ESGE Medtronic Research Award Terms and Conditions

ESGE Medtronic Research application is open to ESGE Individual Members working in a medical institution within the ESGE zone (Central and Western Europe, Mediterranean and North Africa).

ESGE will be responsible for monitoring the progress of the Research Projects and may terminate the support in the event there is no progress or if there is a breach of these terms and conditions.

1. Financial support

To cover the costs incurred by Successful Applicants in performing the Research Project pursuant to this Agreement excluding expenses for French Healthcare Professionals. Each Research Project is entitled to a maximum of 8.000 EUR from this Financial Support to cover direct costs such as ethical committee fees and travel. At the beginning of the research project (after Ethics Committee approval confirmation has been supplied), 50% (€4,000) will be transferred to the Successful Applicant's institution. A further €4,000 will be transferred at the end of the Research Project on receipt of the final report. Funding is transferred solely to Successful Applicants' institutions. It will not be transferred to individuals.

2. Equipment support

The Successful Applicants shall use the Equipment solely for the purpose of the Research Projects. Reverse engineering, decompiling any firmware or software, disassembly, or other similar uses, whether by Successful Applicant or any other person acting under the direction of or with permission from Successful Applicant, are not uses within the scope of the Research Project, except if expressly and in written agreed upon by Medtronic.

Medtronic shall retain all rights of ownership of the Equipment and the Successful Applicant shall acquire no rights of ownership of the Equipment pursuant to this Agreement or otherwise. Successful Applicant shall be responsible and carry all costs in relation to the installation, operation and maintenance, storage and safekeeping of the Equipment in accordance with the documentation supplied with the Equipment.

The Successful Applicant shall be responsible for any necessary notifications regarding the provision and/or use of the Equipment to the applicable authorities and ensure traceability of the Equipment in accordance with applicable laws and regulations.

Upon Medtronic's reasonable request, Successful Applicant shall make available to Medtronic the Equipment for calibration purposes and maintenance validation. Upon ending of this Agreement, Successful Applicant shall immediately return and deliver the Equipment to Medtronic at Medtronic's cost.

3. Equipment delivery

Upon confirmation of ESGE regarding the Successful Applicants and the number of devices which are required for the execution of the Research Projects, Medtronic will deliver Equipment to the Successful Applicants' institution.

Upon confirmation that the Research Project has been terminated, Medtronic will arrange for retrieval of Equipment.

4. Reporting/Access to Research Results

The Successful Applicants are required to provide progress reports of the Research Projects during regular Award Committee meetings. In addition, Successful Applicant shall provide Medtronic a final written report summarizing the results of the research ("Research Reports").

The Successful Applicants will be committed to submitting the report results to the journal *Endoscopy*.

Medtronic may use all the information in the Research Reports for any lawful purpose including, but not limited to, education, research & development or for regulatory submissions.

Medtronic may reach out directly to Successful Applicants to negotiate access to raw study data.

5. Purpose, scope and conduct of the research

The Successful Applicants shall perform the Research Project diligently and to the highest professional standards and in compliance with the defined protocol and all applicable laws and regulations.

Prior to transferring any support for the Research Project, Successful Applicant must:

(i) obtain all necessary governmental notifications, licenses and authorizations, including, if required, authorizations by the medical and/or research institutions whose staff, premises or equipment will be used in performing the Research Project; and

(ii) obtain all other regulatory and/or ethics committee approvals, if required by local law, to proceed with the Research Project ((i) and (ii) hereinafter referred to as the "**Regulatory Approvals**").

