

System-wide Policy: **Outside Interests and Conflicts Management**
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System-wide Policy Ownership Group: Compliance Department
System Policy Information Resource: Office of Outside Interests & Conflicts Management (OICM)

Stakeholder Groups
Enterprise Risk Oversight Committee
Legal Department
Research Compliance
Human Resources
Innovation Department
Supply Chain Management / Procurement Office

SCOPE:

Sites, Facilities, Business Units	Departments, Divisions, Operational Areas	People applicable to
Abbott Northwestern Hospital, Buffalo Hospital, Cambridge Medical Center, District One Hospital, Mercy Hospital, New Ulm Medical Center, Owatonna Hospital, River Falls Area Hospital, St. Francis Regional Medical Center, United Hospital, United Hospital – Hastings Regina Campus, Allina Health Group; System Office; All other Business Units	All	All Covered Individuals (as defined in Scope)

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POLICY STATEMENT

I. Scope.

This Policy is organized into Sections that apply to specified groups of individuals as follows:

SECTION		APPLIES TO:
II	Statement of Principles & General Obligations	Covered Individuals, including: <ul style="list-style-type: none"> • Employees • Board Members • Key Individuals <ul style="list-style-type: none"> ▪ Leaders ▪ Providers ▪ Vendor Selection & Procurement Personnel • Key Officials for Research • Research & Sponsored Program Personnel
III	Gifts and Standards for Interactions with Outside Parties	<ul style="list-style-type: none"> • Employees • Key Individuals <ul style="list-style-type: none"> ▪ Leaders ▪ Providers ▪ Vendor Selection & Procurement Personnel
IV	Written Disclosures and Conflict Management	<ul style="list-style-type: none"> • Board Members • Key Individuals <ul style="list-style-type: none"> ▪ Leaders ▪ Providers ▪ Vendor Selection & Procurement Personnel • Key Officials for Research • Research & Sponsored Program Personnel
V	Preapproval Requirements for Outside Professional Activities	Covered Employees (<i>.5 FTE or greater</i>), including: <ul style="list-style-type: none"> • Leaders • Providers • Vendor Selection & Procurement Personnel

VI	Research & Sponsored Program Disclosures & Conflict Management	<ul style="list-style-type: none"> • Key Officials for Research • Research & Sponsored Program Personnel
VII	Program Structure and Administration	Covered Individuals

Covered Individuals who have more than one role described under this Policy must meet the obligations for each of their roles. For example, an employee who is a Leader must follow all obligations for Employees and all obligations for Leaders. Employed providers who are involved in research must follow obligations for Employees, Providers, and Research Personnel.

System-wide Policy

II. Statement of Principles & General Obligations

A. Scope. This Section II applies to Allina Health Employees, Key Individuals (Leaders, Providers, and Procurement & Vendor Selection Personnel), Research & Sponsored Program Personnel, and Board Members (collectively, “Covered Individuals”). It further applies to Interests held by Allina Health

B. Overview. Allina Health recognizes that relationships and interests with Outside Parties have the potential to interfere with an individual’s exercise of independent judgment in Allina Health’s best interest. Allina Health strives to assure integrity and independence in all aspects of Allina Health operations and strategic decisions, including governance, management, clinical care, research and procurement, and to avoid even the appearance of impropriety.

Covered Individuals must not solicit or accept gifts from any outside entity or individual that has a direct interest in a decision that will be considered by the individual receiving the gift. Covered Individuals must not accept gifts that would or are intended to influence the Covered Individuals decisions or activities on behalf of Allina Health.

Covered Individuals are expected, at all times, to conduct their work for Allina Health in an impartial and unbiased manner, and in the best interest of Allina Health patients, families, the organization and the communities we serve.

Relationships between Covered Individuals and Outside Parties can be beneficial and important to Allina Health, and to the effective and high quality delivery of patient care. Conflicts of Interest and Conflicts of Commitment naturally occur from time-to-time in the course of conducting Allina Health’s daily affairs. They are often unavoidable, and are not inherently unethical or impermissible. However, a Conflict of Interest or Commitment can compromise integrity and independence in making decisions and exercising judgment in Allina Health’s best interest, and therefore, must be identified, assessed and appropriately managed.

Allina Health will establish and administer a program to identify Financial Interests and Non-financial Interests (collectively, “Outside Interests”). Allina Health will assess the actual or perceived effect of the Outside Interests related to an individual’s decisions or activities for or at Allina Health and manage Outside Interests that are determined to present a Conflict of Interest or Conflict of Commitment for the Covered Individual in carrying out decisions or activities for Allina Health.

This Policy and the [Allina Health Code of Conduct](#) provide the basis for implementation of a standardized, risk-based program and approach that is consistent with Allina Health’s organizational mission, vision and values.

C. Identifying Outside Interests. Covered Individuals or a Covered Individual’s Family Members may have Outside Interests that have the potential to compromise or bias the judgment or objectivity of the individual’s decisions or actions at or for Allina Health, or create the appearance of compromise or bias. Covered Individuals should be aware that any Outside Interest has the potential to create real or perceived conflicts. Identification of Outside Interests and sensitivity to how these Outside Interests can be perceived by others are an important part of managing conflicts and potential conflicts.

Allina Health is further committed to identifying and managing Institutional Conflicts of Interest (ICOI) to safeguard the integrity of Allina Health, Institutional Conflicts of Interest may arise from either the Financial Interests of Allina Health as an organization. ICOIs are of concern when Institutional Interests create the potential to compromise, or reasonably appear to compromise, Allina Health.

D. Identifying Conflicts of Interests and Conflicts of Commitment. In general, a Conflict of Interest exists when an Outside Interest has the potential to compromise or bias the judgment or objectivity of the individual's decisions or actions, or create the appearance of compromise or bias. A Conflict of Commitment exists when an outside activity or relationship may deter an individual from devoting an appropriate amount of time, energy, creativity, or other personal resources to the individual's Allina Health responsibilities. The mere existence of an Outside Interest does not necessarily result in a Conflict of Interest or Conflict of Commitment. Covered Individuals are expected to disclose Outside Interests regardless of whether the Covered Individual believes the Outside Interest presents a conflict, or are required to complete an annual disclosure statement

E. Disclosure Obligations when Participating in Allina Health Decisions.

1. *Disclosure of [Outside Interests](#).* If, in the course of their responsibilities for Allina Health, a Covered Individual provides a recommendation, votes or makes Allina Health decisions about a product, service, transaction or organizational strategy, the person should disclose to the person responsible for the related decision-making process any Outside Interest held by the Covered Individual or the Covered Individual's Immediate Family Member which has the potential to compromise or bias the judgment or objectivity of the individual's decisions or actions, or create the appearance of such compromise or bias.
 - a. For example, if a Covered Individual holds an interest in a company that is under consideration to do work for Allina Health, the Covered Individual should disclose the Outside Interest to the person responsible for making the decision about whether to hire the company so that the responsible person can take steps to assure the interest does not compromise or bias the decision.

In addition, Vendor Selection and Procurement Personnel will, when contacting Vendor Selection and Procurement Participants for advice or recommendations, request information about Outside Interests held by the Participant or Participants' Immediate Family Member related to the product, service or vendor under consideration. Covered Individuals are only required to disclose Outside Interests of an Immediate Family Member if the Interest is known to the Covered Individuals without asking the Immediate Family Member.

Ad Hoc Disclosures. There may be situations in which an Employee after discussion with their manager/supervisor determines that the Employee complete a disclosure form, in this situation, the manager/supervisor must contact the Office of OICM for this request. It will be the Office of OICM discretion if the manager/supervisor or the Office of OICM will manage any potential conflicts.

2. *Management of Disclosed Outside Interests.* After an Outside Interest has been disclosed, the individual responsible for the affected decision-making process should

consider whether it may affect the Covered Individual's ability to exercise independent judgment in Allina Health's best interest or create the appearance of compromise or bias. The person responsible for the decision or decision-making process should also determine what measures, if any are needed to manage a Conflict of Interest. Some ways in which the person responsible for the decision or decision-making process could manage a potential conflict and reduce the likelihood that the Outside Interest may compromise or bias the decision may include:

- Disclosure of information about the interest to the decision makers;
- Not voting on or making decisions related to products, services, transactions or organizational strategies related to the Outside Interest;
- limiting the individual's access to information about or participation in discussions related to decision;

The person responsible for the decision process and/or the Covered Individual should consult with the Office of OICM about appropriate ongoing disclosure and management of the conflict if needed.

Covered Individuals who have a Conflict Management Plan applicable to an Outside Interest must disclose the Outside Interest and follow any other requirements related to participation in the decision-making process as set forth in the Conflict Management Plan.

F. Other Obligations for Covered Individuals. Covered Individuals are responsible to:

1. (1) consult and follow the requirements of this Policy and any related policies, procedures, guidelines and forms related to disclosure of Outside Interests and as necessary to meet the Covered Individual's obligations related to management of identified conflicts;
2. (2) seek guidance from the Office of OICM, General Counsel or the Chief Compliance Officer regarding any Outside Interests, potential disclosure situations or other matters covered by this Policy and any related policies, procedures, guidelines or forms that may be unclear to the Covered Individual;
3. (3) cooperate with the Audit and Compliance Committee of the Allina Health System Board of Directors, the General Counsel, the Chief Compliance Officer or/and the Office of OICM as the Committee's designees, in the administration of this Policy and any related policies, procedures, guidelines or forms; and
4. (4) comply with any Conflict Management Plan for any Conflict of Interest identified through the Written Disclosures and Conflict Management obligations in Section IV.

