Preamble

This Amended and Restated Code of Ethics (the “Code of Ethics”) for the Childhood Arthritis and Rheumatology Research Alliance (“CARRA”) is meant to apply to the entire CARRA organization including its leaders, directors, members, staff, and volunteers. This Ethics Code is to be enforceable within the CARRA organization itself.

This Code provides guidelines which are intended to ensure that the mission of the research organization CARRA and its leaders, directors, principal investigators of projects, members, staff, and volunteers is maintained. A primary goal of this Code is to focus on the ethical issues that are pertinent to the research, scientific and educational missions of CARRA.

I. Organizational Ethics

Pediatric rheumatology research is built upon ethically sound foundations and must promote the well-being of children, adolescents, and families who participate in this research.

1. CARRA’s mission is to conduct collaborative research to prevent, treat, and cure pediatric rheumatic diseases.
2. CARRA’s leadership will be accountable to its members, patients, and families and will be transparent with the public about its policies.
3. CARRA will hold scientific meetings that are of the highest scientific caliber and are devoid of undue external influence.
4. CARRA’s publications will reflect editorial independence and integrity as well as scientific rigor.

II. General Principles of Medical Research Ethics

These general ethical principles are accepted standards of professional conduct which CARRA members should follow in their relationships with colleagues, patients, families and the general public.

1. In all research endeavors, members will maintain the highest standards of research integrity and respect the rights of children, adolescents and family members as research subjects. Members will:
   a. Ensure all research is reviewed by IRBs and informed consent has been obtained from each participant per local or coordinating center IRB guidelines as appropriate.
   b. Ensure that the research protocol is scientifically sound and meets ethical guidelines for research with participants.
c. Avoid or mitigate real or perceived conflicts of interest in research.

d. Adhere to rigorous scientific and ethical standards in conducting, supervising, publishing and disseminating results of the research. Members will not engage in scientific misconduct.

2. In the research endeavors of CARRA at individual institutions, CARRA members will provide medical care of the highest quality with compassion and respect for human dignity and justice as well as for patient and family rights, consistent with what they would provide for patients to whom they provide clinical care in a therapeutic relationship. The best interest of the child participating in CARRA research is paramount; members will safeguard the confidentiality of the professional/child and family relationship.

3. Members will strive to ensure that research participation includes and reflects the patient population in terms of races, ethnicity, socioeconomic status, disabilities, and gender, gender identity, and sexual orientation

4. A member’s judgment in CARRA’s research activities at CARRA meetings and at the individual institutions will not be influenced by economic interest.

5. CARRA members will uphold the highest standards of professionalism and honesty in all professional interactions and behaviors.

6. Members will report any state, province or federal disciplinary actions taken by any other regulatory body due to their professional or personal activities, to CARRA’s Advisory Committee on Ethics.

III. Specific Principles

The rules and policies of ethics listed below are mandatory as standards of conduct for all CARRA members:

1. Members will comply with all the CARRA policies including but not limited to CARRA bylaws, Code of Ethics, Conflict of Interest Guidelines, as well as all laws, government regulations and requirements of other organizations/bodies that govern the conduct of CARRA-related activities.

2. All CARRA leaders, directors, staff and volunteers will abide by the same ethical, COI, and COC guidelines as the CARRA members.

3. CARRA members, directors, staff, and volunteers will not engage in illegal, unethical or unauthorized activities. These activities include but are not limited to ones that are not appropriate and not in accordance with CARRA bylaws, Conflict of Interest (COI) or Conflict of Commitment (COC) as defined in CARRA’s Conflict of Interest Guidelines, and other documents addressing the responsibilities of CARRA leaders, directors, members, staff, and volunteers.

4. Members will ensure that all communications and statements to the media, other organizations, and other individuals preserve patient confidentiality and are accurate and not deceptive or misleading.

