

Statement of Understanding (SOU)

Defining the relationship between:

Health Level Seven International
3300 Washtenaw Avenue, Suite 227
Ann Arbor, Michigan 48104-4261

Hereinafter identified as HL7

AND

Regenstrief Institute, Inc.
1101 West 10th Street
Indianapolis, IN 46202-4800

Hereinafter identified as the Associate

This SOU shall have an effective date of October 5, 2022

Statement of Purpose

Health Level Seven[®] International (HL7) is an ANSI-accredited, not-for-profit standards developing organization with the mission of empowering global health interoperability. With affiliates in over 30 countries, HL7's global membership envisions a world in which everyone can securely access and use the right data when and where they need it. Widely implemented by vendor and health care systems, and required by governing bodies around the world, HL7 standards deliver solutions for health information technology, including HL7[®] Fast health care Interoperability Resources (FHIR[®]), Version 2 (V2) and Clinical Document Architecture (CDA[®]).

The Regenstrief Institute, Inc is a dynamic, not-for-profit, people-centered research organization driven by a mission to connect and innovate for better health. Building on a 35+ year history of creating and using clinical data standards, Regenstrief leads the development of the Logical Observation Identifiers Names and Codes (LOINC) and Unified Code for Units of Measure (UCUM) standards and collaborates with many other standards developers. The purpose of LOINC[®] is to facilitate the exchange and pooling of clinical results for clinical care, outcomes management, and research by providing a set of universal codes and names to identify laboratory and other clinical observations. The purpose of UCUM is to facilitate unambiguous electronic communication of quantities together with their units by providing a universal code system for units of measure used in international science, engineering, and business.

Recognizing that complementary efforts are underway to create and extend comprehensive standards in the healthcare community, HL7 enters into relationships to further these goals. This SOU defines the rights and obligations inherent in such relationships and shall be the sole governing document regarding the relationship between HL7 and the Associate. Associates are independent, non-profit entities whose mission is to advance, nationally or internationally, the acceptance and usage of standards within healthcare. Such entities include, but are not limited to, other Standards Development Organizations (SDO), industry associations or consortiums, and other groups that share the vision of improved healthcare through standards.

1.0 Introduction

1.1 An entity is eligible to be recognized as an Associate, at the discretion of the HL7 Board of Directors, based upon the entity's petition to establish a relationship with HL7.

1.2 The Associate may establish meeting schedules similar to HL7, and in addition may establish meetings with other Associates when convenient. The Associate is also encouraged to work with other standards organizations toward harmonization.

1.3 Official joint meetings between the Associate and HL7 may be scheduled where such meetings serve a common purpose and are convenient to the HL7 meeting agenda.

1.4 The parties to this SOU shall appoint a liaison to represent each to the other. It is expected, although not required, that the liaison hold joint membership in HL7 and the Associate.

1.5 Such projects as might be jointly undertaken by HL7 and the Associate will be clearly defined and delineated by a joint project proposal which must include a succinct description of the proposed project, an estimate of time required, and resources expected to be committed by each party.

2.0 Rights Granted

2.1 The HL7 Working Group Meeting (WGM) or the equivalent Associate assemblage may be convened and conducted as a joint meeting of the two organizations.

2.2 Such joint meetings, when conducted, shall at all times adhere to the rules of the host organization. When voting within the joint meeting context to propose changes to the standard, or to conduct other business specific to either HL7 or the Associate, the relevant procedures of the respective organization shall be enforced.

2.3 If the Associate is a member-based organization, then

2.3.1 Members of the Associate, while encouraged to participate in HL7 Work Groups, may not seek leadership positions within HL7 unless they also hold HL7 membership. In turn, HL7 members, while encouraged to participate in the Associate's Work Groups, may not seek leadership positions within the Associate's Work Groups unless they also hold Associate membership.

2.4 Participation in HL7 through the Associate does not convey free access to or the right to distribute any HL7 intellectual property.

2.5 HL7 and the Associate support and encourage the harmonization of any information model(s) with relevant HL7 standards.

3.0 Fees and Payments

3.1 No monies shall be exchanged between HL7 and the Associate as a result of this SOU.

4.0 Obligations

4.1 HL7 and the Associate expressly agree:

- a. That ownership rights to HL7 trademarks or standards or Associate trademarks or standards are neither extended nor transferred; and
- b. That there shall be no exchange of mailing lists or general membership information; and

- c. That they will comply with all provisions of this SOU.

