

Conflict of Interest Disclosure Form

Lead Researcher Information

Name:	
Institution:	
Phone:	

Access to individual patient data from clinical trials sponsored by Jazz Pharmaceuticals should be restricted to individuals free of any real or perceived significant conflicts of interest, in order to retain objectivity in the interpretation of the results of their research. The source of these conflicts may be financial, proprietary, or scientific/intellectual, be it either professional or personal in nature. Conflicts of interest held by any individual with whom the researcher directly shares income¹ must also be reported and considered. Disclosure of any conflicts does not imply bias, but rather, demonstrates your commitment to transparency.

Indicate all sources of funding for the proposed research project:

¹ Individuals with whom the committee member directly shares income include spouse, domestic partner and dependent children.

Indicate by marking YES or NO if any of the arrangements of concern, as described below, apply and provide additional details as necessary.

Independence from Requested Trial(s)

Are you, or any individual with whom you directly share income, independent from the trial(s) for which you have requested data? This includes independence from the Sponsor, competitors, or any other institution or organization with a commercial interest in the product(s) studied; IRBs, regulatory agencies, trial investigators, steering committee, and advisory board involved with the trial; clinical care of the trial participants; and any other capacity related to conduct and/or management of the trial(s). Relationships with individuals in trial leadership positions as well as emotional involvement in the trial(s) (e.g., close relative is a trial participant) should also be disclosed.

NO YES

If NO, please specify details:

Financial Interest

Employment

Are you, or any individual with whom you directly share income, currently employed with the Sponsor, a competitor, or any other company with commercial interest in the product(s) studied? This includes full or part-time employment or consultancy, membership on the entity's Board of Directors or advisory committee(s), or service as a broker, agent, or representative.

NO YES

If YES, please specify details:

Equity Interest

Do you, or any individual with whom you directly share income, have ownership interest in excess of 5% or for which the value of any remuneration is greater than \$5,000 per year, including stock options, in any privately held company that has a commercial interest in the product(s) studied?

NO YES

If YES, please specify details:

Do you, or any individual with whom you directly share income, have any equity interest valued at \$10,000 or more, as determined through reference to public prices or other reasonable measures of fair market value, in the Sponsor, competitor, or any other publicly traded company that has a commercial interest in the product(s) studied? Equity interest includes stock, stock options, or other ownership interest in any single company, but excludes indirect investments through mutual funds and the like.

NO YES

If YES, please specify details:

Significant Payments

Within the last year, have you, or any individual with whom you directly share income, received any significant payments from the Sponsor, a competitor, or any other company with commercial interest in the product(s) studied? This includes payments from a single company made to support activities that have a value greater than \$10,000 (i.e. a grant to fund ongoing research, compensation in the form of equipment, retainers for speaking engagements or ongoing consultation, or honoraria).

NO YES

If YES, please specify details:

Intellectual Investment

Do you, or any individual with whom you directly share income, have material scientific or intellectual interest pertinent to the trial(s) of interest or to the product(s) studied? This includes aid in the planning of the trial(s), involvement in the inception of the concept tested in the trial(s), or responsibility for early work in establishing the rationale for the product(s) studied; intellectual property rights, including patents or copyrights, whether planned, pending, or issued, licensing agreements, or royalties; planned or current authorship of any publication(s) related to the trial(s) or product(s) studied; or strong prior belief in the trial intervention(s).

NO YES

If YES, please specify details:

Other Competing Interests

Are you, or any individual with whom you directly share income, engaged in any simultaneously occurring competitive studies in any role or have any interests or obligations from other outside activity that could pose a conflict of interest? This includes concurrent service on committees for related, competing products.

NO YES

If YES, please specify details:

I certify that the information reported above is accurate and that I have not altered the wording of any question on this form.

Name: _____

Signature: _____

Date: _____