III. **Standards for Gifts and Interactions with Outside Parties**

A. Scope. This Section III applies to all Allina Health Employees & Key Individuals.

B. Overview.

Gifts. The exchange of Gifts can raise questions about the influence of that Gift on business decisions, and can affect the reputation of the individual or Allina Health, especially if it happens frequently or is of significant value. Allina Health sets limits on the receipt of gifts and prohibits the solicitation of gifts from Outside Parties.

Other Interactions with Outside Parties. Allina Health permits individuals covered by this section to attend certain events or meetings, and to accept sponsorship or payment of expenses by Health Industry Entity or Non-Industry Vendor only where it has determined that because of the nature of the event or meeting, the sponsorship or payment or related expenses by a Health Industry Entity or Non-Industry Vendor is not considered a gift.

Allina Health prohibits Employees and Key Individuals from receiving any payment or benefit, or engaging in any activity that due to the nature of the activity would be likely to harm Allina Health's reputation, including, without limitation, all of [the prohibited arrangements](#) listed in this Section. Employees and Key Individuals should avoid participating in activities and accepting benefits that are likely to interfere with their ability to make decisions in the best interests of Allina Health.

Business Meals and Other Interactions with Outside Parties. Allina Health permits individuals covered by this section to attend certain events or meetings, and to accept sponsorship or payment of expenses by Health Industry Entity or Non-Industry Vendor where it has determined that because of the nature of the event or meeting, the sponsorship or payment or related expenses by a Health Industry Entity or Non-Industry Vendor is not considered a gift (i.e., for the personal benefit of the individual). For example, Allina Health allows an individual to accept a reasonable, business meal from Health Industry Entity or Non-Industry Vendor.

C. Gifts to or from Health Industry Entities and Non-industry Vendors.

1. Gifts from Health Industry Entities Prohibited. Employees and Key Individuals are prohibited from accepting Gifts of any type from Health Industry Entities.
2. Gifts from Non-Industry Vendors. Employees and Key Individuals may accept unsolicited Gifts from Non-Industry Vendors, as long as the annual value of Gifts received from any individual Non-Industry Vendor does not exceed \$50. Individuals may not accept Cash, Gift Cards or other Cash Equivalents of any value.
 - Exceptions process for Non-Industry Vendor Gift Limitations. In some cases, exceptions to the annual \$50 limit for Non-Industry Vendors Gifts may be determined to be in the best of interest of Allina Health. In those cases, meal/beverages in excess of \$50 annually are acceptable if:
 - the exception is approved in advance by the individual's manager/supervisor;
 - it is *not* from a Health Industry Entity; and
 - it is related to a legitimate Allina Health business or education purpose.

Exceptions should not be approved if there is concern that the gift may interfere with the Employee or Key Individual's ability to make decisions that are in the best interest of Allina Health.

3. Gifts provided to Health Industry Entities or Non-Industry Vendors. Employees and Key Individuals may entertain or provide items of value to Health Industry Entities and Non-Industry Vendors if the entertainment is reasonable and consistent with accepted business practices, does not violate any applicable law or ethical standards, and the public disclosure of facts related to the entertainment or gift is not likely to damage

Allina Health's reputation. Individuals should be aware that in some situations, provision of gifts or entertainment may violate the law, such as when dealing with government officials, physicians and referral sources, and should refrain from provision of gifts or entertainment in those circumstances. Employees and Key Individuals should consult with the Allina Health Compliance Department to assure that gifts are consistent with applicable requirements.

D. Event Sponsorship or Funding and Payment of Event-Related Expenses. Because of the nature of the event or meeting and the related benefit to Allina Health or the individual related to responsibilities at Allina Health, Employees and Key Individuals may attend events or meetings, and accept sponsorship or payment of expenses by a Health Industry Entity or Non-Industry Vendor and accepting these benefits *are not considered Gifts* in the following circumstances:

1. Attending Education, Training and Professional Events or Conferences Sponsored by Health Industry Entity or Non-Industry Vendor. Employees and Key Individuals may attend events that have a (a) bona fide educational purpose (i.e., events that meet ACCME or other applicable standards for educational content), or (b) provide a benefit for Allina Health or to the individual related to the individual's work at Allina Health. For example, employees may attend training conducted by Health Industry Entities for safe and effective use of a specific product or service (e.g., cadaver workshops, "hands-on" training sessions, and FDA-mandated training).

2. Payment of Event-Related Expenses by Health Industry Entities or Non-Industry Vendors.

A Health Industry Entity or Non-Industry Vendor may not provide payments, pay on behalf of, or waive payment for an Employee or Key Individual's attendance at education, training, or professional event or conference, or pay for related expenses, except as described in this Policy. *Expenses* include the reasonable and actual costs of registration, lodging, travel, and related costs. Expenses also includes the provision of reasonable meals, food or beverages during or incidental to a permitted event.

Specifically, a Health Industry Entity or Non-Industry Vendor may pay an individual's Expenses only if the following requirements are met:

- i. Attending the event provides a benefit for Allina Health or to the individual related to the individual's work at Allina Health;
- ii. The offer to pay expenses is made in advance of the individual incurring the costs;
- iii. The Expense payment has been approved in advance as required by the Office of OICM; and
- iv. The event meets one or more of the following criteria:
 - [ACCME](#) or other applicable educational standards are met;

- The individual is speaking, presenting¹, or receiving an award or honor at the event;
- the expenses were necessary to obtain services (e.g., training on a product) that were included in a purchase agreement or contract with the Health Industry Entity or Non-Industry Vendor to provide a product or service to Allina Health; or
 - the expenses were related to consideration of the Health Industry Entity or Non-Industry Vendor's product or service and the on-site visit is necessary to evaluate the product or service, e.g., attend a plant tour or a demonstration of non-portable equipment and is approved by the Vice President of the division and the Vice President Supply Chain.

The costs of an individual's spouse or other person accompanying the Employee or Key Individual for reasons other than Allina Health business may not be paid by the Health Industry Entity or Non-industry Vendor.

3. Funding of or Donation to Allina Health Events by Health Industry Entity or Non-Industry Vendor. A Health Industry Entity or Non-Industry Vendor may do any of the following, provided that the donation *must not* involve a prohibited transaction, be conditioned on use of any materials to promote or market the Health Industry Entity or Non-Industry Vendor's products or services, or include any other improper restriction:
- donate to an Allina Health Foundation;
 - purchase or sponsor events or fund an individual's participation in an Allina Health event through donation to an Allina Health Foundation; or
 - fund an Allina Health sponsored event by providing an unrestricted grant to an Allina Health Foundation.

E. Free, Low Cost and Donated Products. Generally free samples of medication, supplies and equipment are considered gifts and therefore should not be accepted from Health Industry Entities or Non-Industry Vendors. Exceptions are that free, low cost or donated samples, supplies or equipment may be provided for the following activities or circumstances, and are not considered gifts:

- For conducting IRB-approved Clinical Trials.
- Supplies of contact lenses and solutions and post-operative ophthalmic procedure kits for optic sites.
- Prescription assistance programs, including:
 - prescription assistance programs for indigent patients; and
 - Coupons and vouchers for patients distributed through prescription assistance programs or an Allina Health Pharmacy.
- For evaluation of new products that the Allina Supply Technology Committee (ASTC) has determined are under consideration for use by Allina Health, provided that the requirements of the [Allina Health New Product Review: Supply and Technology Committee Policy](#) must be followed.

¹ Outside Professional Activities must be preapproved when required by Section V of this Policy.

- Bona fide patient education devices and materials to educate the patient or obtain a patient's informed consent to use the product in connection with the patient's care, provided that use of the product is consistent with current acceptable clinical practice standards. e.g., diabetic patient instruction devices and inhalant devices.
- Medical missions, low-cost clinics or other charitable activities or facilities. If donations for charitable purposes are received or arranged by a Covered Individual in their individual capacity, these must be disclosed as part of the Written Interest Disclosure Process.
- Additional exceptions for which free, low cost or donated samples, supplies or equipment do not constitute a prohibited gift may be approved by the Clinical Leadership Team (CLT).

F. Prohibited Arrangements with Health Industry Entities & Non-Industry Vendors. The following interactions and arrangements between Employees or Key Individuals and Health Industry Entities & Non-Industry Vendors are strictly prohibited:

- Participating in one-to-one marketing techniques used to educate about a vendor's products (e.g., detailing/e-detailing) except where requested by Allina Health regarding a product that the Allina Supply Technology Committee (ASTC) has determined is under consideration by Allina Health.
- Presenting or being attributed as an author on materials (e.g., presentations, articles, publications) primarily designed to promote a product or service;
- Presenting or being attributed as an author on materials (e.g., presentations, articles, publications) where the Employee or Key Individual is not in fact the author (including, but not limited to, ghostwriting);
- Arrangements where payments or other benefits are offered in exchange for or with the explicit expectation of favorable treatment for the Health Industry Entity or Non-Industry Vendor, including payments or benefits:
 - to influence the volume or value of patient referral, prescribing practices or medical decision-making;
 - directly or indirectly based on or tied to an agreement for a provider or Allina Health to use, consider, recommend or change/switch to the Health Industry Entity or Non-Industry Vendor's product or service;
 - for participation by an individual or Allina Health in surveys or activities designed to promote, market or sell a product or service to providers or patients;
 - to complete product or service evaluations (including payments to complete evaluations when Allina Health is considering the product or service);
 - to recruit patients for clinical research activities, except for recruitment activities approved by the appropriate Institutional Review Board (IRB);
 - for use or disclosure of nonpublic research information;
- Endorsement of a product or service related to an individual's Allina Health responsibilities or expertise; and
- Payments or benefits solely in exchange for a particular individual's attendance at an event.

