Operational Guidelines &
Decision-making Practices Document (OG-DMP)

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## Document Revision History

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1.0 Introduction

a. This document details the operational guidelines and decision-making practices (“Guidelines”) of the Gravity Project as an HL7 FHIR Accelerator Project. The Guidelines will be used to help ensure consensus, information sharing, openness, and balance of interests across participating stakeholders including patients, payers, providers, health care organizations, social services organizations, community-based organizations, health information technology vendors, federal and state agencies, terminology suppliers (LOINC, SNOMED CT, ICD-10, and CPT), and HL7.

b. These Guidelines are designed to enable timely decision-making while ensuring consideration of input and expertise across Gravity Project participants.

c. In the event of joint meetings with HL7 Working Groups (WG), the HL7 WG guidelines shall govern. The host of the joint meeting is responsible for making joint meeting participants aware in advance of significant differences and for ensuring compliance.

2.0 Gravity Project Goals

a. The goal of the Gravity Project, initiated in January 2019, is to develop consensus-based standards for the exchange of social determinants of health (SDOH) data within the health care sector and between the health care sector and other sectors for patient/person-centered care, care coordination between the health and human services sectors, population health management, value-based payment, quality reporting, and clinical research. To advance this goal, the Gravity Project joined the HL7 FHIR Accelerator Program in August 2019 to advance the availability and use of social determinants of health data using FHIR.

b. The Gravity Project will develop the following:

   i. Use cases to support documentation of SDOH data in electronic health records (EHR) or related systems.

   ii. Coded common data elements and associated value sets for representation in FHIR and other related standards.

   iii. Description of the technical, implementation, and testing requirements for the use case(s).

      • Implementation Guide (IG) describing the technical solution to a use case.

      • Reference Implementation (RI) that demonstrates the workflow and technical viability of the solution defined by the implementation guide.

      • Testing and validation material specific to the use cases, the IG, and the RI.

   iv. Data justice principles, to ground the Gravity Project’s vision and commitment that SDOH data be used for the good of individuals, communities, and the public, not misused for harm, discrimination, or profiling.
3.0 Gravity Project Practices

Information Sharing Practices

a. All information, documents, tools, and site access will be shared with all Gravity Project participants with the exception of Executive Committee meeting materials that will be shared only with Executive Committee members. All Intellectual Property shall be open source with the exception of HL7 documents that are balloted and published as HL7 standards. All member agreements should require that any IP brought to the table as part of the Gravity Project is treated the same way.

b. HL7 Executives and Gravity Project participants will work with their respective internal staff to ensure that no confidential, proprietary information or business practices are shared as part of Gravity Project work.

c. The Gravity Project does not collect or exchange individuals’ protected health information as defined by the Health Insurance Portability and Accountability Act (HIPAA), and participating parties shall not collect or share individuals’ protected health information as part of the Gravity Project.

Antitrust Practices

a. Gravity Project participants have the responsibility to comply fully with federal and state antitrust laws.

b. Individuals speaking or providing written communications shall refrain from any discussion which may provide the basis for an inference that they have agreed to take any action relating to prices, services, production and allocation of markets or any other matter having a market effect.

c. Participants shall not discuss their pricing or others’ pricing or any term that might affect pricing or fees, such as costs, discounts, terms of sales or profit margins.

d. Adherence to these guidelines involves not only avoidance of antitrust violations, but avoidance of behavior that might be so construed.

Anti-Marketing Practices

a. The Gravity Project’s goals and information sharing practices (see above) require the open sharing of information and the highest level of trust.

b. To maintain these levels of trust and to create a community that focuses on the delivery of common solutions to selected use cases, Gravity Project participants shall refrain from marketing their (individual or company) services/products to other Gravity Project participants during any Gravity Project meeting, call, or activity, or through any Gravity Project communications channel (email list, website, etc.).

c. Gravity Project members shall not advocate that other Gravity Project members should use their products or services as an alternative to completing or piloting the deliverables for a use case.
4.0 Gravity Project Committees and Program Management Office

a. For effective governance of the Gravity Project and representation of the Project’s large number of participants and stakeholders, three separate committees are used: an Executive Committee, a Strategic Advisory Committee (SAC), and a Technical Advisory Committee (TAC). These committees are supported by a Program Management Office (PMO). Figure 1 represents the operating model.

