WHAT IS THE AFFORDABLE CARE ACT?
The Patient Protection and Affordable Care Act (ACA), signed into law March 2010, changed several rules about health care insurance coverage in the United States, including coverage of clinical trials. Clinical trials study new ways to treat, prevent, or diagnose cancer, manage side effects, or improve patients’ quality of life. They often offer treatment options that would not otherwise be available outside of the clinical trial.

HOW ARE CLINICAL TRIALS COVERED THROUGH THE ACA?
The ACA sets the national minimum for coverage of clinical trials. Health plans newly issued or renewed on or after January 1, 2014, will not be allowed to limit or deny your coverage if you choose to participate in an approved clinical trial. This requirement applies to group health plans offered by your employer and plans purchased from an insurance company through an ACA insurance exchange. If your state has a law requiring more coverage, your insurer will continue to follow those requirements in addition to the ACA requirements.

WHICH HEALTH PLANS DO NOT FOLLOW THE ACA REQUIREMENTS FOR CLINICAL TRIALS COVERAGE?
The ACA clinical trial coverage provision does not apply to a “grandfathered” plan, which is a health plan that existed when the ACA was signed into law. Some grandfathered plans may already cover clinical trials. If your grandfathered insurance plan has reduced benefits or increased costs since March 23, 2010, or does so in the future, it is no longer a grandfathered plan. Then, it will need to follow all ACA requirements, including the clinical trials coverage requirement. A grandfathered plan must notify you of its grandfathered status in all informational materials that describe your plan benefits.

WHAT COSTS DOES THE ACA REQUIRE MY HEALTH INSURANCE TO COVER?
Your insurer must provide coverage for routine costs of care. Routine costs of care include any treatments, procedures, and services you need while participating in the clinical trial that would normally be covered if you were not participating in a trial. The ACA does not require your insurer to cover the research costs for the clinical trial. These may include the drug being studied and any treatments, tests, or procedures done to collect data for the study. These research costs are not usually considered part of the standard care for your condition, but they are often covered by the clinical trial sponsor.
QUESTIONS TO ASK A CLINICAL TRIAL’S RESEARCH TEAM
Before participating in a clinical trial, consider asking the research team the following questions about clinical trial costs:

- Who is sponsoring or funding this clinical trial?
- What costs are associated with this clinical trial?
- Which of these costs are covered by the clinical trial sponsor?
- Can you help me find out what costs will be covered by my insurance?
- Which costs will I be responsible for?

Find additional questions related to clinical trials at www.cancer.net/clinicaltrials and questions on the cost of care and the ACA at www.cancer.net/managingthecostofcare.

WHERE TO FIND ADDITIONAL INFORMATION
Several governmental organizations can help you understand required health care coverage:

- Center for Consumer Information and Insurance Oversight (www.healthcare.gov)
- State Insurance Departments (www.medicare.gov/Contacts/staticpages/sids.aspx)
- U.S. Department of Labor (www.askebsa.dol.gov)

Other organizations to help you understand how these health insurance requirements affect your care:

- Patient Advocate Foundation (www.patientadvocate.org)
- CancerCare: (www.cancercare.org)
- Cancer Support Community (www.cancersupportcommunity.org)

For more information, visit ASCO’s patient website, www.cancer.net, or call 888-651-3038.

The ideas and opinions expressed here do not necessarily reflect the opinions of the American Society of Clinical Oncology (ASCO) or The Conquer Cancer Foundation. The information in this fact sheet is not intended as medical or legal advice, or as a substitute for consultation with a physician or other licensed health care provider. Patients with health care-related questions should call or see their physician or other health care provider promptly and should not disregard professional medical advice, or delay seeking it, because of information encountered here. The mention of any product, service, or treatment in this fact sheet should not be construed as an ASCO endorsement. ASCO is not responsible for any injury or damage to persons or property arising out of or related to any use of ASCO’s patient education materials, or to any errors or omissions.

A central IRB has determined that this information is not research and can be distributed to patients considering participation or already participating in a clinical trial.