team members and other staff who have been involved in and can speak to the secondary use of data process.

Time	Activity & Topics	Suggested Organization Participants
	○ Prohibits linking of data sets without prior written permission of the organization ○ Protects the data using reasonable, industry best practices and safeguards ○ Describes in detail appropriate and permissible use cases ○ Prohibits the sale of deidentified data ○ Prohibits sharing with third parties, either wholesale or in derivative works, without prior written permission of the organization • Verify the policy on how DUA terms and conditions apply to any third parties with whom the data recipient allows access to the data. • Verify the process for each data set, the organization maintains oversight of the data either by strict prohibition of redistribution or by allowing redistribution only with prior written permission. • Verify the process for each data set, the organization maintains oversight over linking of data, including an assessment regarding whether such linking increases the likelihood of reidentification. • Verify the organization develops and implements written policies and procedures on how to determine when a data set is sufficiently modified to no longer be considered for redistribution. • Verify that when two or more data sets are linked, the organization reevaluates the risk for reidentification using the appropriate HIPAA method. **Algorithm Validation** • Verify the organization has an initial and recurring process to validate and test algorithms if developed internally by an analytics group, research center, or data science function, and a re-curing co-development process in place to jointly validate the algorithm with the third-party recipient. • Verify the organization implements a process to specify and document use cases and algorithm	

Time	Activity & Topics	Suggested Organization Participants
	accuracy thresholds for contextualization into the clinical workflow. • Verify the organization has a process to test internally developed and/or third-party algorithms that at a minimum evaluates algorithms for nondiscrimination against socioeconomic characteristics in order to address biases in algorithms development. • Verify the organization has a qualified analytics group, research center, or data science function (either internal or contracted) that is responsible for determining whether an algorithm has been tested for the specific population they are serving, accurate contextualization into the clinical workflow, and who may be over- or under-represented in the data sets on which the algorithm is being trained. • Verify the organization educates and trains applicable healthcare staff on the appropriate use of algorithms, including any limitations. **Patient Transparency** • Verify the organization has a written policy and procedures to educate patients using plain patient-centered language on the value of deidentified data to improve healthcare, the potential uses of deidentified data, the process by which patients will be notified of misused data, and responsible healthcare data use the ability of patients to opt-out of data sharing. • Verify the organization has developed and implemented policies and procedures to address patient concerns and/or questions regarding de-identified data which is made available to the public. • Verify the organization has developed and implemented a written policy and procedures for notification in the event of a breach of de-identified data. • Verify the organization has developed and implemented a policy and procedure by which patients may opt out of their de-identified data being disclosed.	

Time	Activity & Topics	Suggested Organization Participants
	• Verify the organization has established a Patient and Family Advisory Council or similar mechanism which is routinely appraised of the organizations policies and procedures related to de-identified data use and sharing of data. **Oversight Structure** • Verify the organization has designated a leader to provide oversite on the disclosure of de-identified data. Oversite includes: o Managing the policies and procedures. o Performing an assessment of risks/benefits to minimizes conflicts of interest when sharing deidentified data sets. o Establishing a multi-disciplinary approach to data sharing that draws upon clinical, research, and other business stakeholders including informatics, innovation, privacy, compliance, and legal functions. • Verify the organization has a governance board to make decisions about the creation and disclosure of de-identified data sets, including consistent criteria to assess and weigh risks, benefits, patient perspectives, research ethics, equity and fairness related to secondary use of deidentified data. • Verify the data governance board meets regularly with the Patient and Family Advisory Council or similar mechanism, to consider patient input regarding the organizations' policies and procedures related to de-identified data use and sharing and adequacy of patient education efforts. • Verify that the organizations' decision-making processes related to de-identified data include the consideration of equity and fairness.	
12:30-1:00 p.m.	**Reviewer Lunch**	

Time	Activity & Topics	Suggested Organization Participants
1:00-1:30 p.m.	**System Tracer – Performance Improvement** Topics to be covered include: • Security Monitoring • Re-evaluation of data sets • Action Plans • Future Initiatives	Data Use leader Administrative and clinical leadership involved in the secondary data use performance improvement plan. Others at organization's discretion
1:30-2:00 p.m.	**Competence Assessment** This session focuses on staff or contracted staff responsible for data security. • Determination of qualifications • If contracted staff, review contract for qualifications • Personnel file review • On-going assessment of competence	Individuals responsible for the organization's human resources process that supports secondary data use. Individuals responsible for assessing staff competency in this area
2:00 – 2:30 p.m.	**Summary Discussion/Report Preparation** This time is reserved for a final discussion prior to the reviewer's report preparation and the exit conference.	Will vary as requested by the review
2:30-3:00 p.m.	**Exit Conference** Reviewer presentation of certification observations and requirements for improvement	Organizational leadership Others at the discretion of the organization

Note: This agenda is a guide and may be modified based on organizational need and reviewer discretion.