TERMS OF REFERENCE

Project Title: Procurement of Consulting Services for the Conduct of Ethical, Legal, Social, and Health Systems Implication (ELSHI) Assessment
Type of Service: Negotiated Procurement (Agency-to-Agency or Scientific Services)
Funding Source: GAA 2023 - Health Technology Assessment Division

I. Background

Pursuant to the Universal Health Care (UHC) Act, all health technologies that the government will implement and cover shall undergo health technology assessment (HTA). This aims to ensure the rational utilization of various health technologies that will be funded by the government.

In this regard, a collaborative approach in HTA through the commissioning of independent academic and research teams via the HTA Research Network as stipulated in Administrative Order 2020-0041 will streamline the work on evidence reviews, and accelerate the delivery of much-needed advice by decision-makers and health policy makers.

In fully assessing the relevance and applicability of health technologies (HT) for government financing, the HTA also takes into account the ethical, legal, and social implications (ELSHI) with regards to the use or non-use of a health technology. This further reinforces the rigorous process in the decision-making tackling other aspects that could affect the intended users of HTs and the overall healthcare system in the local setting.

This project is therefore being undertaken to facilitate the conduct of ELSHI assessment that will generate evidence and form part of the HTAC recommendation. Topicsthat underwent clinical assessment are proceeding to ELSHI assessment in parallel with an economic assessment

This specific Terms of Reference (TOR) is for the contracting of external assessment of the ELSHI assessment of an HTA prioritytopic. The external assessment group (EAG) to be selected shall conduct the ELSHI assessment based on the guidelines stated in this TOR which is based on the Philippine HTA Methods Guides.

II. Objectives

A. General Objective

To conduct the ELSHI assessment of topic of choice that will be used by the HTA Council in developing its recommendation on the coverage decision for DOH and PhilHealth

B. Specific Objectives

Specific Objective	Activity	Outputs
To synthesize relevant existing ELSHI evidence to the assessment through a scoping review, as indicated in the HTA Methods Guide	Scoping review Qualitative Systematic Review (QSR), as deemed needed as a supplemental method	ELSHI Assessment Report *(Midterm Report; Initial Final Report; Final Report)* Presentations to the HTA Council
To supplement scoping review/QSR with primary data on relevant ELSHI themes to the health technology *Note: Optional depending on the relevance and adequacy of existing ELSHI evidence based on initial search, See HTA Methods Guide for details*	Focus Group Discussion (FGD)/ Key Informant Interview (KII)/ Survey	

III. Scope of Work

1. Implement the research project as per the developed and approved (with technical and ethical clearances, if applicable) research proposals;
2. Conduct scoping review on existing ELSHI evidence as standard method for all ELSHI assessment based on extensive literature search using relevant scientific databases;
3. Synthesize ELSHI evidence (either via de novo QSR, adoption of existing QSR, or updating of existing QSR), depending on the adequacy of existing ELSHI evidence based on initial search;
4. Conduct primary data collection, as guided by the findings from the scoping review of existing evidence and as deemed necessary by the HTA Council

5. Submit the outputs of the project according to the prescribed timelines below and following the forms or templates as prescribed in this TOR incorporating the HTA Process Guide and Methods Guide.

Phase	Output(s)
Pre-implementation	1. Pre-implementation meeting before inception report submission 2. Inception report which will include the following: - Scoping of existing ELSHI evidence - Qualitative Systematic Review of ELSHI Evidence (*Refer to Table 15 [page 71 in pdf] for the minimum requirements for QSR), as needed* - Data Gathering Strategy (*Refer to Table 16 [page 73 in pdf] for the common data gathering methods), as needed* - Data Analysis Plan (Optional: May use PROGRESS-Plus and/or HTA Social Value Guide) - Detailed budget proposal - Detailed and Feasible Work Plan
ELSHI Assessment (Initial phase)	Midterm ELSHI Assessment Report including: - Final included studies with extraction - Results of evidence appraisal
ELSHI Assessment (Finalization phase)	1. Initial Final Report prior to the presentation meetings 2. Meetings to present findings: - EAG presentation of findings to the HTAC Subcommittee - HTAC Subcommittee Presentation to the Core Committee where the EAG can be invited as resource persons 3. Final ELSHI Assessment Report *Note: Submitted after the HTAC Core Committee finalizes its recommendation after the appeals period/ stakeholder consultation of the recommendation*
Closing of the project	Final Financial Report

Note: Timelines may vary depending on the methodology that will be submitted by the proponent and approved eventually by the HTA Philippines. According to the HTA Methods Guides, below are the various timelines for ELSHI assessments:

ELSHI Assessment	Timeline of assessment *(in parallel with economic assessment)*
Scoping review only	12 to 20 working days (0.75 to 1.25 months)
Scoping review + primary data collection	33 to 60 working days (1.5 to 3 months)
Scoping review + adopting QSR	36 to 57 working days (1.75 to 2.75 months)
Scoping review + de novo SR/updating QSR	57 to 100 working days (2.75 to 5 months)

4. Provide regular updates to the HTA Division following the prescribed timelines on the status of the assessment
5. Submit the final HTAC-approved technical report one month before end of project and final financial report one month after end of the project
6. Ensure dedicated teams for the overall program management and quality assurance of all the research outputs
7. Communicate results through reports and oral presentations to the HTA Council and Division;
8. By the end of the contract, ensure submission of all deliverables according to the specifications indicated in Section VI.

