PMI SCIENCE
PHILIP MORRIS INTERNATIONAL

TERMS AND CONDITIONS FOR INVESTIGATOR INITIATED STUDIES

1. PURPOSE & SCOPE

These Terms and Conditions (T&C) set out the principles and requirements that govern Philip Morris Products S.A ("PMPSA") support related to Investigator Initiated Studies (IIS).

These T&C detail how PMPSA will evaluate, approve and follow-up on any request for Support for IIS. Participation of the investigator/sponsor in PMPSA IIS Program is contingent on his/her acceptance of the T&C. By submitting a Concept Proposal Form, the investigator/sponsor confirms that he/she has red, understood and accepted the T&C.

PMPSA maintains this IIS Website for your personal use, education, and communication. While you are free to browse the Website, your access to and use of it is subject to these T&C and all applicable laws. By accessing and browsing the IIS Website, you accept, without limitation or qualification, the T&C.

PMPSA reserves the right to modify, limit or discontinue – in full or in part and without prior notice – this IIS Program at any time, to restrict access to the IIS Program and to deny, without notice and at its sole discretion, any investigator/sponsor 's access to the IIS Program or any part thereof.

2. RESPONSIBILITY

Users of PMPSA IIS Program and Website must comply with all applicable laws and regulations. They must refrain from violating or attempting to violate PMPSA's network security, and, in particular, from uploading or attaching virus-containing or corrupted files or any software or programs that might damage the operation of this Website.

The content of this Website is protected under applicable copyright and trademark laws. All images and text are owned by or licensed to Philip Morris International ("PMI") and, except as provided within these T&C, may not be downloaded, distributed, stored, reused, reposted, modified, or otherwise used without the express written permission of PMI or one of its affiliates. PMI neither warrants nor represents that your use of material displayed on this Website will not infringe rights of third parties.

The investigator/sponsor can print a copy of these T&C for his/her own personal, non-commercial use, provided he/she also retains all copyright and other proprietary notices contained in the materials or as specified on the IIS Website. The further use, re-use, copying, distribution, redistribution, modification, publication, or re-posting of or to any part of this IIS Website (including the text, images, audio, and video) is strictly prohibited and nothing contained on this IIS Website should be construed as granting, by implication, estoppel, or otherwise, any license or right to use any PMI and PMPSA intellectual property right (including, but not limited to any patent, trademark, trade name, copyright or trade secret).

Use of PMPSA IIS Program may require prior registration. Investigator/sponsor provide correct and complete information when registering, and update it, if necessary, without undue delay. They must not misuse any access authorization granted to them (for example by transferring data to unauthorized third parties). PMPSA reserves the right to deny registration to any user.

Registered users are responsible for maintaining the confidentiality of their account and password to prevent unauthorized access to that account. Users must take all necessary steps to keep their password secure and must inform PMPSA immediately if it is being or could be used without authorization. Users must not attempt to establish the personal data of any other user of PMPSA IIS Program. Investigator/sponsor(s) and PMPSA employees ("Associates") participating within the above stated scope are responsible for complying with these T&C. IIS program leader(s) are responsible for providing guidance on the interpretation of these T&C and can be reached via **iis.pmi@pmi.com.**

3. INVESTIGATOR-INITIATED STUDIES

3.1. General Principles

3.1.1. By submitting requests for IIS support, investigator/sponsor(s):

3.1.1.1. Agree with T&C, understand that ownership of the Concept Proposal received remains with the investigator/sponsor(s) and to the extent the Concept Proposal contains material that is owned by a third party, investigator/sponsor(s) warrant that he/she has obtained all necessary licenses and consents required for the use of those materials;

3.1.1.2. Understand that PMPSA will keep Concept Proposal confidential and only make it public if/when accepted;

3.1.1.3. Unless differently stated in these T&C, understand that investigator/sponsor(s) have no right or obligation other than that having (i) his/her Concept Proposal reviewed under these T&C, (ii) his/her personal information handled according to applicable privacy law, and (iii) a response given to him/her about his/her Concept Proposal;

3.1.1.4. Understand that PMPSA reserves the right to refuse reviewing any proposal that do not comply with these T&C, are anonymous, not sufficiently documented, or otherwise appear libelous, incomprehensible or insubstantial.

3.1.2. The sponsor of the study is an independent institution or investigator that requests support from PMPSA. IIS are studies where PMPSA is not the sponsor but only provides financial, material and/or technical support to the study ("Support"). T&C which specifically apply to one type of Support are detailed in the appendices.

