A Memorandum of Understanding Template for Guideline Collaboration (MOU-GC)

When is an MOU needed?

The first step is to decide whether any type of agreement is needed among guideline collaborators, and if so, whether an MOU is the most appropriate vehicle. If the groups have not collaborated before, are unfamiliar with each other, have distinct formal governances, or have competing interests, an MOU may be beneficial to avoid misunderstandings. The time to initiate and complete an MOU or similar document is before any work has been done. Weeks to months may be required for the executive and legal arms of multiple groups to agree on the wording of an MOU. In the event of an update of the guideline, it is recommended that the MOU is reviewed and if necessary, revised. This revised MOU should consider any changes in the goals and objectives of the involved organizations if applicable.

The proposed MOU template for Guideline Collaboration (MOU-GC Version 1.1) below is based on the work and publication of the Guideline Collaboration Working Group, Guidelines International Network (GIN-GCWG) [1, 2].

An international panel of representatives from guideline groups and organizations was formed. A review of the literature to find publications and other resources important to the formation of MOUs between two or more guideline groups, enhanced by available source documents, was employed to guide the development

of a draft MOU resource. This was iteratively improved until a consensus was reached [1,2].

This template was intentionally developed to be expansive in order to illustrate multiple potential collaborative scenarios, but can be adapted to better suit organizational needs. Some organizations may decide to prioritize and select a set of elements from this tool if a slightly more informal agreement is preferred. The template also does not include an exhaustive list of potential collaboration formats; as other types of collaborative formats may exist.

The order of the elements included in the following MOU-GC template specifically follows the same order of elements proposed by the GIN-GCWG in its aforementioned MOU key article[1].

Further research is recommended by the GIN-GCWG to examine its usability, practicality, and operationalization. This includes but is not limited to the need of some collaborations to re-order the elements included in the template (e.g., some organizations may potentially need to discuss copyright and ownership first in actual practice) and their need to modify, adapt, or add some relevant elements to this template.

MOU Template for Guideline Collaboration (English)

This template and its elements can be used in conjunction with the list of international glossary of terms related to collaboration in guideline development developed by the GIN-GCWG[3].

Table 1. The key elements of an MOU or other collaboration agreement to support guideline collaboration:

<table>
<tr><th>CATEGORY</th><th colspan="3">KEY ELEMENT</th></tr>
<tr><td rowspan="3">Scope and purpose
(1-3)</td><td colspan="3">1. Defining the aims of the collaboration, including the topic, and included and excluded subtopics</td></tr>
<tr><td colspan="3">§ Target audience(s): ……
……</td></tr>
<tr><td>§ Intended uses:
• Clinical Care:
☐ Prevention
☐ Screening
☐ Diagnosis
☐ Treatment
• Public Health ☐
• Health Policy ☐
• Environmental/ Occupational Health ☐</td><td>Healthcare context:
☐ Primary
☐ Secondary
☐ Tertiary
☐ Outpatient clinics
☐ Inpatient
☐ Other (specify):
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……</td><td></td></tr>
</table>

§ **Type(s) of guidance documents to be delivered (select all that apply):**

☐ Consensus statement

☐ State-of-the-science

☐ Evidence-based guideline (Full guideline document with detailed methodology reporting)

☐ Evidence-based guideline (Quick reference guide)

☐ Position statement paper

☐ Implementation toolkit

☐ Patient information guide (plain language)

☐ Mobile App

☐ Others: Specify:

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§ **What might not be evaluated or discussed in the guideline** (e.g., unlicensed, off-label, or experimental treatments; diagnosis versus prognosis, late-stage versus early-stage disease management, management of certain demographic groups, such as pediatric patients, etc.)[1-4]?

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2. **Delineating the scope of the collaboration,** *including degree of involvement by each participating group (refer to the international glossary from the terminology and definitions)*[3]

- Collaboration will involve the complete guideline process of the following (☐ Yes ☐ No)

☐ De novo development

☐ Adaptation

☐ Adolopment

- Collaboration will involve only specific parts of the guideline process steps: ☐ Yes ☐ No
    - If Yes, please specify the areas of collaboration from the following list of steps (select all that apply):
        - Formulating the guideline development, adaptation, or adolopment group
        - Identification and prioritization of health questions
        - Identification of eligible source guidelines or systematic reviews
        - Quality appraisal of source guidelines
        - Matching source guidelines or systematic reviews to each prioritized question
        - Updating the systematic reviews as needed (with reassessing or developing evidence profiles/ tables).
        - Formulating recommendations through adoption, adaptation, de novo development, or adolopment.
        - Peer review of the finalized guideline document
        - Others (specify):