G. Handling Prohibited Gifts or Payments. Gifts or payments inconsistent with this policy must be declined or returned. If the gift or payment cannot be returned, the person who

received the gift or payment must contact a Foundation Director to donate the item and report the gift or payment to the Office of OICM.

If an Employee or Key Individual attends a Health Industry Entity or Non-Industry Vendor-sponsored event where the nature of the event or value of the event would not be consistent with this Policy, the individual should pay for any expenses incurred on their behalf by the Health Industry Entity or Non-Industry Vendor and, if the expenses are eligible for reimbursement under applicable Allina Health expense reimbursement policies, may submit expenses for department reimbursement.

- H. Gifts to or from Allina Health Patients.** Gifts provided to patients or accepted from patients have the potential to improperly influence or bias actions or decisions of the patient or the employee, or to create the appearance of such influence or bias. Therefore, any gifts provided to patients or received from a patient should be of nominal value. Employees and Key Individuals should not offer or accept gifts that are offered in exchange for more favorable treatment to the individual offering who is offering the gift. Gifts of cash and cash equivalents are prohibited.

Employees and Key Individuals may accept gifts of food or other items of modest value (not to exceed \$50 annually from any individual patient) when offered by a patient as a genuine expression of appreciation for excellent service. Providers should also assure that accepting the gift would be consistent with their professional obligations and ethical standards. Patients who wish to give gifts in excess of \$50 should be assisted in contacting an Allina Health Foundation. Employees and Key Individuals should talk to their manager/supervisor or the Office of OICM if they have any concerns about whether it is appropriate to accept a gift from a patient.

Allina Health also may wish to provide a small token of appreciation to patients for choosing Allina Health to their provide care or services. Gifts to patients from Allina Health must comply with applicable laws and regulations regarding beneficiary inducements. Generally, gifts should not exceed \$15 per instance and \$75 annually or as otherwise determined acceptable by the Compliance Department. Gifts should not be advertised or used to influence patients to receive services or products from Allina Health. Employees or Key Individuals who are considering providing complementary or reduced-price services to patients should consult the Compliance Department before doing so.

IV. Annual Written Disclosure Obligations and Conflict Management

- A. Scope.** This Section IV applies to Board Members, Key Individuals, Key Officials for Research, and Research & Sponsored Program Personnel.
- B. Overview.** Certain roles within Allina Health present an increased risk that an individual's Outside Interests will result in an actual or perceived Conflict of Interest or Conflict of Commitment for the individual while carrying out the obligations of that role. As a result, Allina Health requires individuals in these roles to provide written disclosure to Allina Health of Outside Interests held by the Covered Individual or the Covered Individual's Family Member (if the Interest is known to the Covered Individual without asking the Family Member), and receive guidance and direction from Allina Health on management of these interests while carrying out their Allina Health duties. Individuals covered by this section are required to cooperate in the administration of this interest disclosure and conflict management process.

C. Written Interest Disclosure Requirements. Key Individuals, Board Members, Key Officials for Research, and Research & Sponsored Program Personnel must follow these requirements in order to enable Allina Health to identify, evaluate, and eliminate or manage Outside Interests that may present an actual or perceived Conflict of Interest or Conflict of Commitment:

1. Initial Interest Disclosure Form. When an individual becomes a Key Individual, Board Member, Key Official for Research, or Research & Sponsored Program Personnel, they must promptly complete an Interest Disclosure Form, identifying all Outside Interests. In cases where a particular role or circumstance presents unique risks for a Conflict of Interest or Commitment, the Office of OICM may require completion of an Interest Disclosure Form as part of the offer/consideration process of selecting a person for the Allina Health role, and to allow the individual to determine whether to accept the Conflict Management Plan required to hold the role.
2. Annual Interest Disclosure Form. All Key Individuals, Board Members, Key Officials for Research, and Research & Sponsored Program Personnel must annually complete an Interest Disclosure Form.
3. Ongoing Obligation for Updates to Interest Disclosure Form. If, at any time after submitting an Interest Disclosure Form, a Key Individual, Board Member, Key Official for Research, or Research & Sponsored Program Personnel becomes aware of or acquires an Outside Interest that the individual would have had to disclose on the annual Interest Disclosure Form, the individual must promptly disclose the Outside Interest by submitting an updated Interest Disclosure Form.
4. Attestation of Compliance. When submitting an Interest Disclosure Form, Key Individuals, Board Members, Key Officials for Research, and Research & Sponsored Program Personnel must attest in writing or electronically that the information contained in the Interest Disclosure Form is true, accurate, and complete, and that they have read, understand, and agree to comply with this Policy.

D. Review of Interest Disclosure Form. Allina Health designates individuals who are responsible for review of disclosed interests, evaluation for Conflicts of Interest or Conflicts of Commitment and management of any identified conflicts, which may vary based on a person's role at Allina Health. The [Designated Reviewer](#) shall be the Chief Compliance Officer or their designee. The Designated Reviewer will review responses and updates to the Interest Disclosure Forms and determine whether each Outside Interest presents a possible Conflict of Interest that requires a Conflict Management Plan. To carry out this evaluation the Designated Reviewer will make further inquiry and investigation of disclosed relationships and interests as it deems appropriate.

E. Conflict Management Measures and Plans.

Conflicts of Interest. If an Outside Interest is determined to present a Conflict of Interest, the Designated Reviewer, in consultation with the Office of OICM, will establish a plan for management of that Conflict of Interest. If the Designated Reviewer concludes that the Conflict of Interest is sufficiently managed by compliance with the requirements of this Policy and any related policies, procedures, rules, guidelines, or forms, an individual Conflict Management Plan may not be needed. Measures that may be implemented alone

or in combination to acceptably manage an individual's Conflict of Interest include, but are not limited to:

- Disclosure or information about the interest to specified groups, individuals, or in specified circumstances;
- Recusal from discussions or/and decisions related to products, services, transactions, or other matters related to the Interest or Relationship that presents the Conflict of Interest;
- Review or monitoring of practice patterns;
- Firewalls to limit the individual's access to information about a decision-making process or about Allina Health's relationship with the person or entity;
- Designation of an individual to receive and respond to concerns;
- Divestiture;
- Exclusion from royalty payments for sales or other benefits at Allina Health from Allina Health's licensing arrangements derived from the relationship; and/or
- Any other measure or Conflict Management Plan deemed necessary or appropriate by the Office of OICM, General Counsel, Chief Compliance Officer, or the individual's supervisor/manager.

In some rare circumstances, a Conflict of Interest may be so significant that the individual cannot simultaneously have the Outside Interest and perform their responsibilities for Allina Health. Any such case will be reported to the Office of OICM which will work in consultation with the Designated Reviewer, General Counsel, the Chief Compliance Officer, and, if applicable, the individual's manager/supervisor and Human Resources, to evaluate and determine how to proceed. The individual may have to relinquish the interest or the Allina Health duties with which it conflicts.

Conflicts of Commitment. Allina Health also may consider Conflicts of Commitment related to the Outside Interests disclosed by a Covered Individual. The individual's manager/supervisor may elect to consult with Allina Health Human Resources in determining how to address an Outside Interest determined to present a Conflict of Commitment.

F. Transaction-Based Conflict Management.

1. Arrangements Involving Disqualified Persons. Proposed transactions or arrangements involving a benefit to a Disqualified Person will be managed in accordance with the [Policy on Arrangements with Disqualified Persons](#). The Allina Health General Counsel or Chief Compliance Officer will report to the Enterprise Risk Oversight Committee (EROC) or subcommittees thereof relevant information about Conflicts of Interest otherwise subject to this policy, which are identified and evaluated under the Arrangements with Disqualified Persons policy.
2. Other Arrangements Requiring Additional Management. If the Designated Reviewer concludes that an Outside Interest presents a Conflict of Interest that cannot be effectively managed by limitations on or removal of the individual from the decision-making process, the Designated Reviewer shall refer the matter to the Enterprise Risk Oversight Committee (EROC) or subcommittees thereof for a determination. If the Enterprise Risk Oversight Committee (EROC) or subcommittees thereof agrees with the Designated Reviewer's conclusion, Allina Health shall not engage in or enter into a proposed contract, transaction, relationship, arrangement, or activity that could be affected by the Conflict of

Interest unless the Designated Reviewer has investigated alternatives to the proposed contract, transaction, relationship, arrangement or activity and has determined that:

- a. there are no alternatives that are in the best interest of Allina Health;
- b. Allina cannot obtain a more advantageous contract, transaction, relationship, arrangement, or activity with reasonable efforts under the circumstances; *and*
- c. regardless of whether the Covered Individual participates, the proposed contract, transaction, relationship, arrangement, or activity is:
 - i. in the best interests of Allina Health; *and*
 - ii. fair and reasonable to Allina Health, including consideration, where applicable, of: (i) appraisals or other independent valuations of the Fair Market Value of the contract, transaction or arrangement; (ii) information regarding comparable contracts, transactions or arrangements between unrelated parties; (iii) offers from comparable competing entities; or (iv) studies of comparable compensation arrangements.

