BACKGROUND
The American Heart Association’s public policy agenda provides our federal, state and local advocacy staff with strategic guidance and direction on policy issues and positions that align with and support the Association’s mission and strategic priorities. Additionally, each year the AHA scans the political landscape to identify opportunities and establishes federal and state priorities that serve to focus our immediate advocacy efforts on those issues that present the greatest opportunity for success in achieving mission and strategic priority related health impact through public policy.

EXECUTIVE SUMMARY
This document provides a comprehensive summary of the policy priorities of the American Heart Association in the areas of heart disease and stroke research, cardiovascular health (nutrition, physical activity, obesity treatment and prevention, tobacco cessation and prevention, and air pollution), high quality/high value of heart disease and stroke care, appropriate and timely access to heart disease and stroke care and protection of the non-profit environment. Included in each of these areas is the Association’s commitment to proactively confront and address, through public policy, the health inequities and disparities that exist in our country. Working with our local affiliates and You’re the Cure grassroots advocates, the AHA is in a position itself to address legislative and regulatory opportunities that advance our mission through public policy at the federal, state, and local level. Table 1 summarizes the policy and advocacy strategies in each of these priority areas.

The AHA’s Advocacy Coordinating Committee (AdCC), a committee of the Association’s national board, is responsible for establishing the Association’s policy positions, public policy agenda, and annual legislative and regulatory priorities. The public policy agenda and annual priorities are a product of a rigorous internal process that is informed by our science, guided by our 2020 health impact goal and strategic plan, and the expert advice and counsel of AHA staff and volunteers. The Association’s advocacy priorities are pursued through policy research and analysis, legislative and regulatory advocacy, and media relations with the invaluable assistance of the AHA’s You’re the Cure volunteer advocates.

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## Summary of AHA Policy Priorities for 2010-13

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<th>AHA Strategic Priority</th>
<th>Advocacy Plan to Achieve this Priority</th>
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<td><strong>Support Heart Disease and Stroke Research and the research environment</strong></td>
<td>Provide support for basic, clinical, translational, health services, outcomes, genomics, and comparative effectiveness research and the overall research environment as well as community health services, public health programs, policy evaluation and economics.</td>
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**Increase Funding for:**
- The National Institutes of Health (NIH) and the Institutes and Centers within NIH that conduct heart disease and stroke research as well as cross-cutting areas like obesity, and genetics;
- The Agency for Healthcare Research and Quality (AHRQ);
- The Food and Drug Administration (FDA);
- The Centers for Disease Control and Prevention (CDC);
- Department of Veterans Affairs;
- State health departments and other regulatory agencies.

Funding requests for these various agencies often goes beyond research to include programmatic, service, and/or evaluation/surveillance funding.

**Lift barriers that impede the conduct of medical research:**
- Eliminate any unnecessary recruitment barriers created by the Institutional Review Board Process, Health Insurance Portability and Accountability Act (HIPAA) while maintaining the protection of individual health information;
- Protect individuals undergoing genetic tests from discrimination of any kind;
- Protect researcher access to humane animal research.
HEART DISEASE AND STROKE RESEARCH

In working to achieve its mission, the American Heart Association makes medical research a lead priority. The association believes that basic research is the starting point for all medical advances. Learning more about the life processes of the cardiovascular system is the only sure way the AHA can continue to treat—and prevent—heart disease and stroke and promote cardiovascular health for all Americans.

Although the association is the largest supporter of heart and stroke research outside of the federal government and the pharmaceutical industry, the AHA cannot accomplish its mission without the help of research supported by the federal government, primarily the National Institutes of Health (NIH), but also the Department of Veterans Affairs Medical and Prosthetic Research (VA), Agency of Healthcare Research and Quality (AHRQ), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Centers for Medicare and Medicaid Services (CMS); and the various state agencies. The association also advocates for the identification of additional federal funding sources to supplement, not reduce, monies awarded through the appropriations process. This section focuses on several areas of the association’s advocacy/policy agenda on heart and stroke research.

The association’s research priority includes all forms of scientific studies, including basic science as well as clinical, translational, health services (outcomes), genomics, and comparative effectiveness research and the overall research environment. Effectively preventing and treating disease depends on accurate knowledge about its causes, on how disease affects the body, on drugs that combat disease, on devices that work, and on operations that cure as well as clinical research that helps enable health care professionals to assist their patients and their families in building the skills they need to adopt and maintain a healthy lifestyle. The knowledge, material and skills on which prevention and treatment are based have come from a variety of sources, including information that can only be obtained from research on both animals and humans. Animal research has improved the health and welfare of animals and humans. The decline in death rates in the United States from heart disease and stroke since the 1960s is due to lifestyle changes and new methods of treatment and prevention, many of which are based on animal research. The association generally opposes legislation and regulations that would curtail necessary heart disease and stroke research or make it unduly difficult or costly.

