Memorial Sloan Kettering Cancer Center

CONFIDENTIAL

August 31, 2020

TO: [redacted]

FROM: [redacted]

RE: **ICOI Management Plan –** [redacted]

MSK's *Policy on Institutional Conflicts of Interest* ("ICOI Policy") recognizes that MSK, as an institution, has financial relationships and interests that could create institutional conflicts of interest ("ICOI"). Such potential conflicts may compromise – or appear to compromise – the integrity and objectivity of research or business decisions at or under the auspices of MSK, as well as the oversight and administration of research design, conduct, and reporting.

An ICOI exists if the MSK reasonably determines that the financial interests of MSK, or of an Institutional Official[1] acting within his or her authority on behalf of MSK, could, or could reasonably be perceived to, directly and significantly affect the design, conduct, reporting, review, or oversight of MSK research or the outcome of MSK business decisions. When an ICOI relates to interventional human subjects research ("HSR"), MSK must also assess whether compelling circumstances exist that would justify such research being conducted at MSK despite the ICOI. If such circumstances exist, MSK must implement a management plan that safeguards the rights and welfare of research subjects, the integrity of research design, conduct, and reporting, and the objectivity of decision-making at or under the auspices of MSK.

MSK has reviewed the relationship between MSK and [redacted] ("[redacted]" or "the Company") and determined that MSK (1): has licensed intellectual property to [redacted] that is or is contemplated to be the subject of research (including human subjects research) at MSK; (2) has financial interests in [redacted]; and (3) these financial interests constitute, or create the appearance of, an ICOI. However, MSK has also determined that notwithstanding such ICOI, in certain cases compelling circumstances exist for MSK to conduct research, including interventional human subjects research, involving or evaluating products or technologies developed by MSK and that may ultimately be commercialized by [redacted]. Each contemplated [redacted] research project involving interventional human subjects research will be assessed by MSK to determine whether or not compelling circumstances are present that warrant the research being conducted at MSK. Any such research that is approved must be conducted in accordance with the terms of this ICOI management plan (the "Plan").

This Plan outlines responsibilities on the part of MSK and establishes parameters around any research, clinical trial, compassionate use, or use of MSK resources that arises from the relationship between MSK and [redacted], including but not limited to, the research, license, and other agreements described below.

FINANCIAL INTERESTS

MSK has financial interests in [redacted] in the form of a right to milestone payments in connection with the actual or potential sale of intellectual property or products developed, researched and tested by MSK and licensed

[1] "Institutional Official" includes Senior Executive Officers as defined in MSK's Institutional Conflicts of Interest Policy and means the President, Physician-In-Chief, Director of Sloan Kettering Institute, Chief Operating Officer and Chief Financial Officer.

to and commercialized by [redacted]. Taken together, the nature of these interests with [redacted] and the connection between the company and MSK creates an ICOI when MSK engages in research related to or involving [redacted] and/or intellectual property owned by, licensed to, or intended to be commercialized by [redacted] ("[redacted]").

Specifically, MSK has a right to receive income through the approval and future sales of [redacted] developed from MSK IP and technology and commercialized by [redacted]. This financial interest could be impacted by the outcome of any study involving the technology licensed to [redacted] and other studies conducted in collaboration with [redacted].

NATURE OF RELATIONSHIP

[redacted] is a [redacted] company focused on [redacted] The company's [redacted] MSK entered into an exclusive license agreement with K [redacted] for MSK's IP related to [redacted]

The research projects listed in Appendix A are the research projects deemed [redacted] Research and relative to which the terms of this Plan apply. Should new HSR involving [redacted] or the MSK IP licensed to [redacted] be contemplated, compelling circumstances would have to be demonstrated for the research to be approved. If MSK's involvement in such research is approved, management strategies will be implemented, including, but not limited to, review of study data by an independent oversight committee and appropriate disclosures to study participants, as described below. Appendix A will be updated as necessary to reflect all research covered under this Plan.

INSTITUTIONAL MANAGEMENT PLAN REQUIREMENTS

The components included in this Plan are intended to safeguard the rights and welfare of research subjects and the objectivity of MSK's research and business activities; ensure transparency with respect to MSK's institutional financial interests; and maintain appropriate allocation of MSK resources.