5. Members will not use the imprimatur of CARRA, its name, or logo in a way that suggests that the member is speaking or communicating for the CARRA organization or that CARRA has endorsed any service, treatment, product, person, or idea without the consent of CARRA leadership.
6. Conflicts of interest will be disclosed and appropriately managed - see CARRA Conflict of Interest ("COI") Guidelines attached as Exhibit A.

7. No CARRA member or volunteer will be involved in the review of and/or award process for any project submitted by him/herself, a member of their institution, or a current collaborator.

8. No parent or patient (staff or volunteers) will be involved in the review of and/or award process for any project submitted by him/herself, a member of his/her (child’s) health care institution, or current collaborator.

9. Parents/patients (staff or volunteers) must disclose working/volunteer relationships with their own physicians or physicians from their institution

10. CARRA leaders, directors, members, staff and volunteers will act in the best interest of CARRA and perform their responsibilities with all reasonable care, due diligence, and honesty.

11. Member lists will only be used for the purposes of CARRA-designated activities as approved by CARRA’s Board of Directors or a committee of CARRA’s Board of Directors.

12. CARRA Leaders, directors, members, staff, and volunteers will communicate with appropriate manners and etiquette verbally and electronically in all CARRA activities and maintain the highest professional standards of behavior in interactions with research subjects, CARRA peers and colleagues, and CARRA staff.

13. CARRA leaders, directors, members, staff, and volunteers will not disclose to third parties information about CARRA that is confidential or proprietary and obtained by such individual as a consequence of such person’s association with CARRA unless expressly authorized by CARRA.

The following additional rules and policies of ethics apply to the leaders, directors and staff of CARRA:

14. CARRA leaders, directors and staff will aspire to be open and transparent with regard to CARRA’s practices. All CARRA leaders, directors and staff will endeavor where practical to provide comprehensive and timely information to the public, the media and all stakeholders, including basic information about CARRA’s finances, programs, and organization.

15. CARRA leaders, directors and staff will commit to continually improving the organization’s activities and processes as it relates to transparency and ethical practices. CARRA leaders, directors and staff will regularly review CARRA’s program and grant making effectiveness and incorporate best practices into future programs.

16. CARRA leaders, directors, members and staff will prioritize diversity, equity and inclusion and health equity among one of the organization’s highest values.

17. CARRA leaders, directors and staff will be truthful in the organization’s solicitation materials when raising funds for CARRA. CARRA leaders, directors and staff will respect the privacy concerns of individual donors and funders, expend funds consistent with their intent, and disclose important and relevant information to potential donors and funders.
IV. Administrative Procedures

This section IV delineates the structure and operation of the CARRA Advisory Committee on Ethics (the “Committee”). This section IV also discusses procedures of the Committee and its related committees.

A. The Committee on Ethics

The Advisory Committee on Ethics is responsible for reviewing ethical and COI issues and recommending actions for CARRA, as well as educating the membership regarding the Code of Ethics and COI. Committee members will be elected by the CARRA membership and will include at a minimum 5 members from the general membership in addition to liaisons from CARRA staff and Board of Directors. The chair of the Committee will be elected by the members of the Committee. The Committee will respond to questions and inquiries, investigate issues and concerns as they arise, and make recommendations for action. Refer to the current committee charter for further details regarding the structure and operations of the Committee.

B. Member Misconduct

A CARRA member may be disciplined by CARRA for professional misconduct such as a violation of the CARRA Code of Ethics and COI, by-laws, or policies, unauthorized use of CARRA’s name. In addition, if a CARRA member is disciplined by any other regulatory body due to their professional or personal activities, CARRA may take additional disciplinary action. Any charges will be in writing and directed to the Advisory Committee on Ethics for a preliminary review. After this review, the committee will report its findings to the Board of Directors.

The Board of Directors will determine if disciplinary action is necessary. If so, a special meeting will be convened. The member will be notified of this meeting at the earliest date possible and given the opportunity to appear with or without counsel and present appropriate evidence at the meeting. After the meeting is held, the Board’s appointed representative will develop a written report on the matter and any disciplinary action recommended that may include censure, probation, suspension, or expulsion. The Board then must vote on these actions and an action must be contemplated only if an affirmative majority votes for the action. As appropriate, the disciplinary action will be reported to various institutions relevant to governance and oversight of scientific misconduct. If the Board decides no action is required, the matter will be closed.