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- Collaboration will extend to the next review and update of the guideline: ☐ Yes ☐ No
    - Collaboration will include a 'Living' guideline: ☐ Yes ☐ No
    - Note that this may not be applicable if there are changes within one of the collaborating organizations and they are no longer positioned to collaborate on the update, In this case, the MOU for updating the guideline will need to be revisited.
- Additional comments:

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3. Naming the collaboration, *which may be an official work product of the participating groups*

- Official Name of the collaboration (to be used in public communications regarding the project):

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- The working Title of the guideline (that may be possibly updated if needed near the end of the project):

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- Names of participating groups:
  - Group 1:
  - Group 2:
  - Group 3:
  - Other:
- Is the guideline name preceded by acronyms or names of the groups, and if so, in what order?

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- Guideline registration:

  ☐ GIN international guideline library and registry of guidelines in development. Link: https://guidelines.ebmportal.com/ (Free for members) Guidelines International Network, Perth, Scotland, UK.

  ☐ PREPARE Practice guideline REgistration for transPAREncy or the International Practice Guideline Register Platform (IPGRP) program. Link: http://www.guidelines-registry.org/ (Free) University of Lanzhou, Chengguan District, Lanzhou, Province of Gansu, China.

  ☐ Other

- Registration No./ Link:

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- Adjudication of disagreements: What will happen if there are disagreements in the way the MOU is followed? A process should be

discussed and agreed upon in advance to resolve these disagreements quickly and at low cost (Written here or attached)

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Leadership and team

(4-7)

4. Deciding which participating group(s) are responsible for overall governance structure

- Is this a case of one group inviting others, multiple equal partners, or some other structure?
  ☐ Yes ☐ No

- For member groups, it may be useful to distinguish between *members* with leadership roles in the guideline development, adaptation, or adolopment vs. *staff* in leadership roles (e.g., all groups may name equal numbers of members to the guideline group, but the staff of one group may be the lead).
  - Name of the Chairperson of the guideline development or adaptation group (GDG/ GAG):
  - Name of the Co-chairperson of the GDG/ GAG (if needed):
  - Name of the Clinical Chair:
  - Name of the Project Manager (if needed):
  - Name of the Methodology chair:
  - Members of the Clinical subgroup:
  - Members of the Methodology subgroup and technical support:
  - Members of the Logistics team
  - Others roles (as needed)

· When there is disagreement regarding the steps of guideline development, adaptation, or adolopment process during the guideline production, how will this be resolved?

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5. Selecting individuals to lead the collaboration team

- Will there be a single chair, a co-chair, a vice-chair, or multiple vice-chairs or co-chairs for each of the clinical and methodology groups? If multiple leaders, will there be one from each group?

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6. Determining the number and type of representatives from each participating group

- How many members will participate from collaborator group 1 (number)?
- How many members will participate from collaborator group 2 (number)?
- How many members will participate from collaborator group xx (number)?
- Are there minimum qualifications for members?
  ☐ Yes ☐ No

  If Yes, Specify:
  (for example, completed the INGUIDE Program Level 1 https://inguide.org/ if feasible)

- How much time/ how many hours each group will devote to the project?
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7. Implementing policies and procedures to manage relationships with industry (RWI) and conflicts of interest (COI)

- Will one group's RWI/COI policy be followed, and if so, specify this group and attach the policy.
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- How/When will RWI/COI be disclosed and monitored throughout? How will relevant relationships affect a member's involvement (i.e., no lead of workgroups, abstention from voting on topics, etc.)?
  A useful resource for handling guidelines COI is this GIN publication: https://doi.org/10.1503%2Fcmaj.200651
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- For how long in the past will disclosures need to be reported?
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	• Should external reviewers and the organizational leaders who will provide reviews be required to disclose their COI/RWI and should meet the same standards as guideline group members? Yes/No · Should public commenters be required to disclose who they are, their employment, and roles at their institutions. ☐ Yes ☐ No
Methods and commitment (8-12)	***8. Detailing the methodological framework to be used for data extraction, expert consensus, and writing***
	• ***Choosing the methodology of the guideline*** ☐ De novo development. ☐ Adaptation. ☐ Adolopment. · ***Health Questions Model*** ☐ **PICO.** – Problem/Population, – Intervention, – Comparison, – Outcome ☐ **PIPOH.** – Problem/Population, – Intervention, – Professionals, – Outcome, – Healthcare context ☐ **PICAR.** – Population, clinical indication(s), and condition(s), – Interventions – Comparator(s), comparison(s) and (key) content – Attributes of eligible CPGs – Recommendations characteristics and 'other' considerations

What methods and tools will be used for the original or updated literature search and data extraction?

