Dear Investigator,

With this letter, I invite you to consider participating as a site Principal Investigator in a unique randomized clinical trial funded by the National Heart, Lung, and Blood Institute known as the Cardiovascular Inflammation Reduction Trial (CIRT). I hope you will say “yes” and return the attached Site Evaluation Form as soon as possible.

In brief, inflammation plays a crucial role in atherosclerosis, yet to date no clinical trial has addressed whether reducing inflammation will reduce rates of heart attack, stroke and cardiovascular death in our patients. As described in the attached article from Science, just such a study - the Cardiovascular Inflammation Reduction Trial (CIRT) - is now underway at more than 200 clinical sites like yours across the United States and Canada. In a double-blind fashion, CIRT is randomizing stable atherosclerosis patients to either a common anti-inflammatory therapy routinely used for rheumatoid arthritis (low dose methotrexate) or to placebo. CIRT will determine whether this anti-inflammatory treatment will reduce the rate of MI, stroke or cardiovascular death among stable atherosclerosis patients with either diabetes or metabolic syndrome, a group with a known persistent pro-inflammatory response.

We welcome the participation of any clinical site that can enroll at least 20 patients. The following is an abbreviated list of the CIRT inclusion criteria:

- Age > 18 years
- Myocardial infarction and/or evidence of multi-vessel coronary artery disease by angiography in the past
- Type 2 diabetes and/or metabolic syndrome
- No contraindication to low-dose methotrexate

We estimate that the average per participant reimbursement to each study site will be $5,250 so that a site able to randomize and follow 20 participants will have $100,000 available during the trial to defer costs of participation. I hope you decide to join us in this exciting scientific and clinical endeavor. Attached to this letter you will find a protocol summary of CIRT, the Science reprint, a Site Evaluation Form, 1572 Form and W9 Form. If you are interested in participating, please fill out the Site Evaluation Form, 1572 Form and W9 Form as soon as possible. Please fax back these forms and signed copies of your CV and medical license to 855-605-6326.

Sincerely yours,

Paul M Ridker, MD, MPH
Principal Investigator, CIRT
Eugene Braunwald Professor of Medicine
Harvard Medical School

CIRT@partners.org
www.theCIRT.org
CIRT
Cardiovascular Inflammation Reduction Trial
Site Evaluation Form

Please FAX to CIRT with our return fax cover sheet to (855) 605-6326 or email to CIRT@partners.org

☐ I am interested in participating in this trial
☐ I am not interested in participating in this trial
   ☐ I do not have this patient population in my practice
   ☐ Other: _________________________________

Principal Investigator:
Name: __________________________________ Degree: _______________________________
Address: ______________________________________________________________________
City: ____________________________________ State: _________ Zip:___________________
Telephone: (_____) _________-______________ Fax :(_____) ________ -________________
Email: ___________________________________________________________

Study Coordinator: (Location where subjects will be enrolled)
Name: __________________________________ Degree: ______________________________
Site Name: __________________________________________________________
Type of Practice: _______________________________________________________
Address: ____________________________________________________________
City: ___________________________________ State: __________ Zip:___________________
Telephone: (_____ ) _______-_______________ Fax: (_____ ) _______-________________
Cell: (_____ ) ___-__________ Email: ________________________________________

Authorized Official: (Individual to receive the purchase service agreement/contract)
Name:_________________________________ Telephone: (_______)________-___________
Organization:____________________________ Email:_________________________________

Best time and number to reach Principal Investigator:
time: ____:_____am/pm #: (_____ )______-________________

Best time and number to reach Study Coordinator:
time: ____:_____am/pm #: (_____ )______-________________
To Be Completed By Study Coordinator:

Site Information:

1. Is your site able to use a central IRB?  
   ____Yes  ____No

2. Are you able to use LabCorp (US) /GDML (Canada)?  
   ____Yes  ____No

3. Do you have an on-site phlebotomist?  
   ____Yes  ____No
   3.a. Is there a centrifuge onsite?  
   ____Yes  ____No

4. Do you have secured space for study drug?  
   ____Yes  ____No

5. Have you participated in any NIH-funded trials?  
   ____Yes  ____No

6. Have you participated in any pharmaceutical funded trials?  
   ____Yes  ____No

7. Do you have the ability to enter patient data electronically?  
   ____Yes  ____No

8. Do you have an electronic medical record system?  
   ____Yes  ____No

9. What is your Federal Wide Assurance number?  
   ____________________
   All participating sites must have their own FWA. Please let us know if you need any assistance applying for this assurance.

10. Do you have high speed internet access in the office available for use for activities in this trial?  
    ____Yes  ____No

11. Will you commit to enroll at least 20 patients during the trial enrollment period?  
    ____Yes  ____No

12. Do you anticipate needing copies of the informed consent in a language for which a translation is required, such as  
    ____Spanish  ____French  Other Language_________________

Practice Information:

1. Principal Investigator specialty:  
   _____ Cardiology  _____ Endocrinology  _____ Internal Medicine  _____ Primary Care  
   _____ Other (Please specify):_________________________________________________

2. Will any additional physicians participate as co-investigators?  
   ____Yes  ____No
   Name of Co-I’s  __________________________  __________________________

3. Do you have a study coordinator who could take on the requirements of this trial immediately after the investigator meeting?  
   __________ Full Time  __________ Part Time  __________ No

4. We would like to start enrolling as soon as possible. In your experience do you think your contract and IRB could be finalized within 60 days of receipt?  
   ____Yes  ____No

Completed by: _____________________________________ Title: _______________________
    (Print Name)

Thank you for taking the time to complete this evaluation. If you have any questions about completing this evaluation, please contact us at: (855) 437-9330 (toll-free) or (617) 278-0858
### Cardiovascular Inflammation Reduction Trial - CIRT

#### Protocol Summary

<table>
<thead>
<tr>
<th><strong>Scientific Aim</strong></th>
<th>To test directly the inflammatory hypothesis of atherosclerosis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>To determine in a randomized, double-blind, placebo-controlled setting whether treatment with low dose methotrexate (LDM) will reduce the rate of myocardial infarction, stroke, or cardiovascular death among patients with atherosclerosis</td>
</tr>
<tr>
<td><strong>Funding Agency</strong></td>
<td>National Heart Lung and Blood Institute (NHLBI)</td>
</tr>
</tbody>
</table>
| **Inclusion Criteria** | • Age ≥ 18 years  
• Myocardial infarction in the past and/or evidence of multivessel coronary artery disease by angiography  
• Type 2 diabetes and/or metabolic syndrome  
• Completed all planned revascularization procedures  
• Medically stable for 60 days from index MI, surgical procedure or other significant illness (including newly diagnosed diabetes) |
| **Exclusion Criteria** | • Chronic liver disease  
• Chronic inflammatory condition such as lupus or rheumatoid arthritis, ulcerative colitis or Crohn’s disease  
• Chronic infectious disease  
• Interstitial lung disease or pulmonary fibrosis  
• Myeloproliferative disease in past 5 years  
• HIV positive  
• Requirement for, or intolerance to, methotrexate or folate  
• History of non-basal cell malignancy or treatment for lymphoproliferative disease in past 5 years  
• Requirement for use of drugs that alter folate metabolism  
• History of alcohol abuse or unwillingness to limit consumption to < 4 drinks per week  
• Women of childbearing potential (even if using oral contraceptive agents) or intention to breastfeed  
• Men who plan to father children during the study period or are unwilling to use contraception  
• Life expectancy < 3 years or unlikely to comply in judgment of investigator  
• Chronic use of oral or IV steroid therapy or other immunosuppressive or biologic response modifiers (see drug list in Manual of Operations)  
• History of hepatitis B or C  
• Chronic pericardial effusion, pleural effusion or ascites  
• New York Heart Association Class IV heart failure |
| **Participants** | • 7,000 men and women from the United States and Canada |
| **Primary Endpoint** | • Time to first major cardiovascular event (a composite of CV death, non-fatal MI and stroke) |
| **Secondary Endpoints** | • All-cause mortality  
• Percutaneous or surgical coronary revascularization  
• Hospitalization for congestive heart failure  
• Incident venous thromboembolism  
• Incident atrial fibrillation  
• Incident diabetes among those without diabetes at randomization  
• Incident peripheral artery disease  
• Clinically worsening aortic stenosis |
| Study Design | Event driven trial of 3-4 year therapy with LDM (target dose 15-20 mg once weekly) or matching placebo. All participants will receive 1 mg folate 6 days/week to reduce nuisance side effects of LDM. |
| Study Procedures | **Active run-in**  
  - Open label 5-6 week run-in with LDM initiated at 5mg weekly and titrated to 15 mg weekly among all participants  
**Randomization**  
  - Participants compliant and free of side effects during run-in randomized to 15 mg weekly or matching placebo in a 1:1 allocation ratio  
  - Monthly safety lab evaluation for first 6 months (complete blood count, liver function tests, and renal function tests)  
**Follow-up**  
  - Clinic visits every 4 months  
  - After 4 months, LDM titrated to 20mg weekly  
  - After 6 months safety lab evaluations will occur bimonthly |
| Safety Considerations | **Follow-up visits**  
  - During follow-up visits signs and symptoms of LDM side effects or toxicity will be assessed  
**Laboratory measurements**  
  - Detailed algorithms have been developed to guide temporary dose reduction or discontinuation of LDM if specific lab thresholds are crossed  
**Clinical Coordinating Center (CCC)**  
  - Using data gathered from follow-up visits and safety labs, the CCC will determine study drug dosing centrally  
  - Sham titrations will take place in placebo arm to ensure study blind |
| Medical Monitor | An experienced rheumatologist will be on call 24/7. Monitors will help determine whether possible symptoms being described by subjects are concerning, whether interruptions in study drug are warranted, and whether re-initiating study drug is safe. |
| Statistical Analysis | **Event driven trial**  
  - In the absence of extreme effects, the trial will end after accrual of at least 530 primary endpoints  
  - Trial designed to provide 90 percent power to detect a 25 percent relative risk reduction  
**Stratification will occur by time since index event (<6 months vs. ≥6 months), by the presence of diabetes or metabolic syndrome at entry, and by site** |
Massive Trials to Test Inflammation Hypothesis

It’s not often that eminent scientists enlist 24,000 volunteers and tens of millions of dollars to put their credibility on the line, but that’s exactly what cardiologist Paul Ridker is doing. More than 20 years ago, early in his career at Harvard Medical School’s Brigham and Women’s Hospital in Boston, he began nurturing the idea that inflammation is deeply intertwined with cardiovascular disease. Ridker has never been able to prove that the body’s inflammatory response causes heart attacks—or that blocking it can save lives. But he has built his case bit by bit. Now, his theory is being put to the test in a pair of massive clinical trials, both of which he’s heading. One was launched last year by Novartis, and the other was announced last month by the U.S. National Heart, Lung, and Blood Institute (NHLBI).

“The question has always arisen, is inflammation simply a marker for risk, or is it a target for therapy?” says Steven Nissen, chair of cardiovascular medicine at the Cleveland Clinic in Ohio. With a pair of trials now focused on his thesis, Ridker has “two shots on goal,” Nissen says, and if one or both succeed he will have identified the first new class of antiatherosclerosis drugs since 1987, when statins were introduced.

NHLBI’s study aims to sign up 7000 volunteers to test methotrexate, now used to treat rheumatoid arthritis and, at much higher doses, certain cancers. The Novartis trial is recruiting 17,000 others, about three-quarters of whom will inject different doses of a monoclonal antibody approved for an extremely rare class of inflammatory diseases. Both trials will treat patients for up to 4 years. Novartis has not revealed the cost of its trial, but NHLBI is budgeting nearly $80 million.