3.1.3. IIS proposals should be evaluated by a pre-established and centralized IIS committee to ensure scientific merit, investigator/sponsor's qualifications and expertise and that the proposal meets scientific and validity criteria as set forth below. The IIS committee members should be individuals qualified to make these scientific assessments.

3.1.4. Criteria to be evaluated related to the quality of the proposal include the following: the IIS is for a legitimate research purpose and has the prospect to be published in a peer reviewed journal; the study protocol is valid and scientifically rigorous, and is designed to yield results that advance scientific / medical knowledge or independently verify PMI science; and, the amount of the IIS Support is reasonable and justified (fair market value) in relation to the study protocol requirements.

3.1.5. Associates who engage in the promotion and marketing of PMPSA products shall not be involved in the requests, handling, or provision of IIS applications or help in the preparation, review, or evaluation of IIS applications for IIS Support, or otherwise attempt to influence Support decisions. If a commercial associate (i.e., Marketing & Sales force) receives a request to support a potential IIS, the commercial associate should refer the request to the appropriate scientific contact within PMPSA who can be reached via **iis.pmi@pmi.com.**

3.1.6. While PMPSA may communicate its general areas of scientific interest, individual IIS requests must be unsolicited.

3.1.7. The details of IIS Support must be set out in a written IIS agreement reflecting these T&C.

3.2. IIS Support

3.2.1. IIS recipients shall only be chosen to receive Support from PMPSA based upon their qualifications, expertise to conduct the proposed research and the scientific merit of the proposed study.

3.2.2. IIS Support shall not be offered or provided with the intent to, either directly or indirectly, influence or encourage the recipient to purchase, sell, or recommend PMPSA's products.

3.2.3. IIS Support shall not be used in any way to pay for a recipient's ordinary operating expenses (i.e., expenses of activities that the recipient is already required to perform or customarily performs) or support research that has already occurred.

3.2.4. The study proposal and provision of Support between PMPSA and the institution and/or investigator/sponsor must be appropriately documented to define roles and responsibilities. The agreed Support shall be linked with pre-defined quality milestones and shall only be provided if these milestones are achieved.

3.2.5. PMPSA shall not seek, directly or indirectly, to influence the content or the outcome of the IIS. However, PMPSA may appropriately condition IIS Support on rights to refer to or submit the results of the research in support of regulatory filings for PMPSA products.

3.2.6. If PMPSA considers that Support is not appropriate without significant changes to the IIS protocol, PMPSA reserves the right to decline to Support the IIS.

3.3. Investigator/sponsor

3.3.1. Permitted investigator/sponsors include individual researchers and institutions, organizations or associations that conduct research with a proven track record in the subject matter of the proposal. Any misrepresentation of investigator/sponsors credentials will result in the immediate withdrawal of PMPSA Support.

3.3.2. The investigator/sponsor must agree to the following contractual obligations:

3.3.2.1. Submission to the IIS program leader of periodic progress and safety reports; and

3.3.2.2. At the conclusion of the IIS, a written final study report which summarizes all relevant data will be completed and forwarded to PMPSA. This final study report will be provided to PMPSA for informational purposes only. PMPSA will have no right to amend this final study report.

3.4. Study Execution

3.4.1. PMPSA will not be responsible for the execution of the IIS, including regulatory approvals or requirements. The sponsor accepts and acknowledges that it is solely responsible for the initiation, conduct and management of the IIS and that it does so entirely independently of PMPSA. PMPSA shall not be responsible in any manner whatsoever for the initiation, conduct or management of the study or for any use of the product in the study and sponsor shall not indicate to any third party (including without limitation, any study subject, regulatory authority, or ethics committee), that PMPSA is in any manner responsible for the study.

3.4.2. Sponsor acknowledges that PMPSA shall have no liability (whether by indemnity or otherwise) to the sponsor or any employee or subject or agent of the sponsor in connection with the conduct of the study.

3.4.3. Investigator/sponsor shall provide periodic progress updates and safety reports to ensure that study objectives and the agreed milestones are being met.

3.4.4. PMPSA reserves the right to reconsider its support if the research described in final study plan/protocol is materially different from what is in the approved proposal.

3.4.5. PMPSA reserves the right to contract a third party to verify the scientific quality of execution.

3.4.6. PMPSA reserves the right to withhold Support for an IIS where in PMPSA's judgment the applicant for Support has or may be perceived to have a conflict of interest in respect of PMPSA, its affiliates or products, or the outcome of the research. Examples of such circumstances might include, without limitation, pre-existing or past consultancy or investigator relationships with PMPSA; significant share holdings in PMPSA; or other commercial interests in PMPSA, its products or research efforts.