I. DISCLOSURE OF THE INSTITUTIONAL FINANCIAL INTEREST

1. Disclosure of MSK's ICOI to human research subjects.

   a) MSK's institutional financial interests related to [redacted] must be disclosed to each human research subject involved in any HSR study that is [redacted] Research in the study's informed consent document(s), where applicable. This disclosure shall include information about the ICOI and provide contact information for additional questions. An example of what this disclosure must encompass is included as Appendix B.

   b) This Plan, including its description of the nature of the ICOI with [redacted], will be provided to MSK's IRB. Nothing in this Plan shall restrict the IRB's authority to require additional steps and management strategies to ensure the protection of the rights and welfare of human subjects participating in [redacted] Research that is HSR.

2. Disclosure of MSK's institutional financial interests in [redacted] must be included in all publications and presentations by MSK researchers, as well as in any press releases, arising from [redacted] Research.

3. Each research project team member[2] involved in [redacted] Research shall be provided with a notification from either the primary investigator on the study or the Compliance Department ("Compliance") that discloses MSK's institutional financial interest in [redacted]. This notification shall include information about the ICOI and provide contact information for additional questions. An example of what this notification must encompass is included as Appendix C.

II. OVERSIGHT

1. MSK shall make efforts to ensure that the integrity of [redacted] Research performed at MSK, including but not limited to interventional HSR, is not influenced by MSK's institutional financial interests. To this end, [redacted] Research may be subject to independent review and monitoring.
2. MSK's Conflict of Interest Committee ("COIC") has established standing subcommittees to perform oversight monitoring of research studies for which ICOIs have been identified and for which the COIC determines that such oversight and monitoring are required. These subcommittees include a subset of COIC members and one or more representatives outside of the COIC and may include additional representatives inside or outside of MSK, the necessity of which will be determined by the COIC Chair with input from Compliance.
3. The COIC has determined that [redacted] Research involving interventional human subjects research ("[redacted] HSR") will require the oversight of the Clinical Research Oversight Committee ("C-ROC").[3]
4. Oversight of [redacted] HSR. For any [redacted] HSR, the C-ROC shall review the study and results of the research for evidence of bias[4] in the design, conduct, or reporting of the study. Specifically, such review may include some or all of the following:
   a) On at least an annual basis, the C-ROC shall:
      1) Review the study protocol, protocol status summary, continuing renewal applications, available data safety monitoring reports, and/or other documents, where applicable, for adherence to protocol(s), study procedures and standard scientific practices in the relevant discipline.
      2) Review available results of the research and/or experiments for evidence of bias.
   b) The C-ROC may request, as needed, a review of enrollment practices for adherence to eligibility criteria and any evidence of bias.
   c) The C-ROC shall timely report any concerns with [redacted] HSR to the COIC and the IRB, as applicable.
   d) On at least an annual basis, the C-ROC will convene to generally review this Plan and the C-ROC's related responsibilities thereunder for possible modification. In conducting this review, the C-ROC will evaluate: (1) the nature of the ICOI with [redacted]; (2) the nature of the research conducted under all [redacted] HSR and how the ICOI with [redacted] could impact the research or bias of the research; (3) the nature and level of involvement of MSK in the [redacted] HSR to date; and (4) safeguards in place that minimize risk of bias.

[2] For purposes of disclosure of an ICOI, research project team members will include named MSK key personnel as well as personnel named on a study's IRB face sheet.

[3] MSK requires that all interventional human subjects research is subject to review by a data monitoring safety board or data safety monitoring committee ("DMSB" or "DSMC"). The Oversight Committee outlined in this Plan is not a replacement for any existing data and safety monitoring oversight, such as a data monitoring committee imposed by a Sponsor or by MSK.

[4] Bias is defined as a systematic distortion, prejudice or deviation from generally accepted scientific practice or standards, whether in results or inferences.

5. Oversight of Other [redacted] Research. For any [redacted] Research that is not interventional human subjects research, the COIC will institute independent review and monitoring of the research by the Laboratory Research Oversight Committee ("L-ROC") on a case by case basis, as needed.

6. Compliance and the COIC will monitor compliance with the terms and conditions of this Plan.

III. PROPOSED NEW RESEARCH

1. Before any new [redacted] Research is undertaken at MSK, whether it be basic science, pre-clinical, or HSR, the research must be reviewed and approved by the COIC.

2. Before any [redacted] Research involving [redacted] HSR is undertaken at MSK, the contemplated research will be reviewed by the COIC to specifically determine whether compelling circumstances (as defined in the ICOI Policy) exist for an exception to the general principle that MSK is prohibited from conducting interventional human subjects research that evaluates products or technologies invented at MSK and in which MSK has an institutional financial interest.