5.0 Copyright and Distribution Agreement

5.1 Both HL7 and the Regenstrief Institute agree that the Regenstrief Institute will retain sole copyright of LOINC and UCUM content, including any additions and/or modifications to undertaken as part of a joint project but grant HL7 permission to include and reprint any applicable LOINC or UCUM content within the resulting HL7 copyrighted document subject to the provisions in Sections 5.2 and 5.3 below.

5.2 Inclusion of LOINC content in HL7 copyrighted documents is subject to the most current version of LOINC license agreement, available at <https://loinc.org/license> which specifies the terms of use and attribution required. Such inclusion may result from projects undertaken jointly by both HL7 and the Regenstrief Institute. The version of the attribution statement from the LOINC license as the time of this agreement is given in Appendix A.

5.3 Inclusion of UCUM content in HL7 copyrighted documents is subject to the most current version of UCUM license agreement, available at <https://ucum.org/license>, which specifies the terms of use and attribution required. Such inclusion may result from projects undertaken jointly by both HL7 and the Regenstrief Institute. The version of the attribution statement from the UCUM license as the time of this agreement is given in Appendix A.

5.4 No other use by HL7 of LOINC or UCUM content is provided under this agreement. Any other use by HL7 would be subject to the standard LOINC license available at <https://loinc.org/license> the UCUM license available at <https://ucum.org/license>, or would require a separate agreement between the parties.

5.5 Both HL7 and the Regenstrief Institute agree that HL7 will hold sole copyright of any standards or implementation guides developed collaboratively through HL7's ballot processes. HL7 agrees to work with the Regenstrief Institute to maintain, as needed, such documents that incorporate LOINC or UCUM content.

6.0 Warranties

6.1 HL7 and the Associate make no express or implied warranties other than those that may be contained in or appended to this SOU.

7.0 Termination

7.1 Either HL7 or the Associate may terminate this SOU upon 30 days written notice.

7.2 In the event of such termination all registrations for HL7 or Associate sponsored events recorded prior to the termination date shall be honored.

8.0 Term

8.1 This SOU shall have a five-year term, renewable upon expiry by written agreement for subsequent two-year terms.

9.0 Miscellaneous

9.1 This SOU constitutes the entire agreement and complete understanding of the relationship between HL7 and the Associate.

9.2 HL7 or the Associate may propose alterations to this SOU in writing upon appropriate action of their respective governing body. The receiving party shall be afforded sixty (60) days to adopt any proposal for change and/or amendment to this SOU and shall acknowledge such acceptance in writing to the submitting party. In the event such proposals are deemed unacceptable and cannot be resolved through negotiation, either party may execute the Termination provisions afforded above.

Authorized Signatures:

For
HL7 INTERNATIONAL


Signed: 

Charles Jaffe, MD PhD
Chief Executive Officer

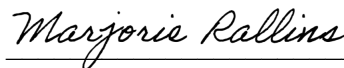
Signed: 

Mark McDougall
Executive Director

For
REGENSTRIEF INSTITUTE, INC.

Signed: 
Karen L. Crow (Oct 10, 2022 08:39 EDT)

Karen Crow, CPA, CGMA
Chief Financial Officer

Signed: 

Marjorie Rallins
Executive Director, LOINC and
Health Data Standards

Appendix A

The following wording shall be used to attribute LOINC content in HL7 copyrighted materials:

"This material contains content from LOINC (<http://loinc.org>). LOINC is copyright © 1995-2022, Regenstrief Institute, Inc. and the Logical Observation Identifiers Names and Codes (LOINC) Committee and is available at no cost under the license at <http://loinc.org/license>. LOINC® is a registered United States trademark of Regenstrief Institute, Inc."

The following wording shall be used to attribute UCUM content in HL7 copyrighted materials:

"Copyright 1999-2021 Regenstrief Institute, Inc. All rights reserved. Licensed under the UCUM License, Version 1.0 (the "License"); you may not use this file except in compliance with the License. You may obtain a copy of the License at <https://ucum.org/license>. Unless required by applicable law or agreed to in writing, software distributed under the License is distributed on an "AS IS" BASIS, WITHOUT WARRANTIES OR CONDITIONS OF ANY KIND, either express or implied. See the License for the specific language governing permissions and limitations under the License."