If the individual under investigation is a member of the Board of Directors, that member will recuse him/herself from any of the above process and an independent adjudicator may be needed.

V. Affirmation Statement

CARRA shall provide a copy of this Code of Ethics to every leader, director, member, staff member, and volunteer. An Affirmation Statement shall be signed and/or electronically acknowledged annually by each leader, director, member, staff member, and volunteer, affirming that such person has received a copy of this Code of Ethics, has read and understands it, and agrees to comply with it.
Exhibit A
Conflict of Interest Guidelines
Childhood Arthritis and Rheumatology Research Alliance (CARRA) Guidelines for Management of Conflict of Interest and Conflict of Commitment

Part I. Purpose and Guiding Principles

The purpose of these Conflict of Interest Guidelines (“Guidelines”) is to protect the interests of CARRA when it is contemplating entering into a transaction or arrangement that might benefit the private interest, or might result in a possible excess benefit transaction, of any CARRA leader, volunteer, staff member, principal investigators of projects, or other individuals potentially impacted by conflicts of interest. 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 the pharmaceutical industry (“industry”) and other funding agencies 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, 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 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 disclose the conflict and 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, 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: CARRA leaders are defined as:
   a. Members of Committees that include elected and/or appointed positions, including but not limited to:
      - CTP Advisory Committee
      - Data and Sample Share Committee
      - Diversity, Equity and Inclusion (DEI) Advisory Committee
      - Elections Committee
      - Ethics Committee
      - Finance Advisory Committee
      - Internally Funded Research Oversight Committee (IROC)
      - Membership Committee
      - Publications Committee
      - Registry Parent/Patient Advisory Committee (RPAC)
      - Research and Registry Oversight Committee (RROC)
      - Steering Committee (including all elected leadership positions)
      - Scientific Review Committee (SRC)
   b. Members of the Board of Directors
   c. CARRA officers
   d. Staff

2. Conflict of interest (COI): For the purpose of these guidelines, COI arises when two conditions are met:
   a. A leader’s 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 but not limited to:
         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, a COI results if a leader has a significant proprietary interest in a test, device, or pharmaceutical agent where the individual receives 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.

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, payments that you/your institution receives for participation in the CARRA Registry and similar core CARRA programs are not considered industry-sponsored projects and are excluded from considerations of COI. These exceptions are reviewed periodically by the Ethics Committee.

The disclosure process and relevant forms are found in Appendix A (“Financial Interest Disclosure For CARRA”) and Appendix B (“Conflict of Commitment Disclosure for CARRA”).

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 discussions and 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 >$5,000 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 engagements where the content of the talk serves to promote a single company’s product (Category I).

5. Executive Committee members other than the President (i.e., Treasurer, Vice President, Immediate Past President) bear no formal restrictions on allowable interactions with industry distinct from those of Steering Committee members who are not on the Executive Committee. These exceptions are in part to accommodate the long term (8 years) of the leadership commitment from Treasurer through Immediate Past President. 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 President 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 President 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 President, interactions with industry consistent with the President’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 President’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 President 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 Board of Directors to help determine which ongoing commitments are compatible with the President position.

7. The Chair of the Board of Directors should adhere to the same COI guidelines as the President 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 discussions and 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, member, staff member, and volunteer will sign and submit an annual affirmation statement affirming that s/he:
   a. Has received a copy of CARRA Code of Ethics, which includes these 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 “Financial Interest Disclosure For CARRA” (see Appendix A) “Conflict of Commitment Disclosure for CARRA” (see Appendix B)

3. A CARRA Ethics Committee meeting will be convened at least annually to review all leaders’ COI and COC.

4. Process to determine whether a 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 councils or committees 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 Part III:
     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 Board of Directors regarding management (potential transactions or arrangements as described in Part III) of significant COI and COC.
   b. 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 the result of any vote(s) taken in connection with the proceedings.
   c. Where a difference exists between the Ethics Committee and the Board of Directors, the

