

Audit Review Period:	
-----------------------------	--

Issue of non-compliance:	Restraints
---------------------------------	------------

Scope:	<ul style="list-style-type: none">• The scope of this Impact Analysis is no more than 50% of the participants enrolled during the audit review period who were not included in the provision of services sample selection.• The auditor will select the participants to be reviewed and enter their identifying information on the Participant Impact tab.
---------------	---

Instructions:	<ul style="list-style-type: none">• Review only the participant medical records selected by the auditor. The selected participants are identified in the Participant Impact tab.• Review the selected medical records to determine if restraints were utilized for any participants.• Read each question carefully before responding.• Respond to the questions in the Participant Impact tab.• The review timeframe is the audit review period. Errors noted prior to the audit review period should not be included.• After completing the Impact Analysis, if any changes need to be made to the Root Cause Analysis, please update the RCA tab.
----------------------	--

Impact Analysis Due Date:	
----------------------------------	--

<p>Brief Description Of Issue (Completed By The CMS Audit Lead)</p>	<p>Type of Issue Identified (Completed By The CMS Audit Lead)</p> <p>(Applies to condition <u>1P.02 Only</u>. For all other conditions enter N/A)</p>	<p>Detailed Description of the Issue (Explain what happened)</p>
---	---	--

Date Identified (MM/DD/YY) (Completed By The CMS Audit Lead)	Brief Description Of Issue (Completed By The CMS Audit Lead)	Condition Language (Completed By The CMS Audit Lead)
---	---	---

Root Cause Analysis for the Issue (Explain why it happened)	Methodology - Describe the process that was undertaken to determine the # of individuals (e.g. participants) impacted	# of Individuals Impacted	Action Taken to Resolve System/ Operational Issues
--	--	----------------------------------	---

Date System/ Operational Remediation Initiated (MM/DD/YY)	Date System/ Operational Remediation Completed (MM/DD/YY)	Actions Taken to Resolve Negatively Impacted Individuals Including Outreach Description and Status	Date Individual Outreach and Remediation Initiated (MM/DD/YY)	Date Individual Outreach and Remediation Completed (MM/DD/YY)
--	--	---	--	--

Participant First Name	Participant Last Name	Research Branch/Study Identifier	Participant ID	MM/YY/YY											

Pending OMB Approval (0938-New)

Were the restraints imposed in accordance with safe and appropriate restraining techniques? (Yes/No)	Were any less restrictive methods utilized prior to the use of physical or chemical restraints? (Yes/No)	Describe the less restrictive methods utilized prior to the use of physical or chemical restraints.	Did staff document that less restrictive methods were ineffective in protecting the participant and/or others from harm before the use of the restraint was initiated? (Yes/No)	Was the condition of the restrained participant continuously assessed, monitored, and reevaluated? (Yes/No)	If the participant experienced negative outcomes, did they occur, in some part, as a result of the use of restraints? (Yes/No)	If yes, describe the negative outcomes. Enter NA if the participant did not experience negative outcomes.	Optional: Please note, you do not have to complete this column. If there are any mitigating factors that you would like CMS to consider related to a specific participant, please enter the information in this column.

Pending OMB Approval (0938-New)