Outside Activity Agreement Review Checklist

Instructions: This document is intended to guide School-based administrative staff in the review and triage of a Covered Individual’s foreign outside activities agreement when submitted for institutional review. This checklist, which may be used to document the review as needed, addresses the requirements for review and inclusion of supporting documentation as attachments to Other Support, including verification that Support to a Covered Individual and his/her Conduct of Research is appropriately disclosed (i.e., in Other Support vs Biosketch) and does not impermissibly overlap (i.e., scientific, budgetary or commitment overlap) with a federally supported project. Concerns that might hold submission of an application, Just In Time (JIT), or Research Performance Progress Report (RPPR) because they raise risks of NIH regulatory/policy violation are highlighted and will lead to Heightened Review. Concerns under other Harvard Policies are highlighted and will lead to a REFER instruction. These latter matters require additional School-based review and resolution consistent with applicable policies, but will not prevent an executed and active agreement from being attached as supporting documentation to Other Support and submitted to NIH. Relevant definitions for capitalized terms are attached.

1. Has the relationship covered by the Agreement been accurately (i.e., nature of relationship, personal income and time commitment) reported in OAIR?
   a. If YES, go to Question 2.
   b. If No, reach out to Covered Individual to request reporting in OAIR within the thirty-day timeframe required under the FCOI regulations and/or revision for accuracy. Agreement cannot be attached to Other Support associated with JIT, or RPPR and submitted to NIH until OAIR reporting and School-based review has occurred. Once reporting is completed in OAIR, go to Question 2.

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1 Capitalized terms are defined in attachment.

2 A “foreign outside activities agreement” is any personal agreement of a Covered Individual has with an entity organized outside the United States (i.e., foreign entity) or that otherwise governs the Conduct of Research outside of the U.S.

3 As noted as part of NIH FAQs, when determining the likelihood of a compliance risk related to improper influence (foreign or domestic), the institution should consider and identify relationships, existing and potential, that may impact research integrity, financial conflict of interest, and/or overlap. In evaluating these relationships, institutions should consider the following questions and factors:

   a) Does the relationship affect the integrity of the research by impacting established professional norms and ethical principles in the performance of all activities related to scientific research? In answering this question, institutions should consider the following factors:
      a. The “relationship” could be with a collaborator, an outside employer, an external appointment relationship, etc.
      b. The “impact” could be real or apparent
      c. The “compensation” could be of any type or level; NIH has not established a de minimis level of compensation and considers all types of support, in-kind or otherwise.

   b) Is there potential overlap in any of the following areas?
      a. Scientific
      b. Budgetary
      c. Commitment

   c) Is there a potential Financial Conflict of Interest?
2. Has the relationship been subject to School-based administrative review, including as part of OAIR reporting, for compliance with applicable conflict of interest and commitment policies and FCOI regulations? This includes verification of compliance with the following:
   i. School-based Policy on Conflict of Interest and Commitment (i.e., School-based policy that implements University Policy on Individual Conflicts of Interest)
      • For all policies, this includes the conflict of commitment standard that outside activities of a full-time Covered Individual should cumulatively represent no more than 20% of a Covered Individual’s total professional time. This also includes compliance with NIH FCOI regulations.
   ii. University Statement on Outside Activities for Holders of Academic Appointments as applied by a School
      • For each School, approval and consent requirements of this policy may be “deemed satisfied” if the arrangement otherwise complies with the School-based Conflict of Interest and Commitment Policy and FCOI regulations, including reporting requirements set forth therein. It is a School decision as to whether stricter review processes are required.

b. If YES, go to Question 3.

c. If No, reach out to the appropriate School-based administrator to determine the status of the review. Agreement cannot be attached to Other Support associated with JIT, or RPPR and submitted to NIH until in compliance with applicable COI and conflict of commitment requirements of the School. Once compliance is confirmed, go to Question 3.

3. Has the Covered Individual included the relationship covered by the Agreement in Other Support? (Note: Assumption is that Covered Individuals will only submit a foreign Agreement if it (i) involves the Conduct of Research or (ii) is an Employment, Affiliation or Appointment Agreement. See NIH Disclosure Agreement Flowchart.)
   • If Yes, confirm that Agreement is also listed in BioSketch and go to Question 4.
   • If no, does a review of the Agreement reveal that the Covered Recipient may be involved in the “Conduct of Research” under the Agreement and/or that the Agreement provides Support to the Covered Recipient’s Research at Harvard or outside of Harvard?
     • If yes, send for Heightened Review. Reviewer will err on side of sending for heightened review if any doubt. Also confirm that Agreement is listed in BioSketch.