In the event that the Research Project involves patients, Successful Applicants:

(i) shall also submit the Protocol, the Patient Informed Consent and all other relevant information and/or documentation to the ethics committee for approval

(ii) shall ensure that the Patient Informed Consent is accurate and satisfies the legal and ethics committee requirements

(iii) obtain the written informed consent of each patient participating in the Research Project

(iv) shall only enrol patients after receipt of all necessary Regulatory and Ethical Committees Approvals

With regard to the devices and/or equipment used for this Research Project, the Successful Applicant:

(i) has legal reporting obligations under the authorized Protocol and under applicable laws and regulations in connection with the use of the medical devices used in the Research Project and shall immediately report any adverse event arising in the course

of the Research Project to the responsible regulatory authorities and/or ethics committees in accordance with applicable reporting requirements having appropriately evaluated this for potential reporting. Successful Applicant similarly acknowledges and accepts that following such reporting it has legal responsibility for taking all necessary remedial steps required of a sponsor in compliance with applicable law and regulations. Successful Applicant shall be solely responsible for taking such steps and for providing to the regulatory authority and/or ethics committee any information and assistance that they may request.

(ii) acknowledges and accepts that - whenever Medtronic devices and/or equipment are used, Medtronic as the legal manufacturer has vigilance reporting requirements and Successful Applicant shall immediately report any adverse event arising in the course of the Research Project to the local Medtronic Regulatory Department or regular contact person, providing all the information and assistance necessary to enable Medtronic to evaluate such adverse event for potential reporting or corrective action.

(iii) ensure that the devices and/or equipment shall be accurately and appropriately labeled.

The Successful Applicant shall ensure the timely registration of the Research Project at a public database such as "www.clinicaltrials.gov" to comply with the Declaration of Helsinki and the requirements from the Committee of Medical Journal Editors, if necessary.

6. Data protection

The Successful Applicant warrants that the Research Reports will not contain any personal data of patients enrolled in the Research Project.

Successful Applicants must comply with all applicable local and European data protection laws, including but not limited to the General Data Protection Regulation (EU) 2016/679.

In the event patients (data subjects) are involved in the Research Project, each Successful Applicant's Institution is acting as data controller in the sense of the EU General Data Protection Regulation (EU) 2016/679 when processing personal data of the patients. Except explicitly stated otherwise (see 4. "Reporting/Access to Research Results") or in the Appendix of the Agreement, Successful Applicant will not share any personal data of patients with Medtronic.

7. Publications

For any publication or presentation of the results of the Research Project or any portion thereof, a manuscript of the paper, abstract or other materials will be provided by Successful Applicant to Medtronic for its review at least thirty (30) days prior to outside submission. Such paper, abstract or other materials shall include a full, clear and prominent statement setting out the source of funding or support for the Research Project. Medtronic shall only have the right:

a) to check the technical accuracy regarding Medtronic products;
b) to check whether Confidential Information has been disclosed,
c) to check that the source of funding or support for the Research Project has been fully and adequately disclosed, and

d) to request reasonable modifications in relation to (a) to (c) of any manuscript or other materials to be published or presented.

8. Warranties

The Successful Applicant warrants:

(i) it has full right and authority to enter into this Agreement under the law of the Home Country, and

(ii) that the Research Project is not proposed nor undertaken with a view to commercial market approval of any product or service in any country.

9. Intellectual Property

Background Intellectual Property means any title and rights in any ideas, inventions (whether patentable or not), improvements, know how, databases, data, information, copyrights and software, which (i) are owned by either party on the Effective Date, or (ii) which have been conceived or reduced to practice prior to the expiry of this Agreement outside of the scope of this Agreement and without reliance on any Confidential Information disclosed by the other party. Any Background Intellectual Property belonging to either party shall remain the property of such party. For purposes of this Agreement, any Background IP of Researcher shall be deemed included in Background IP of Research Center.

Should any of the Research Projects lead to the creation of Intellectual Property within the scope of this Agreement, Medtronic will be able to reach out to the Successful Applicants to negotiate access rights.

Contact
European Society of Gastrointestinal Endoscopy (ESGE)
c/o Hamilton Services, Landwehr Str. 9, 80336 Munich, Germany
Tel: +49-89-9077936-11
Fax: +49-89-9077936-20
secretariat@esge.com