Dear participant,

We hereby provide you with all documents you will need to obtain (local) ethical / IRB approval for participation in the PRO-MC Collaboration. We would like to point out that obtaining ethical approval is the responsibility of the local investigator. After obtaining (local) ethical approval, a copy of the approval letter needs to be send to the PRO-MC steering group.

Note: some documents might need additions or might require translations to your national language before submission. Additions you might have to make:

- Submission letter
  - the date of the letter and the name of the local investigator submitting the study documents
- Study protocol
  - A signature of the local investigator has to be added to the signatures box on page 3
  - local ethical requirements, not yet included in the protocol, can be added to the ethics section of the protocol on page 18.
- Patient information brochure
  - Name of the ethical committee which will handle the proposal, has to be added to page 3
  - The name and contact details of the local investigator have to be added to page 4.
- Documents that might need translation to the local language are:
  - Patient information brochure
  - Informed Consent form
  - Patient defaecation diary
  - The “Short health scale” form, a quality of life questionnaire (SHS)

Good luck with obtaining ethical approval to initiate the PRO-MC Collaboration in your centre.

In name of the PRO-MC Steering Group,

Andreas Münch - Chairman

Bas Verhaegh - Project Manager