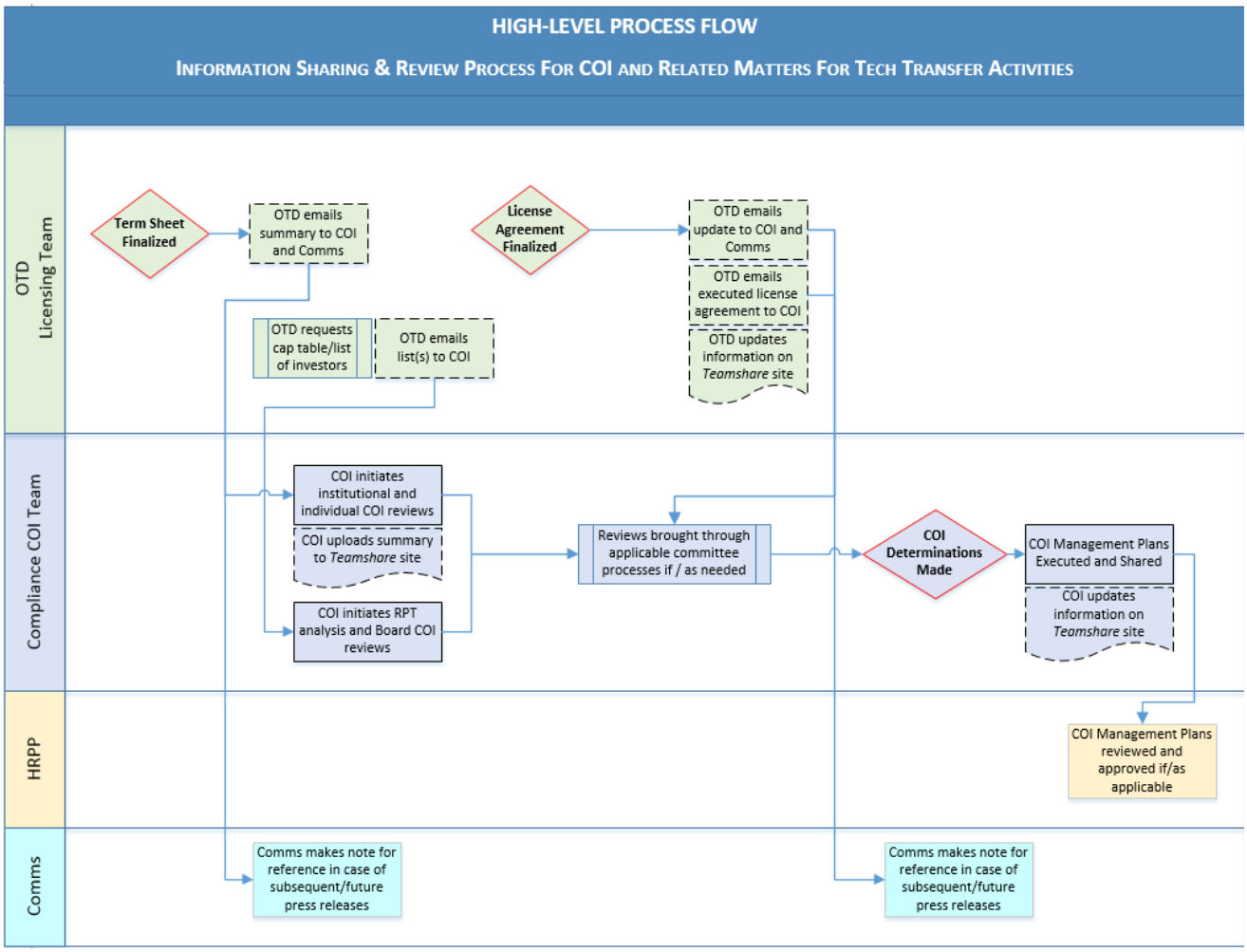
INFORMATION SHARING & REVIEW PROCESS FOR COI AND RELATED MATTERS FOR LICENSE ARRANGEMENTS

I. Purpose

This standard operating procedure (SOP) outlines the multi-functional processes, touch-points, and sharing of information among several MSK stakeholder groups, specifically relative to the intersection of technology transfer activities and conflict of interest (COI). The key objective of this SOP is to facilitate consistent and organized information sharing around license activities and associated COI, research, IRB, and communication activities.

Notably, the *New and Enhanced COI Principles*, approved by the Board in April 2019, call for MSK to establish a mechanism for the review of licensing agreements prior to execution by personnel external to OTD to ensure business terms are appropriate and in MSK's best interests.

