

**Childhood Arthritis and Rheumatology Research Alliance (CARRA) Guidelines for
Management of Conflict of Interest and Conflict of Commitment for CARRA Leadership
“Conflict of Interest Guidelines”**

Part I. Purpose and Guiding Principles

The purpose of these conflict of interest guidelines is to protect the interests of **CARRA** when it is contemplating entering into a transaction or arrangement that might benefit the private interest of any CARRA leader (including members of the Steering Committee, Board of Directors, or principal investigators of projects potentially impacted by conflicts of interest or employee of CARRA) or might result in a possible excess benefit transaction. These guidelines are intended to supplement but not replace any applicable state and federal laws governing conflicts of interest applicable to nonprofit and charitable organizations.

The mission of CARRA is to *conduct collaborative research to prevent, treat and cure pediatric rheumatic diseases*. This mission requires that the organization and its members properly manage conflict of interest (COI) and conflict of commitment (COC) in order to avoid undue influence, or the appearance of undue influence, of external interests, including those of for-profit commercial entities.

However, interaction with industry is appropriate and indeed necessary for CARRA members and for the organization itself. A CARRA member’s research and other professional activities external to CARRA may properly involve collaboration with industry and/or with other professional organizations whose interests overlap those of CARRA. CARRA itself cannot pursue its mission without interaction with, and support by, industry. Similarly, the industry at-large has a legitimate need to work with experts in the pediatric rheumatology community in order to promote the optimal discovery, study, and utilization of therapies for the treatment of children with rheumatic diseases. In many cases, the interests of industry members align with those of CARRA, CARRA members, and our patients and their families.

To balance these competing demands, CARRA adopts guidelines to manage COI and COC based on three principles:

1. **Transparency** – Disclosure of the nature and extent of external interests allows others to assess the extent of potential influence on the activity of CARRA and its members.
2. **Proportionality** – Increased caution about COI/COC is appropriate in proportion to the extent of potential divergence of interest and the degree to which the conflicted CARRA leader is in a position to directly influence related CARRA activities.
3. **Seemliness** – The mission of CARRA requires that the organization and its leadership be seen to be above commercial influence. Therefore, particular restrictions upon permissible COI/COC may be appropriate for members whose leadership roles carry the symbolic authority of CARRA.

Application of these three principles defines three categories of conflict to inform how a leader’s specific external activity should be managed based on the leader’s role within CARRA and the relevant CARRA activity for which a decision is required.

- a. Category I – Types of COI/COC that must be avoided entirely.

- b. Category II – Types of COI/COC that require the conflicted party to recuse him/herself from discussions, votes or both (to be determined at time of recusal).
- c. Category III – Types of COI/COC that require the conflicted party only to disclose the conflict, without recusal from either discussions or votes.

The CARRA Board of Directors, based on recommendations from CARRA Ethics Committee and as endorsed by CARRA Steering Committee (see Section IV), may permit specific exceptions to the general rules outlined below, on a case-by-case basis, if such exceptions are found to be both important for the external professional activities of the leader and in the best interests of CARRA.

Part II. Definitions

1. **CARRA leader:** Members of the Steering Committee (including all elected leadership positions), Members of the Board of Directors, CARRA officers and employees
2. **Conflict of interest (COI)**—For the purpose of these guidelines, COI arises when two conditions are met:
 - a. A leaders’ activities outside of CARRA translate into the possibility of a Personal Benefit (as defined below) from his or her leadership role within CARRA.
 - i. A “Personal Benefit” consists of any interest a leader has, directly or indirectly, through business, investment, or family, in a certain transaction or arrangement, including:
 1. An ownership or investment interest in any entity with which CARRA has a transaction or arrangement;
 2. A Compensation Arrangement (as defined below) with CARRA or with any entity or individual with which CARRA has a transaction or arrangement; or
 3. A potential ownership or investment interest in, or Compensation Arrangement with, any entity or individual with which CARRA is negotiating a transaction or arrangement.
 - ii. A “Compensation Arrangement” includes any direct and indirect remuneration as well as gifts or favors that are not insubstantial.
 - b. It is determined that the benefit is not intrinsically aligned with the advancement of CARRA’s interests.