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4 Compliance for purpose of the FCOI regulations means that the interests have been appropriately reported in OAIR, but does not require that project-specific FCOI review has been completed for a pending application. If a FCOI has been identified (if review occurring in connection with RPPR or JIT), compliance will, however, include full compliance with any FCOI management plan, if applicable.
• If no, confirm that Agreement is listed in BioSketch and do not attach Agreement. No further action is required.

4. Do the terms of the Agreement raise concerns of potential overlap in any of the following areas: (i) scientific; (ii) budgetary and/or (iii) commitment as assessed through the following questions that will be required to be answered by each Covered Individual upon submission of an Agreement, but also separately evaluated by the administrative reviewer (hereafter referred to as Agreement Reviewer):

   i. Is this Agreement a grant application, award or other Agreement that provides Support for Research on which the Covered Individual is serving as Project Director, Principal Investigator and/or the equivalent? When in doubt on role’s equivalency, faculty are encouraged to err on the side of disclosure.

   ii. Does this Agreement provide Support for Research or involve the Conduct of Research related to the Covered Individual’s Research conducted at Harvard or the Research proposed by the Covered Individual in a pending grant application? A Research project is related to the Covered Individual’s grant application if it could reasonably impact the design, conduct or reporting of the Research proposed in the Covered Individual’s grant application.

   iii. Is the Covered Individual providing (or committing to providing) measurable effort to Research as part of the Agreement?

   iv. Is the Covered Individual required to spend time in excess of more than 20% of his/her total professional effort as part of the Agreement (whether via an express effort commitment or reasonable interpretation of the individual’s obligations)?

   v. Does the Agreement require the Covered Individual to automatically award authorship to a third party in a manner inconsistent with University or School Authorship Guidelines?

   vi. Does the Agreement require Covered Individual to include their affiliation with an entity that is not Harvard as part of their reporting, publication and/or presentation of Research results (e.g., Covered Individual will be required to state they are an affiliate of X entity in addition to being a faculty member at Harvard)?

   vii. Does the Agreement require confidentiality regarding either the relationship or key terms governing the relationship?

   viii. Does the Agreement include participation by the Covered Individual in a foreign government Talents Program or its equivalent?

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5 Support includes any resources (i.e., financial, in-kind, personnel, provision of high-value materials that are not freely available) made available to a Covered Individual for use by the Covered Individual to pursue the Covered Individual’s Conduct of Research at Harvard or outside of Harvard. This includes include in-kind resources directly provided to the Covered Individual (e.g., office/laboratory space, equipment, supplies or employees or students funded by outside sources). This does not include institutional resources, such as core facilities or shared equipment, that are made broadly available.
ix. Does the Agreement contemplate activities that could impact, directly or indirectly, US foreign policy?

x. Does this Agreement raise any other issue that could affect the integrity of the research by impacting established professional norms and ethical principles in the performance of the Covered Individual’s Research?

a. **If Covered Individual answers YES to any of the above:**
   - Agreement subject to [Heightened Review](#) to eliminate any scientific, budgetary or commitment overlap and/or to ensure appropriate disclosure of related commitments. Once overlap is eliminated/resolved, go to Question 5.

b. **If Agreement Reviewer believes answer is YES to any of the above:**
   - Agreement subject to [Heightened Review](#) to eliminate any scientific, budgetary or commitment overlap and/or to ensure appropriate disclosure of related commitments. Once overlap is eliminated/resolved, go to Question 5.

c. **If No to all:** Go to Question 5.