Figure 1: Gravity Operating Model

b. Committees shall rely upon Robert’s Rules of Order in the event that these Guidelines do not provide the formal guidance or parliamentary procedure needed or requested.

c. Proxies are not allowed on the Executive Committee but are allowed on the Strategic Advisory Committee and the Technical Advisory Committee in accordance with this OG-DMP.

d. For HL7 FHIR Implementation Guide issues, committees shall adopt the basic decision-making practices set forth by the HL7 for its Work Groups as outlined in the HL7 Governance and Operations Manual (GOM).

Executive Committee

a. The Executive Committee is responsible for approval and governance of the Gravity Project through the following main activities:

i. Approves overall strategic priorities with input from the PMO and SAC, at least annually.
ii. Reviews and approves budgets and budget narratives.

iii. Approves and oversees Contracts.

iv. Approves the Guidelines and any amendments, as needed, which will then be effective 30 days following notice and delivery to sponsors having a signed statement of understanding (SOU) in effect at that time.

v. Supports the PMO in fundraising by identifying and reaching out to potential sources of funding, as needed.

b. The Executive Committee consists of 15 members selected to represent the six key Gravity stakeholder groups:

1) Patients/Consumers  4) Health IT Vendors
2) Providers  5) Community Based Organizations (CBO)
3) Private Payers  6) Federal Government

Each of the six stakeholder groups shall have at least two representative members.

One HL7 Representative will also be invited to participate in meetings to ensure coordination with other HL7 activities and broader HL7 Governance.

c. Members are appointed for three-year staggered terms. In 2020, members will be appointed by the 2019 Gravity Steering Committee. In subsequent years members will be appointed by existing Executive Committee members.

i. Terms. Terms begin on April 1 and end after three years on March 31. Members may serve only one term. If a member resigns or is removed before the end of the member’s term, the vacancy is filled according to the provisions herein for vacancies. For new terms, the Executive Committee shall solicit nominations from the Gravity collaborative community by public notice at least 45 days before the commencement of the new term, with nominations due at least 30 days before the new term begins in order to allow time for the vote in advance.

ii. Vacancies. The Executive Committee appoints new members to fill vacancies by majority vote after soliciting nominations from the Gravity collaborative community by public notice at least 30 days in advance of the vote, due at least fifteen days in advance of the vote; except that in case of vacancy in a position held by a sponsor in good standing, the sponsor nominates the new member to fill the vacancy for the remainder of its sponsorship agreement’s term or the remainder of the vacant term on the Executive Committee, whichever occurs first. If the Executive Committee does not vote to appoint the sponsor’s nominee, the sponsor may submit another nomination.

iii. Staggered terms.
Gravity Project Operational Guidelines

(a) One third of the fifteen authorized number of members shall be elected each year.

(b) Transition provisions. The foregoing provisions on terms and staggered terms notwithstanding, the initial Executive Committee commencing service on April 1, 2020, shall comprise five members serving initial terms of two years ending March 31, 2022; five members serving initial terms of three years ending March 31, 2023; and five members serving initial terms of four years ending March 31, 2024. The Executive Committee shall determine which members shall serve initial terms of two, three, or four years, by a blind drawing of members’ names from a hat. After these initial terms have expired, these transition provisions shall have no further effect.

d. When acting as the Executive Committee, members will make decisions in the best interest of the Gravity Project.

e. Members of the Executive Committee shall elect a chair and co-chair from amongst the Executive Committee members to help manage Executive Committee operations.

f. The Executive Committee will meet quarterly unless the co-chairs determine that more frequent meetings are needed.

