**NOTE**: To use Track Changes, turn off “protection” by clicking on (pre-MS Word 2007) Tools > Unprotect Document or (MS Word 2007 and higher) Review > Protect Document.

**PSS-Lite/Investigative Projects: Sections surrounded by a BOLD OUTLINE must be completed for approval of "Investigative Projects" (a.k.a PSS-Lite).**

1. Project Name and ID

|  |  |  |
| --- | --- | --- |
|  | |  |
| **Definition of negation requirements for standards** | | Project ID: |
| |  |  | | --- | --- | |  | TSC Notification Informative/DSTU to Normative Date : | |  | |
|  | | |
| |  |  | | --- | --- | |  | Investigative Project Date : | | | |
| **Check this box when the project is investigative or exploratory in nature, which allows limited project scope definition. Sections in bold outline are mandatory for project approval of an investigative project; all other sections are optional. (Sections 1, 2, 3a, 3b, 3g [limited, 6b [if known], and 6c [applicable] are required).**  **Investigative Project specific instructions are yellow highlighted.**  **An investigative project must advance in two WGM cycles, requiring a full scope statement. Otherwise the project will be closed.** | | |

1. Sponsoring Group(s) / Project Team

|  |  |
| --- | --- |
| Primary Sponsor/Work Group (**1 Mandatory**) | **Patient Care** |
| Co-sponsor Work Group(s) | Vocabulary (Term Info) |
|  | Clinical groups:  Spec designers: CIMI, CQI  No response:  Clinical groups: OO, PA, CIC  Spec designers: SD, FHIR, CDS |
| Co-Sponsor Group Approval Date | Co-Sponsor Approval Date CCYY-MM-DD |
| Indicate the level of involvement that the co-sponsor will have for this project:   |  |  |  | | --- | --- | --- | |  | Request formal content review prior to ballot | | |  | Request periodic project updates. Specify period: | Monthly, at WGMs, etc. | | |  | Other Involvement. Specify details here: | Enter other involvement here | | | |
|  |  |
| **Project Team:** |  |
| Project facilitator (**1** **Mandatory**) | **Jay Lyle** |
| Other interested parties and their roles |  |
| Multi-disciplinary project team (recommended) |  |
| Modeling facilitator |  |
| Publishing facilitator |  |
| Vocabulary facilitator | **Rob Hausam** |
| Domain expert rep |  |
| Business requirement analyst |  |
| Conformance facilitator (for IG projects) |  |
| Other facilitators (SOA, SAIF) |  |
|  |  |
| Implementers **(2** **Mandatory** for DSTU projects)  ***FHIR Project Note:*** *The implementer requirement will be handled by the “balloting” project. Therefore work groups do not fill out the above section. However, feel free to list implementers specific to your work group’s resources if you know of any.* | |
| 1) | |
| 2) | |

1. Project Definition
   1. Project Scope

|  |
| --- |
| **Provide a set of classified requirements for the representation of negated clinical data, which standards developers can use to confirm coverage of requirements, demonstrate recommended patterns, and identify out-of-specification patterns.** |

* 1. Project Need

|  |
| --- |
| The ways current interoperability standards handle negation, or propose to do so,  > are inconsistent & may not support transformations among different standards  > may not support representation requirements  > may not support computation requirements  Having a consistently articulated set of clinical requirements will allow standards designers to confirm support for these requirements and to provide clear guidance on recommended and prohibited patterns. |

* 1. Success Criteria

|  |
| --- |
| **Publication of a set of requirements**  **Validation of pattern assessments by standards authors** |

* 1. Project Risks

|  |  |
| --- | --- |
| Risk Description: | **It is not known whether requirements will converge to a manageable list.** |
| Impact: | |  |  |  |  | | --- | --- | --- | --- | | Critical | Serious | Significant | Low | |
| Likelihood: | |  |  |  | | --- | --- | --- | | High | Med | Low | |
| Risk Type: | |  |  |  |  | | --- | --- | --- | --- | | Requirements | Resources | Social-Political | Technology | |
| Risk To HL7: | |  |  |  |  | | --- | --- | --- | --- | | Internal to HL7 |  | External to HL7 |  | |
| Mitigation Plan: | **If the set does not converge, we recognize that the list will be of limited utility.** |

|  |  |
| --- | --- |
| Risk Description: | **Development of CIMI and maturation of FHIR mean that this tool will be less useful the longer it takes to develop.** |
| Impact: | |  |  |  |  | | --- | --- | --- | --- | | Critical | Serious | Significant | Low | |
| Likelihood: | |  |  |  | | --- | --- | --- | | High | Med | Low | |
| Risk Type: | |  |  |  |  | | --- | --- | --- | --- | | Requirements | Resources | Social-Political | Technology | |
| Risk To HL7: | |  |  |  |  | | --- | --- | --- | --- | | Internal to HL7 |  | External to HL7 |  | |
| Mitigation Plan: | **Complete draft of work for May meeting.** |