3.5. Publication and Study Data

3.5.1. All study data and information belong exclusively to the investigator/sponsor. Data should be made openly accessible and shared through recognized data repositories while safeguarding the privacy of study participants.

3.5.2. All study data and information should be shared in order to enable a third party to repeat the study and should be made available together with any publication(s) and/or presentation materials arising from or relating to this IIS.

3.5.3. Publications are under the sole responsibility of the investigator/sponsor, they do not belong to PMPSA, and must be published under Open Access and identifiable as such.

3.5.4. PMPSA's Support must be appropriately disclosed with the corresponding IIS identification number in the relevant section(s) of any publication(s) and/or presentation materials arising from or relating to this IIS. PMPSA will disclose on its website the support and funding provided.

3.5.5. Investigator/sponsor should inform PMPSA within five (5) days following acceptance of publication by a journal and provide PMPSA with the appropriate publication details (name of the publication, date etc.) as well as a copy of the accepted publication for informational purposes only.

3.5.6. PMPSA may financially support the investigator/sponsor to make study data, information and publications openly accessible and shared.

4. EVALUATION AND APPROVAL

4.1. Requests

4.1.1. PMPSA represents that it will establish and document a process for the submission of requests for IIS. At a minimum, the process will require that requests must be:

4.1.1.1. unsolicited; and

4.1.1.2. in writing and provide a detailed description of the activities requiring support, including timing and budget, and any other appropriate information necessary to meet relevant accounting and records requirements.

4.2. Evaluation and Approval

4.2.1. PMPSA represents it will establish and document a process for the evaluation and approval of IIS requests. The process will:

4.2.1.1. evaluate IIS requests according to criteria outlined in section 3.1.4.;

4.2.1.2. assess the ability of the investigator/sponsor and/or institution, organization or association to conduct research in the subject matter of the proposal;

4.2.1.3. ensure that all requests are evaluated and administered by appropriate PMI Technical Associates with the appropriate expertise; are reviewed by Legal for compliance with local regulations; and that Sales and Marketing Associates do not participate in the evaluation or decision process with respect to specific requests; and

4.2.1.4. ensure that the requestor of the IIS Support is notified in writing whether their request is approved or denied.

4.3. Accounting and Records

4.3.1. PMPSA represents that all IIS Support is adequately documented and recorded and that it maintains documentation that at a minimum identifies:

4.3.1.1. requests for IIS Support, including any project descriptions, budgets, and similar materials;

4.3.1.2. the dates of internal evaluation of requests;

4.3.1.3. the disposition of requests (approved or denied);

4.3.1.4. the names of approvers;

4.3.1.5. copies of documentation notifying the requestors of the status of their requests; and

4.3.1.6. copies of proof of electronic transfer of funds or disbursed check and other related materials.

5. TRANSPARENCY AND PUBLIC DISCLOSURES

5.1.1. Sponsor agrees that PMPSA may, without prior consent, publicly disclose information about sponsor as required by applicable laws, including, but not limited to identifying sponsor as conducting the IIS, and the amount of funding provided and expenses covered by PMPSA. Sponsor further agrees to provide, at PMPSA's reasonable request, any information necessary for PMPSA to make such disclosure.

5.1.2. Sponsor shall comply with any requirements under applicable laws or institutional policies to obtain approval from any regulatory authorities or professional associations and any other employers or institutions prior to performing the IIS, and will do so on a timely basis. Evidence of such notifications and/or approvals shall be provided to PMPSA upon request.

6. RECORD RETENTION, DISCLOSURE AND TRACKING

All documentation required by these T&C must be maintained in accordance with applicable records retention policies.

SCHEDULE 1: Specific T&C for Financial Support

1) PMPSA may decide to provide Financial Support to an IIS. Financial Support will be paid as research procedures are completed, either by reimbursing for specific procedures and/or materials, or by dividing the grant into milestone payments.

2) Requested funding must be consistent with the fair market valuation for the research procedures contemplated and detailed in the study protocol. The sponsor should provide PMPSA with a detailed description of the activities requiring support, including timing and budget, and any other appropriate information required for relevant accounting and records requirements.

3) The provision of Financial Support by PMPSA to the institution and/or the investigator/sponsor must be appropriately documented to define roles and responsibilities. The agreed Financial Support shall be linked with pre-defined milestones and shall only be provided if these milestones are adequately achieved.

4) IIS Financial Support is provided to test and further the scientific research and knowledge of reduced risk products. IIS Financial Support must only be provided to help cover the reasonable and justified costs of specified and documented research that will be conducted. Any payments shall be made at fair market value. PMPSA shall not seek, directly or indirectly, to influence the content or the outcome of the IIS. Thus, payments must not be conditioned on the recipient achieving specific results.