Demographics

Death rates from coronary heart disease and stroke have each fallen by almost 30 percent since 1999. (Lloyd-Jones, Adams et al. 2009) This decline is directly related to heart and stroke research, with scientists on the verge of new and exciting discoveries that could lead to innovative treatments and even cures for heart disease and stroke. However, as baby boomers age, heart disease, stroke and other forms of cardiovascular disease will cost more lives and money. Heart disease and stroke are the number 1 and 3 causes of death, respectively, in the U.S. (Lloyd-Jones, Adams et al. 2009) Lifetime cardiovascular disease (CVD) risk in people free of disease at age 40 is 2 in 3 for men and more than 1 in 2 for women. (Lloyd-Jones, Adams et al. 2009) As the baby boomers age, heart disease deaths are projected to increase 2.5 times faster than the population, and the prevalence of heart disease is projected to increase by 16% each decade. (Foot, Lewis et al. 2000) Deaths from the most common type of stroke (ischemic stroke) are projected to increase nearly 100 percent to 275,000 between 2000 and 2032. (Elkins and Johnston 2003) CVD will cost our nation an estimated $500 billion in medical expenses and lost productivity, making it the most costly disease. (Lloyd-Jones, Adams et al. 2009) Treatment costs for CVD are expected to rise 64-84 percent by 2025. (Steinwachs, Collins-Nakai et al. 2000) Stroke treatment alone is projected to exceed $2 trillion by 2050. (Brown, Boden-Albala et al. 2006)

Research Can Save Money

Heart and stroke research can reduce healthcare costs. For example, every $1 spent in technological improvements in treating heart attacks saves $7. (Cutler and McClellan 2001) NIH research has shown that ordinary aspirin, with or without other anti-platelet drugs, can reduce the risk of recurrent stroke. (Sacco, Adams et al. 2006) The drug, tPA (tissue plasminogen activator) is the only FDA-approved emergency treatment for the most common type of stroke. (1995) Patients treated with tPA within 3 hours of onset of stroke symptoms are 30% more likely to have minimal or no disability at a 3-month follow-up. (1995) A recent study estimates the original National Institute of Neurological Disorders and Stroke (NINDS)-funded tPA trial resulted in a 10-year net benefit of $6.47 billion. (Johnston, Rootenberg et al. 2006) NINDS’S Stroke Prevention in Atrial Fibrillation (AF) Trial 1 showed treatment with aspirin or Warfarin could reduce stroke in AF victims by 80%, resulting in a 10-year net benefit of $1.27 billion, with a savings of 35,000 quality-adjusted life years. (Johnston, Rootenberg et al. 2006) Death rates from CVD have dropped by 63% and from stroke by 70% in the last 30 years, in large part as a result of NIH-funded research. (Zerhouni 2006) Reduction in heart disease death rates increased the value of life by
about $1.5 trillion annually from 1970-1990. Eliminating deaths from heart disease would generate about $48 trillion in economic value from increased life expectancy. (Murphy 1999)

Research Improves Care

Heart and stroke research has revolutionized patient care. The following are some examples of life-saving treatments:

Revolutionary clot-busting drugs reduce disability from heart attack or stroke by dissolving the blood clots that cause the attack.

- The use of drugs to lower cholesterol has reduced the average cholesterol level in the U.S. to the ideal range for the first time in about 50 years; (Schober 2007)
- Small, wire-mesh stents are one option for widening narrowed arteries in the heart or neck;
- Pacemakers, implantable cardiac defibrillators, automated external defibrillators (AEDs), and minimally invasive surgical techniques have significantly improved health care outcomes;
- FDA has approved the first totally implanted permanent artificial heart for patients with advanced heart failure;
- Constraint-induced Movement Therapy—a rehabilitative method forcing use of a partially paralyzed arm—can help stroke survivors regain arm function. Rehabilitation can also include prosthetic valves including those deployed percutaneously, closure devices that can be deployed without surgery.

The AHA’s Policy Agenda to Address Heart Disease and Stroke Research

Increase Funding

The National Institutes of Health

The NIH is our nation’s premier medical research agency and includes 27 Institutes and Centers. According to the NIH, it is the primary federal agency for conducting and supporting basic, clinical and translational medical research, and it investigates the causes, treatments, and cures from both common and rare diseases. To reduce disability and death from cardiovascular disease, the Association seeks to obtain steady, long-term significant growth in funding for the NIH, including for heart disease, stroke, sudden cardiac and respiratory arrest, and other cardiovascular diseases. This includes significant real growth in federal funding primarily for medical research programs of the

- National Heart, Lung, and Blood Institute: the NHLBI plans, conducts, and supports research related to the causes, prevention, diagnosis, and treatment of heart, blood vessel, lung, and blood diseases; and sleep disorders. The Institute also administers national health education campaigns on women and heart disease, healthy weight for children, and other topics;
- National Institute of Neurological Disorders and Stroke: the NINDS is the nation’s leading funder of research on the brain and nervous system. The Institute’s mission is to reduce the burden of neurological disease—a burden borne by every age group, by every segment of society, by people all over the world.

Attention should also be given to other 20 to 22 NIH institutes (out of 27), centers and divisions that conduct heart and stroke research, primarily the:

- National Institute on Aging (NIA): the NIA leads the federal effort supporting and conducting research on aging and the medical, social and behavioral issues of older people;
- National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK): the NIDDK conducts and supports basic and clinical research and research training on some of the most common, severe and disabling conditions affecting Americans. The Institute’s research interests include: diabetes and other endocrine and metabolic diseases; digestive diseases, nutrition, and obesity; and kidney, urologic and hematologic diseases; and
- National Institute of Nursing Research (NINR): the NINR supports basic and clinical research that develops the knowledge to build the scientific foundation for clinical practice, prevent disease and disability, manage and eliminate symptoms caused by illness, and enhance end-of-life and palliative care.

NIH-supported research has revolutionized patient care and holds the key to finding new ways to treat and prevent heart disease and stroke and promote cardiovascular health for all Americans, resulting in longer, healthier lives and reduced health care costs. In addition, NIH generates economic growth, creates jobs and preserves the U.S. role as the world leader in pharmaceutical and biotechnology industries. Specifically, NIH invests resources in every state and in 90% of congressional districts. Further, each NIH grant is associated with seven jobs.

Department of Veterans Affairs Medical and Prosthetic Research (VA)

The VA provides patient care and federal benefits to veterans and their dependents. Although the primary purpose of the VA health care system is quality care to qualified veterans, VA medical research contributes greatly to our overall medical research effort and patient care. Specifically, the VA’s Medical and Prosthetic
Research program supports heart and stroke research, so the association advocates for increased federal funding for this initiative. The VA’s support for heart and stroke research makes up a small but important portion of federal research in this area. VA heart and stroke research is largely clinical, playing a unique role by immediately translating research findings into patient care.

Agency for Healthcare Research and Quality
The AHRQ is the lead federal agency charged with improving the quality, safety, efficiency, and effectiveness of health care for all. This agency develops scientific evidence to improve health and health care. Through its Effective Health Care Program, AHRQ supports research focused on outcomes, comparative effectiveness and the appropriateness of pharmaceuticals, devices and health care services for conditions such as heart disease, stroke and high blood pressure. In addition, AHRQ’s health information technology (HIT) plan will help bring health care into the 21st century. The agency and its partners identify challenges to HIT adoption and use and develop solutions and best practices; and produce tools that help hospitals and clinicians successfully integrate HIT. This work is a key component to health reform. To reduce disability and death from heart disease and stroke, the Association advocates for increased federal funding for AHRQ’s clinical, behavioral and outcomes research.

Centers for Disease Control and Prevention (CDC)
The CDC, based in Atlanta, GA works to protect public health and safety by providing information, and conducting surveillance and programming to enhance health decisions, and promote health through partnerships with state health departments and other organizations. The CDC focuses national attention on developing and applying disease prevention and control, environmental health, occupational safety and health, health promotion, prevention and education. The American Heart Association works closely with CDC across several areas and advocates for funding for CDC and its initiatives. The CDC remains under-funded to fully achieve its mission in cardiovascular health—prevention of risk factors, detection and treatment of risk factors, early identification and treatment of heart attacks and strokes, and prevention of recurrent cardiovascular events—with unfulfilled potential to translate knowledge into public health practice through policy/environmental/system change and to evaluate the impact of these changes on improved cardiovascular health of the nation. The Association advocates for increased federal and state funding for CDC’s work, supporting activities focused on surveillance, chronic disease prevention, school-based health, and population-based prevention. The Association strives to decrease the percentage of people at risk for heart disease, stroke and other cardiovascular diseases that effectively reduce the risk factors to goal levels established by the Association’s guidelines for primary and secondary prevention. In particular, the Association is focused on federal funding for the Division for Heart Disease and Stroke Prevention, which includes funding for surveillance, evaluation, research and the state Heart Disease and Stroke Prevention Program. The Association works to secure and protect dedicated state appropriations for state Heart Disease and Stroke Prevention Programs in state health departments. Other areas are the tobacco cessation and prevention work within the Office of Smoking and Health, and obesity prevention, nutrition, and physical activity grants, surveillance and programming within the Division of Adolescent and School Health.