* 1. Security Risks

|  |  |  |  |
| --- | --- | --- | --- |
| Will this project produce executable(s), for example, schemas, transforms, stylesheets, executable program, etc. If so the project must review and document security risks. | Yes | No | Unknown |

* 1. External Drivers

|  |
| --- |
|  |

* 1. Project Objectives / Deliverables / Target Dates

|  |  |
| --- | --- |
|  | **Target Date** |
| **Solicit sponsorship from clinical workgroups** | **2/14/16** |
| **Solicit examples & other requirements from clinical workgroups** | **2/14/16** |
| **Classify examples (clinically & logically) in order to facilitate consistent management of similar scenarios** | **3/31/16** |
| **Produce notional mapping to existing designs, possibly with recommendations** | **4/30/16** |
| **Request design team confirmation** | **4/30/16** |
| **Assemble ballotable artifact** | **7/31/16** |
| **Conduct ballot** | **9/30/16** |
| **Publish results** | **11/30/16** |
|  |  |
|  |  |

* 1. Common Names / Keywords / Aliases

|  |
| --- |
|  |

* 1. Lineage

|  |
| --- |
| **A project on this topic was proposed (1135) but has not been executed.** |

* 1. Project Requirements

|  |
| --- |
| **Requirement documentation will be the focus of the project. Project assets will be kept on the wiki, under the existing page “Representing Negation.”** |

* 1. Project Dependencies

|  |
| --- |
|  |

* 1. Project Document Repository Location

|  |
| --- |
| **http://wiki.hl7.org/index.php?title=Representing\_Negation** |

* 1. Backwards Compatibility

[*Click here*](#Backwards_Compatibility_help) *to go to Appendix A for more information regarding this section and FHIR project instructions.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Are the items being produced by this project backward compatible? | Yes | No | Unknown | N/A |
|  | | | | |
| For V3, are you using the current data types? | Yes | No |  |  |
| If you check 'No' please explain the reason: | | | | |
|  | | | | |

* 1. External Vocabularies

[*Click here*](#External_Vocabularies_help) *to go to Appendix A for more information regarding this section.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Will this project include/reference external vocabularies? | Yes | No | Unknown | N/A |
| If yes, please list the vocabularies: | | | | |

1. Products

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| |  |  | | --- | --- | |  | Non Product Project- (Educ. Marketing, Elec. Services, etc.) | | |  |  | | --- | --- | |  | V3 Domain Information Model (DIM / DMIM) | |
| |  |  | | --- | --- | |  | Arden Syntax | | |  |  | | --- | --- | |  | V3 Documents – Administrative (e.g. SPL) | |
| |  |  | | --- | --- | |  | Clinical Context Object Workgroup (CCOW) | | |  |  | | --- | --- | |  | V3 Documents – Clinical (e.g. CDA) | |
| |  |  | | --- | --- | |  | Domain Analysis Model (DAM) | | |  |  | | --- | --- | |  | V3 Documents - Knowledge | |
| |  |  | | --- | --- | |  | Electronic Health Record (EHR) Functional Profile | | |  |  | | --- | --- | |  | V3 Foundation – RIM | |
| |  |  | | --- | --- | |  | Logical Model | | |  |  | | --- | --- | |  | V3 Foundation – Vocab Domains & Value Sets | |
| |  |  | | --- | --- | |  | V2 Messages – Administrative | | |  |  | | --- | --- | |  | V3 Messages - Administrative | |
| |  |  | | --- | --- | |  | V2 Messages - Clinical | | |  |  | | --- | --- | |  | V3 Messages - Clinical | |
| |  |  | | --- | --- | |  | V2 Messages - Departmental | | |  |  | | --- | --- | |  | V3 Messages - Departmental | |
| |  |  | | --- | --- | |  | V2 Messages – Infrastructure | | |  |  | | --- | --- | |  | V3 Messages - Infrastructure | |
| |  |  | | --- | --- | |  | FHIR Resources | | |  |  | | --- | --- | |  | V3 Rules - GELLO | |
| |  |  | | --- | --- | |  | FHIR Profiles | | |  |  | | --- | --- | |  | V3 Services – Java Services (ITS Work Group) | |
| |  |  | | --- | --- | |  | New/Modified/HL7 Policy/Procedure/Process | | |  |  | | --- | --- | |  | V3 Services – Web Services (SOA) | |
| |  |  | | --- | --- | |  | New Product Definition | |  |
| |  |  | | --- | --- | |  | New Product Family | |  |
| **Requirements specification for negation. Exact correlation with DAM outline in HDF to be determined.** | |

