Conformal believes the proposed subject injury reimbursement language is appropriate for the following reasons:

1. Pursuant to the Medicare National Coverage Determination dated September 7, 2007 (Publ. No. 100-03), the routine costs of a clinical trial include complications arising from participation in a clinical trial: "Effective for items and services furnished on or after July 9, 2007, Medicare covers the routine costs of qualifying clinical trials, as such costs are defined below, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trial." (*See* Medicare National Coverage Determination dated September 7, 2007, Pub. 100-03 ¶ 310.1.)

2. Routine costs are defined by CMS to include "all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, coverage is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial." (*Id.* ¶ B, Policy.) Routine costs also include: "Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service – in particular, for the diagnosis or treatment of complications." (*Id.*)

3. On March 23, 2022, Conformal received CMS Approval, under which the "routine costs," (i.e., costs associated with the treatment of a subject injury in either the treatment or control arm" will be paid by CMS. *See https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?MCDId=27* ("Under CED, routine costs of an approved clinical trial in both the treatment arm and the control (standard of care or placebo) arm are paid.")

Based on the foregoing, and to ensure consistency with its CMS approval and the National Coverage Determination (Pub. No. 100-3), Conformal has proposed the updated subject injury language. Conformal believes this approach is preferrable for several reasons:

1. First, as the Protocol requires Conformal's device to be randomized against current, commercial treatments there is a risk the control group would receive differential treatment in response to a subject injury as compared to the treatment group. To avoid potentially differential treatment, consistent billing practice (i.e., tender to insurance for all subject injuries) is a preferrable approach;

2. Second, due to the use of control devices under the Protocol, all of which are commercially available, any subject injuries relating to the use of such control devices should be paid for by insurance. Conformal should not be obligated to pay for subject injuries relating to the use, defect or malfunction of the control devices, which would effectively require Conformal to assume the risk of loss or defect with another manufacturer's device;

3. Third, Conformal estimates that approximately 90% of its enrollments in the Study will be Medicare beneficiaries, and that few patients will be privately insured. Therefore, the risk of the lack of coverage for subject injury reimbursement is low compared to other clinical trials;

4. Fourth, Conformal suggests an insurance pre-authorization process be completed as part of the Study enrollment to help ensure coverage for a clinical trial subject's diagnosis or treatment of a

subject injury. This proposed pre-authorization will minimize adverse coverage determinations for the reimbursement of a subject injury expenses for a privately-insured or uninsured clinical trial subjects.

5. Fifth, Conformal cannot agree to pay cost-sharing subsidies due to inducement concerns under the Anti-Kickback Statute and the Medicare Secondary Payer Rule and, therefore, proposes the uniform method for reimbursing subject injuries by tendering to insurance coverage. For example, any payment of cost-sharing obligations that Medicare beneficiaries participating in the study would otherwise owe for Medicare-reimbursable items and services constitutes a violation of the Anti-Kickback statute. As the HHS-OIG has explained, an arrangement in which a clinical trial sponsor offers to pay or pays any cost-sharing amounts for billable items and services provided to Medicare beneficiaries participating as subjects in a clinical study implicates the Anti-Kickback statute. (*See* OIG Advisory Opinion 22-05.) Further, the OIG has explained such an arrangement does not fall within any exception to the definition of remuneration or safe harbor to the Anti-Kickback statute. (*See id.*) Nonetheless, in limited circumstances, the OIG has reviewed proposed arrangements through its advisory opinion program in which a clinical trial sponsor has offered to pay the cost-sharing obligations of a Medicare beneficiary and has concluded it would not impose administrative sanctions in those specific arrangements due to a minimal risk of fraud and abuse under the Anti-Kickback Statute. (*See* OIG Advisory Opinion 22-05 p.8.) Unfortunately, the OIG's Advisory Opinions are limited to the specific arrangement reviewed by the OIG, does not apply to any other arrangement by any other clinical trial sponsor, and "cannot be relied upon by, any other person." (*Id.*)

6. Finally, Conformal also has concerns under the Anti-Kickback statute in which any arrangement based on the knowing and willful payment of remuneration to induce or reward referrals or generate business involving any service payable by the Federal health care programs is illegal. It is immaterial whether the arrangement results in increased costs to federal health programs; a violation of the Anti-Kickback statute exists if the intent to induce is present. Because Conformal has obtained CMS Approval for the CONFORM study, and the procedures performed during the trial are reimbursed by CMS at specified rates (including the treatment of subject injuries), the payment of any compensation beyond the CMS specified rates for the treatment of a subject injury could be perceived as a kickback and considered illegal remuneration under the Anti-Kickback statute.

While Conformal understands it is sites preference to have a sponsor pay for all subject injuries relating to a Study, and many other pharmaceutical/device companies with whom site contracts likely agree to fully-reimburse expenses relating to subject injuries, Conformal should not assume the financial exposure of paying for all subject injuries under the Protocol when it has obtained CMS Approval for the Study. Nor would such a financial exposure be equitable in light of the fact the control devices in the Study are commercially-approved, manufactured by other device companies, and are reimbursed by CMS. As a result, Conformal has carefully considered and proposed the language in the agreement to balance the interests at issue. Conformal appreciates the consideration of its proposal.