g. Members are encouraged to participate at least in one SAC meeting per quarter.

h. Quorum for purposes of meetings and official action by the Executive Committee is a minimum of seven members, with at least one payer; one provider; and one from the patient/consumers group or CBO group.

i. Members will disclose and abstain on voting on Gravity budgets, contracts, and decisions that pose a conflict of interest.

j. A Finance Subcommittee of the Executive Committee is responsible for considering financial matters as needed between meetings of the Executive Committee, in consultation with the Program Manager, and for making recommendations to the Executive Committee for any action. The Finance Subcommittee’s chair shall also be responsible for approving invoices. The Finance Subcommittee comprises the Executive Committee’s co-chairs and any other members of the Executive Committee which the Executive Committee might appoint, in consultation with the Program Manager.

Strategic Advisory Committee

a. The Gravity Strategic Advisory Committee (SAC) is responsible for providing strategic input and project priorities to the PMO for consideration by the Executive Committee.

b. The SAC members include all financial sponsors and invited in-kind contributors, as determined by the PMO.

c. Members will be selected to generate a diversity of views and include at least two representatives from each of the six key Gravity stakeholder groups:
1) Patients/Consumers  
2) Providers  
3) Payers  
4) Health IT Vendors  
5) Community Based Organizations  
6) Federal/ State Government

d. Members will be appointed for two-year staggered terms, with possibility of renewal. In 2020, members will be identified by the PMO. Subsequently, members will be appointed by the Executive Committee with guidance from the PMO.

e. The SAC will meet monthly, except when more frequent meetings are needed. Members are expected to participate in and contribute to meetings and to provide feedback on project artifacts. Members are responsible for soliciting feedback from their constituents on key questions and representing those perspectives in SAC meetings.

f. Members of the SAC will select a chair and co-chair from amongst the SAC members to help manage SAC operations and facilitate coordination with the PMO.

g. Quorum for purposes of meetings and official action by the Strategic Advisory Committee is a minimum of seven members, with at least one payer; one provider; and one from the patient/consumers group or CBO group.

Technical Advisory Committee

a. The Gravity Technical Advisory Committee (TAC) is responsible for assisting the Gravity Project team with direction and content for the SDOH domain data set build.

b. Members are appointed by the PMO to include at least two representatives from each of the six key Gravity stakeholder groups and to provide the breadth of technical expertise needed to carry out the Project:

1) Patients/Consumers  
2) Providers  
3) Payers  
4) Health IT Vendors  
5) Community-Based Organizations  
6) Federal/ State Government

c. The TAC will meet at least monthly, with more frequent ad hoc meetings to be scheduled as necessary.

d. Members are responsible for gathering feedback from their stakeholder groups on key questions and representing those perspectives.

e. Members of the TAC will select two co-chairs from amongst the TAC members to help manage TAC operations and facilitate coordination with the PMO.

f. Members will participate in at least one Gravity Public Collaborative meeting per month.
g. Quorum for purposes of meetings and official action by the Technical Advisory Committee is a minimum of five members, with at least one payer; one provider; and one from the patient/consumers group or CBO group.

Public Collaborative

a. The Gravity Public Collaborative provides consensus feedback on data element identification and adjudication and promotes the adoption of Gravity goals and defined standards.

b. The Public Collaborative is open to anyone to participate, to encourage a diversity of views and stakeholder perspectives. Participants are asked to register as either:

   I. **Committed Members**: Members who can regularly participate in project meetings and actively contribute to the development and review of project deliverables. These individuals will be expected to vote on all project deliverables.