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disinterested members of the Board of Directors (BOD) will review and adjudicate, potentially including outside advice from other resources including CARRA’s legal counsel.

d. 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 Ethics 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 Ethics 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, the Board of Directors will ensure that periodic reviews shall be conducted as needed. 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 Committees that include elected and/or appointed positions, including but not limited to:
  o CTP Advisory Committee
  o Data and Sample Share Committee
  o Diversity, Equity and Inclusion (DEI) Advisory Committee
  o Elections Committee
  o Ethics Committee
  o Finance Advisory Committee
  o Internally Funded Research Oversight Committee (IROC)
  o Membership Committee
  o Publications Committee
  o Registry Parent/Patient Advisory Committee (RPAC)
  o Research and Registry Oversight Committee (RROC)
  o Steering Committee (including all elected leadership positions)
  o Scientific Review Committee (SRC)
• Members of the Board of Directors
• CARRA officers
• Staff

Leaders must disclose any Significant Financial Interests related to their CARRA Activities upon appointment to membership, annually at the time of membership renewal, when participating in the election to a potential 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).

We recognize that other individuals associated with CARRA may have outside or other interests that may impact their role in CARRA. Please disclose these at your discretion. If you have any questions, please email info@carragroup.org.

What financial interests should be disclosed?
We recognize that leaders associated with CARRA may have interests that may impact their role with CARRA. Please disclose them even if you think they may not be relevant. These potential conflicts will be reviewed by the Ethics Committee on behalf of the Board.

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 $5,000 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 $5,000; 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 a 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 recompened 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

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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 $5,000? **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 $5,000, 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

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CARRA FINANCIAL CONFLICT OF INTEREST DISCLOSURE SUPPLEMENT

III. Leader Information

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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, defined as
- Members of Committees that include elected and/or appointed positions, including but not limited to:
  - CTP Advisory Committee
  - Data and Sample Share Committee
  - Diversity, Equity and Inclusion (DEI) Advisory Committee
  - Elections Committee
  - Ethics Committee
  - Finance Advisory Committee
  - Internally Funded Research Oversight Committee (IROC)
  - Membership Committee
  - Publications Committee
  - Registry Parent/Patient Advisory Committee (RPAC)
  - Research and Registry Oversight Committee (RROC)
  - Steering Committee (including all elected leadership positions)
  - Scientific Review Committee (SRC)
- Members of the Board of Directors
- CARRA officers
- Staff

Leaders must disclose any Significant Competing Commitments related to their CARRA Activities upon appointment to membership, annually at the time of membership renewal, when participating in the election to a potential 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).

We recognize that other individuals associated with CARRA may have outside or other interests that may impact their role in CARRA. Please disclose these at your discretion. If you have any questions, please email info@carragroup.org.

What conflicts of commitment must be disclosed?
We recognize that leaders associated with CARRA may have interests that may impact their role with CARRA. Please disclose them even if you think they may not be relevant. These potential conflicts will be reviewed by the Ethics Committee on behalf of the Board.

For example, CARRA leaders should disclose:
- All leadership positions in any other entity or program with interests that substantially overlap CARRA interests except where serving as a designated CARRA representative.
- All interactions with industry or competing organizations.
- All known CARRA-related working and/or volunteer relationships with patients or parents of patients who receive care at their institution.

CARRA parent/patient volunteers and staff should disclose:
- All CARRA-related working and/or volunteer relationships with CARRA leaders working at their (child’s) health care institution.
CONFLICT OF COMMITMENT DISCLOSURE FOR CARRA

Leader Information

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<th>Last Name</th>
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Please use the space below to describe the nature and sources of any Conflict(s) of Commitment per the above guidance on what must be disclosed. Attach additional pages as needed. If you have no conflicts to report, please state "No conflicts to report".


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 ________________________