V. Preapproval Requirements for Outside Professional Activities

A. Scope. This Section V applies to [Covered Employees](#), unless otherwise noted in the grid below (which more broadly applies to Key Individuals and [Employees](#)).

B. Overview. Covered Employees are not permitted to engage in Outside Professional Activities, unless the activity has been approved in advance, as set forth in this Policy. Outside Professional Activities includes any provision of Professional Services for an Outside Party, including:

1. Outside Professional Activities where the Covered Employee receives compensation or benefits for performing the Professional Services and
2. Outside Volunteer Activities for which the Covered Employee performs a Professional Service but receives no compensation or benefit in return. Allina Health may, in its sole discretion, choose not to approve or may restrict Outside Professional Activities by Covered Employees when the proposed Outside Professional Activity presents a Conflict of Interest, Conflict of Commitment, or is otherwise determined to be inconsistent with the interests of Allina Health.

C. Preapproval Requests. Preapproval by a Covered Employee's manager/supervisor is required before a Covered Employee may engage in any Outside Professional Activities..

Certain Outside Professional Activities present a greater risk of a Conflict of Interest or have a greater potential effect on Allina Health's interests or reputation. These Outside Professional Activities must be reviewed and approved by a subject matter expert who is designated ("Designated SME") for the type of Outside Professional Activity for which approval has been requested and applies to Covered Individuals and others as noted in the grid below.

The following Outside Professional Activities must be preapproved by both the persons Supervisor/Manager and Designated SME(s) (if applicable – see grid below) before the person is permitted to engage in the Outside Professional Activity. Please contact the Office of OICM for any of these Outside Professional Activities in the grid below.

The Office of OICM may require additional SME approvals as it determines necessary based on the facts and circumstances of the proposed Outside Professional Activity.

Outside Professional Activity	Designated SME	Applicability
1. Outside Professional Activities with Health Industry Entities and Non-Industry Vendors	Office of OICM	All Key Individuals
2. Medical/Clinical Services	Manager/Supervisor or other leader as designated by the Office of OICM	All Key Individuals
3. Providing Expert Medical Opinions in Proceedings or Publications	Legal Department – Litigation Team	All Key Individuals
4. Publications, Interviews or Presentations involving Medical Opinions, Allina Health Strategic or Confidential Information	Public Relations, Marketing & Communications; Legal Department; or other leader as designated by the Office of OICM	All Employees
5. Outside Professional Activities that involve Use or Disclosure of Allina Health patient information	Chief Privacy Officer	All Employees
6. Outside Professional Activities that involve Use or Disclosure of Personally Identifiable Information (PII)	Chief Information Security Officer & Chief Privacy Officer	All Employees
7. Outside Professional Activities that involve Use or Disclosure of Allina Health employee information	HR	All Employees
8. Outside Volunteer Activities for which the Covered Employee is seeking Allina Health professional liability coverage.	Office of OICM & Corporate Risk Manager	All Employees
9. Outside Professional Activities that involve potential authoring, discovery, creation, or development of	Allina Health Innovation Department	All Employees

Intellectual Property, or assignment of Royalty or Ownership Interest to the Covered Employee		
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D. Threshold Criteria for All Outside Professional Activities.

A proposed Outside Professional Activity must meet all of the following criteria before it may be considered for approval:

1. The [Professional Services](#) are not competitive with Allina Health;
2. Does not interfere with, undermine, or usurp an Allina Health interest;
3. Does not interfere or conflict with the Covered Employee’s duties or responsibilities as an employee of Allina Health;
4. Will be performed solely during times when the Covered Employee is not assigned or responsible for Allina Health duties;
5. Will be performed without use of any Allina Health resources (including, without limitation, Allina Health space, equipment, supplies, nurses, technicians, or dictation);
6. Is of specified duration and scope;
7. The relationship is entered into by the Covered Employee in their individual capacity, and not in any capacity as an employee or agent of Allina Health;
8. Ownership/Royalty Interests must comply with Allina Health’s Policies on [Intellectual Property](#);
9. If an Outside Volunteer Activity, must contribute to Allina Health’s “mission, vision and values” or otherwise relate to Allina Health’s community activism;

E. Requests for Preapproval.

As in C above preapproval by a Covered Employee’s manager/supervisor is required before a Covered Employee may engage in any Outside Professional Activities, once this approval has granted from their manager/supervisor and if applicable the SME; then the Covered Employee must add the information to their annual disclosure form. The Office of OICM will track this information on a regular basis and report it to Clinical Service Lines

F. Decision about Approval. If the Designated SME(s) and the Covered Employee’s manager/supervisor determine, in their sole discretion, whether the proposed activity meets the above Threshold Criteria. If both the Designated SME(s) and the Covered Employee’s manager/supervisor conclude that the proposed Outside Professional Activity meets the Threshold Criteria, they may, but are not required to, approve the activity after consideration of the following factors:

1. Whether the activity does or is likely to present a Conflict of Interest;
2. Whether the activity does or is likely to present a Conflict of Commitment, including consideration of whether (a) the time commitment would or is likely to interfere with the individual’s job duties for Allina Health (e.g., a full time employee typically should not have greater than one day per week committee to Outside Professional Activates) and (b) the Covered Employee currently satisfactorily fulfills the obligations of the job duties the Allina Health services to which the Covered Employee is assigned.

None of the individual factors are determinative, however these should be considered in deciding whether approval of the request is consistent with the best interests of Allina

Health. The determinations of the Designated SME and the manager/supervisor about approval of the request will be promptly communicated to the Covered Employee.

In rare cases, a Designated SME or manager/supervisor may conclude that an Outside Professional Activity which is either prohibited or does not meet the Threshold Criteria is nonetheless in the best interests of Allina Health. The Designated SME or manager/supervisor may present the request to the COI Committee for consideration of an exception.

G. Compensation, Insurance, and Liabilities for Outside Professional Activities.

1. Outside Professional Income. Covered Employees will be entitled to retain all Outside Professional Income related to an approved Outside Professional Activity. All compensation associated with Outside Professional Activities must be consistent with the requirements of this Policy. Covered Employees may not receive any compensation of any kind for an Outside Volunteer Activity.
2. Insurance & Liability. Except as specifically stated in this Section IV, Allina Health assumes no liability or obligation, express or implied, for a Covered Employee's Outside Professional Activities, even if Allina Health undertakes a review of the agreement between the Covered Individual and the Third Party in connection with this Policy. Allina Health is entitled but not obligated to request review of all or part of the agreement for purposes of assuring compliance with this policy and any related policies, procedures, protocols, guidelines, forms or tools, but undertakes no liability or obligation in connection with its review of the agreement.

Covered Employees are responsible for obtaining any necessary liability or other insurance coverage, including but not limited to professional liability insurance, related to the Outside Professional Activity. Allina Health *will not* provide insurance coverage or defense and indemnification to a Covered Employee for any type of liability arising out of the Outside Professional Activity.

3. Insurance Exception for Approved Outside Volunteer Activities. Allina Health will provide only professional liability insurance coverage and/or defense and indemnification to a Covered Employee related to an approved Outside Volunteer Activity only if advance approval was obtained from the Office of OICM. Any other liability and related insurance coverage will be the responsibility of the Covered Individual, not Allina Health. If advance approval is not obtained, Allina Health will not provide any insurance coverage and/or defense and indemnification.

H. Withdrawal of Approval. Allina Health reserves the right to withdraw its approval for an Outside Professional Activity that it has previously approved if new information is available or circumstances change in a way that causes the activity to no longer meet the requirements for approval, including that continued approval of the Outside Professional Activity is inconsistent with the best interests of Allina Health.

VI. Research and Sponsored Program Disclosures and Conflict Management

A. Scope. This Section IV applies to Research and Sponsored Program Personnel and Activities. It further applies to Interests held by Allina Health and Allina Health Key Officials

for Research, and addresses both individual and Institutional Conflicts of Interest which may arise related to the conduct of Allina Health Research or Sponsored Programs.

- B. Overview.** Allina Health is committed to evaluating and appropriately addressing the relationships of personnel involved in research or Federal Projects and the relationships of Allina Health related to research to help ensure the work is free from potential or actual bias in order to focus on well-designed or scientifically sound discoveries and programs that will serve our patients and their communities.

Allina Health is further committed to identifying and managing individual and Institutional Conflicts of Interest (ICOI) to safeguard the integrity of Allina Health Research, and protect patients who participate in Allina Health Research. Institutional Conflicts of Interest may arise from either the Financial Interests of Allina Health as an organization, or personally-held interests of Allina Health's Key Officials for Research given their leadership and supervisory responsibilities. ICOIs are of concern when Institutional Interests create the potential to compromise, or reasonably appear to compromise, Allina Health Research or Sponsored Programs.

