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# The NIDDK Bariatric Surgery Clinical Research Consortium (LABS)

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Along with the increasing prevalence of obesity in the United States is the increased prevalence of obesity-related comorbidities, including type 2 diabetes, hypertension, serum lipid abnormalities, degenerative arthritis, and obesity-associated hypoventilation. Psychosocial correlates of excess weight, although less well documented, may include low self-esteem and confidence, perceived discrimination and stigmatization, social isolation and avoidance, poor social networks and relations, and frank psychopathology including depression and anxiety. The consequences of severe obesity cause disease and disability for the individual and are a major public health concern, in part due to the large burden put on health-related resources. Although behavioral interventions can lead to weight losses over time, leading to some reduction in comorbidities, weight rebounds are common and such treatments are not typically as effective in people with severe obesity. For such patients, bariatric surgery is an alternative.

In 1991, the National Institutes of Health held a Consensus Development Conference, at which time several research questions were posed that have not yet been answered (e.g., mechanisms by which surgery leads to weight reduction and improvements in comorbid conditions, and safety and efficacy of bariatric surgery), in part because improvements are still needed with respect to data collection methods, procedures, and outcomes assessments. A National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)-sponsored Working Group on Research in Bariatric Surgery, convened in May, 2002, advised that a consortium of centers that perform bariatric surgical procedures be established, in part to develop a database to collect information on clinically important predictors and outcomes that would benefit clinical research and help to understand better bariatric surgery and its sequelae.

In response, a Request for Applications (RFA) was released by NIDDK in November, 2002 to establish and maintain a Bariatric Surgery Research Consortium, comprised of clinical



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centers and a data coordinating center. The primary focus of this consortium is to support collaborative clinical, epidemiologic, and behavioral research in bariatric surgery by focusing on the role of bariatric surgery in treating obesity and its complications.

The Longitudinal Assessment of Bariatric Surgery (LABS) consortium, funded by NIDDK with the assistance of the NIH Office of Research on Women's Health, includes 6 clinical centers in New York (Principal Investigator [PI]: Paul Berk, M.D.), University of Washington (PI: David Flum, M.D., M.P.H.), Neuropsychiatric Research Institute, Fargo ND (PI: James Mitchell, M.D.), East Carolina University (PI: Walter Pories, M.D.), University of Pittsburgh Medical Center (Original PI: Philip Schauer, M.D.; Current PI: Anita Courcoulas, M.D., M.P.H.), and University of California-Davis (PI: Bruce Wolfe, M.D.). The Coordinating Center is located at the University of Pittsburgh Graduate School of Public Health (PI: Steven Belle, