1. Purpose

Organizational and/or individual Significant Interests (SI) may present real or perceived risks to research integrity and to the welfare and rights of human research participants. Therefore, Significant Interests are subject to disclosure and review and appropriate management by Aurora’s Research Conflict of Interest Committee (RCOIC) if deemed to create a Conflict of Interest.

2. Scope

Principal Investigators, Investigators/Key Personnel, IRB Members, Consultants to the IRB, RSPP Staff, and Aurora Leadership are subject to Aurora System Policies 269 “Conflicts Of Interest In Research – Individual” and 270 “Conflicts Of Interest In Research – Institutional” and this SOP. These policies apply both to studies overseen by the Aurora IRB and those ceded to external IRBs.

3. Definitions

See section 3 of System Policies 269 and 270.

4. Policy Statements

4.1. Institutional Conflicts of Interest Disclosure Process

   a) See section 5.1 of Aurora System Policy 270.

   b) Review and management of SI is noted within section 5.2 of Policy 270.

4.2. Individual Conflicts of Interest Disclosure Process

   a) See section 5.2 of Aurora System Policy 269.

5. Procedures

5.1. Compliance with System Policy 269, section 5.2

   a) Ensuring Required Disclosures are Completed by Investigators/Key Personnel for new research submissions

      i. RSPP staff will verify completion of annual disclosures for all Investigators/Key Personnel named on each new study IRB application by reviewing completion status in the electronic disclosure software system (COI Smart). All Investigators/Key Personnel must complete their annual interest disclosure prior to RSPP acceptance of the submission application for review.

      ii. As part of the IRB application process for each new study, Principal

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Investigators will be asked to verify completeness of their annual disclosure and to indicate whether they believe any disclosed interest is related to the proposed research.

iii. RSPP will remind all Investigators/Key Personnel of their obligations to: 1) notify the IRB of SIs they believe are related to a project on which they are named; and 2) update their disclosure within 30 days of discovery or acquisition of a new Significant Interest (SI). This notification may be done via email, the bi-monthly RSPP newsletter or other written methods of communication.

b) Noncompliance of Research Personnel Who Do Not Complete the Annual Significant Interest Disclosure

i. Key Research Personnel

1. One working day after the Compliance due date for completion of the research SI disclosure has passed, the RSPP Office will create a list of noncompliant research key personnel using COI Smart. A status check will be made using ProIRB to ascertain whether the noncompliant individual is participating on an open research study.

2. If the individual is a key research personnel on a currently open research study, within 1-2 working days of the due date, he/she will be sent an email from the RSPP Office notifying him/her of the noncompliance with Aurora System policy 269 and RSPP SOP 104. In this email, the noncompliant individual will also be informed that five working days from the date of the email he/she will be removed from all open research studies on which he/she participates if the SI disclosure is not received within 5 working days.

3. If the SI disclosure is not received five working days from the date of the notification email, the RSPP Office will generate a modification removing the noncompliant individual from all open research studies on which he/she participates. The modification form will be attached to an email sent to the study PI(s), study contact person(s), and the ARI Manager (if applicable) that oversees the research study. The PI signature on this modification will be waived by the RSPP Office.

4. The email will inform the study PI that it will be his/her responsibility to ensure that the duties of the removed individual are overseen by others on the study team or by the addition of a new person to the study team. Should the PI wish to add the noncompliant individual back
onto the research study, he/she can only do so after the annual SI disclosure has been completed.

ii. Principal Investigator (PI)

1. Should the noncompliant individual be the PI of a research study, a process similar to that noted in 5.1.2.1 will be undertaken. The difference will be that the ARI Manager (if applicable) that oversees the research study will be instructed that he/she has 5 working days to 1) close the affected research study, if appropriate; 2) find a replacement PI; or 3) convince the current study PI to complete his/her annual SI disclosure.

2. If the SI disclosure is not received after 5 working days have passed, the noncompliant PI will be removed from the study via modification generated by the Aurora RSPP. If no replacement PI has been found, and the study remains open, the IRB Chair and/or Institutional Official will suspend the research study per RSPP SOP 407. Consideration will be given to protection measures for currently enrolled subjects. The study suspension will be reported externally per the procedures outlined in RSPP SOP 408.

c) Ensuring Required Disclosures are Completed by IRB Members, and that Members do not Participate in Review when Conflicted

i. Upon appointment to the IRB, the RSPP Office will require the new IRB Member to complete the IRB Conflict of Interest Agreement (Form 104-A) that serves to notify members of their obligation to recuse in the review, discussion or voting on any research project in which they or a family member have a SI except to provide information requested by the IRB.

ii. RSPP staff will require that any newly appointed IRB Member complete the COI Smart research questionnaire prior to the initial distribution of IRB study submission materials for their review.

iii. Annually (January of each year), RSPP staff will require IRB Members to complete the COI Smart research questionnaire. Members will have 30 days from the request in order to meet the annual interest submission requirements. IRB members who do not complete the mandatory annual disclosure using COI Smart will not be allowed to participate as an IRB member in the vote or discussion of any new or ongoing research project. Once the COI Smart disclosure process is complete, the IRB member may again participate in the review and vote of any new or ongoing research project in which they do not hold an SI.

iv. For any SI identified as part of the review of the COI Smart disclosure (see
System Policy 269, section 5.3), RSPP staff will ensure that the IRB Member is not assigned to a related research submission as a Primary Reviewer or expedited reviewer.

v. IRB Chairs will remind the convened IRB at the beginning of each meeting of the need to recuse from the deliberation or vote on any research study of which he/she may have a SI except to provide information requested by the IRB.

vi. RSPP will remind all IRB members of their obligations to update their disclosure within 30 days of discovery or acquisition of a new Significant Interest (SI). This notification may be done via email, the IRB Member Connection (website) or other written methods of communication.

d) Ensuring Required Disclosures are Completed by RSPP Staff, and Staff do not Participate in Review when Conflicted

i. The RSPP Director will require that new RSPP Staff members complete the COI Smart research questionnaire within one week of starting employment in the RSPP office.

ii. Annually (January of each year), the RSPP Director will require all RSPP Staff to complete the COI Smart research questionnaire. Staff members will have 30 days from the request in order to meet the annual interest submission requirements. Staff members who do not complete the mandatory annual disclosure using COI Smart will not be allowed to participate in the review of study materials related to new or ongoing research until such time that they have completed the disclosure process. Noncompliance with this requirement will be taken into consideration during the staff member’s annual caregiver review.

iii. For any SI identified from the review of the COI Smart disclosure (see System Policy 269, section 5.3), the RSPP Director will ensure that the Staff Member is not assigned to review of any new or ongoing research that is related to the SI.

iv. RSPP staff may not participate in the review or discussion of new or ongoing research of which they or their immediate family members have a SI except to provide information requested by the IRB.

v. RSPP Staff members will be reminded of their obligation to update their disclosure within 30 days of discovery or acquisition of a new Significant Interest (SI). This notification will be completed at the monthly staff meeting.
e) Ensuring Required Disclosures are Completed by Consultants to the IRB, and that Consultants do not Participate in Review when Conflicted

i. Consultants to the IRB must complete a Consultant Conflict of Interest Statement (Form 104-D), and return the completed form to the RSPP Office prior to the review of each research project requested by the Aurora IRB.

ii. Any SI held by a Consultant related to ongoing or proposed research automatically prohibits that individual from participating in the review of the research except to provide information requested by the IRB.