1. Project Intent (check all that apply)

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  | | --- | --- | |  | Create new standard | |  | Revise current standard (**see text box below**) | |  | Reaffirmation of a standard | |  | New/Modified HL7 Policy/Procedure/Process  Withdraw an Informative Document | |  | N/A (Project not directly related to an HL7 Standard) | | |  |  | | --- | --- | |  | Supplement to a current standard | |  | Implementation Guide (IG) will be created/modified | |  | Project is adopting/endorsing an externally developed IG: Specify external organization in Sec. 6 below;  Externally developed IG is to be (select one): | |  | Adopted - OR -  Endorsed |  | Endorsed | |
|  | |

* 1. Ballot Type (check all that apply)

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  | | --- | --- | |  | Comment Only | |  | Informative | |  | DSTU to Normative | | |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | |  |  | | --- | --- | |  | Normative (no DSTU) | |  | Joint Ballot (with other SDOs or HL7 Work Groups) | |  | N/A (project won’t go through ballot) | | |
|  | |
|  | |

* 1. Joint Copyright

*Check this box if you will be pursuing a joint copyright. Note that when this box is checked, a Joint Copyright Letter of Agreement must be submitted to the TSC in order for the PSS to receive TSC approval.*

|  |  |  |
| --- | --- | --- |
| |  |  | | --- | --- | |  | Joint Copyrighted Material will be produced | |

1. Project Logistics
   1. External Project Collaboration

|  |  |  |
| --- | --- | --- |
|  | | |
| For projects that have some of their content already developed: | | |
| How much content for this project is already developed? |  | |
| Was the content externally developed (Y/N)? |  | |
| Date of external content review by the ARB? |  | |
| Is this a hosted (externally funded) project? (not asking for amount just if funded) | Yes | No |

* 1. Realm

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  | | --- | --- | |  | Universal | | Realm Specific |
|  | Check here if this standard balloted or was previously approved as realm specific standard |
|  |  |

* 1. Project Approval Dates

|  |  |
| --- | --- |
| Affiliate/US Realm Task Force Approval Date  (for US Realm Specific Projects) | **USRTF Approval Date CCYY-MM-DD** |
| Sponsoring Work Group Approval Date | **PC: 2/1/2016**  **CIMI: 2/11/16**  **CQI: 2/12/16** |
| FHIR Project: FHIR Management Group Approval Date | **FMG Approval Date CCYY-MM-DD** |
| Steering Division Approval Date | **SD Approval Date CCYY-MM-DD** |
| |  |  |  | | --- | --- | --- | | [PBS Metrics and Work Group Health Reviewed](http://gforge.hl7.org/gf/download/docmanfileversion/7241/10172/PBSMetricGuidanceforSDCoChairs2013Final.doc)? (required for SD Approval) | Yes | No | | |
| Technical Steering Committee Approval Date | **TSC Approval Date CCYY-MM-DD** |
| |  |  |  | | --- | --- | --- | | TSC has received a Copyright/Distribution Agreement (which contains the verbiage outlined within the SOU), signed by both parties. | Yes | No | | |

* 1. Stakeholders / Vendors / Providers

*This section must be completed for projects containing items expected to be ANSI approved, as it is an ANSI requirement for all ballots*

|  |  |  |
| --- | --- | --- |
| **Stakeholders** | **Vendors** | **Providers** |
| Clinical and Public Health Laboratories | Pharmaceutical | Clinical and Public Health Laboratories |
| Immunization Registries | EHR, PHR | Emergency Services |
| Quality Reporting Agencies | Equipment | Local and State Departments of Health |
| Regulatory Agency | Health Care IT | Medical Imaging Service |
| Standards Development Organizations (SDOs) | Clinical Decision Support Systems | Healthcare Institutions (hospitals, long term care, home care, mental health) |
| Payors | Lab | Other (specify in text box below) |
| Other (specify in text box below) | HIS | N/A |
| N/A | Other (specify below) |  |
|  | N/A |  |
| |  | | --- | |  | | | |

* 1. Synchronization With Other SDOs / Profilers

|  |  |  |
| --- | --- | --- |
| Check all SDO / Profilers which your project deliverable(s) are associated with. | | |
| ASC X12 | CHA | LOINC |
| AHIP | DICOM | NCPDP |
| ASTM | GS1 | NAACCR |
| BioPharma Association (SAFE) | IEEE | Object Management Group (OMG) |
| CEN/TC 251 | IHE | The Health Story Project |
| CHCF | IHTSDO | WEDI |
| CLSI | ISO | Other (specify below) |
|  | | |