C. Written Disclosure Requirements

1. Investigator Interest Disclosures. All Investigators who apply for federal funding or submit an application to the IRB must disclose the information, interests, and roles required on the Interest Disclosure Form, including all Financial Interests and Non-financial Interests held personally, or by their spouse and dependent children. Interest disclosures must be made at the following times:
 - prior to the submission of a proposal for federal funding;
 - prior to the approval of a research protocol by the IRB;
 - annually after an initial submission has been made, so long as the Investigator has an active research or Federal Project at Allina Health;
 - within thirty (30) days of discovery or acquisition (e.g., through purchase, marriage, or inheritance) of Significant Financial Interests or Significant Non-financial Interests; and
 - as otherwise requested by Research Compliance;

2. Investigator Travel Disclosures. Investigators also must disclose the occurrence of any reimbursed or sponsored travel (including all disclosures required by the COI Smart Interest Disclosure Form by the Investigator or the Investigator's spouse or dependent children related to the Investigator's Institutional Responsibilities). Disclosures must be submitted within ten (10) business days of returning from the travel, and must provide all information required by the Interest Disclosure Form, including, but not limited to, the following information about the travel:
 - purpose of the trip;
 - destination;
 - duration; and
 - identity of the sponsor / organizer.

Investigators also must disclose the occurrence of any reimbursed or sponsored travel, including all disclosures required by the COI Smart Interest Disclosure Form (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their Institutional Responsibilities; provided, however, this disclosure requirement *does*

not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

3. IRB or Research COI Committee Member Disclosures. Individuals serving on Allina Health's Institutional Review Board (IRB) or the Research COI Committee must disclose their Financial and Non-financial interests by completing an Interest Disclosure Form upon appointment and annually thereafter.
4. Disclosure and Identification of Institutional Interests. Institutional Interests held by Key Officials for Research are disclosed pursuant to [Section IV: Written Disclosure and Conflict Management Obligations](#) of this Policy. Interests held by Allina Health, including royalties, technology transfers and patents, philanthropic gifts to Allina Health, Allina Health investments, and Allina Health's vendors and strategic partners will be identified by specific departments within the organization and reported by those departments to Research Compliance. Research Compliance will maintain a list of all entities in which Allina Health has an Institutional Interest.

D. Review of Disclosed Interests and Conflict of Interest Determinations.

1. Review of Disclosed Interests. All disclosed interests will be reviewed by the Designated Reviewer or their designee. The review of individual interests will include a determination of whether the disclosed interests constitute a Significant Financial Interest or a Significant Non-financial Interest.
2. Review of Significant Financial Interests and Significant Non-financial Interests. The Designated Reviewer will review the Significant Financial Interests and Significant Non-financial Interests to determine if these interests present Conflicts of Interest related to the research or Federal Project. Specifically, the Designated Reviewer will determine whether these Interests:
 - Are related to the research or Federal Project (i.e., could the interest be affected by the research or Federal Project or is the interest in an entity whose financial interest could be affected by the research or Federal Project?); and
 - Are a Conflict of Interest (i.e., could the interest directly and significantly affect the design, conduct or reporting of the research or Federal Project?).

If the Designated Reviewer determines that the interests are related to the research or Federal Project and constitutes a conflict of interest (i.e., both questions above are answered "yes"), the Research COI Committee will manage the Research COI according to [Section E: Management of Research & Sponsored Program COI](#) (below). The Research COI Committee also may, in its discretion, manage a disclosed interest that does not constitute a Significant Financial Interest or a Significant Non-financial Interest related to the research or a Federal Project, or is not a Research COI.

3. Financial Interest Disclosures Not Reviewed in a Timely Manner. The following applies only to research or Federal Projects funded by the Public Health Service. If Research Compliance determines a Significant Financial Interest was not reviewed in a timely manner the Research COI Committee shall, within sixty (60) days of identifying the Significant Financial Interest, review to determine whether the Interest (1) is related to the research or Federal Project, and (2) constitute a Financial COI.

If the Research COI Committee determines that the Interest is related to the research or Federal Project and constitutes a conflict of interest the Research COI Committee shall:

- Implement, on at least an interim basis, a management plan that specifies the actions that have been, and will be, taken to manage the Financial COI; and
 - Complete, within one hundred twenty (120) days of a determination by Research Compliance of non-compliance, a retrospective review of the Investigator's activities and the research or PHS-funded project consistent with the requirements in 42CFR50.605.
4. Review of Travel Disclosures. All travel disclosures will be administratively reviewed.
 5. Review of Institutional Interests. Research Compliance will review all Allina Health Research together with the list of Institutional Interests to identify any Institutional Interests that:
 - Are related to the research (i.e., could the interest be affected by the research or is the interest in an entity whose financial interest could be affected by the research?); and
 - Constitute a potential ICOI.

If a potential ICOI affecting Allina Health Research is identified, the Research COI Committee will review the ICOI and determine appropriate management.

E. Management of Research Conflicts of Interest

1. Research COI Committee Determinations. The Research COI Committee shall determine the appropriate response to manage an identified COI, which may include the following:
 - a. the research or Federal Project may not proceed because of the COI, in which case the COI must be eliminated through divestiture of the Significant Financial Interest, severance of the Significant Non-financial Interest relationship causing the conflict, or other action specified by the Research COI Committee; or
 - b. the research or Federal Project may proceed if the COI is managed in accordance with the plan approved by the Research COI Committee; or
 - c. the Investigator must not participate in the research or Federal Project.

The Research COI also may, in its discretion, manage a disclosed interest that does not constitute a Significant Financial Interest or a Significant Non-financial Interest related to the research or a Federal Project, or is not a COI, by imposing administrative requirements to manage the perceived, potential or actual conflict.

2. IRB Notification of Research COI Committee Determination. If the research or Federal Project is subject to the jurisdiction of an IRB, the Research COI Committee determination shall be provided to the responsible IRB. The IRB may impose further management or restrictions.
3. Greater than Minimal Risk Research. Certain Financial Interests are presumed to be prohibited for Investigators involved in greater than minimal risk research, unless the Research COI Committee finds compelling justification for permitting an Investigator to simultaneously hold the financial interest while participating in the research.

Therefore, the follow requirements apply to Investigators related to the conduct of greater than minimal risk research:

- a. Investigators who have a financial interest in the sponsor (or company that makes the test article) that exceeds the financial interest thresholds identified by the Research COI Committee must identify compelling circumstances to justify allowing the Investigator to participate in the research study; and
 - b. If the Research COI Committee determines that compelling circumstances justify allowing the Investigator to participate in the research, the Investigator will be permitted to participate in the research study subject to any management imposed by the Research COI Committee and/or other institutional oversight (e.g., IRB).
4. PHS-funded Research or Projects. Prior to expenditure of any PHS funds under an award, Research Administration will assure that any identified Financial Conflict of Interest has been managed, reduced or eliminated in accordance with Section 50.604(g)(c) and reported as required by Section G: Reporting & Public Access (below). Significant Financial Conflicts that are subsequently identified and determined to be a conflict of interest will be managed, reduced, or eliminated, at least on an interim basis, within sixty (60) days of that identification and will be reported as required by [Section G: Reporting & Public Access](#) (below).
 5. Undisclosed Interests and Clinical Trials. If the Department of Health and Human Services determines that an NIH-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a conflict of interest that was not managed or reported as required by the applicable regulation, Allina Health requires the Investigator(s) involved in the research to disclose the conflict of interest in each public presentation of the results of the research and to request an addendum that discloses the conflict of interest in previously published presentations.
 6. IRB and Research COI Committee Member Conflict Management. The respective Committee Chairperson is responsible for determining at the beginning of each duly-convened committee meeting whether the attending members may have a conflict of interest. If an attending member is determined to have a conflict of interest, the following Conflict of Interest management measures apply:
 - IRB and Research COI Committee members generally must be recused from review of any project in which they have a conflict of interest;
 - A member who has unique expertise or can provide the information to assist members in their review, may provide such information to the members; and
 - The member must not, in any instance, vote or otherwise participate in the approval or evaluation process of the research or Federal Project.
 7. Management of potential ICOI. The Research COI Committee shall determine the appropriate response to manage an identified potential ICOI. Management strategies implemented by the Research COI Committee may include:
 - Recusal;
 - Designation of individual to whom concerns can be raised;
 - Disclosure to the IRB, research participants, study team, other sites, or journals and conference organizers;

- Divestiture; and/or
- Exclusion of royalty payments for sales at Allina Health from Allina Health's licensing arrangements.

If the research is subject to the jurisdiction of an Institutional Review Board (IRB), the Research COI Committee determination shall be provided to the IRB and the IRB may impose further management or restrictions.

F. Subrecipient COI Requirements. When carrying out PHS-funded research or Federal Projects through a subrecipient, Allina Health must take reasonable steps to ensure that any subrecipient complies with federal regulations by:

1. Incorporating, as part of a written agreement with the subrecipient, terms that establish whether this Policy or the subrecipient Conflict of Interest policy will apply to the subrecipient's Investigators;
2. Providing Financial Conflict of Interest reports to the PHS Awarding Component identifying all Financial Conflicts of Interest of all subrecipient Investigators prior to the expenditure of PHS funds and within sixty (60) days for any subsequently-identified Financial Conflict of Interest; and
3. If a Financial Conflict of Interest is identified for a subrecipient Investigator who must comply this Policy, Allina Health will monitor compliance with the required management plan on an ongoing basis until completion of the PHS-funded research or Federal Project.