What methods and tools will be used for the development of evidence tables?

What methods will be used for content review?

What methods will be used for development of recommendations?

What recommendations grading schema will be used (e.g., GRADE, USPSTF, or another system)?

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- ***For guideline adaptation:***

Which adaptation methodology will be used:

☐ ADAPTE. ☐ RAPADAPTE. ☐ Adapted ADAPTE. ☐ KSU-Modified-ADAPTE. ☐ Turkish ADAPTE. ☐ PAGE. ☐ CAN-IMPLEMENT. ☐ MAGIC (SNAP-IT). ☐ GRADE-ADOLOPMENT. ☐ Other:

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Which guideline appraisal tool(s) will be used

☐ AGREE II. ☐ AGREE-REX. ☐ iCAHE Guideline Quality Checklist. ☐ NEATS instrument. ☐ PANEL VIEW instrument. ☐ GuideLine Implementability Appraisal (GLIA). ☐ AGREE-S. ☐ Other:

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Which guideline checklist(s) will be used
Development

☐ AGREE Reporting. ☐ RIGHT. ☐ GIN-McMaster GDC. ☐ GIN-McMaster GDC-RG.

☐ Other:

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Adaptation

☐ RIGHT-Ad@pt.

· *What methods and thresholds will be used for achieving an agreement at a virtual or in-person consensus meeting?*

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· *If the systematic review will be submitted to PROSPERO, who will prepare the submission?*

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Other possible registries for systematic reviews include the Open Science Foundation (OSF)

☐ Other:

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Underlying evidence

- Who is conducting the reviews?

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- Will this be based on *systematic reviews* of the literature?

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- How many reviews? This may be updated if needed (if warranted by substantial new evidence becoming available during the guideline development).

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- Using what methods?

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Quantitative analyses and feasibility assessments (if this will be included as a component of the guideline project, please address the following points, otherwise, skip this section)

· *Who will perform feasibility assessments to determine if the evidence will support direct or indirect meta-analyses, cohort, sensitivity analyses, etc.?*

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· *If these services are to be contracted out to external consultants or methodologists, who will pay for these analyses?*

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· *What platforms are to be used?*

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- *Will the Systemic Reviews and Guidelines be published separately?*

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- *All parties should commit to providing the guideline methodologists and consultants with authorship when their contributions meet the criteria for authorship (e.g., the International Committee of Medical Journal Editors (ICMJE) or the Contributor Roles Taxonomy (CRediT) author statements) (details in item 17)*

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9. Clarifying rules associated with confidentiality of the work process

· *What rules govern confidentiality, and what information is deemed confidential?*

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· *Will there be a signed intellectual property and confidentiality agreement? If yes, provide a copy of the IP & Confidentiality Agreement as an Addendum to the MOU.*

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· *Will there be an embargo? If Yes, when will the embargo be lifted (after publication)?*

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10. Establishing a timeline, and estimating time commitment for all team members

· *What is the expected time from inception to completion, and for various parts of the process (e.g., data extraction, peer review/public comment, manuscript writing/editing)?*

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Will a commitment letter or similar device be used with the Co-chairs and Expert Panelists to confirm understanding of project scope and timeline, requirements for authorship, and willingness to complete the guideline?

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· *How many consensus meetings (in-person or virtual) are planned, and when?*

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· *Consider using a Gantt chart or other graphical representation of the timeline of the overall process.*

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· *May virtual meetings suffice, thereby reducing travel for both financial and climate-change reasons?*

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II. Estimating financial costs

· *The group needs to define and agree on the financial costs, shared costs, and in-kind costs (or payment-in-kind) (e.g., staff time, librarian payment, medical writer payment, etc.)*

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· *Which group(s) will bear the financial cost of development/ adaptation and dissemination of the results?*

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If costs will be shared, how exactly (e.g., equally among the collaborating groups, or by size of membership, annual budget, or proportion of representation in the guideline group)?

