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The Columbia Suicide Severity Rating Scale (C-SSRS)
Globally Standardized Training and Verification Process

DESCRIPTION: As the Columbia Suicide Severity Rating Scale **(C-SSRS)** Instrument becomes widely accepted and used by healthcare and clinical research professionals internationally, there is a need for global harmonization and standardization in the proper use of the C-SSRS to improve inter-rater reliability, to provide human subject protection, patient safety and reassure public confidence in the use of the instrument.

DEFINITIONS:

1) The Columbia Suicide Severity Rating Scale **(C-SSRS)** – Scientific Instrument used by healthcare professionals to assess patients in neuroscience and other therapeutic areas.
2) ACTIVITY – Package containing the training and certification course modules.
3) MODULE – Container that delivers materials, questions, answers, and other activities to the user's computer or phone screens.
4) COURSE – Container that controls the delivery of the module, including training and certification activities and its controls of competencies.
5) CRP – Clinical Research Professional
6) CRA – Clinical Research Associate
7) GDPR – General Data Protection Regulation, international laws put in place to protect people's personal identifiable information (PII)
8) GDPR/PRIVACY Account – Electronic Account created and owned by the HCP, CRP, or Rater
9) GDPR/Privacy Wallet – Location where participants keep their own personal documents and certificates.
10) PII – Personal Identifiable Information
11) HCP – Healthcare Professional
12) PARTICIPANT – Rater, healthcare, or clinical research professional
13) PM – Clinical Research Project / Trial Manager
14) QA - Quality Assurance
15) RATER – Healthcare or clinical research professional administering the scale.
16) REDI – Regulatory, Equity, Diversity, and Inclusion
17) SCALE – A scientific validated patient, subject assessment, or diagnostic instrument.

RATIONAL FOR STANDARD: As scientific instruments become internationally accepted a quality assurance (QA) control mechanism must be developed to minimize fraud, waste, abuse, and redundancies in the process of documenting competencies of healthcare and clinical research professionals for the following purposes but not limited to:

1) Reassuring payers that HCPs are providing patients with the best care possible,
2) Reassuring regulatory agencies of the competencies of HCP and CRP,

3) Reassuring clinical research sponsors and payers of the harmonized competencies of their clinical trial raters,
4) Minimize the possibility of Data Variance in clinical trials.
5) Minimize the possibility of Variance in the assessment of patients in healthcare.
6) Provide government entities with auditable and duplicatable Delivery, Distribution, Implementation and Tracking mechanisms and processes.
7) Improve global patient, subject and public safety.

THE STANDARDIZED PROCESS

The training and certification program is controlled using the following standardized quality assurance (QA) methodologies to help control redundancies, fraud waste, abuse as well as to help sponsors and healthcare providers minimize data variance in healthcare and clinical research programs.

Creating a GDPR / Privacy Account

1) Participant must create their own personal GDPR / Privacy Account to comply with national, international, and multinational process of sharing and tracking personal identifiable information (PII) including, but not limited to, a) certificates of completion and profile information across vendors, providers, and consumers, b)to identify users across platforms, c) to standardize user documents, certificates and PII to reduce gaming, fraud, waste, abuse and limit redundancies across activity providers.
2) Participant must provide proper profile information as requested by the international GDPR laws and USA privacy laws based System.
3) Participant is identified by the system and placed in a local GDPR Directory where participant can perform the assigned globally standardized activity.

Methodology Assignment of the Activity

1) Healthcare Professional: The activity can be automatically released based on what activity the participant needs to complete.
2) Healthcare Entity: The activity can be released by a manager or local quality assurance individual at the local entity.
3) Clinical Research Entity: The Activity can be released by a clinical research manager, CRA, or PM.

The Training Process

1) All first-time participants must complete the initial training module.
2) Participants need to complete the 8 case studies after reviewing the training video.
3) Participants can receive subsequent training certificates by completing subsequently assigned training modules (2^{nd} – 3^{rd} – 4^{th} and so on)
4) Training certificates are valid for a maximum of up to 2 years.
5) Participants may request re-training earlier than the maximum of 2 years when required by sponsors or local clinics project specific SOPs.
6) Certificates can be shared by participant across healthcare and clinical research industry stakeholders.

The Verification Process

1) With proper permissions, regulatory agencies as well as other industry stakeholders can verify the authenticity of the training certificates by connecting to the participants' GDRP / Privacy Wallet.
2) Sponsors, including medical device, pharma, universities and other industry stakeholders can verify the authenticity of the training certificates by connecting to the participants GDPR / Privacy Wallet

ALIGNMENT WITH REDI-DAP: Regulatory, Equity, Diversity, and Inclusion Action Plans. National and international government organizations have developed Guidances and implemented laws to improve the participation of diverse populations in clinical trials (Equity, Diversity, and Inclusion). To comply with these Guidances and modern laws, globally harmonized translations based on language and dialects have been created so that healthcare professionals following the program standards can align communication with patients including, but not limited to, patient, subject, geographical location race, religion, socio-economic status, or political affiliations. This activity has been translated into multiple languages and dialects to comply with these modern laws, guidances and regulations. Same training and certification standards must be followed for all languages and dialects accordingly.

CONCLUSION

The program authors, including but not limited to universities, governments and regulatory agencies need to collect all clinical research trial / healthcare project information in a globally standardized format to improve the use of the instrument, monitor its use to prevent fraud, waste and abuse while improving patient, subject and public safety. The standardized process on this SOP allows the authors to collect and examine the data in standardized format, record trends to improve the program while adhering to regulatory requirements, current and future laws and regulations and improve the monitoring for General Data Protection Regulations (GDPR) globally and Privacy requirements in the US. Therefore, standards on how the healthcare and clinical research industry stakeholders train and certify "must" be followed and monitored internationally accordingly.

DISCLAIMER

NATIONAL, INTERNATIONAL AND MULTINATIONAL PROGRAM DISCLAIMER

Neither the advisory working groups, the universities nor any other individual or entity involved in the development of these globally standardized program, are responsible for any regulatory, privacy, GDPR or legal liabilities, issues or litigations that may arise from the improper use of this standard. Anyone using this program, including but not limited to, healthcare professionals, pharmaceutical companies, medical device companies, sponsors, hospitals, research sites, government and all other healthcare or clinical research entities need to follow program standards accordingly. Users of this globally standardized training and certification program, using this

program to document competencies, the execution, implementation, tracking of inter-rater reliability to minimize data variance, are advised to properly follow standards herein created for this program which is originally intended for the improvement of patient, subject and public safety globally.

CHANGE HISTORY

DESCRIPTION	DATE	ACTION	REVIEWED BY
Originated	12-3-2012	Establishment	Kelly Posner, Al Pacino
Reviewed	4-3-2016	Creation of GDPR Wallet for Shareable Certificate Storage and PII privacy protection	Al Pacino
Reviewed	12-20-2020	REDI Inclusion	Al Pacino
Reviewed	2-3-2022	No Updates	Al Pacino
Reviewed	2-16-2024	No Updates	Al Pacino