G. Reporting and Public Access.

1. Reporting to Public Health Service (PHS) and Other Governmental Agencies
 - a. Allina Health will submit reports to governmental agencies as required by the Awarding Component(s).
 - b. If the research or Federal Project is funded by the PHS or another federal funding source, that agency will be notified of a Financial Conflict of Interest (FCOI) as follows:
 - i. Prior to expenditure of any PHS funds under an award, Allina Health will submit an initial report to the PHS Awarding Component identifying all identified Financial Conflicts of Interest;
 - ii. If Allina Health identifies any Significant Financial Interest as a conflict subsequent to Allina Health's initial report to PHS, Allina Health will report the Significant Financial Interest to PHS within 60 days of identification;
 - iii. For any Financial Conflict of Interest previously reported by Allina Health related to an ongoing PHS-funded research project, Allina Health shall provide to the PHS Awarding Component an annual Financial Conflict of Interest report that addresses:
 - the status of the Financial Conflict of Interest, including specifically whether it is still being managed or explain why it no longer exists; and
 - any changes to the Financial Conflict of Interest management plan for the duration of the PHS-funded research project.

Allina Health will provide the annual Financial Conflict of Interest reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS/NIH Awarding Component.

2. Public Access for PHS-Funded Research. Prior to expenditure of any funds under PHS-funded research, Allina Health, in compliance with federal regulations, must ensure public accessibility of information concerning senior/key personnel who have any Significant Financial Interest determined to be a Financial Conflict of Interest. This information will be made publicly accessible as follows:
 - a. Publicly accessible information will include:
 - i. Investigator's name;
 - ii. Investigator's title and role with respect to the research project;
 - iii. Title of the research project;
 - iv. Name of entity in which the SFI is held;
 - v. Nature of the significant financial interest; and
 - vi. Approximate dollar amount, in one of the following categories:
 - \$0 - \$4,999
 - \$5,000 - \$9,999
 - \$10,000 - \$19,999
 - Amounts between \$20,000 - \$100,000 by increments of \$20,000
 - Amounts above \$100,000 by increments of \$50,000; or
 - Statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.
 - b. Requests for information must be submitted in writing to Allina Health's Research Compliance division of the Compliance Department at researchcompliance@allina.com and must specify the name of the senior/key personnel and the name or number of the PHS-funded grant.
 - c. Allina Health Research Compliance will respond to written requests received by it within five (5) working days of receipt.

H. Research COI Training. Investigators must complete conflict of interest training by successfully completing the CITI COI training module as follows:

1. Prior to engaging in any research or Federal Project at Allina Health; and
2. Investigators must renew this training:
 - at minimum, every four (4) years;
 - immediately when:
 - Allina Health revises its policies and/or procedures regarding financial conflicts of interest in any manner that affects the requirements of the Investigators;
 - An Investigator is new to Allina Health; or
 - Allina Health finds that an Investigator is not in compliance with this Policy or a management plan; and
3. At other times, when required by the Allina Health IRB and/or Allina Health.

Exceptions to the CITI COI training requirement may be granted if an Investigator has completed training determined to be sufficient by Allina Health Research Compliance.

IRB and Research COI Committee members must complete conflicts of interest training by successfully completing the CITI COI training module at the time they first become a committee member and thereafter as required by Research Compliance.

Other training may be required and/or conducted by Allina Health Research Compliance division of the Compliance Department.

- I. **Records Management.** Allina Health must maintain records relating to all disclosed interests and the Allina Health's review of, and response to, such disclosures (whether or not a disclosure resulted in a determination of a COI), and all actions under Allina Health's policy or retrospective review, if applicable, for at least three (3) years from the date of final payment or, where applicable, for the time periods specified in 48 CFR Part 4, Subpart 47 (four (4) years) or Allina Health's Retention Policy, whichever is longer.
- J. **Sanctions.** Failure to file a completed disclosure form for each PHS-funded project or to update this information annually and within thirty (30) days of any change in the status of the disclosure, as required by this policy, may be grounds for termination of the award. Further sanctions also may apply.

VII. Program Structure & Administration

- A. **Policy Posting and Updates.** Allina Health will electronically post this Policy and will make this Policy available to all Covered Individuals upon request.

- B. **Program Structure and Oversight.**

The ACC has delegated responsibility for establishing, administering and monitoring a program for the identification, evaluation and management of Conflicts of Interest and Conflicts of Commitment that may arise in conducting the affairs of Allina Health, and which have the potential to affect have the potential to interfere with individuals' exercise of independent judgment in Allina Health's best interest and affect the reputation of Allina Health. Specifically:

- EROC is responsible for oversight of the establishment, administration, and monitoring of the program.
- The Office of OICM is responsible for:
 - Implementation of this Policy and any related policies, procedures, tools, forms, and guidelines, and for monitoring and enforcing compliance with it.
 - Administering, or overseeing administration by appropriate designees, the following elements of conflicts oversight:
 1. Annual Written Interest Disclosure Process for Covered Individuals;
 2. Requests for Approval/Renewal of Outside Professional Activities;
 3. Conflict of Interest Identification, Assessment, and Management.
 - Developing, in consultation with the General Counsel, Chief Compliance Officer and Human Resources, measures to identify trends and areas of potential risk related to Third Party Relationships, and reporting on these measures periodically to the General Counsel and Chief Compliance Officer

who will be responsible for reporting and making any appropriate recommendations to the EROC and ACC.

- The Office of OICM, and Chief Compliance Officer:
 - may delegate or assign responsibilities for identifying, assessing, and managing Conflicts of Interest or Conflicts of Commitment that arise, and for review, approval decisions and management of Outside Professional Activities, and any other responsibilities or activities as they determine is necessary to accomplish effective implementation of this Policy;
 - may retain independent advisors or experts as deemed necessary to assist in making their determinations and decisions;
 - will review this Policy every three years or more frequently if indicated, and recommend for approval any changes as they consider necessary and appropriate;
 - may develop and recommend for approval policies, procedures, guidelines, and similar materials as needed to fully address Outside Relationships as contemplated by and consistent with this Policy; and
 - may make nonmaterial changes to this policy, with ECOC endorsement, as needed to support implementation of the OICM consistent with the objectives of the ACC.
- EROC or a subcommittee thereof comprised of at least the Chief Compliance Officer, General Counsel and one other member of EROC shall be responsible for review and decisions for:
 1. Conflict Management Plans involving cross-disciplinary assessment and management;
 2. Any Conflict of Interest requiring complex conflict management; and
 3. Any other Conflict of Interest review identified by the General Counsel or Chief Compliance officer as complex or high risk.
- A Research Conflicts of Interest Committee shall address Conflicts of Interest that arise in the in the conduct of research and sponsored projects at Allina Health, as described in this Policy.

The ACC may, in its discretion, undertake review or direct the conflict management plan for any particular individual or circumstances in which it determines. The ACC is further available as determined appropriate or necessary by the General Counsel, Chief Compliance Officer, or EROC for review and direction on conflict evaluation and management for individual cases.

C. Joint Arrangement COI Requirements. When Allina Health participates in an arrangement that involves joint ownership, control or management responsibilities, Allina Health will take reasonable steps to assure that a Conflict of Interest program is in place to manage Conflicts of Interest that arise related to the joint arrangement by doing the following:

1. the Chief Compliance Officer, in consultation with the General Counsel, shall determine whether the requirements of this Policy or an alternative conflict of interest policy will apply to the activities of the joint arrangement; and
2. establishing and documenting whether this Policy or another Conflict of Interest policy will apply to the arrangement and which party to the arrangement is responsible for administering the Conflict of Interest program.

D. Policy Exceptions. The Chief Compliance Officer and General Counsel may, upon mutual agreement, except other arrangements or Covered Individuals from this Policy, or certain identified requirements of this Policy. Any exceptions approved under the process described in this Section will be documented and maintained by the Compliance Office. The Chief Compliance Officer will prepare an annual report to the ACC of any exceptions to the Policy.

E. Responding to Reports of Concerns.

Covered Individuals are encouraged to report situations in which they believe an Outside Interest may not have been properly disclosed, a conflict management plan is potentially not being followed or is not sufficient to manage a Conflict of Interest, or other circumstances which may be a violation of this Policy. Reports may be made to the person's manager or supervisor, the Office of OICM, or the Chief Compliance Officer, or the Chair of the ACC, as appropriate for the circumstances and roles of the individuals involved in the report. The recipient of the report will review the concern and follow up as appropriate to resolve the concern.

The Office of OICM, the General Counsel, the Chief Compliance Officer or a Covered Individual's manager or supervisor may, after inquiry that it deems appropriate for the circumstances, recommend and/or impose discipline or sanctions on any Covered Individual who has violated the requirements of this Policy (e.g., removal of a director or officer from their position, termination of employment).

F. Records Management and Confidentiality.

Records of disclosures and conflict management plans will be maintained as determined appropriate by the Office of OICM.

Information disclosed by Covered Individuals during the Outside Interest disclosure and review process will be disclosed as necessary to implement this Policy, to conduct the governance or other management obligations of Allina Health, or as otherwise required by law.

Research COI Records will be maintained as described in [Section VI: Research & Sponsored Projects Disclosures and Conflict Management](#).

FORMS:

N/A

FAQs: N/A

REFERENCES:

RELATED REGULATION AND LAWS:

[42 U.S. Code § 1395nn](#), and regulations promulgated thereunder. (The “Stark” law prohibits certain remuneration to physicians.)

[42 U.S. Code § 1320a-7b](#), and regulations promulgated thereunder. (The “Anti-Kickback Act” prohibits certain remuneration intended to influence referrals.)