For example (for more details, see the attached “Financial Interest Disclosure for CARRA Leaders”), a COI results if a leader has a significant proprietary interest in a test, device or pharmaceutical agent where the individual receive a Personal benefit through CARRA’s use of such test, device or pharmaceutical agent in its activities. Interactions with industry as a consultant, speaker, or recipient of grants for education or research may also represent COI, because the opportunity to participate in these activities may reflect in part an effort by industry to secure contact and/or gain influence. By contrast, COI does not arise when a leader benefits from CARRA activities through receipt of salary or travel support for CARRA duties or academic advancement based on CARRA service, because it is likely that the incentives offered by these benefits will be determined to intrinsically align with CARRA’s interests.

A particular instance of COI may be of greater or lesser significance depending upon the nature of a leader’s work in CARRA. Significance varies with 1) the divergence between the external interest and CARRA’s interests; and 2) the degree to which the leader is in a position to influence CARRA decisions with respect to his/her external interest.

COI is not by itself an ethical concern. However, COI does impose upon the leader an ethical obligation to address the conflict in accordance with these guidelines. The process to evaluate COI and determination of whether a problematic COI exists shall be made as described in Part IV below.

3. Conflict of commitment (COC) –COC arises when a leader’s activity within an external organization potentially introduces competing priorities that could limit the ability or willingness of the leader to perform the full range of his or her CARRA duties.

- a. A COC is a related category to a COI arising when a leader also serves an external organization whose interests overlap, but do not intrinsically align with, those of CARRA, but where there is not necessarily the presence of a Personal Benefit to such leader.

A COC becomes problematic only to the extent that the priorities of the external organization(s) diverge from those of CARRA. In most cases, such divergence will not arise, and indeed CARRA interests may best be served by leaders who also participate actively in external organizations. The determination of whether a problematic COC exists shall be made as described in Part IV.

Part III. Specific Guidelines for Management of COI and COC

Restrictions on COI and COC increase as a CARRA leader assumes increased authority and responsibility within the CARRA leadership structure. For the purposes of these guidelines, the CARRA Registry and similar core CARRA programs are not considered industry-sponsored projects, and excluded from considerations of COI. These exceptions are reviewed periodically by the Ethics Committee.

The disclosure process and relevant forms are found in attached “Financial Interest Disclosure for CARRA Leaders”

1. All CARRA leaders should disclose interactions with industry or with competing organizations that bear potential relevance to CARRA activities (i.e. all interactions are at least Category III).
2. All CARRA leaders should avoid industry interactions that could be construed as personal gifts (Category I).
3. Leaders should recuse themselves from CARRA decision-making votes bearing on interaction with industry (Category II) where either:
 - a. The CARRA activity relates directly to a particular interaction with industry or personal commercial interest.
 - i. For example, a CARRA leader should recuse him/herself when decision-making concerns a trial design proposed by Company X where s/he consulted to Company X on the design, or a drug or test in which the leader holds intellectual property or other equity interest.
 - b. The leader has received >\$10,000 in direct personal payment from a company over the prior 12 months. Salary support directed through the leader’s primary employer (e.g. grant effort) is not considered direct personal payment.
4. CARRA leaders should avoid participation in Speakers’ Bureaus or similar industry-funded speaking engagement where the content of the talk serves to promote a single company’s product (Category I).
5. Non-Chair leaders of the Executive Committee (Finance Chair, Vice Chair, Immediate Past Chair) bear no formal restrictions on allowable interactions with industry distinct from those of

Steering Committee members who are not on the Executive Committee. This is in part to accommodate the long term (9 years) of the leadership commitment from Vice Chair through Immediate Past Chair. However, members of the Executive Committee are expected to consider their symbolic roles in the community as they evaluate which opportunities for interaction with industry are appropriate to pursue.