   II. **Other Interested Parties**: Participants who intend to follow the progress of the project as an observer and participate in project discussions. These individuals will be able to submit comments on a project deliverable but not cast a vote during a deliverable consensus voting period.

c. The Public Collaborative meets as needed (weekly, bi-weekly, or monthly).

d. Public Collaborative meetings are open to all regardless of their membership status to ensure that viewpoints of all interested parties have an opportunity to be shared and considered. Everyone will be given an opportunity to speak; however, the Project Manager may limit discussion on topics to ensure the ability to cover agenda items for the call and to ensure project progress against milestones is accomplished with ample flexibility to change when warranted.

e. Persons who have not officially joined the Public Collaborative may still attend meetings, however, all meeting announcements, summaries, and other notices will be sent only to the Gravity Public Collaborative member list and posted to the Project’s Confluence page.

f. All registered Public Collaborative members will be added to the Gravity listserv and included in regular communications. Gravity member names, organization, and membership status will be published on the public Gravity Confluence page.

g. All Public Collaborative meetings are recorded. All meeting materials and recordings will be published on the Gravity Confluence page to allow all interested stakeholders to review and access at any time.

h. See Appendix A for URLs to the Gravity Membership Page, Gravity Confluence page, and instruction on how to join the project.

Program Management Office
a. The Program Management Office (PMO) is responsible for managing and implementing the Gravity Project as a program, including budget planning, fundraising, contracting, use case planning, outreach & education, and artifact approval. The PMO supports all strategic, operational, and technical activities, including developing project teams, organizing project meetings, and ensuring project deliverables are developed on schedule and within budget.

b. Key members of the PMO include:

   • Program Manager: responsible for the overall management of the Gravity Project and each of the individual Project Teams.
   
   • Technical Director: responsible for the overall technical direction of the Gravity Project and the development of technical artifacts.
   
   • SDOH Clinical Informatics Director: responsible for coordinating and managing all SDOH Domain Project Activities and the TAC.
   
   • SDOH Policy Advisor: responsible for aligning Gravity Project deliverables with broader national SDOH policy and program initiatives.
   
   • Payer Advisor: responsible for aligning Gravity Project deliverables with payer initiatives.
   
   • Project Manager: designated to oversee all PMO functions and coordinate across Domain and Technical workstreams.

c. The PMO’s Management Committee makes the PMO’s formal decisions and comprises the Program Manager, SDOH Clinical Informatics Director, and Technical Director, and any additional members that the Program Manager may appoint after consulting with the Executive Committee’s co-chairs. The Management Committee strives to make decisions by consensus. Should consensus not exist and further discussion prove fruitless, the Program Manager decides.

d. The Executive Committee appoints the members of the PMO and the PMO’s Management Committee upon recommendation from the Program Manager. The Program Manager chairs the PMO and its Management Committee, manages and supervises the PMO’s work and members, and reports to and is responsible to the Executive Committee for the work of the PMO and Management Committee.

e. The Program Manager is responsible for preparing an annual budget and workplan for Executive Committee approval.

f. PMO members will be financed through the Gravity Project Budget. The Finance Subcommittee’s chair serves as the primary approver for invoices submitted by the PMO.

g. The Executive Committee will approve any changes in budget and contracted resources.

h. PMO meets weekly or bi-weekly as needed.
Domain Project Team

a. The Gravity Domain Project team is responsible for the execution of the SDOH domain data set (e.g. housing, transportation) identification, adjudication, presentation for public input, incorporating relevant feedback, and developing recommendations to PMO for final approval.

b. Key members include:
   - Project Manager
   - SDOH Clinical Informatics Director
   - Domain Subject Matter Experts (In-kind)
   - Coding Expert
   - Project Analyst

c. The Project team is established based on the Gravity Project Roadmap.

d. The SDOH Clinical Informatics Director represents the Project at the PMO level.

e. The project team consists of contracted and in-kind members.

f. The Executive Committee will approve any changes in budget and contracted resources.

g. The project team meets once per week or as needed.