[42 U.S. Code § 1320a-7a](#), and regulations promulgated there under. (The Civil Monetary Penalty law prohibits certain payments with intent to influence choice of medical decisions.)

[Internal Revenue Code § 501\(c\)\(3\)](#), and regulations and guidance promulgated by the Internal Revenue Service. (Tax-exempt entities may not confer “private benefit” on non-exempt entities or persons.)

[Section 6004 of the Patient Protection and Affordable Care Act \(P.L. 111-148\)](#) (requires drug manufacturers to report to the federal government the name and address of practitioners who requested and received drug samples in the previous calendar year.)

[Section 6002 of the Patient Protection and Affordable Care Act \(P.L. 111-148\)](#) (requires drug and device manufacturers to report, beginning March 31, 2013, and on an annual basis thereafter, all payments or other transfers of value to physicians.)

Allina Health IP Disclosure Form: <https://akn.allinahealth.org/innovation/Pages/default.aspx>.

Alternate Search Terms: Conflict of Interest; Third Party Relationships; COI; Ethical Relationships; Industry; Vendor Relationship; Professional Activities; Outside Activity; Expert Review; Gift; Interest Disclosure

RELATED POLICIES/DOCUMENTS:

Name of Policy	Content ID	Business Unit where Originated
Travel, Entertainment, and other Business Expense Reimbursement.	SYS-FIN-FCouncil-105-02	System Office
Code of Conduct	SYS-COMPLIANCE-CODE	System Office
Intellectual Property	SYS-ADMIN-AHID-001	System Office
New Product Review: Supply and Technology Committee Policy	SYS-SC-ASCM-009	System Office
Arrangements with Disqualified Persons	SYS-ADMIN-Legal-#004	System Office
Compliance Program Policy	SYS-COMPLIANCE-900	System Office

POLICIES/DOCUMENTS REPLACING:

Name of Policy	Content ID	Business Unit where Originated
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Ethical Relationships with Industry for Providers	402-01.43	System Office
Ethical Relationships with Industry for Workforce	402-01.45	System Office
Conflict of Interest	100-4 (CONFLICT_OF_INTEREST_POLICY)	System Office
Outside Professional Activities		System Office
Research and Sponsored Programs Conflicts of Interest	SYS-ADMIN-RA-004	System Office
Institutional Conflicts of Interest for Research	SYS-ADMIN-RA-009	System Office
Supply Advisory Groups – Conflict of Interest	SYS-ADMIN-SC-ASCM-005	System Office

DEFINITIONS

ACCME (Accreditation Council for Continuing Medical Education) Standards: Program content must (1) be prepared by the Covered Individual without any approval or conditions by the Outside Party, except to the extent that specific content or language is required by law, regulation, or a regulatory agency (e.g., FDA requirements regarding marketing), (2) designed to provide evidence-based medical information; (3) reflect a balanced assessment of medical information; and (4) not be focused on a particular Outside Party's product or service; and disclose all Financial Interests.

Advanced Practice Professional (“APP”): An individual other than a physician, dentist, or podiatrist who is a licensed or certified health professional, including but not limited to an Acupuncturist, Audiologist, Speech Language Pathologist, Clinical Nurse Specialist, Certified Nurse Midwife, Chiropractor, Licensed Therapist, Nurse Practitioner, Optometrist, Physician Assistant, Psychologist, and any other person otherwise qualified by training and/or experience to be granted privileges to practice as an APP at Allina Health.

Ad Hoc Disclosures. COI disclosures on the request of a supervisor or manager with the approval of the OICM Office

Allina Health: Allina Health System and entities that directly or indirectly control or are controlled by or are under common control with Allina Health System.

Allina Health Research: Research at Allina Health and/or research that is subject to the review of the Allina Health IRB or an external IRB requiring Allina Health to enter into an Inter-Institutional Authorization Agreement with such external IRB.

Audit & Compliance Committee (ACC): The Audit and Compliance Committee of the Allina Health System Board.

Board Committee: A committee appointed by a board that is permitted pursuant to the applicable governing documents and applicable state law to act on behalf of the board.

Board Members: Board Members and Board Committee Members of Allina Health System and Allina Health Foundation Boards, and the Board Members of legal entities in which Allina Health owns a majority interest, has majority membership on the entity board or manages the entity.

Compensation: Any payment or other transfer of value provided or received in exchange for the performance of services, including (a) cash and non-cash compensation including salary, fees, consulting fees, bonuses, honoraria, severance payments, ownership interests, intellectual property rights or a grant, paid authorship, and deferred and noncash compensation; and (b) all other compensatory benefits, including medical, dental, life and professional liability insurance, expense allowance, or other economic benefits provided in exchange for services.

Compensation Interest: The receipt or expectation to receive Compensation as an employee, independent contractor, consultant, or any other capacity from an entity or individual.

Conflict Management Plan (CMP): A plan developed, approved, monitored, and enforced for the purpose of managing a Conflict of Interest or potential Conflict of Interest.

Conflict of Commitment: A set of circumstances in which an outside activity or relationship may deter an individual from devoting an appropriate amount of time, energy, creativity, or other personal resources to the individual's Allina Health responsibilities.

Conflict of Interest: A set of circumstances in which a Financial Interest or Non-financial Interest, or any other professional or personal relationship or interest held by an individual or an individual's Family Member has the potential to compromise or bias the judgment or objectivity of the individual's decisions or actions, or create the appearance of such compromise or bias.

Covered Employees: Key Individuals who, are employed by Allina Health, in a role with a .5 or greater FTE and other individuals as may be determined by Allina Health's Office of OICM, General Counsel, or Chief Compliance Officer.

Covered Individuals: Individuals who based on their relationship with responsibilities for or obligations to Allina Health are subject to this policy and are required to comply with one or more of the requirements as specified in this policy, including all Allina Health employees, Board Members, Leaders, Providers, Vendor Selection & Procurement Personnel, Key Officials for Research, Research & Sponsored Program Personnel, and other individuals as may be determined by Allina Health's Office of OICM, General Counsel, or Chief Compliance Officer.

Designated Reviewer: Individual assigned the responsibility for review and assessment of disclosed interests and determinations about appropriate management of identified Conflicts of Interest.

Disqualified Person. Any one or more of the following shall be considered a Disqualified Person with respect to a Covered Transaction:

- a. Any person who is or has been in a position to exercise Substantial Influence over the affairs of an Allina Health entity at any time during the five year period ending on the date of the applicable Covered Transaction;
- b. Any Family Member of such person; and

- c. Any corporation, partnership, trust or estate of which such person (or their Family Member) owns or holds more than 35% of the combined voting power, profits, interest or beneficial interest, respectively at any time during the five year period prior to the applicable Covered Transaction.

The capitalized terms within this definition are defined as set forth in the [Arrangements with Disqualified Persons policy](#).

Employee: Any person who has an employment relationship with Allina Health, regardless of the percentage or form of that employment relationship.

Equity Interest: Any type of ownership interest in any entity, such as stock, stock options, or other investment interest.

Expenses: The reasonable and actual costs of registration, lodging, travel, and related costs. Expenses also includes the provision of reasonable meals, food, or beverages during or incidental to a permitted event.

Fair Market Value (“FMV”):

- FMV for Services: within the range of Compensation that would be paid by like organizations for similar services performed by like individuals as the result of bona fide bargaining between well-informed parties who are not otherwise in a position to generate business for each other at the time of the services arrangement.
- FMV for property or the right to use property: the price at which property or the right to use property would change hands between a willing buyer and a willing seller, neither being under any compulsion to buy, sell or transfer property or the right to use property, and both having reasonable knowledge of relevant facts.

Family Member: An individual who is related to a Covered Individual in any of the relationships listed below. “Parents”, “siblings” and “children” include all individuals related by blood, adoption, and marriage/step relationships. “Spouse” includes a domestic partner.

- great-grandparent
- grandparent
- parent (and their spouses)
- sibling (and their spouses)
- child (and their spouses)
- grandchildren (and their spouses)
- great-grandchildren (and their spouses)
- spouse
- spouse's parent (and their spouses)
- spouse's sibling (and their spouses)
- spouse's grandchildren (and their spouses)
- a person who is a member of the Covered Individual's household for tax or insurance purposes.

Federal Project: Federal financial assistance and Federal cost-reimbursement contracts that Allina Health receives directly from Federal awarding agencies or indirectly from pass-through entities. It does not include procurement contracts, under grants or contracts, used to buy goods or services from vendors.

Fiduciary Relationship: A relationship with an Outside Party that involves a fiduciary duty to the Outside Party, such as acting as an Officer, Board Member, committee member, or member of a scientific review panel.

Financial Conflict of Interest (FCOI): A Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of PHS-funded research or a Federal Project.

Financial Interest: An actual or anticipated/planned interest or relationship that are any of the following:

- (a) "Equity Interest"; or
- (b) a Compensation Interest; or
- (c) Gifts.

Provided, however, Covered Individuals generally will not be expected to identify the following as Financial Interests unless specifically requested by Allina Health:

- compensation paid by Allina Health to a Covered Individual who is currently employed or otherwise appointed by Allina Health (including agreements to share in compensation for Intellectual Property rights assigned to Allina Health);
- income from seminars, lectures, or teaching engagements sponsored by or service on advisory committees or review panels for a Federal, state, or local government agency, and Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or
- income from and Equity Interests in diversified investment vehicles, (such as mutual funds, pensions and other retirement accounts) and as long as the Covered Individual does not directly control the investment decisions made by or directly influence the performance of the interests held in these vehicles.