IV. Expected Outputs or Deliverables

- Inception report
  - Scoping of existing ELSHI evidence: Literature Search
  - Qualitative Systematic Review of ELSHI Evidence (*Refer to Table 15 [page 71 in pdf] for the minimum requirements for QSR), if deemed necessary:* Systematic search and list of included studies
  - Primary data gathering: Actual data gathering plans (e.g. schedule and location of interviews/FGDs, target list of participants)

    ELSHI assessment for HTA comprise of:

    ➢ Part 1: Scoping Review

    ➢ Part 2: Conduct of systematic review of ELSHI evidence, if deemed necessary

➢ Part 3: Conduct of primary data collection (i.e., survey, key informant interview, focus group discussions), if deemed necessary by the HTA Council

- Midterm Report:
  - Scoping review: included studies and local regional/provincial data (if applicable)
  - QSR, *if deemed necessary:* Final included studies with extraction
  - Primary data gathering: Completed data gathering and transcribed/encoded data

- Initial ELSHI Assessment Report:
  - Scoping review: Methods and results of synthesis of ELSHI evidence
  - QSR, *if deemed necessary*: Methods and results of evidence appraisal and synthesis
  - Primary data gathering, *if deemed necessary*: Methods and results of data analysis
  - Appraisal of ELSHI evidence & data analysis (*Optional*: May use PROGRESS-Plus and/or HTA Social Value Guide)

- Final ELSHI Assessment reports including oral presentation to HTAC
  - Scoping review: Methods and results of synthesis of ELSHI evidence
  - QSR, *if deemed necessary*: Methods and results of evidence appraisal and synthesis
  - Primary data gathering, *if deemed necessary*: Methods and results of data analysis
  - Appraisal of ELSHI evidence & data analysis (*Optional*: May use PROGRESS-Plus and/or HTA Social Value Guide)
  - Refer to the HTA MG Annex 12 for the outline of reports for ELSHI analysis

Note: Initial ELSHI Assessment Report and Final ELSHI Assessment Report essentially require the same content except that the initial report is the one submitted before the presentation to the HTA Council and the final report is the version which already incorporates all the comments.

V. Project Duration

Duration shall depend on the proposed approved methodology for the assessment. It will be finalized during the selection of the proponent.

VI. Implementation Agreement

A. Contact persons:
All communications and reports must be addressed to:

ANNE JULIENNE GENUINO-MARFORI, RPh, MSc
Chief Health Program Officer
Health Technology Assessment Division
Department of Science and Technology
DOST Central Office, Bicutan, Taguig City

B. Reporting Obligations, notices and approval process including minimum or essential reports' contents

Deliverable	**Technical and formatting requirements**
Inception Report	*Outline of the Inception report* 1. Title 2. Protocol information 3. Background 4. Research question 5. Methodological Plan for ELSHI Assessment a. Scoping Review b. Qualitative Systematic Review *(optional)* c. Primary Data Collection *(optional)* 6. References 7. Annexes 8. Declarations 9. Timelines
Midterm Assessment Report	*Outline of the Midterm Assessment report* 1. Title 2. Background 3. Research question 4. Methodological Plan for ELSHI Assessment a. Scoping Review b. Qualitative Systematic Review *(optional)* c. Primary Data Collection *(optional)* 5. Initial Results of ELSHI Assessment a. Scoping review i. Final included studies ii. Local regional/provincial data (if applicable) b. Qualitative Systematic Review *(optional)*

		i. Final included studies with data extraction c. Primary data gathering *(optional)* i. Transcribed/encoded data 6. References 7. Annexes 8. Declarations 9. Timelines
	Initial ELSHI Assessment Report	*Outline:* 1. Executive Summary 2. Health problem and clinical management options 3. Description, technical characteristics, and use of the health technologies 4. Methodology a. Ethical b. Legal c. Social d. Health Systems 5. Results of Synthesis of ELSHI Evidence a. Scoping Review b. Adoption or appraisal of existing SR *(optional)* c. Primary Data Collection *(optional)* 6. Discussion and Conclusion 7. Relevant attachments (should include, but not necessarily be limited to, those listed below) a. CV of all Research Team members b. Technical Clearance of Research Proposal c. Ethics Clearance d. Data Collection Tools (e.g., survey questionnaire, interview guide, focus group discussion guide) e. Informed consent and non-disclosure agreement form f. Datasets g. Protocol including search strategy and methods h. Data sources and reference
	Final ELSHI Assessment Report *Note: The Initial and Final Assessment Report follows the same template content. The*	*Outline of final report:* 1. Executive Summary 2. Health problem and clinical management options 3. Description, technical characteristics, and use of the health technologies

key difference is that the Initial Assessment Report is the first version of the report, prior to the presentation meetings to the HTA Council. Meanwhile, the Final Assessment Report already incorporates the comments of the HTA Council, as well as possible comments from stakeholders (found by the HTA Council to be meritorious) during the public consultation of the HTA Council recommendation on the health technology which presents the EAG report as evidence.	4. Methodology a. Ethical b. Legal c. Social d. Health Systems 5. Results of Synthesis of ELSHI Evidence a. Scoping Review b. Adoption or appraisal of existing SR *(optional)* c. Primary Data Collection *(optional)* 6. Discussion and Conclusion 7. Relevant attachments (should include, but not necessarily be limited to, those listed below) a. CV of all Research Team members b. Technical Clearance of Research Proposal c. Ethics Clearance d. Data Collection Tools (e.g., survey questionnaire, interview guide, focus group discussion guide, field notes) e. Informed consent and non-disclosure agreement form f. Datasets g. Protocol including search strategy and methods h. Data sources and reference

VII. Proposed Terms of Payment by Major Outputs:

Release	% of Fund	Requirements
1st	15%	• Signed and Notarized Memorandum of Agreement
2nd	40%	• Approved full proposal • Approved inception report
3rd	35%	• Approved Midterm Report
4th	10%	• Approved Final ELSHI Assessment Report

Project outputs should be submitted to the HTA Division. The audited financial report of the total project cost shall be submitted within one month after the release of the last tranche.