FHIR Development Team

a. The FHIR Development team is responsible for the development, testing, balloting, and publishing of FHIR IG specifications to represent data sets identified by the Domain Project team.

b. The FHIR Development team provides feedback and education to the Public Collaborative, oversees all Connectathon planning and testing, and manages development of FHIR IGs.

c. The FHIR Development team interacts directly with HL7 Working Groups and participates in HL7 in-person and testing events.

d. The team coordinates and manages the development of Reference Implementations with approval from the PMO.

e. Key members include the Technical Director and the FHIR IG Development Team.

f. The Executive Committee will approve any changes in budget and contracted resources.

g. The team consists of contracted and in-kind members.
5.0 Decision Making

a. The Committees will strive for consensus (66% or more of voting members present) in decision-making; however, decisions only require a simple majority of a quorum. Co-chairs are voting members.

b. A variety of informal techniques may be used at the chair’s discretion to determine if consensus may be reached including, but not limited to, straw poll, Robert’s Rules of Order, seeking a response to a hypothetical opposing view, and polling each participant to voice their position on the issue.

c. The Executive Committee, Strategic Advisory Committee, and Technical Advisory Committee shall make decisions by formal motion, second, and majority vote of a quorum.

6.0 Electronic Voting

a. Any decision required or permitted to be taken by the Executive Committee, Strategic Advisory Committee, or Technical Advisory Committee, may be taken without a meeting if all members consent in writing to that action, by written or electronic mail. Such action by written consent shall have the same force and effect as the unanimous vote of the committee. A written consent shall be filed with the committee’s minutes.

7.0 Working with HL7 Working Groups

a. When the Gravity Project plans to produce an artifact, such as an Implementation Guide, that shall be balloted by HL7, an HL7 Project Scope Statement (PSS) shall be created and taken to the appropriate HL7 Work Group(s) for discussion, ownership to manage the PSS, and submission to HL7’s approval process.

b. Gravity Project participants will work with the appropriate HL7 Work Group(s) to prepare materials necessary to take the artifact to Notice for Intent to Ballot (NIB), balloting, resolution of ballot comments, and submission for publication.

c. HL7 related Gravity Project artifacts will be subject to all relevant HL7 policies and procedures when submitted using a PSS and in the subsequent standards effort related to the specific artifacts defined in the PSS.

d. Artifacts submitted for HL7 balloting (via the PSS process) will become intellectual property owned and distributed under HL7 published guidelines.

8.0 In-Kind Work

a. Gravity Project participants and Committee members are encouraged to provide resources from within their organization to assist with the development of Gravity Project deliverables.
9.0 Contracting

a. Contracting for all resources (e.g., people, tools, services), and associated terms of contracts, shall be approved by the Executive Committee or its authorized delegate.

b. Gravity Project membership and sponsorship fees paid to HL7 may only be used at the discretion and direction of the Executive Committee.

c. HL7 will issue and maintain a contract to a Gravity Project PMO contractor designated by the Executive Committee. The PMO will be in charge of identifying and contracting individuals as directed by the Executive Committee.

d. Requests to HL7 for contracted Gravity resources shall include, at a minimum, the name of the individual or organization, a reference to a quotation if it is a product or service, the contact information for the individual or organization, the cost, payment terms, and duration of the contract. For contracted individuals, requests shall include a statement of work, deliverables, start/end date, and the fixed price or hourly rate and any applicable caps on hours.

e. The Executive Committee may authorize HL7 to issue contracts for any level of expenditure without the need for an RFP if the funding exists in the Gravity account held by HL7, considering the full terms and value of all active contracts.

10.0 Trademarks and Publicity

a. All use of Gravity Project trademarks shall be approved by the Executive Committee or its authorized delegate.

b. All publicity related to the Gravity Project will be approved by the Executive Committee or its authorized delegate. No organization’s name shall be used in Gravity Project publicity without expressed written consent of the appropriate representative from that organization.

c. Gravity Project members shall not use organization names of other members without the express approval of the organization, except when using or referring to Executive Committee approved Gravity materials (e.g. Gravity web site).