Gift: Any gratuity, favor, discount, entertainment, hospitality, loan, forbearance, goods, services, training, transportation, lodging, meals, or other item (in cash or in kind) that provides a personal benefit to the recipient. It does not include an award given for merit, excellence in a certain field of expertise, or a particular accomplishment. It also does not include a gift made to Allina Health or its Foundation for Allina Health purposes.

Health Industry Entity: Person or entity (or an entity controlled by, or under common control with such a person or entity), that manufactures, distributes, or otherwise provides a health-related product or service that is or may be recommended, prescribed, purchased or used by Allina Health related to the delivery of patient care or may be provided to a patient of Allina Health.

- Examples include, but are not limited to, persons or entities that market or sell pharmaceuticals, medical devices, medical equipment, implants, medical supplies, health-related technology hardware and software, biotechnology, medical

publications, health care consulting services, health-related startups, and any Medical Education and Communication Company.

Immediate Family Member: Individuals who are related to a Covered Individual as a spouse, domestic partner, child, parent or sibling. “Parents”, “siblings” and “children” include all individuals related by blood, adoption and marriage/step relationships.

Institution: Allina Health.

Institutional Conflict of Interests (ICOI) in Research: An Institutional Interest that might affect or reasonably appear to affect the conduct, review, or oversight of human subject research.

Institutional Interest: A Financial Interests held by:

- Key Officials, or the spouse or dependent children of Key Officials, or
- Allina Health including royalties, technology transfers and patents, philanthropic gifts to Allina Health, Allina Health investments, significant purchasing relationships with Allina Health, and other institutional relationships as identified by the Research COI Committee. The Research COI Committee may establish thresholds below which these financial interests are not considered Institutional Interests for purposes of this Policy.

Institutional Responsibilities: Research, education, clinical practice, service on institutional committees and panels, administrative activities and other professional activities.

Interest: A Financial Interest or Non-financial Interest.

Interest Disclosure Form: (*f.k.a.* Conflict of Interest Disclosure Form) The form used by Covered Individuals to document and disclose to Allina Health information about interests and relationships that are relevant to identification, assessment and management of potential Conflicts of Interest or Conflicts of Commitment.

Investigator: The Project Director, Principal Investigator, sub-investigators, study coordinators, key scientific personnel and any other person who is responsible for the design, conduct, or reporting of research or a Federal Project. It also generally includes any individuals listed on a grant budget, research protocol or IRB application. In some cases it includes other personnel (such as technologists or research fellows) if these personnel are responsible for the design, conduct or reporting of the research or Federal Project.

Key Individuals: Leaders, Providers who are either employed by or hold a direct contract with Allina, Vendor Selection & Procurement Personnel and other individuals as may be determined by Allina Health’s Office of OICM, General Counsel, or Chief Compliance Officer.

Key Officials for Research: Members of the Allina Health System Board, members of the Allina Health Executive Leadership Team, the Institutional Official for Research, the Vice President of Research, and any other employees identified by the Research Conflicts of Interest Committee.

Leader: Any individual that holds the title of Vice President or above and any other individual who holds a position of trust at Allina Health, any person who has a contractual arrangement to provide leadership services to Allina Health (including, but not limited to, Medical Directors).

Non-financial Interest: An existing or anticipated/planned non-economic relationship, role, involvement with or interest in an individual or entity other than Allina Health. The interest may be formal or informal and includes, but is not limited to a non-compensated fiduciary position (such as a member of the board or a board committee) and relationships of a non-business nature (such as family or friendships).

Non-industry Vendor: A person or entity other than a Health Industry Entity that manufactures, distributes, or otherwise provides a product or service that is or may be recommended, prescribed, purchased, or used by Allina Health or may be provided to a patient of Allina Health.

Outside Interest: A Financial Interest or Non-financial Interest, other than interests in Allina Health.

Outside Party: Any individual or corporation, foundation or other entity or organization, including any governmental entity, which is not an Allina Health entity.

Outside Professional Activities: The provision of Professional Services to Outside Parties that are *not* part of the duties assigned to an individual as an employee of Allina Health. Outside Professional Activities includes both Outside Volunteer Activities and other professional activities for which the individual may receive compensation from an Outside Party.

Outside Professional Income: Compensation received by an individual relating to an Outside Professional Activity.

Outside Volunteer Activity: An Outside Professional Activity that is completely volunteer and for which the individual receives no Compensation.

PHS Rule: The regulation that applies to federal funding by certain federal agencies that the Department of Health and Human Services categorizes as the Public Health Service (PHS), such as National Institutes of Health or the Centers for Disease Control. The PHS Rules are comprised of the following two regulations: [Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought \(42 C.F.R. Part 50, Subpart F\)](#) and [Responsible Prospective Contractors \(45 C.F.R. Part 94\)](#).

Professional Services: Services which relate to the same job responsibilities, activities, expertise, training, qualifications, or subject matter as a Covered Employee uses or applies in performing work for Allina Health.

Providers: Physicians, dentists, podiatrists, and Advanced Practice Professionals who are (1) employed by Allina Health; or (2) credentialed as a member of The [Allina Health Medical Staff](#); or (3) or other providers as designated by the General Counsel or Chief Compliance Officer.

Research Conflict of Interest (Research COI): A Significant Financial Interest or a Significant Non-financial Interest that could directly and significantly affect the design, conduct, or reporting of research or a Federal Project.

Research Conflicts of Interest Committee (Research COI Committee): Allina Health's Research Conflicts of Interest Committee.

Research & Sponsored Programs Personnel: Includes the following individuals involved in research or sponsored programs:

- All employed and non-employed personnel who are responsible for the design, conduct, or reporting of research at Allina Health and/or research that is subject to the review of the Allina Health IRB or an external IRB requiring Allina Health to enter into an Inter-Institutional Authorization Agreement with the external IRB. This includes all research regardless of if it is publicly or privately funded, Humanitarian Use Device (HUD) submissions and all other expanded access submissions.
- Employees responsible for the design, conduct, or reporting of a Federal Project.
- Non-employed personnel who are involved in the design, conduct, or reporting of research or a PHS-funded Federal Project when neither the individual nor the individual's employer has a COI policy that meets the requirements set forth in the Public Health Service's Rule (42 CFR Part 50, Subpart F);
- Members of Allina Health's Institutional Review Board (IRB);
- Members of Allina Health's Research Conflicts of Interest Committee (Research COI Committee); and
- Other Allina Health personnel designated by the Research COI Committee.

Service(s): The supply or performance by an individual of an activity or function to or for another individual or entity.

Significant Financial Interest (SFI): A [Financial Interest](#) of the Investigator, or the Investigator's spouse or dependent children, that reasonably appears to be related to an Investigator's Institutional Responsibilities and includes one or more of the following:

- a. Intellectual Property rights and interests, upon receipt of income related to such rights and interests;
- b. With regard to any non-publicly traded entity, the value of any compensation received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator, Investigator's spouse or dependent children hold an equity interest; or
- c. With regard to any publicly traded entity, the value of any [Compensation](#) received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000, as determined through reference to public prices or other reasonable measures of fair market value.

Significant Non-financial Interest: With respect to research, a fiduciary relationship (e.g. board member), an advisory relationship (e.g., Scientific Advisory Board member), or instances when an Investigator is the inventor of a product licensed to the company.

Vendor: Entity or individual that manufactures, distributes, or otherwise provides a product or service that is or may be recommended, prescribed, purchased or used by Allina Health or may be provided to a patient of Allina Health. Vendors may be a Health Industry Entity or may be other Non-Industry Entities that provide such products or services.

Vendor Selection & Procurement Personnel: Individuals who have procurement responsibility or who are responsible for selection of a Vendor to provide a product or service to Allina Health, and individuals who have been identified as having the authority to effectively recommend or decide upon purchase or use of a product, service, or Vendor for Allina Health as part of a

procurement or vendor selection decision-making process (as identified by the Vice President of Supply Chain Management in consultation with the Office of OICM, General Counsel and/or Chief Compliance Officer). It also includes an individual who requests or is assigned to pursue use or procurement use in the care of patients or to provide to patients at Allina Health. (“Product Sponsor”, as defined in the [Allina Health New Product Review Policy](#)).

Vendor Selection & Procurement Participants: Individuals who are not identified as Procurement Personnel but who otherwise request or are asked or offer to, recommend, provide a professional opinion or decide upon purchase or use of product, service or vendor for Allina Health as part of a procurement or vendor selection decision-making process.

System-wide Policy

Appendix A: Covered Individuals and Applicable Requirements Grid

	General Requirements	Standards for Gifts & Interactions with Outside Parties	Written Disclosure Requirements	Outside Professional Activities	Research & Sponsored Program Requirements
All Covered Individuals	X				
All Employees	X	X			
Board Members	X		X		
Leaders – Employed	X	X	X	X*	
Leaders - Contracted	X	X	X		
Providers - Employed	X	X	X	X*	
Providers – PSA w/ billing	X	X	X		
Vendor Selection & Procurement Personnel – Employed	X	X	X	X*	
Vendor Selection & Procurement Personnel – Non-Employees	X	X	X		
Research & Sponsored Program Personnel	X				X
Key Officials for Research	X				X

*Employed .5 FTE or greater