Guidelines for Rome Foundation Clinician Monitors

Adult and Pediatric Questionnaires July 2017

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The following are the Rome Foundation guidelines for its clinician monitors. The role of the RF clinician monitor is to accompany the translation process for RF questionnaires (adult or pediatric).

The clinician monitor is not involved in translating itself. He/she represents the Rome Foundation, working with the translating team to ensure the highest quality translation outcome.

The RF clinician monitor is a medical doctor (usually a gastroenterologist) who is a native speaker of the target language (the language the questionnaire is being translated to) and a fluent speaker of the source language (usually English).

The functions of the clinician monitor are:

- 1. Be familiar with the RF translation guidelines and the clinician monitor guidelines, sign them and return them signed to Mr. Mark Schmitter of the Rome Foundations (mschmitter@theromefoundation.org) before the beginning of the translation process.
- 2. Establish communication with the head of the translation team and determine how the collaborative process will be conducted. The usual means of communication is e-mail, but other methods of communications (telephone, in-person, etc.) are welcome.
- 3. Confirm that the translators who will do the two independent forward translations are professional translators with experience in medical translation (see step 1 in the guidelines for questionnaire translations). Approve the translators.
- 4. Participate in the reconciliation process for the two independent forward translations with the two translators (step 2).
- 5. Assure that the translator doing the backward translation (step 3) fulfills the criteria for a translator (see #1 above) and is not one of the two translators who did the forward translations.
- Together with the translators and the translation team conduct a comparison of the two source language versions (original questionnaire and back-translated version, usually English) (step 4). This is an item-by-item comparison, on two dimensions, i.e., similarity of language (literal translation) and comparability of interpretation (cultural adaptation).
- 7. Confirm that the cognitive-debriefing process (step 5) is conducted in accordance with the translation guidelines.
- 8. Proofread the final version before submission to the Rome Foundation for approval (step 6).
- 9. Prepare a letter of recommendation for the final version of the target language questionnaire and send it together with all translation process documents (see below) to Mr. Mark Schmiter at the Rome Foundation (step 7).

• Required documentation

- Files of the two forward translations
- File of the backward translation
- File of the target language version for cognitive debriefing
- A file documenting the comments made for each item (if any) during cognitive debriefing.
- A file with the final, proofread translation

In recognition of the important work done by the Rome Foundation Clinician Monitor, he/she will receive an honorarium, based on the size of the questionnaire.

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Signature	
Date:	