6. The Chair of CARRA has the greatest leadership authority within the organization, and serves an important symbolic role as the elected voice of the US and Canadian pediatric rheumatology research community. For these reasons it is expected that the Chair should avoid (Category I) interactions with industry that could raise concerns about undue commercial influence or suggest CARRA endorsement.
 - a. Interactions with the potential to raise such concerns include, but are not limited to:
 - i. Industry advisory board membership.
 - ii. Industry-arranged and -funded speaking engagements.
 - iii. Paid expert testimony in commercial litigation (not including malpractice suits).
 - iv. Mock FDA panels.
 - v. Paid industry DSMB membership.
 - b. However, given the extended term of the chair, interactions with industry consistent with the Chair's academic role are permissible with appropriate disclosure and, if needed, recusal. Requests for exceptions to the above recommendations may be reviewed on a case-by-case basis as described in Part IV. Ongoing interactions may also be approved with appropriate disclosure and, if needed, recusal. Examples of potentially allowable exceptions include:
 - i. Scientific collaborations with industry (including sharing data, samples and/or reagents; planning and executing clinical trials; investigator-initiated research including grant awards and research sponsorship).
 - ii. Consultation with industry on areas of established professional expertise (for example, clinical trial design, disease mechanisms).
 - iii. Receipt of industry funds to support the Chair's home division or institution that reflect usual and customary practice and are appropriately managed according to the policies of the home institution (for example, multi-industry sponsorship of educational programs or fellowship training).
 - iv. Commitments ongoing at the time that the Chair begins his or her term and that could be disruptive if discontinued, for example, chairmanship of the DSMB of an ongoing clinical trial. The Ethics Committee will advise the Steering Committee to help determine which ongoing commitments are compatible with the Chair position.
7. The Chair of the Board of Directors should adhere to the same COI guidelines as the elected Chair of CARRA.
8. With respect to COC, any CARRA leaders should avoid leadership positions of any other entity or program with substantially overlapping interests except as a designated CARRA representative. Positions of responsibility in another entity or program should be reviewed on a case-by-case basis as described in Part IV.
9. Any voting member of a governing board or committee who receives compensation from CARRA shall recuse him/herself from voting on matters pertaining to such member's compensation (Category II).

Part IV. Process for review and determination of COI and COC

1. Every CARRA leader will sign and submit an annual Conflict of Interest Disclosure (“Financial Interest Disclosure for CARRA Leaders”), affirming that s/he:
 - a. Has received a copy of the conflicts of interest guidelines and has the opportunity to disclose any/all conflicts.
 - b. Has read and understands the guidelines.
 - c. Has agreed to comply with the guidelines.
 - d. Understands CARRA is charitable and in order to maintain its federal tax exemption it must engage primarily in activities which accomplish one or more of its tax-exempt purposes.
2. Each CARRA leader will sign and submit an annual “Conflict of Commitment Disclosure for CARRA Leaders” via the attached disclosure form.
3. A CARRA Ethics Committee will be convened at least annually to review all leaders’ COI and COC.
4. Process to determine whether COI or COC exists:
 - a. At any point in this process, a leader who has disclosed and discussed a potential COI or COC, shall leave the committee or governing board meeting while the remaining board or committee members decide if a COI or COC exists.
 - b. During research committee deliberations regarding design of studies involving industry products, committee members should disclose any potential COI or COC. The member shall leave the committee meeting while the remaining committee members decide if a COI or COC exists and, if so, what the approach should be to manage the COI or COC if necessary.
 - c. Members of the External Advisory Council should disclose any potential COI or COC related to specific agenda topics. The potentially conflicted member shall leave the committee meeting while the remaining committee members decide if a COI or COC exists and, if so, what the approach should be to manage the COI or COC if necessary.
 - d. The CARRA Ethics Committee will evaluate potential COI and COC based on the following guidelines, while also taking into account Parts III and IV above:
 - i. The significance and magnitude of the divergence between the external interest and CARRA’s interests
 - ii. The degree to which the leader is in a position to influence CARRA decisions with respect to his or her external interest.
5. Process to manage potential COI and COC:
 - a. The CARRA Ethics Committee will make recommendations to the CARRA Steering Committee regarding management (potential transactions or arrangements as described in Part III) of significant COI and COC.
 - b. The CARRA Steering Committee will review and present final recommendations to the CARRA Board of Directors for final approval.
 - c. The minutes of each committee or board meeting regarding determination of COI or COC shall include the name of the conflicted leader, the nature of the conflict, any discussion related to the transaction or arrangement, alternatives to the proposed

transaction or arrangement, and a record of any votes taken in connection with the proceedings.