5. Does the Agreement raise concerns under other applicable Harvard policies? Agreement Reviewer will assess the following to determine whether additional escalation may be required.

   i. Does the Agreement confer a voting faculty position at another academic or research institution to the Covered Individual?

   ii. Does the Agreement, on its face, allow for compensation in excess of [[$800-$1,000]] per hour or [[$X]] per year?

   iii. Does the Agreement provide for automatic renewal without ability for Covered Individual to terminate without cause (with or without notice)?

   iv. Does the Agreement allow for use of the Harvard name, insignia, trademarks, tradenames or otherwise raise concerns of implied endorsement under the Harvard Use of Name policy?

   v. Does the Agreement allow for a transfer, license or other preferential access to Harvard-owned intellectual property (including patents, copyrights or other protected rights), other unpublished data or methodologies owned by Harvard or otherwise produced utilizing Harvard facilities, personnel or resources?

   vi. Does the Agreement allow for access to Harvard campus or other resources owned by or obligated to Harvard? This includes space, equipment, personnel, services or other in-kind resources.

   vii. Does the Agreement call for promotional activities by the Covered Individual?

   viii. Does the Agreement require the Covered Individual to provide recommendation letters or mentorship to non-Harvard students/trainees?

   ix. Does the Agreement otherwise raise concerns to the Agreement Reviewer under Harvard policies?
a. **If Yes to any of above:** REFER Agreement to local School compliance office for resolution within [60 days] of the Other Support submission. Agreement will be attached “as is” to Other Support as supporting documentation.

b. **If No to all of above:** Agreement will be attached “as is” to Other Support as supporting documentation and no further action required.

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6 The local School compliance office may be the same office conducting the initial agreement review.
Applicable Definitions

**Affiliation**: Any formal or informal arrangement that provides for a Covered Individual to engage in Conduct of Research, teaching or clinical activities through an academic, governmental or non-profit research institution.

**Agreement**: Any document relating to an agreement or a relationship between a Covered Individual and a non-Harvard entity, which may include but is not limited to paid or unpaid activities for employment, consulting, a grant application/award, provision of advisory service, acting as subject matter expert, or an appointment or affiliation, including faculty appointments (honorary, adjunct, visiting, etc.).

**Appointment**: Any academic or research appointment, including but not limited to visiting, adjunct, honorary or temporary appointments with an academic, governmental or non-profit research institution AND any fiduciary (e.g., board of directors) or executive appointment with a for-profit entity.

**Conduct of Research**: To be a Project Director, Principal investigator or to otherwise be responsible for the design, conduct or reporting of Research regardless of title or position (e.g., an Investigator). This definition does not normally include service on scientific or clinical advisory boards or more general scientific consulting unless the Covered Individual is anticipated to make a direct and significant intellectual contribution to a specific Research project for the entity.

**Consulting Agreement**: Any written agreement between a covered individual and a non-Harvard entity to provide consulting services as an independent contractor, paid or unpaid, that falls outside of an individual’s institutional responsibilities defined under the terms of their Harvard employment or appointment.

**Covered Individuals**: All individuals listed as program directors/principal investigators (PD/PIs) or as senior/key personnel in an application for funding from NIH or NSF.

**Employment Agreement**: Any written agreement through which a Covered Individual becomes employed by a non-Harvard or non-Harvard-affiliated entity under laws of applicable jurisdiction.

**Foreign Agreements**: Any written agreement outlining a relationship between a Covered Individual and an entity organized outside the United States, such as a contract, a grant application/award, or an

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7 For clarity, this does not include most consulting agreements when one is acting as an independent contractor.
appointment, affiliation, and/or employment with an entity organized outside the U.S. (e.g., university, company, medical center/hospital, foundation), whether paid, unpaid, full time, or part time.

Research: As defined in the “Common Rule” (45 CFR §46.102), this shall mean a systematic investigation-including research development, testing and evaluation-designed to develop or contribute to generalizable knowledge.

Scientific Appointment: Per NIH’s deferral to each institution (i.e., Harvard) to define “Scientific Appointment”, this shall mean any academic or research appointment, including visiting, adjunct or temporary academic appointments, with a university, college, governmental or non-profit research institution and any fiduciary or executive level appointment with a for-profit entity engaged in commercial or research activities of a biomedical nature.

Support: Any resources (i.e., financial, in-kind, personnel, provision of high-value materials that are not freely available) made available to a Covered Individual for use by the Covered Individual to pursue the Covered Individual’s Conduct of Research. This includes include in-kind resources directly provided to the Covered Individual (e.g., office/laboratory space, equipment, supplies or employees or students funded by outside sources). This does not include institutional resources, such as core facilities or shared equipment, that are made broadly available.

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8 https://grants.nih.gov/faqs/#other-support-and-foreign-components.htm?anchor=question56216