11.0 Sponsorship

a. The following are the annual sponsorship levels offered for the Gravity Project:
   - Premier: $80,000/year
   - Partner: $50,000/year
   - Associate: $25,000/year

b. All sponsors who pledge funding in 2019 and 2020 will be named Founding Sponsors of the Gravity Project.
c. All sponsors will be listed on the Gravity Project Confluence and acknowledged in all Gravity Project deliverables, according to their sponsorship level.

d. Sponsors pledging at the Premier and Partner levels will be granted the opportunity to be considered for a seat on the Executive Committee. All Sponsors will have a seat on the Strategic Advisory Committee as outlined in this document.

e. HL7 will collaborate with the Executive Committee to establish ongoing membership fees for Gravity organizational membership and resources.

f. Ongoing membership fees, levels, and participants will be public and maintained by the Program Management Office.
Appendix A: Gravity Project Web Pages

1. Gravity Project Web Site: https://thegravityproject.net/
2. HL7 Gravity Project Page: https://www.hl7.org/gravity/
3. HL7 Gravity Confluence Page: https://confluence.hl7.org/display/GRAV/The+Gravity+Project
4. HL7 Gravity Project Membership List: https://confluence.hl7.org/display/GRAV/Join+the+Gravity+Project
6. Consensus Approved Food Insecurity Data Set: https://confluence.hl7.org/display/GRAV/Food+Insecurity+Domain
7. Gravity SDOH Clinical Care FHIR IG Build: https://confluence.hl7.org/display/GRAV/Gravity+FHIR+IG
Appendix B: Key Terms

a. **FHIR® Accelerator Program**: Established by HL7 to convene and work with communities and implementers with an interest in using the Fast Health Interoperability Resources (FHIR®) specifications to address common use cases.

b. **Gravity Project**: The Gravity Project is the nationwide public collaboration convened by the Social Interventions Research and Evaluation Network (SIREN), at the Center for Health and Community, University of California, San Francisco, with funding from the Robert Wood Johnson Foundation, to standardize medical codes to facilitate the use of social determinants of health-related data in patient care, care coordination between the health and human services sectors, population health management, value-based payment and clinical research.

c. **Gravity Project Participants**: All individuals involved in the Gravity Project, whether as members or participants in the Gravity Public Collaborative, or as members of the Executive Committee, Project Management Office, Strategic Advisory Committee, or Technical Advisory Committee.

d. **Gravity Stakeholder Groups**: The Gravity Project recognizes the diversity of the Gravity stakeholder community and categorizes the community into six key stakeholder groups:
   
   I. **Patients and consumers**: these are the individuals and their representatives that receive care and services, consent to the sharing of their electronic information, and mediate the exchange of their electronic information.
   
   II. **Providers**: these represent the entities and individuals that furnish health care such as a hospital, critical access hospital, skilled nursing facility, primary care clinic, and physicians.
   
   III. **Payers**: the entities that have primary and secondary responsibility for paying a claim. These include public payers such as the Centers for Medicare & Medicaid Services (CMS), State Medicaid Agencies, the Department of Defense, and the Veterans Health Administration, and commercial payers such as UnitedHealthcare, Kaiser, Blue Cross Blue Shield, and AmeriHealth Caritas.
   
   IV. **Health IT Vendors**: refer to the entities that provide health and human services or products in exchange for a fee, which includes contractors and suppliers. These include electronic health record (EHR) and practice management systems, health information exchange (HIE) platforms, clearinghouse systems, digital health platforms, and community-referral platforms.
   
   V. **Community-Based Organizations**: a public or private nonprofit organization of demonstrated effectiveness that: (1) is representative of a community or significant
segments of a community; and (2) provides educational or related services to individuals in the community.

VI. *Federal and State Government*: these are the United States federal and state-based agencies that encourage, incentivize, or require the use of social determinants of health data.

e. **Social Determinants of Health (SDOH)**: The conditions in the places where people live, learn, work, and play that affect a wide range of health risks and outcomes.\(^1\)

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\(^1\) https://www.cdc.gov/socialdeterminants/index.htm