3. If it is determined by the COIC that [redacted] Research may be conducted at MSK, the new [redacted] Research will be added to Appendix A of this plan and will be subject to the requirements of this plan and any modifications thereof.

IV. COMPLIANCE WITH MSK POLICIES

1. MSK resources, including but not limited to space, personnel, time, equipment, information, and data, must be used consistent with MSK policies and any applicable agreements between MSK and [redacted].

2. Consistent with MSK policies, and to reduce the risk of an appearance of institutional endorsement, no MSK employee may publicly promote, market or endorse any product or therapy that [redacted] currently provides or may provide in the future.

3. Nothing in this Plan shall be interpreted as limiting or modifying any other MSK policy or procedure designed to reduce or eliminate conflicts of interest in MSK decisions.

Acknowledged on behalf of
Memorial Sloan Kettering Cancer Center

_____ _____
[redacted] Date

Cc: [redacted]

Appendix A – Summary of MSK [redacted] Research

This section summarizes current [redacted] Research (as of the date of this plan) subject to the terms of the plan described above. Should new [redacted] Research as described in this plan be contemplated, the COIC will review and determine whether the new research can be covered under this plan, or whether amendments to this plan must be made to appropriately manage the new aspects of the conflict.

[redacted] RESEARCH PROJECTS

PI name	Project Title/Description	IRB No.	Dept.	Sponsor
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Appendix B – Example of Notification/Disclosure Language for Prospective Research Subjects

You have been asked to participate in a research study that will include [Technology/Drug under Study]. [Technology/Drug under Study] involves [technology/products] owned by Memorial Sloan Kettering Cancer Center (MSK or "the Institution") and that was invented by MSK scientists. MSK licensed the inventions being used in this study to [redacted]. ("[redacted]"), an outside company. As a result of this relationship and arrangement, MSK has financial interests in [redacted] and may benefit financially from the results of this research study. This is what is known as an "institutional conflict of interest."

MSK is committed to protecting the rights and welfare of those who participate in MSK research and the integrity of our research activities. As part of this commitment, MSK fully discloses the existence of its institutional conflicts of interest to research participants.

If you are interested in details about the steps MSK has taken to protect your best interests on this study, please contact the MSK Patient Representative Department at [redacted].

Appendix C – Example of Notification/Disclosure Language

EXAMPLE TEMPLATE LANGUAGE

[Your Letterhead]
CONFIDENTIAL

FROM: [Your Name]

TO: All Personnel Involved in [redacted] Research

DATE:

This notification is to inform you that MSK has institutional financial interests with the company [redacted], which are relevant to research in which you are engaged *(this means you are named as an investigator on a research study sponsored by or related to* [redacted]*)*. MSK has a right to receive income related to [redacted] developed by MSK and intended to be commercialized by [redacted]. This financial interest could be impacted by the outcome of the research in which you are engaged, and other studies conducted in collaboration with [redacted]. This notice is informational only.

This relationship and related research is covered under an institutional conflict of interest management plan (ICOI Plan) overseen by MSK's Compliance Department and MSK's Conflict of Interest Committee (COIC). This ICOI Plan includes a number of restrictions and requirements intended to safeguard research subject welfare and research objectivity and promote transparency relative to the relationship. Individuals who have personal financial conflicts of interests related to [redacted] are subject to separate management plans also overseen by the Compliance Department and COIC.

Federal law allows and promotes the transfer of ideas from the nonprofit to the for-profit sector; researchers and research institutions invent diagnostics, treatments, therapies, and products, and have intellectual property rights to these inventions. Conflicts of interest are inherent in the transfer of intellectual property from MSK to the for-profit sector that is required for further development. MSK must balance promoting innovation with ensuring the integrity of its clinical care, research, and education missions. MSK's mission and obligations to its patients, research participants, staff members, students, trainees, and larger community are the primary driver for institutional decisions. This principle applies to MSK as an institution and to each member of the MSK staff. When addressing conflicts of interest in research, protecting the rights and welfare of those who participate in our research and the integrity of our research activities is paramount.

If you feel at any time that your MSK activities are compromised by this relationship, or you have concerns related to the objectivity of MSK research as a result of this conflict of interest, you may contact COIC Chair Dr. [redacted] ([redacted]) and/or the Compliance Department ([redacted]), and/or the Office of the Ombudsperson ([redacted]).
Thank you,

[Your Signature]
Cc: [redacted]