



## Pharmaceutical/Corporate Relationship Guidelines and Principles

### EXECUTIVE SUMMARY

#### Introduction & Background

The Lupus Research Alliance's vision is a world free of lupus and its mission is to prevent, treat and one day cure this disease. Working with pharmaceutical and biotech companies and other commercial entities who share our vision to develop new treatments is a key part of moving the Lupus Research Alliance ("LRA") closer to this goal. It is important that all LRA employees operate under consistent, clear, and transparent principles with standards that keep the best interests of people with lupus and lupus patients first and foremost in our minds to inform our work with these partners.

In using and adhering to the Pharmaceutical/Corporate Relationship Guidelines and Principles, please reach out to Corporate Relations team members with any questions, concerns or clarifications. Contact: [corprelations@lupusresearch.org](mailto:corprelations@lupusresearch.org)

We recognize that we cannot anticipate or address every possible situation in these guidelines. Because every decision in this area has the potential to impact us all, please seek advice from the members of the Corporate Relations Team regarding any complicated and/or unique situation that is not addressed directly in these guidelines.

#### LRA's Purpose in Working with the Pharmaceutical and Biotech Industries and related commercial entities

In order to achieve our mission of preventing, treating and finding a cure for lupus, LRA works with companies, organizations and individuals that share our objectives and can help us advance toward that goal. Among these organizations are pharmaceutical, biotech, clinical research organizations, biologic testing, technology, and other companies that may play a pivotal role in leading to the development of potential new FDA-approved treatments and providing access to existing treatments for the care of people with lupus. We therefore work with companies in these industries to:

- Speed promising research findings towards development of new treatments.
- Bring attention to the specific issues, needs, and perspectives of people with lupus.
- Provide scientific and clinical expertise to ensure study development, availability, access and appropriate utilization of FDA-approved therapies for lupus.
- Leverage and deploy resources to raise public awareness about what lupus is, how to recognize it, push for more lupus research, and increase understanding of what it means to live with lupus.
- Create awareness and information for people with lupus and encourage their participation in the research process when and where appropriate for them.

LRA seeks to keep people affected by lupus at the center of our decisions and to make sure that their best interests drive our work. When LRA works with any commercial entities connected to the drug development industry, we:

- Earn and maintain the trust of people with lupus and all who support the drive to new treatments, prevention and a cure by always acting with the utmost integrity;
- Give a strong voice to the needs and concerns of people living with lupus regarding potential new treatments for lupus and the related quality of life issues they experience, including issues of efficacy, safety and access to translational research studies and clinical trials available;
- Are transparent as to the purpose and nature of our relationships with commercial entities, including the disclosure of any funding we receive from commercial entities, how such funding is utilized by LRA and what the funding supports, the business we conduct with commercial entities, when and why we may seek the input of commercial entities on certain pertinent research issues/processes and when and why we may urge them to listen closely to the patient voice/needs;
- Maintain independence and vigilantly safeguard our organization and our work against any potential for undue or unintended influence by the pharmaceutical industry or its agents; and
- Seek to adhere to the various federal and state laws, regulations, guidelines, and best practices that relate to the protection of patient rights, the sponsoring and collaboration into the conduct of medical research, and best/standard practices for discovery, translational, and/or clinical research and advocacy for appropriate research participation by people with lupus. LRA must comply with laws and regulations to which it is directly subject (such as IRS regulations regarding our tax exempt status and data privacy laws, including HIPAA and GDPR, if LRA is maintaining patient data) and with certain laws and regulations which LRA agrees to adhere to under its contracts with third parties (e.g. the Sunshine Act, the Anti-Kickback Statute, the federal False Claims Act).

LRA will seek opportunities to partner with industry in ways that are appropriate and that advance our mission. We will use appropriate disclaimers as LRA does not recommend any particular treatment or study over another and always recommends that people with lupus seek the counsel of a proper physician.

**Business to business relationships.** LRA carefully considers, actively seeks out, and enters into collaborative research agreements with industry that is specifically related to LRA's charitable mission.

**Honorarium.** LRA staff are prohibited from accepting personal honorarium for work performed in the course of their employment. If extensive time and expertise is required for a given project of a pharmaceutical company by an LRA employee, the corporate relations staff will be responsible for negotiating an appropriate fee for the time and expertise involved. Such fee will be used to support LRA's charitable mission.

In closing, LRA works hard to forge appropriate and transparent relationships with commercial entities that are dedicated to helping bring new treatments to people with lupus to reality. The LRA seeks to keep the needs of the person with lupus at the forefront of these relationships.

**For a full detailed copy of the LRA's Corporate Relations Guidelines, write to:**

[correlations@lupusresearch.org](mailto:correlations@lupusresearch.org)