II. High-Level Illustration of Key Process Touchpoints



III. Process Details

A. New License Arrangements
B. Institutional COI Management Plans
C. Updates to RTM *Teamshare* site
D. Ongoing Information Sharing relative to Existing License Arrangements

A. New License Arrangements.

1. OTD will provide to Compliance, via email ([redacted][1]), notification of a potential license arrangement, including amendments to existing licenses, at the time a term sheet is finalized in order for Compliance to perform additional diligence. The notification email will include: (1) high-level summary of the technology, (2) basic terms of the agreement, (3) names of MSK inventors, and (4) estimated timing for finalization of the license agreement.
    a. OTD will specify in this communication whether or not the agreement involves:
        i. Exclusive license of MSK clinical data, images, patient samples or other "institutional works" (i.e. creations made by or paid for by MSK or one of its Departments, the creation is not covered by patents and individual intellectual contributions (consistent with the definition of "inventor" in MSK's Intellectual Property Policy) cannot be identified; and made in the regular course of business by MSK employees performing their assigned job duties); **or**
        ii. Non-exclusive licenses to a set of >[1000] MSK records, images or samples, for which the commercial end-product includes either (i) the very same raw or re-packaged MSK data, images, and samples; or (ii) algorithms based on those MSK data, images or samples.
2. OTD will request a contemporaneous cap table or list of investors for the potential licensee and send to Compliance, via email ([redacted][2]), for review to confirm if a related party holds equity in that company. OTD will also notify Compliance if they become aware in the course of their standard due diligence process that an MSK Director/Officer has a board and/or management role with the potential licensee.[3]
3. Compliance will complete their review expeditiously and notify OTD whether there are any potential conflict issues that may require additional information or review by the Tech Transfer Committee and the Joint Conflict of Interest Committee prior to entering the licensing arrangement.
4. Compliance will perform individual and institutional COI reviews, facilitating engagement of appropriate committees if/as needed. If COI determinations are made that requirement management plans, Compliance will draft and issue such management plans and share with the HRPP and OTD where applicable.
5. Upon finalization of license, OTD will provide to Compliance, via email ([redacted][4]), a copy of the executed license agreement.

[1] COI coordinator will forward to applicable COI staff and save in internal records
[2] COI coordinator will forward to applicable COI staff and save in internal records
[3] As a reminder, under MSK's Board COI Policy, MSK directors may not invest in or serve as a board member or an executive officer of an MSK spin-off, with narrow exceptions. "MSK spin-offs" include any entity that is (1) funded by MSK and/or (2) driven largely by IP licensed from MSK.
[4] COI coordinator will forward to applicable COI staff and save in internal records

B. Institutional COI (ICOI) Management Plans.

1. Specific to this SOP, an ICOI exists when a license agreement is executed in exchange for which MSK receives certain financial interests or rights to such interests (including equity, royalties, or milestones), and there is current or planned research at MSK further developing or evaluating the IP.
2. Compliance will bring the matter to the Conflict of Interest Committee (COIC) or COIC designee for review and disposition. If the research study involves interventional human subjects research (HSR), then the existence of compelling circumstances to conduct that research at MSK despite the ICOI must be demonstrated. Pre-clinical research does not require compelling circumstances, just review and approval.
3. If the research is approved, an ICOI management plan will be issued by Compliance, and signed by [redacted] on behalf of MSK. The plan will outline responsibilities on the part of MSK and establish parameters around any research, clinical trial, compassionate use, or use of MSK resources that arises from the relationship between MSK and the licensee. Plans will also reflect oversight delegation to the Clinical Research Oversight Committee (C-ROC) or Laboratory Research Oversight Committee (L-ROC), where applicable.
4. Research projects covered by an ICOI plan are listed in Appendix A of the plan. Appendices are updated as new projects arise and go through the review and approval process. ICOI plans, including updated appendices, are reviewed by [redacted] on annual basis.
5. Compliance uploads executed ICOI plans to the "Institutional COI Management Plan" folder on the *TeamShare* site. Notification of the ICOI is sent to every research project team member named on a project covered under the plan, and copies of the plan are sent to all project PIs and co-PIs.

C. Responsibility for Updates to RTM *TeamShare* Site. Stakeholders will be responsible for maintaining and updating the columns and tabs of the COI Monthly Report, and folders available on *TeamShare* as follows:

Stakeholder	COI Monthly Report/*TeamShare* Responsibilities
OTD	• New license arrangements (including options) will be added to the COI Monthly Report, in red, prior to finalization. • The following columns will be maintained in the COI Monthly Report by OTD: (1) Licensing Manager; (2) MSK Spinoff (yes/no); (3) Year Obtained; (4) Technology; (5) Inventors; (6) Expectation of Pre-Clinical Research Funding (yes/no); (7) Expectation of Clinical Research Funding (yes/no); and (8) Institutional Interest. • Updates to status of existing/potential licenses will be incorporated, in red, as applicable.
Compliance	• The "Active Pre-Clinical Research" and "Active Clinical Research" columns of the COI Monthly Report will be updated to reflect the most current information available based on thorough transactional reviews. • Entities associated with ICOIs which are expected to be reviewed by an external IRB should be flagged by PAC team for early COI review. These entities will be added to the COI Monthly Report 'COI Check Needed at Pac Sub' tab. • COI Management Plans: ○ Institutional COIs: Updates will be made to the COI Monthly Report to reflect existing institutional COI Management Plans and copies of executed ICOIC Management Plans will be added to "Institutional COI Management Plans" *TeamShare* folder. ○ Individual COIs: The existence of individual COI management plans will be noted in an excel spreadsheet report available in "Individual COI Management Plan Report" *TeamShare* folder. Individual COI Management plans are not available here, but the report includes material information for each plan.
HRPP	• Reviewing HSR information in monthly report for completeness/accuracy. • Raising questions or concerns regarding license agreements in the context of HSR. • Note that entities on the "Check at PAC" tab of the monthly RTM report are those that require COIC review and approval prior to research prior to ceding IRB review to an external IRB (entities under ICOI management and relative to which research must be reviewed and approved by COIC as being ok to conduct at MSK despite the ICOI, and which are specifically planned for external IRB review). • Referring to Individual COI Tracker for as key resource for inventory of current individual COI management plans.

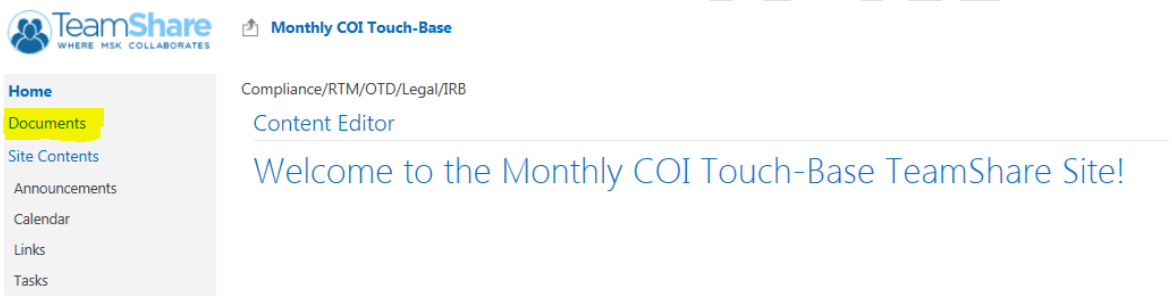
D. Ongoing Information Sharing relative to Existing License Arrangements.

1. OTD will notify Senior Director [redacted] via email ([redacted]), if they become aware in the course of their routine license management process that an MSK Director/Officer has a financial interest in or board/management role with an existing licensee.

2. OTD will provide most recent copies of cap tables upon request from Compliance in context of related party transaction or other COI reviews.

IV. Key Resources & Contacts

- **Link to *TeamShare* site**



- **TeamShare Folders within "Documents" section of site**

a. Company and License Agreement Summaries – Copies of license agreement summaries sent to Compliance (via email) by OTD. *Maintained by Compliance.*

b. Institutional COI Management Plans – Copies of executed institutional COI management plans. *Maintained by Compliance.*

c. Individual COI Management Plan Report – Excel spreadsheet containing material details of all existing individual COI management plans. *Maintained by Compliance.*

d. Licensing Activity Reports – Current and archived versions of COI Monthly Report tracking spreadsheet of current license (and option) arrangements. *Maintained by all stakeholders.*

- **Key MSK Policies:**
  - Conflict of Interest and Commitment Policy
  - Institutional Conflict of Interest Policy
  - Boards of Managers Conflict of Interest Policy
  - Policy on Intellectual Property

- **Key Contacts List**
  - **Compliance**
    - Main email – [redacted] (only COI team has access)
    - Overall – [redacted]
    - Clinical Research/C-ROC – [redacted]
    - Pre-Clinical Research/L-ROC – [redacted]
    - Related Party Inquiries/ICOI – [redacted]
  - **OTD**
    - Overall – [redacted]
    - Clinical research agreements – [redacted]
    - Licensing Managers
      - [redacted] – portfolio focuses on device licenses
      - [redacted] – portfolio focuses data and digital IP licenses
      - *Other licensing managers' portfolios assigned by inventor/entity*
    - Pre-clinical basic science research agreements – [redacted] (*OTD confirming participation*)
  - **HRPP**
    - IRB – [redacted]
    - PAC – [redacted]
  - **OGC**
    - [redacted]
  - **Communications**
    - [redacted]
    - Main Email [redacted]