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· *Will one or more organizations pay for specific items such as the following (the list is not exclusive):-*

☐ *Systematic literature review and analyses*

☐ *Patient education materials based on the guidelines*

☐ *Provision of staff management*

☐ *Librarian payment*

☐ *Medical Writer payment*

☐ *Graphical design of the final full guideline document*

☐ *Permission or user license costs that are sometimes required for published evidence tables or source guidelines.*

	12. Assigning team members or other professionals to draft and revise the guideline document
	· *Who will be responsible for writing drafts, and for revisions?* …… …… · *Will only group leaders write, or will other members be involved, and if so, how?* …… …… · *Will a medical writer participate?* ☐ Yes ☐ No …… ……
Review and endorsement (13-15)	***13. Setting up a process for expert review and public comment***
	· *Will the leadership of the groups be allowed to designate members (of the participating groups who are not also members of the guidelines group) to provide subject matter expert review on behalf of the participating groups prior to submission to a journal that will provide independent peer review?* …… …… · *To whom and for how long will the guideline be opened for public comment?* …… ……
	14. Obtaining endorsements and approvals of the work product from leadership of participating groups
	· *How will approval or endorsement be obtained from each of the groups?* ……

· *Is there a process for adjudicating disagreements, or making edits if a group requests changes?*

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15. When necessary, ensuring the orderly exit or withdrawal of dissatisfied participating group(s)

· *What happens if some groups do not approve the guideline, or choose to exit before the guideline is complete?*

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· *Can the final product still be released by the remaining group(s)?*

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· *Is the withdrawing group(s) allowed to develop a separate guideline on the same topic? Also consider defining a mechanism whereby new organizations may be able to collaborate on future editions or updates to living guidelines.*

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Publication and dissemination

(16-20)

16. Assigning copyright, ownership, and other rights to the guideline to various participating groups

Ownership and rights of use should be agreed to in advance. Any such agreement should be in accordance with the prevailing norms and laws of the applicable jurisdictions.

· *Will ownership be by one group, or will it be shared?*

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· *Will there be license agreements that entitle groups to disseminate it, post it, or otherwise share it?*

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· *Will any publication bear the group logos of the participating groups?*

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The executive staff of the groups should confirm that the ownership and licensure are implemented properly.

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17. Preparing rules for conferring authorship to team members, and choosing author order

· *How will authorship and acknowledgment be reported?*

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· *Which groups (guideline committee members, chairs, vice- chairs, co-chairs, group staff members, external writers, other key personnel) will be authors or contributors, and which will be acknowledged?*

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· *On what basis will first, last, and corresponding authorship be assigned? (Co-first?)*

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· *Will reviewers be acknowledged? Information specialists? others?*

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· *How will authorship be determined for any guideline derivative products? All parties should agree that authorship should comply with ICMJE rules.*

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18. Arranging in order of preference the journal(s) to which the guidelines are submitted for publication

- *How will the guideline be disseminated? Assuming publication, is there agreement regarding the preferred journal(s) (e.g., is there an obvious journal or flagship journal; or do any of the groups in the collaboration own or control a journal[s] in which publication would be appropriate) or online platforms?*

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- *If there is expectation of simultaneous publication, which journal will be in charge of copy editing the guideline for publication?*

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- *Have the various editors committed to coordinating the timing of peer review and publication? Will there be a joint or separate journal peer review process?*

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- *Are some journals committed to publishing only an executive summary vs. the full document? It should be prearranged by when endorsements and approvals listed in the publication will need to be obtained and where in the publication they should be listed.*

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19. Preparing for other methods of dissemination, including social medial, email, and web postings

- *Will groups post guideline documents on their websites, or include a link to the primary publication?*

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- *Will groups be authorized (e.g., licensed, if they are not guideline owners) to develop their own implementation tools, quality measures, and other applications based on the guideline?*

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· *Are the collaborating groups free to create other products, events, and services based on the guideline? If they would like their logos included on the guideline posted by other groups, will this be permitted, encouraged, or required?*

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· *Will groups be able to push guidelines to their members via various active communication channels, including but not limited to newsletters, email, social media, mobile apps, knowledge-platforms, decision support systems, and didactic sessions?*

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· ***Computable guidelines***

  o *If developing computable guidelines is part of the project, how will these be developed and managed?*

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  o *Who will take the lead?*

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20. Considering the possibility of collaboration on related work products, such as quality measures

- *Are future collaborations envisioned?*
- *Will the work product be repurposed for other uses (e.g., development of quality or performance measures, or incorporated into registries)?*
- *Will the guideline be updated according to a prearranged schedule?*
- *Will the Checklist for the Reporting of Updated Guidelines (CheckUp) be used to guide the update process?*
- *How will retirement/reaffirmation be handled?*

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- *Who can trigger an update & how does that happen?*
- *What happens if someone wants to leave the MOU?*
- *Protection from societies in the MOU creating a competing guideline with this MOU*

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