5) PMPSA's Financial Support to IIS must not be excessive, so as to jeopardize the independence of the investigator/sponsor.

6) Payments must be directed by wire transfer or check to the account of an institution, organization or association and not by cash or cash equivalent. IIS Financial Support should not be paid directly to individuals. Even when IIS Financial Support is awarded to an individual, the payment should be made to an account administered by the individual's institution, organization or association, not to the individual's personal bank account. PMPSA should keep copies of proof of electronic transfer of funds or disbursed check and other related materials.

7) PMPSA must comply with any local legal and business restrictions related to the provision of Financial Support to IIS (for example, funding caps, contributions declarations, anti-bribery rules etc.). PMPSA must establish a process to meet any local legal requirement for disclosure of payments to investigator/sponsors, institutions, organizations or associations that conduct research or perform services related to the study.

SCHEDULE 2: Specific T&C for Material Support

1. PMPSA may decide to provide Material Support to IIS which includes the provision of product(s) and/or equipment(s) necessary to conduct the study. Such product(s) and/or equipment(s) will be (a) provided only for the length of the study and arrangements shall be made at the conclusion of the study to pick up the equipment(s); (b) equipment(s) will be conveyed or sold to the study site at fair market value as evaluated by PMPSA at the end of the study; or (c) product(s) and/or equipment(s) will be destroyed on site and documented accordingly. The terms of any such conveyance must be explicitly included in the IIS agreement concluded between PMPSA and the sponsor.

2. Material Support may be provided at the initiation of the study and/or at different stages of the research procedures as defined in the IIS agreement.

3. Requested Material Support must be consistent with the research procedures contemplated and detailed in the study protocol. The sponsor should provide PMPSA with a detailed description of the activities requiring support, including timing and budget, and any other appropriate information required for relevant accounting and records requirements.

4. The provision of Material Support by PMPSA to the institution and/or investigator/sponsor must be appropriately documented to define roles and responsibilities in particular regarding damages caused by or to product(s) and equipment(s).

5. IIS Material Support is provided to test and further the scientific research and knowledge of reduced risk products. IIS Material Support must only be provided to help cover the reasonable and justified needs of specified and documented study that will be conducted. PMPSA shall not seek, directly or indirectly, to influence the content or the outcome of the IIS. Thus, Material Support must not be conditioned on the recipient achieving specific results relating to the use of these product(s) and/or equipment(s).

6. PMPSA's Material Support to IIS must not be excessive, so as to jeopardize the independence of the investigator/sponsor. Material Support should therefore be compliant with applicable industry standards.

7. IIS Material Support should not be provided directly to individuals. Even when IIS Material Support is awarded to an individual, product(s) and/or equipment(s) should be provided to the individual's institution, organization or association, not to the individual. PMPSA should keep proper record of product(s) and/or equipment(s) provided to the sponsor.

8. PMPSA must comply with any local legal and business restrictions related to the provision of Material Support to IIS (for example, insurance requirements, contributions declarations etc.).

SCHEDULE 3: Specific T&C for Technical Support

1. PMPSA may decide to provide Technical Support to IIS which includes technical know-how with regards to PMI-specific equipment and/or methodologies, necessary to conduct the study according to the pre-defined milestones and timelines.

2. Technical Support may be provided at the initiation of the study and at different stages of the research procedures as defined in the IIS agreement.

3. Requested Technical Support must be consistent with the research procedures contemplated and detailed in the study protocol. The sponsor should provide PMPSA with a detailed description of the activities requiring support, including timing and venue.

4. The provision of Technical Support by PMPSA to the institution and/or investigator/sponsor must be appropriately documented to define roles and responsibilities.

5. IIS Technical Support is provided to further the scientific research and knowledge of reduced risk products. IIS Technical Support must only be provided to help cover the reasonable and justified needs of specified and documented research conducted pursuant to the study proposal. PMPSA shall not seek, directly or indirectly, to influence the content or the outcome of the IIS. Thus, Technical Support must not have any impact on the conduct and/or the outcome of the IIS.

6. PMPSA's Technical Support to IIS must not be excessive or invasive, so as to jeopardize the independence of the investigator/sponsor. Technical Support should therefore be compliant with applicable industry standards.

7. PMPSA should keep proper record of Technical Support provided to the sponsor.

8. PMPSA must comply with any local legal and business restrictions related to the provision of Technical Support to IIS (for example, insurance requirements, contributions declarations etc.).