- d. Where a difference exists between the Ethics Committee and the Steering Committee, the disinterested members of the Board of Directors (BOD) will review and adjudicate, potentially including outside advice from other resources including the External Advisory Council.
 - e. If a more advantageous transaction or arrangement that would not give rise to a COI or COC, is not reasonably possible under the circumstances, the CARRA BOD shall determine by a majority vote of the disinterested directors whether the transaction or arrangement is in CARRA's best interest, for its own benefit, and whether it is fair and reasonable. Taking into account the foregoing, the Board of Directors shall make its decision whether CARRA shall enter into the transaction or arrangement.
6. Violations of the CARRA Guidelines for Management of COI and COC
- a. If the Steering Committee or the CARRA Board of Directors has reasonable cause to believe a leader has failed to disclose an actual or possible COI or COC, either entity shall inform the leader of the basis for such belief or afford the leader an opportunity to explain the alleged failure to disclose.
 - b. If, after hearing the leader's response and after making further investigation as warranted by the circumstances, the Steering Committee or Board of Directors determines the leader has failed to disclose an actual or possible COI or COC, the leader shall be subject to appropriate disciplinary and corrective action.

Part V: Periodic Reviews

To ensure CARRA operates in a manner consistent with charitable purposes and does not engage in activities that could jeopardize its tax-exempt status, periodic reviews shall be conducted. The periodic reviews shall, at a minimum, include the following subjects:

1. Whether compensation arrangements and benefits are reasonable, based on competent survey information and the result of arm's length bargaining, and
2. Whether partnerships, joint ventures, and arrangements with management organizations conform to CARRA's written policies, are properly recorded, reflect reasonable investment or payments for goods and services, further charitable purposes and do not result in inurement, impermissible private benefit or in an excess benefit transaction.

When conducting such periodic reviews, CARRA may, but need not, use outside advisors. If outside experts are used, their use shall not relieve the governing board of its responsibility for ensuring periodic reviews are conducted.

APPENDIX A

FINANCIAL INTEREST DISCLOSURE FOR CARRA

FORM INSTRUCTIONS

Who must submit this form?

All CARRA Leaders, defined as Members of the Steering Committee (including all elected leadership positions), Members of the Board of Directors, CARRA officers and employees, must submit this form, Leaders must disclose any Significant Financial Interests related to their CARRA Activities upon appointment to membership, annually at the time of membership renewal, election to a new role, and within thirty (30) days of acquiring or discovering any new Significant Financial Interest. The requirement for disclosure of Significant Financial Interests extends to the Leader's spouse, registered domestic partner and/or dependent child(ren).

What must be disclosed?

All Significant Financial Interests related to a Leader's CARRA Activities. **CARRA Activities** are defined as research, teaching/education, outreach, and/or administrative service performed on behalf of CARRA or directly related to programs or functions of CARRA as defined in the CARRA Guidelines for Management of Conflict of Interest and Conflict of Commitment for CARRA.

Significant Financial Interest(s) consisting of any one or more of the following interests of the Leader, Leader's spouse, registered domestic partner and/or dependent child(ren) that may reasonably appear to be related to the Leader's CARRA activities must be disclosed:

Publicly-Traded Entity: Any combination of income (including salary, consultant payments, honoraria, royalty payments, dividend, loan, or any other payments or consideration with value) received in the 12 months preceding disclosure and the value of any equity interests as of the date of disclosure exceeding \$10,000 when summed for a Leader, Leader's spouse or domestic partner, and/or dependent child(ren). Equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

Privately Held or Not-For-Profit Entity: Any combination of income from (including salary, consultant payments, honoraria, royalty payments, dividend, loan, or any other payments or consideration with value) received in the 12 months preceding disclosure that exceeds \$10,000; or ANY equity interest (e.g., stock, stock option, or other ownership interest) by a Leader, Leader's spouse or domestic partner, and/or dependent child(ren).

