

Rome Foundation Research Institute (RFRI) Guidelines for Handling Research Projects and Data Access and Consultation

Rationale

The RFRI Executive Committee (RFRI Research Director, Rome Foundation Chief Operating Officer, and Rome Foundation President)) coordinate RFRI policy and activities. This document provides a uniform approach to handle proposals and requests from industry and academic entities who wish to engage with the Executive Committee in projects with RFRI. This is a guidance to external parties for initiating and progressing formal engagements with RFRI and for conducting individual, short-term projects that can lead to mutually beneficial and satisfactory long-term collaborations.

Operational Guidelines

External parties submit research proposals or requests for data access or analysis to the RFRI (see attached template). The RFRI Executive Committee reviews such solicitations with applicants to inform prospective processes and investigational objectives. Factors to consider include:

- 1) a general discussion about the benefits of sponsorship regarding participation in collaborative projects and discounts for budgeted costs,
- 2) setting up a contractual agreement about how RFRI and company will work together, including definition and specification of work products and deliverables
- 3) establishing up-front charge for protocol development,
- 4) establishing a consultation arrangement

Project approvals, fee structures, and execution

- 1) The contractual agreement will include base costs for initial protocol development that addresses applicants' research proposals and/or requests for data access or data analyses. Contractual agreements for approved projects will address invoicing and milestone payments for work product deliverables by RFRI.
- 2) Prioritization of project approvals will reflect RFRI interests, capabilities, and abilities to meet applicants' requests, as well as applicants' sponsorship

relationships with RFRI and the Rome Foundation. Costs for approved projects will be differentially discounted based on applicants' sponsorship relationships:

- a. RFRI diamond sponsorship
 - b. RFRI gold sponsorship
 - c. Rome Foundation sponsorship alone
 - d. Non sponsor
- 3) We will develop contractual agreements stating expectations and responsibilities, including establishment of appropriate confidentiality and non-disclosure agreements, before formally beginning the work.

Opportunities For Collaboration

The RFRI owns a continuously expanding set of databases consisting of demographic and questionnaire data and a growing repository of biological samples.

- 1) The RFRI biorepository containing biopsies, stool, urine and blood samples from well characterized patients with DGBI and controls will be available for data access and analysis. We will receive requests from industry and academic partners, as well as for pairing with other research investigations
- 2) The global study database is a major asset for the RFRI. The data and the questionnaires relate to a normative population and a cohort of patients with IBS and other Disorders of Gut Brain Interaction regarding:
 - Prevalence of the disorders and their impact
 - Healthcare practices including diet
 - Co-morbid features including anxiety and depression
 - Living conditions
 - Linguistic and cultural background
 - History of infection
 - Phenotypic features.
- 3) We will be able to offer similar and more expanded data from newly acquired datasets. This would apply to data obtained by the RFRI Investigator Platform currently underway along with datasets collected jointly with industry.

The RFRI Executive committee or members of the Biometry, Clinical or Biobank cores can provide a fixed fee consultation to external parties related to study development,

interpretation of datasets or general aspects of DGBI research. This may be provided as part of or independent of a study contract.

For more specific details or questions please contact Johannah Ruddy M.Ed. at jruddy@theromefoundation.org