Food and Drug Administration (FDA)
The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security for several important areas including human drugs, biological products, medical devices, the nation’s food supply, and most recently the regulation of tobacco. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get accurate, science-based information to use medicines and foods to improve health. The AHA supports increased funding for the FDA to achieve its far-reaching mission and also supports and tracks the research conducted by the agency in the areas of food labeling, devices, pharmaceuticals, consumer awareness, and tobacco marketing and advertising. The AHA encourages cross-institutional funding of appropriate research programs.

State Agencies
Public funding for research and prevention efforts at the state level is essential if AHA is to achieve its health impact goals. The AHA promotes public funding for heart disease and stroke prevention programs, securing and protecting dedicated state appropriations for Heart Disease and Stroke Prevention programs in state health departments. In those states without Heart Disease and Stroke Prevention Programs, the AHA tries to secure the establishment of new programs, which have priorities consistent with those of the CDC’s National Heart Disease and Stroke Prevention program, and works to secure dedicated state appropriations to support program implementation. The AHA routinely explores opportunities to generate and direct additional fiscal resources for these programs and initiatives and support efforts to leverage new and existing federal funds and grant opportunities to supplement these efforts and support other public health initiatives.

Remove Barriers to Medical Research
Over the years, medical research has faced various barriers, including proposed constraints on animal research, peak and valley funding and undue constraints within the Institutional Review Board processes and HIPPA
regulations. The AHA advocates on several of these issues to limit the following barriers to effective medical research.

**Animal Research Constraints**
A small group of extreme animal-rights activists will not rest until all animal research is banned. For example, for more than a decade, these activists have tried to ban the use of U.S. Department of Agriculture licensed and regulated Class B dealers as a source of non-purpose bred dogs and cats in medical research. In addition, they strive to discourage pounds from providing unwanted animals for medical research. The goal to end Class B dealers is based on an erroneous assumption that these individuals routinely sell abused or stolen animals to scientific laboratories. Most recently activists have focused their efforts on both the legislative and appropriations processes to prohibit the use of these dealers through both the farm bill and NIH-supported researchers, respectively. Prohibition of the use of these Class B dealers would jeopardize cardiovascular disease research because certain studies and training to fight this condition are best performed on dogs that are large in size, older and represent a genetically diverse population. In many areas, suitable animals of these types are only available from Class B dealers. If these dealers are ultimately banned, the association wants to ensure that suitable animals required for all types of medical research will be accessible and affordable.

**Peak and Valley Funding for the NIH**
Historically, the NIH budget has grown on average 8 percent a year. However, from 1998 to 2003, the NIH budget was doubled. Unfortunately, from 2004 to 2008, the NIH suffered flat funding, losing 17 percent of its inflation-corrected purchasing power. Then, in 2009, NIH received the largest dollar increase ever. Specifically, the NIH secured two separate significant funding increases: $10 billion increase in the economic stimulus package to be spent during FY 2009 and FY 2010; and nearly a $1 billion increase in the FY 2009 appropriations law. The medical research community has learned its lesson after the NIH’s hard landing, following the end of the doubling of its budget. The community has vowed to do everything in its power to avoid a similar fate for the NIH when the stimulus resources end in September 2010 to avoid large swings in the magnitude of support. Plans are already in the works to aggressively lobby to maintain and build upon the expanded medical research capacity achieved with the stimulus resources.

**A Disproportionate Lack of NIH Funding for Heart and Stroke Research**
Despite considerable progress, heart disease, stroke and other forms of cardiovascular disease remain major causes of permanent disability and our Nation’s No. 1 and most costly killer, with a death every 38 seconds. In the face of these staggering statistics, heart disease and stroke research remains woefully underfunded. For example, NIH invests only 4 percent of its budget on heart research and a mere 1 percent on stroke research. This level of funding falls far short of being commensurate with scientific opportunities, the number afflicted and the human and economic toll exacted on our Nation.

**Institutional Review Board Processes/HIPAA Regulations**
Institutional Review Board processes and HIPAA privacy rules do create patient and research participant confusion, inhibit recruitment of research subjects and impose costly administrative procedures. (2008) Research conducted by the AHA has shown that respondents felt their research was “impacted” by HIPAA, public trust in research is not enhanced and others said the “research enterprise” is damaged—specifically 49% of respondents said recruitment is decreased, 67% said submissions are more complex, 78% said costs are increased and 79% said studies are longer. Additional research from AHA has shown that potential subjects were overwhelmed with minutiae to the point where the aim of the study was lost in "necessary text" making a full reading of the form nearly impossible for patients. This in turn discouraged many patients from participating in clinical research; and some researchers noted that it is often difficult to get busy clinicians to make contact with families to ask them "permission" for a third party to contact them about research. AHA research also found that current process requirements lead to more administrative costs including additional staff and/or increased number of meetings with legal, compliance, administration, to discuss roles, business relationships, and procedures that need to be followed; and delays now inherent in IRB review and re-review nearly ensure delays unacceptable to funding agencies.