Intellectual property rights and interests: Income from such rights and interests that exceeds \$5,000 during the 12 months preceding disclosure. **Significant Financial Interests** do **NOT** include royalties received through an institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education.

Travel: Sponsored travel or reimbursements made to or on behalf of the Leader exceeding \$5,000 in value during the twelve months preceding disclosure. You do **NOT need to** report travel reimbursed or paid by a Federal, state, or local government agency, an institution of higher education, or an academic teaching hospital, medical center, or affiliated research institute.

Examples of disclosable Significant Financial Interests

Significant Financial Interests need only be disclosed as they relate to or might reasonably be considered to overlap with CARRA interests. Examples include income or equity received from entities for: Providing expert testimony or consulting services; Serving on a board of directors, scientific advisory board, committee, panel or commission, including paid service to professional or scholarly societies; Income received for acting in an editorial capacity for a professional journal, reviewing journal manuscripts, book manuscripts, or grant or contract proposals; Salary or honoraria received from an entity other than an academic institution, hospital or affiliated research institute; Any equity interest in a company that is developing, manufacturing or selling products or providing services used in an Leader's CARRA-related activities; Royalties from any organization other than an academic institution, hospital or affiliated research institute, including for use or sale of patented or copyright intellectual property, such as software, textbooks, or other scholarly works; Travel reimbursed or sponsored by a professional society, foreign university or company for which the Investigator provides recompensed advice.

Significant Financial Interests do **NOT** include: Payments made from CARRA or by an academic institution, hospital or research institute affiliated with an academic institution (salary, royalties, honoraria, expense reimbursement or any other remuneration); Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an institution of higher education, or an academic teaching hospital, medical center, or affiliated research institute; Investments via a mutual fund, pension fund or other investment vehicle over which the Leader or his/her immediate family member does NOT hold control or exercise management of investment decisions.

FINANCIAL INTEREST DISCLOSURE FOR CARRA

I. Leader Information

First Name		Last Name	
Street Address		City, State, Zip	
Primary Employer		E-mail address	

I. Disclosure

For the purposes of this disclosure, the questions below refer to significant financial interests related to CARRA Activities. **CARRA Activities** are defined as teaching/education, research, outreach, and/or administrative service performed on behalf of CARRA or directly related to programs or functions of CARRA.

Significant Financial Interests do **NOT** include: Payments made from CARRA or by an academic institution, hospital or research institute affiliated with an academic institution (salary, royalties, honoraria, expense reimbursement or any other remuneration); Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an institution of higher education, or an academic teaching hospital, medical center, or affiliated research institute; Investments via a mutual fund, pension fund or other investment vehicle over which the investigator or his/her immediate family member does NOT hold or exercise management of investment decisions.

A. Publicly Traded Entity

Equity Interest + Compensation

1. In the past 12 months, have you, your spouse, registered domestic partner and/or dependent child(ren) received income from or hold equity interest in publicly traded entities developing, manufacturing or selling products or providing services related to CARRA activities that exceeds \$10,000? *When determining your response to this question, please add the value of any equity interest held as of the date of this disclosure and any compensation received in the twelve months preceding this disclosure. Please see Form Instructions for detailed explanation of inclusions and exclusions.*

No Yes (if Yes, please provide a detailed explanation on the next page)

B. Privately Held or Not-For-Profit Entity

Equity Interest + Compensation

2. In the past 12 months, have you, your spouse, registered domestic partner and/or dependent child(ren) received income exceeding \$10,000, or currently own, or have held in the past 12 months, equity interest (includes any stock, stock option or other ownership interest) in **any** privately-held or not-for-profit Entity that is developing, manufacturing or selling products or providing services related to CARRA activities?

No Yes (if Yes, please provide a detailed explanation on the next page)

C. Intellectual Property Rights and Interests

4. In the past 12 months, have you, your spouse, registered domestic partner and/or dependent child(ren) received payments in excess of \$5,000 for any intellectual property rights or interests (e.g. patents, royalties or copyrights assigned or licensed to a party other than an academic institution, hospital or affiliated research institute)?