“This is testing a whole new paradigm, a whole new approach, towards treating atherosclerosis,” because anti-inflammatory drugs are not now a therapy of choice, says Michael Lauer, director of the Division of Cardiovascular Sciences at NHLBI. Ridker’s trial went through five rounds of review before being approved.

Ridker is well known among cardiologists for his work on C-reactive protein (CRP), a protein in blood that rises along with inflammation. High levels of CRP, he found, correlate tightly with an increased risk of heart attacks and strokes. In 1997, Ridker published a paper about apparently healthy men taking a low dose of aspirin, which both inhibits blood clots and is an anti-inflammatory. Those with the highest CRP levels who took aspirin had the best shot at avoiding heart attacks. After that, “[w]e jumped fast through dozens and dozens of papers,” he says; in 2008—the same year he proposed the methotrexate trial to NHLBI—he published the JUPITER trial, which was similar to the aspirin study but looked at the effects of cholesterol drugs.

J U P I T E R recruited nearly 18,000 people with high CRP levels and normal cholesterol. Half took the statin Crestor that lowers both LDL cholesterol and CRP. The drug reduced heart attacks and strokes by 50% and deaths by 20% (Science, 14 November 2008, p. 1039).

In both the aspirin and Crestor studies, Ridker tried to tease out whether the benefits of the drugs came from targeting inflammation, or from their anticoagulating or anticholesterol effects. But he couldn’t get a definitive answer. Crestor may have helped not because it lowered CRP but because it pushed cholesterol down in people with supposedly normal levels. The results were only “indirect suggestions” about inflammation’s role, Ridker admits.

“Half the world said Paul is wrong, and the other half said Paul is right,” says John Kastelein, a vascular medicine specialist at the Academic Medical Center in Amsterdam. Ridker has some recent findings on his side. Among them is a paper published in The Lancet in March by a worldwide genetics consortium. The group found that people with a gene variant that blunted interleukin-6 signaling, and thereby reduced systemic inflammation, had a somewhat lower risk of heart disease. “I find that one of the most important pieces of information in the last 10 years” coming from human data, says Kastelein, who, like Ridker, is a member of the consortium. (Kastelein is also involved in the Novartis trial.)

Still, many believe that the Ridker trials are a long shot. Some see a stronger scientific rationale for testing the Novartis therapy, canakinumab, because it specifically targets interleukin-1 and interleukin-6, both of which have been linked to heart disease. Methotrexate targets inflammation much more broadly. On the other hand, canakinumab has been injected by only a few thousand people, which makes unexpected side effects more likely, whereas millions have taken methotrexate since it was introduced for cancer therapy about 40 years ago. It’s also a cheaper generic, which captured NHLBI’s attention. Even so, the drug is foreign to cardiologists. One who spoke to Science said his colleagues “thought I was joking” when he asked if they could imagine giving it to patients.

Ridker hopes to boost his chance of success by enrolling only patients with systemic inflammation into the trials—either by screening for high CRP, or for type 2 diabetes or metabolic disease, which also correlate with inflammation. Participants must also have had a prior heart attack. About one-third of those who’ve had a heart attack also have systemic inflammation. The results from these two trials will be “the endgame for 20, 25 years’ worth of inflammation biology,” Ridker says. And now the waiting begins.

—JENNIFER COUZIN-FRANKEL
Request for Taxpayer Identification Number and Certification

Give Form to the requester. Do not send to the IRS.

Name (as shown on your income tax return)

Business name/desregarded entity name, if different from above

Check appropriate box for federal tax classification:
- Individual/sole proprietor
- C Corporation
- S Corporation
- Partnership
- Trust/estate

Exemptions (see instructions):
- Exempt payee code (if any)
- Exemption from FATCA reporting code (if any)

Limited liability company. Enter the tax classification (C=corporation, S=S corporation, P=partnership)

Other (see instructions)

Address (number, street, and apt. or suite no.)

City, state, and ZIP code

Requested’s name and address (optional)

List account number(s) here (optional)

Part I  Taxpayer Identification Number (TIN)

Enter your TIN in the appropriate box. The TIN provided must match the name given on the “Name” line to avoid backup withholding. For individuals, this is your social security number (SSN). However, for a resident alien, sole proprietor, or disregarded entity, see the Part I instructions on page 3. For other entities, it is your employer identification number (EIN). If you do not have a number, see How to get a TIN on page 3.

Note. If the account is in more than one name, see the chart on page 4 for guidelines on whose number to enter.

Part II  Certification

Under penalties of perjury, I certify that:

1. The number shown on this form is my correct taxpayer identification number (or I am waiting for a number to be issued to me), and

2. I am not subject to backup withholding because: (a) I am exempt from backup withholding, or (b) I have not been notified by the Internal Revenue Service (IRS) that I am subject to backup withholding as a result of a failure to report all interest or dividends, or (c) the IRS has notified me that I am no longer subject to backup withholding, and

3. I am a U.S. citizen or other U.S. person (defined below), and

4. The FATCA code(s) entered on this form (if any) indicating that I am exempt from FATCA reporting is correct.

Certification instructions. You must cross out item 2 above if you have been notified by the IRS that you are currently subject to backup withholding because you have failed to report all interest and dividends on your tax return. For real estate transactions, item 2 does not apply. For mortgage interest paid, acquisition or abandonment of secured property, cancellation of debt, contributions to an individual retirement arrangement (IRA), and generally, payments other than interest and dividends, you are not required to sign the certification, but you must provide your correct TIN. See the instructions on page 3.

Sign Here

Signature of U.S. person

Date

General Instructions

Section references are to the Internal Revenue Code unless otherwise noted.

Future developments. The IRS has created a page on IRS.gov for information about Form W-9, at www.irs.gov/w9. Information about any future developments affecting Form W-9 (such as legislation enacted after we release it) will be posted on that page.

Purpose of Form

A person who is required to file an information return with the IRS must obtain your correct taxpayer identification number (TIN) to report, for example, income paid to you, payments made to you in settlement of payment card and third party network transactions, real estate transactions, mortgage interest you paid, acquisition or abandonment of secured property, cancellation of debt, or contributions you made to an IRA.

Use Form W-9 only if you are a U.S. person (including a resident alien), to provide your correct TIN to the person requesting it (the requester) and, when applicable, to:

1. Certify that the TIN you are giving is correct (or you are waiting for a number to be issued),

2. Certify that you are not subject to backup withholding, or

3. Claim exemption from backup withholding if you are a U.S. exempt payee. If applicable, you are also certifying that as a U.S. person, your allocable share of any partnership income from a U.S. trade or business is not subject to the withholding tax on foreign partners’ share of effectively connected income, and

4. Certify that FATCA code(s) entered on this form (if any) indicating that you are exempt from FATCA reporting, is correct.

Note. If you are a U.S. person and a requester gives you a form other than Form W-9 to request your TIN, you must use the requester’s form if it is substantially similar to this Form W-9.

Definition of a U.S. person. For federal tax purposes, you are considered a U.S. person if you are:

- An individual who is a U.S. citizen or U.S. resident alien,
- A partnership, corporation, company, or association created or organized in the United States or under the laws of the United States,
- An estate (other than a foreign estate), or
- A domestic trust (as defined in Regulations section 301.7701-7).

Special rules for partnerships. Partnerships that conduct a trade or business in the United States are generally required to pay a withholding tax under section 1446 on any foreign partners’ share of effectively connected taxable income from such business. Further, in certain cases where a Form W-9 has not been received, the rules under section 1446 require a partnership to presume that a partner is a foreign person, and pay the section 1446 withholding tax. Therefore, if you are a U.S. person that is a partner in a partnership conducting a trade or business in the United States, provide Form W-9 to the partnership to establish your U.S. status and avoid section 1446 withholding on your share of partnership income.

Cat. No. 10231X
In the cases below, the following person must give Form W-9 to the partnership for purposes of establishing its U.S. status and avoiding withholding on its allocable share of net income from the partnership conducting a trade or business in the United States:

- In the case of a disregarded entity with a U.S. owner, the U.S. owner of the disregarded entity and not the entity;
- In the case of a grantor trust with a U.S. grantor or other U.S. owner, generally, the U.S. grantor or other U.S. owner of the grantor trust and not the trust, and
- In the case of a U.S. trust (other than a grantor trust), the U.S. trust (other than a grantor trust) and not the beneficiaries of the trust.

Foreign person. If you are a foreign person or the U.S. branch of a foreign bank that has elected to be treated as a U.S. person, do not use Form W-9. Instead, use the appropriate Form W-8 or Form 9333 (see Publication 515, Withholding of Tax on Nonresident Aliens and Foreign Entities).

Nonresident alien who becomes a resident alien. Generally, only a nonresident alien individual may use the terms of a tax treaty to reduce or eliminate U.S. tax on certain types of income. However, most tax treaties contain a provision known as a "saving clause." Exceptions specified in the saving clause may permit an exemption from tax to continue for certain types of income even after the payee has otherwise become a U.S. resident alien for tax purposes.

If you are a U.S. resident alien who is relying on an exception contained in the saving clause of a tax treaty to claim an exemption from U.S. tax on certain types of income, you must attach a statement to Form W-9 that specifies the following five items:

1. The treaty country. Generally, this must be the same treaty under which you claimed exemption from tax as a nonresident alien.
2. The treaty article addressing the income.
3. The article number (or location) in the tax treaty that contains the saving clause and its exceptions.
4. The type and amount of income that qualifies for the exemption from tax.
5. Sufficient facts to justify the exemption from tax under the terms of the treaty article.

Example. Article 20 of the U.S.-China income tax treaty allows an exemption from tax for scholarship income received by a Chinese student temporarily present in the United States. Under U.S. law, this student will become a resident alien for tax purposes if he or her stay in the United States exceeds 5 calendar years. However, paragraph 2 of the first Protocol to the U.S.-China treaty (dated April 30, 1984) allows the provisions of Article 20 to continue to apply even after the Chinese student becomes a resident alien of the United States. A Chinese student who qualifies for this exemption (under paragraph 2 of the first protocol) and is relying on this exception to claim an exemption from tax on his or her scholarship or fellowship income would attach to Form W-9 a statement that includes the information described above to support that exemption.

If you are a nonresident alien or a foreign entity, give the requester the appropriate completed Form W-8 or Form 8333.

What is backup withholding? Persons making certain payments to you must under certain conditions withhold and pay to the IRS a percentage of such payments. This is called "backup withholding." Payments that may be subject to backup withholding include interest, tax-exempt interest, dividends, broker and barter exchange transactions, rents, royalties, nonemployee pay, payments made in settlement of payment cards and third party network transactions, and certain payments from fishing boat operators. Real estate transactions are not subject to backup withholding.

You will not be subject to backup withholding on payments you receive if you give the requester Form W-9, make the certifications, and report all your taxable interest and dividends on your tax return.

Payments you receive will be subject to backup withholding if:

1. You do not furnish your TIN to the requester,
2. You do not certify your TIN when required (see the Part II instructions on page 3 for details),
3. The IRS tells the requester that you furnished an incorrect TIN,
4. The IRS tells you that you are subject to backup withholding because you did not report all your interest and dividends on your tax return (for reportable interest and dividends only), or
5. You do not certify to the requester that you are not subject to backup withholding under 4 above (for reportable interest and dividend accounts opened after 1983 only).

Certain payees and payments are exempt from backup withholding. See Exempt payees on page 3 and the separate Instructions for the Requester of Form W-9 for more information.

Also see Special rules for partnerships on page 1.

What is FATCA reporting? The Foreign Account Tax Compliance Act (FATCA) requires a participating foreign financial institution to report all United States accounts held by United States persons. Certain payees are exempt from FATCA reporting. See Exemption from FATCA reporting code on page 3 and the Instructions for the Requester of Form W-9 for more information.

Updating Your Information

You must provide updated information to any person to whom you claimed to be an exempt payee if you are no longer an exempt payee and anticipate receiving new payments in the future from this person. For example, if you need to provide updated information if you are a C Corporation that elects to be an S corporation, or if you no longer are a tax exempt. In addition, you must furnish a new Form W-9 if the name or TIN changes for the account, for example, if the grantor of a grantor trust dies.

Penalties

Failure to furnish TIN. If you fail to furnish your correct TIN to a requester, you are subject to a penalty of $50 for each such failure unless your failure is due to reasonable cause and not to willful neglect.

Civil penalty for false information with respect to withholding. If you make a false statement with no reasonable basis that results in no backup withholding, you are subject to a $500 penalty.

Criminal penalty for falsifying information. Willfully falsifying certifications or affirmations may subject you to criminal penalties including fines and/or imprisonment.

Misuse of TINs. If the requester discloses or uses TINs in violation of federal law, the requester may be subject to civil and criminal penalties.

Specific Instructions

Name

If you are an individual, you must generally enter the name shown on your income tax return. However, if you have changed your last name, for instance, due to marriage without informing the Social Security Administration of the name change, enter your first name, the last name shown on your social security card, and your new last name.

If the account is in joint names, list first, and then circle, the name of the person or entity whose name you entered in Part I of the form.

Sole proprietor. Enter your individual name as shown on your income tax return on the "Name" line. You may enter your business, trade, or "doing business as (DBA)" name on the "Business name/disregarded entity name" line.

Partnership, C Corporation, or S Corporation. Enter the entity's name on the "Name" line and any business, trade, or "doing business as (DBA)" name on the "Business name/disregarded entity name" line.

Disregarded entity. For U.S. federal tax purposes, an entity that is disregarded as an entity separate from its owner is treated as a "disregarded entity." See Regulation section 301.7701-2(c)(2)(ii). Enter the owner's name on the "Name" line. The name of the entity entered on the "Name" line should never be a disregarded entity name. The name on the "Name" line must be the name shown on the income tax return on which the income should be reported. For example, if a foreign LLC that is treated as a disregarded entity for U.S. federal tax purposes has a single owner that is a U.S. person, the U.S. owner's name is required to be provided on the "Name" line. If the direct owner of the entity is also a disregarded entity, enter the first owner that is not disregarded for federal tax purposes. Enter the disregarded entity's name on the "Business name/disregarded entity name" line. The owner of the disregarded entity is a foreign person, the owner must complete an appropriate Form W-8 instead of a Form W-9. This is the case even if the foreign person has a U.S. TIN.

Note. Check the appropriate box for the U.S. federal tax classification of the person whose name is entered on the "Name" line (individual/sole proprietor, Partnership, C Corporation, S Corporation, Trust/estate).

Limited Liability Company (LLC). If the person identified on the "Name" line is an LLC, check the "Limited liability company" box only and enter the appropriate code for the U.S. federal tax classification in the space provided. If you are an LLC that is treated as a partnership for U.S. federal tax purposes, enter "P" for partnership. If you are an LLC that has filed a Form 8332 or a Form 29153 to be taxed as a corporation, enter "C" for C corporation or "S" for S corporation, as appropriate. If you are an LLC that is disregarded as an entity separate from its owner under Regulation section 301.7701-3 (except for employment and excise tax), do not check the LLC box unless the owner of the LLC (required to be identified on the "Name" line) is another LLC that is not disregarded for U.S. federal tax purposes. If the LLC is disregarded as an entity separate from its owner, enter the appropriate tax classification of the owner identified on the "Name" line.

Other entities. Enter your business name as shown on required U.S. federal tax documents on the "Name" line. This name should match the name shown on the compliance or other legal document creating the entity. You may enter any business, trade, or DBA name on the "Business name/disregarded entity name" line.

Exemptions

If you are exempt from backup withholding and/or FATCA reporting, enter in the Exemptions box, any code(s) that may apply to you. See Exempt payee code and Exemption from FATCA reporting code on page 3.
Exempt payee code. Generally, individuals (including sole proprietors) are not exempt from backup withholding. Corporations are exempt from backup withholding for certain payments, such as interest and dividends. Corporations are not exempt from backup withholding for payments made in settlement of payment card or third party network transactions.

Note. If you are exempt from backup withholding, you should still complete this form to avoid possible erroneous backup withholding.

The following codes identify payees that are exempt from backup withholding:

1—An organization exempt from tax under section 501(a), any IRA, or a custodial account under section 403(b)(7) if the account satisfies the requirements of section 401(f)(3)

2—the United States or any of its agencies or instrumentalities

3—a state, the District of Columbia, a possession of the United States, or any of their political subdivisions or instrumentalities

4—an foreign government or any of its political subdivisions, agencies, or instrumentalities

5—a corporation

6—a dealer in securities or commodities required to register in the United States, the District of Columbia, or a possession of the United States

7—a futures commission merchant registered with the Commodity Futures Trading Commission

8—a real estate investment trust

9—an entity registered at all times during the tax year under the Investment Company Act of 1940

10—a common trust fund operated by a bank under section 584(a)

11—a financial institution

12—a middleman known in the investment community as a nominee or custodian

13—a trust exempt from tax under section 664 or described in section 4947

The following chart shows types of payments that may be exempt from backup withholding. The chart applies to the exempt payees listed above, 1 through 13.

**IF the payment is for . . . THEN the payment is exempt for . . .**

<table>
<thead>
<tr>
<th>Interest and dividend payments</th>
<th>All exempt payees except for 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Broker transactions</td>
<td>Exempt payees 1 through 4 and 6 through 11 and all C corporations. S corporations must not enter an exempt payee code because they are exempt only for sales of noncovered securities acquired prior to 2012.</td>
</tr>
<tr>
<td>Barter exchange transactions and patronage dividends</td>
<td>Exempt payees 1 through 4</td>
</tr>
<tr>
<td>Payments over $600 required to be reported and direct sales over $5,000¹</td>
<td>Generally, exempt payees 1 through 5²</td>
</tr>
<tr>
<td>Payments made in settlement of payment card or third party network transactions</td>
<td>Exempt payees 1 through 4</td>
</tr>
</tbody>
</table>

¹ See Form 1099-MISC, Miscellaneous Income, and its instructions.

² However, the following payments made to a corporation and reportable on Form 1099-MISC are not exempt from backup withholding: medical and health care payments, attorneys’ fees, gross proceeds paid to an attorney, and payments for services paid by a federal executive agency.

Exemption from FATCA reporting code. The following codes identify payees that are exempt from reporting under FATCA. These codes apply to persons submitting this form for accounts maintained outside of the United States by certain foreign financial institutions. Therefore, if you are only submitting this form for an account you hold in the United States, you may leave this field blank.

Consult with the person requesting this form if you are uncertain if the financial institution is subject to these requirements.

A.An organization exempt from tax under section 501(a) or any individual retirement plan as defined in section 7701(e)(57)

B.—The United States or any of its agencies or instrumentalities

C.—A state, the District of Columbia, a possession of the United States, or any of their political subdivisions or instrumentalities

D.—A corporation the stock of which is regularly traded on one or more established securities markets, as described in Reg. section 1.1472-1(c)(3)(i)

E.—A corporation that is a member of the same expanded affiliated group as a corporation described in Reg. section 1.1472-1(c)(1)(i)

F.—A dealer in securities, commodities, or derivative financial instruments (including notional principal contracts, futures, forwards, and options) that is registered as such under the laws of the United States or any state

G.—A real estate investment trust

H.—A regulated investment company as defined in section 851 or an entity registered at all times during the tax year under the Investment Company Act of 1940

I.—A common trust fund as defined in section 584(a)

J.—A bank as defined in section 581

K.—A broker

L.—A trust exempt from tax under section 664 or described in section 4947(a)(1)

M.—A tax exempt trust under a section 403(b) plan or section 457(g) plan

**Part I. Taxpayer Identification Number (TIN)**

Enter your TIN in the appropriate box. If you are a resident alien and you do not have and are not eligible to get an SSN, your TIN is your IRS individual taxpayer identification number (ITIN). Enter it in the social security number box. If you do not have an ITIN, see How to get a TIN below.

If you are a sole proprietor and you have an EIN, you may enter either your SSN or EIN. However, the IRS prefers that you use your SSN.

If you are a single-member LLC that is disregarded as an entity separate from its owner (see Limited Liability Company (LLC) on page 2), enter the owner’s SSN (or EIN, if the owner has one). Do not enter the disregarded entity’s EIN. If the LLC is classified as a corporation or partnership, enter the entity’s EIN.

**Note.** See the chart on page 4 for further clarification of name and TIN combinations.

**How to get a TIN.** If you do not have a TIN, apply for one immediately. To apply for an SSN, get Form SS-5, Application for a Social Security Card, from your local Social Security Administration office or get this form online at www.ssa.gov. You may also get this form by calling 1-800-772-1213. Use Form W-7, Application for IRS Individual Taxpayer Identification Number, to apply for an ITIN, or Form SS-4, Application for Employer Identification Number, to apply for an EIN. You can apply for an EIN online by accessing the IRS website at www.irs.gov/businesses and clicking on Employer Identification Number (EIN) under Starting a Business. You can get Forms W-7 and SS-4 from the IRS by visiting IRS.gov or by calling 1-800-TAX-FORM (1-800-829-3676).

If you are asked to complete Form W-9 but do not have a TIN, apply for a TIN and write “Applied For” in the space for the TIN, sign and date the form, and give it to the requestor. For interest and dividend payments, and certain payments made with respect to readily tradable instruments, generally you will have 60 days to get a TIN and give it to the requestor before you are subject to backup withholding on payments. The 60-day rule does not apply to other types of payments. You will be subject to backup withholding on all such payments until you provide your TIN to the requestor.

**Note.** Entering “Applied For” means that you have already applied for a TIN or that you intend to apply for one soon.

**Caution:** A disregarded U.S. entity that has a foreign owner must use the appropriate Form W-8.

**Part II. Certification**

To establish to the withholding agent that you are a U.S. person, or resident alien, sign Form W-9. You may be requested to sign by the withholding agent even if the items 1, 4, or 5 below indicate otherwise.

For a joint account, only the person whose TIN is shown in Part I should sign (when required). In the case of a disregarded entity, the person identified on the “Name” line must sign. Exempt payees, see Exempt payees code earlier.

**Signature requirements.** Complete the certification as indicated in items 1 through 5 below.

1. **Interest, dividend, and barter exchange accounts opened before 1984** and broker accounts considered active during 1983. You must give your correct TIN, but you do not have to sign the certification.

2. **Interest, dividend, broker, and barter exchange accounts opened after 1983 and broker accounts considered inactive during 1983.** You must sign the certification or backup withholding will apply. If you are subject to backup withholding and you are merely providing your correct TIN to the requestor, you must cross out item 2 in your certification before signing the form.

3. **Real estate transactions.** You must sign the certification. You may cross out item 2 of the certification.

4. **Other payments.** You must give your correct TIN, but you do not have to sign the certification unless you have been notified that you have previously given an incorrect TIN. “Other payments” include payments made in the course of the requestor’s trade or business for rents, royalties, goods (other than bills for merchandise), medical and health care services (including payments to corporations), payments to a nonemployee for services, payments made in settlement of payment card and third party network transactions, payments to certain fishing boat crew members and fishermen, and gross proceeds paid to attorneys (including payments to corporations).

5. **Mortgage interest paid by you, acquisition or abandonment of secured property, cancellation of debt, qualified tuition program payments (under section 529), IRA, Coverdell ESA, Archer MSA or HSA contributions or distributions, and pension payments.** You must give your correct TIN, but you do not have to sign the certification.
What Name and Number To Give the Requester

<table>
<thead>
<tr>
<th>For this type of account:</th>
<th>Give name and SSN of:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Individual</td>
<td>The individual</td>
</tr>
<tr>
<td>2. Two or more individuals (joint account)</td>
<td>The actual owner of the account or, if combined funds, the first individual on the account¹</td>
</tr>
<tr>
<td>3. Custodian account of a minor (Uniform Gift to Minors Act)</td>
<td>The minor²</td>
</tr>
<tr>
<td>4. a. The usual revocable savings trust (grantor is also trustee)</td>
<td>The grantor-trustee¹</td>
</tr>
<tr>
<td>b. So-called trust account that is not a legal or valid trust under state law</td>
<td>The actual owner¹</td>
</tr>
<tr>
<td>6. Sole proprietorship or disregarded entity owned by an individual</td>
<td>The owner³</td>
</tr>
<tr>
<td>6. Grantor trust filing under Optional Form 1099 Filing Method 1 (see Regulation section 1.671-4(b)(2)(ii)(A))</td>
<td>The grantor⁴</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>For this type of account:</th>
<th>Give name and EIN of:</th>
</tr>
</thead>
<tbody>
<tr>
<td>7. Disregarded entity not owned by an individual</td>
<td>The owner</td>
</tr>
<tr>
<td>8. A valid trust, estate, or pension trust</td>
<td>Legal entity⁴</td>
</tr>
<tr>
<td>9. Corporation or LLC electing corporate status on Form 2532 or Form 2553</td>
<td>The corporation</td>
</tr>
<tr>
<td>10. Association, club, religious, charitable, educational, or other tax-exempt organization</td>
<td>The organization</td>
</tr>
<tr>
<td>11. Partnership or multi-member LLC</td>
<td>The partnership</td>
</tr>
<tr>
<td>12. A broker or registered nominee</td>
<td>The broker or nominee</td>
</tr>
<tr>
<td>13. Account with the Department of Agriculture in the name of a public entity (such as a state or local government, school district, or prison) that receives agricultural program payments</td>
<td>The public entity</td>
</tr>
<tr>
<td>14. Grantor trust filing under the Form 1041 Filing Method or the Optional Form 1099 Filing Method 2 (see Regulation section 1.671-4(b)(2)(ii)(B))</td>
<td>The trust</td>
</tr>
</tbody>
</table>

¹ List first and circle the name of the person whose number you furnish. If only one person on a joint account has an SSN, that person's number must be furnished.
² Circle the minor's name and furnish the minor's SSN.
³ You must show your individual name and you may also enter your business or "DBA" name on the "Business name/disregarded entity" name line. You may use either your SSN or EIN (if you have one), but the IRS encourages you to use your SSN.
⁴ List first and circle the name of the trust, estate, or pension trust. (Do not furnish the TIN of the personal representative or trustee unless the legal entity itself is not designated in the account title.) Also see Special rules for partnerships on page 1.
⁵ Note: Grantor also must provide a Form W-9 to trustee of trust.

Note: If no name is circled when more than one name is listed, the number will be considered to be that of the first name listed.

Secure Your Tax Records from Identity Theft

Identity theft occurs when someone uses your personal information such as your name, social security number (SSN), or other identifying information, without your permission, to commit fraud or other crimes. An identity thief may use your SSN to get a job or may file a tax return using your SSN to receive a refund.

To reduce your risk:
- Protect your SSN,
- Ensure your employer is protecting your SSN, and
- Be careful when choosing a tax preparer.

If your tax records are affected by identity theft and you receive a notice from the IRS, respond right away to the name and phone number printed on the IRS notice or letter.

If your tax records are not currently affected by identity theft but you think you are at risk due to a lost or stolen purse or wallet, questionable credit card activity or credit report, contact the IRS Identity Theft Hotline at 1-800-908-4490 or submit Form 14039.

For more information, see Publication 4535, Identity Theft Prevention and Victim Assistance.

Victims of identity theft who are experiencing economic harm or a system problem, or are seeking help in resolving tax problems that have not been resolved through normal channels, may be eligible for Taxpayer Advocate Service (TAS) assistance. You can reach TAS by calling the TAS toll-free case intake line at 1-877-777-4776 or TTY/TDD 1-800-632-4459.

Protect yourself from suspicious emails or phishing schemes. Phishing is the creation and use of email and websites designed to mimic legitimate business emails and websites. The most common act is sending an email to a user falsely claiming to be an established legitimate enterprise in an attempt to scam the user into surrendering private information that will be used for identity theft. The IRS does not initiate contacts with taxpayers via emails. Also, the IRS does not request personal detailed information through email or ask taxpayers for the PIN numbers, passwords, or similar secret access information for their credit card, bank, or other financial accounts.

If you receive an unsolicited email claiming to be from the IRS, forward this message to phishing@irs.gov. You may also report misuse of the IRS name, logo, or other IRS property to the Treasury Inspector General for Tax Administration at 1-800-366-4484. You can forward suspicious emails to the Federal Trade Commission at: spam@uce.gov or contact them at www.ftc.gov/didtheft or 1-877-IDTHEFT (1-877-438-4338).