5.2. IRB review of Management Plans

a) See section 5.4 of Aurora System Policy 269.

b) Studies overseen by the Aurora IRB

i. The convened IRB, or IRB Chair (or designee) for research that can be approved by an expedited process, has the final authority to decide whether the conflict of interest and its management allows for the research to be approved per the regulatory criteria for approval.

ii. The convened IRB or IRB Chair may require the addition, but not the removal, of conflict elimination/reduction strategies to the management plan.

iii. If it is determined by the convened IRB or IRB Chair that the study meets (or continues to meet) the regulatory criteria for approval, the study (or modification of ongoing research) is approved. For studies reviewed by the convened IRB, the meeting minutes will document the IRB’s determination.

iv. Should the Aurora IRB make additions to the RCOIC management plan, the affected key personnel will be notified in writing by the RSPP Director per 45 CFR 46.109(d).

v. The RSPP Director will inform the Research Compliance Officer of the result of the IRB review.

vi. The IRB approval letter (or modification) for the study will not be released to the study PI until the affected key personnel acknowledges the COI management plan from the Aurora Compliance Department.

5.3. Compliance with System Policy 269, section 5.6

a) Ensuring Required Management Plan is Implemented by Conflicted Individual
i. Should the conflicted individual not respond to requests by the Compliance Department to verify that all components of the management plan have been appropriately implemented, as indicated in System Policy 269 section 5.6, the Research Compliance Officer and the RSPP Office will be notified by the Compliance Department.

ii. Within one working day of Compliance Department notification, the RSPP Office will send an email to the conflicted individual notifying him/her of the noncompliance with Aurora System policy 269 and RSPP SOP 104. In this email, the noncompliant individual will be informed that five working days from the date of the email he/she will be removed from the research study on which he/she has a conflict of interest if Compliance Department requests are not appropriately responded to. The study contact person will be copied on this email.

iii. Five working days from the date of the noncompliance email, unless notified by Compliance that the conflicted individual has since completed the requirement, the RSPP Office will generate a modification removing the noncompliant individual from the research study on which he/she has a conflict of interest. The modification form will be attached to an email sent to the study PI (if not the conflicted individual), study contact person, and the ARI Manager that oversees the research study (if applicable). The PI signature on this modification will be waived by the RSPP Office.

iv. The email will inform the study PI that it will be his/her responsibility to ensure that the duties of the removed individual are overseen by others on the study team or by the addition of a new person to the study team. Should the PI wish to add the noncompliant individual back onto the research study, he/she can only do so after the required reports are received by the Compliance Department.

v. Should the noncompliant individual be the PI of the study, a process similar to that noted in 5.3.a.i-iv will be undertaken. The difference will be that the ARI Manager (if applicable) that oversees the research study will be instructed that he/she has 5 working days to 1) close the affected research study, if appropriate; 2) find a replacement PI; or 3) convince the current study PI to comply with the monitoring requirements.

1. If the PI fails to comply with the requirements after 5 working days have passed, the noncompliant PI will be removed from the study via modification generated by the Aurora RSPP. If no replacement PI has been found, and the study remains open, the IRB Chair and/or Institutional Official will suspend the research study per RSPP SOP 407. Consideration
will be given to protection measures for currently enrolled subjects. The study suspension will be reported externally per the procedures outlined in RSPP SOP 408.

b) Ensuring Required Annual Monitoring Reporting Form is Completed by Conflicted Individual

i. The same procedures as outlined in section 5.3.a. will be implemented by the RSPP Office once notification is received by the Compliance Department that the annual monitoring report has not been completed by the conflicted individual.

5.4. Studies ceded to an external IRB

i. The RSPP Director will inform the IRB of record of the RCOIC management plan and inform them that they may add to, but not remove any conflict elimination/reduction strategies from the management plan.

ii. Documentation from the IRB of record of the IRB’s determination will be obtained.

iii. Should the IRB make additions to the RCOIC management plan, the affected key personnel will be notified in writing by the IRB of record.

iv. The RSPP Director will inform the Research Compliance Officer of the result of the IRB review.

Applicable Regulations, Guidelines and Standards

Aurora System Policies 269 and 270


References To Other Applicable SOPS

This SOP affects all other RSPP SOPs.

Owner: Aurora RSPP Director

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