No Yes (if Yes, please provide a detailed explanation on the next page)

D. Travel Reimbursement/Sponsorship

5. In the past 12 months, has any organization sponsored or reimbursed you, your spouse, registered domestic partner and/or dependent child(ren) for any travel expenses in excess of \$5,000 that is related to your work for CARRA? *This can include travel that is reimbursed or sponsored by a professional society, foreign university, or an Entity for which you are providing compensated or non-compensated services.*

No Yes (if Yes, please provide a detailed explanation on the next page)

II. Acknowledgment and Certification

I **acknowledge** that by signing my name below that it is my responsibility to disclose, *within 30 days*, any new significant financial interests obtained during the term of the above proposed project. I **certify**, to the best of my knowledge, that this is disclosure of significant financial interests related to my Institutional Responsibilities is complete and accurate. My signature further attests that I have read and understand the CARRA Guidelines Conflict of Interest and agree to comply with the guidelines.

Name

Date

CARRA FINANCIAL CONFLICT OF INTEREST DISCLOSURE SUPPLEMENT

III. Leader Information

First Name		Last Name	
------------	--	-----------	--

For the purposes of this disclosure, the questions below refer to significant financial interests related to CARRA Activities. **CARRA Activities** are defined as teaching/education, research, outreach, and/or administrative service performed on behalf of CARRA or directly related to programs or functions sponsored by CARRA.

Significant Financial Interests do **NOT** include: Payments made from CARRA or by an academic institution, hospital or research institute affiliated with an academic institution (salary, royalties, honoraria, expense reimbursement or any other remuneration); Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an institution of higher education, or an academic teaching hospital, medical center, or affiliated research institute; Investments via a mutual fund, pension fund or other investment vehicle over which the Leader or his/her immediate family member does NOT hold control or exercise management of investment decisions.

Please provide comments regarding the nature and sources of Significant Financial Interests noted on the form above. Attach additional pages as needed.

IV. Acknowledgment and Certification

I **acknowledge** by signing my name below that it is my responsibility to disclose, *within 30 days*, any new significant financial interests related to CARRA activities. I **certify**, to the best of my knowledge, that the information above is complete and accurate to the best of my ability.

Name

Date

APPENDIX B

CONFLICT OF COMMITMENT DISCLOSURE FOR CARRA

FORM INSTRUCTIONS

Conflict of Commitment (COC) arises when a leader’s activity within an external organization potentially introduces competing priorities that could limit the ability or willingness of the leader to perform the full range of his or her CARRA duties. A COC becomes relevant only to the extent that the priorities of the external organization(s) diverge from those of CARRA. In many cases such divergence will not arise, and indeed CARRA interests may best be served by leaders who also participate actively in external organizations. Determination of whether a COC is problematic shall be made as described in the CARRA Guidelines for Management of Conflict of Interest and Conflict of Commitment for CARRA Leaders and Members.

Who must submit this form?

All CARRA leaders, specifically Members of the Steering Committee and the Board of Directors, and others as defined in the CARRA Guidelines for Management of Conflict of Interest and Conflict of Commitment. CARRA Leaders must disclose any Conflict of Commitment related to their CARRA Activities upon election, annually at the time of membership renewal, and within thirty (30) days of acquiring any new Conflict of Commitment. The requirement for disclosure of Conflict of Commitment extends to the Member’s spouse, registered domestic partner and/or dependent child(ren).

What must be disclosed?

CARRA leaders should report all leadership positions in any other entity or program with interests that substantially overlap CARRA interests except where serving as a designated CARRA representative.

Member Information

First Name		Last Name	
-------------------	--	------------------	--

Please describe the nature and sources of Conflict of Commitment. Attach additional pages as needed.

Acknowledgment and Certification

I **acknowledge** by signing my name below that it is my responsibility to disclose, *within 30 days*, any new conflict(s) of commitment related to CARRA activities. I **certify**, to the best of my knowledge, that the information above is complete and accurate to the best of my ability.

Name

Date