Visit IRS.gov to learn more about identity theft and how to reduce your risk.

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Privacy Act Notice

Section 6109 of the Internal Revenue Code requires you to provide your correct TIN to persons (including federal agencies) who are required to file information returns with the IRS to report interest, dividends, or certain other income paid to you; mortgage interest you paid; the acquisition or abandonment of secured property; the cancellation of debt; or contributions you made to an IRA, Archer MSA, or HSA. The person collecting this form uses the information on the form to file information returns with the IRS, reporting the above information. Routine uses of this information include giving it to the Department of Justice for civil and criminal litigation and to cities, states, the District of Columbia, and U.S. commonwealths and possessions for use in administering their laws. The information also may be disclosed to other countries under a treaty, to federal and state agencies to enforce civil and criminal laws, or to federal law enforcement and intelligence agencies to combat terrorism. You must provide your TIN whether or not you are required to file a tax return. Under section 3406, payers must generally withhold a percentage of taxable interest, dividend, and certain other payments to a payee who does not give a TIN to the payer. Certain penalties may also apply for providing false or fraudulent information.
1. NAME AND ADDRESS OF INVESTIGATOR

<table>
<thead>
<tr>
<th>Name of Principal Investigator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address 1</td>
</tr>
<tr>
<td>City</td>
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<tr>
<td>State/Province/Region</td>
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<tr>
<td>Country</td>
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<tr>
<td>ZIP or Postal Code</td>
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<tr>
<td>Address 2</td>
</tr>
</tbody>
</table>

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED (SELECT ONE OF THE FOLLOWING.)

- Curriculum Vitae
- Other Statement of Qualifications

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED

<table>
<thead>
<tr>
<th>Name of Medical School, Hospital, or Other Research Facility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address 1</td>
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<tr>
<td>City</td>
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<tr>
<td>State/Province/Region</td>
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<tr>
<td>Country</td>
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<tr>
<td>ZIP or Postal Code</td>
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<tr>
<td>Address 2</td>
</tr>
</tbody>
</table>

4. NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY

<table>
<thead>
<tr>
<th>Name of Clinical Laboratory Facility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brigham and Women's Hospital</td>
</tr>
<tr>
<td>Address 1</td>
</tr>
<tr>
<td>961 Commonwealth Ave</td>
</tr>
<tr>
<td>City</td>
</tr>
<tr>
<td>Boston</td>
</tr>
<tr>
<td>State/Province/Region</td>
</tr>
<tr>
<td>MA</td>
</tr>
<tr>
<td>Country</td>
</tr>
<tr>
<td>USA</td>
</tr>
<tr>
<td>ZIP or Postal Code</td>
</tr>
<tr>
<td>02215-1204</td>
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5. NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW AND APPROVAL OF THE STUDY(IES)

<table>
<thead>
<tr>
<th>Name of IRB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Copernicus Group IRB</td>
</tr>
<tr>
<td>Address 1</td>
</tr>
<tr>
<td>One Triangle Drive</td>
</tr>
<tr>
<td>City</td>
</tr>
<tr>
<td>Durham</td>
</tr>
<tr>
<td>State/Province/Region</td>
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<tr>
<td>NC</td>
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<tr>
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<tr>
<td>27709</td>
</tr>
</tbody>
</table>

6. NAMES OF SUBINVESTIGATORS (IF NOT APPLICABLE, ENTER "NONE")

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR

Cardiovascular Inflammation Reduction Trial
8. PROVIDE THE FOLLOWING CLINICAL PROTOCOL INFORMATION. (Select one of the following.)

☐ For Phase 1 investigations, a general outline of the planned investigation including the estimated duration of the study and the maximum number of subjects that will be involved.

☐ For Phase 2 or 3 investigations, an outline of the study protocol including an approximation of the number of subjects to be treated with the drug and the number to be employed as controls, if any; the clinical uses to be investigated; characteristics of subjects by age, sex, and condition; the kind of clinical observations and laboratory tests to be conducted; the estimated duration of the study; and copies or a description of case report forms to be used.

9. COMMITMENTS

I agree to conduct the study(ies) in accordance with the relevant, current protocol(s) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

I agree to personally conduct or supervise the described investigation(s).

I agree to inform any patients, or any persons used as controls, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review and approval in 21 CFR Part 56 are met.

I agree to report to the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with 21 CFR 312.64. I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for inspection in accordance with 21 CFR 312.68.

I will ensure that an IRB that complies with the requirements of 21 CFR Part 56 will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

INSTRUCTIONS FOR COMPLETING FORM FDA 1572
STATEMENT OF INVESTIGATOR

1. Complete all sections. Provide a separate page if additional space is needed.

2. Provide curriculum vitae or other statement of qualifications as described in Section 2.

3. Provide protocol outline as described in Section 8.

4. Sign and date below.

5. FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROVIDED TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND). INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINISTRATION.

10. DATE (mm/dd/yyyy)  11. SIGNATURE OF INVESTIGATOR

(WARNING: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)

The Information below applies only to requirements of the Paperwork Reduction Act of 1995.

The burden time for this collection of information is estimated to average 100 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to the address to the right:

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

DO NOT SEND YOUR COMPLETED FORM TO THIS PRA STAFF EMAIL ADDRESS.
Name of Clinical Laboratory Facility
Laboratory Corporation of America Holdings Esoterix Clinical Trials Services

<table>
<thead>
<tr>
<th>Address 1</th>
<th>Address 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>4307 Emperor Boulevard</td>
<td>Suite 200</td>
</tr>
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<table>
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<tr>
<th>City</th>
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<tbody>
<tr>
<td>Durham</td>
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Name of Clinical Laboratory Facility

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Name of Clinical Laboratory Facility

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Add Second Continuation Page for Item 4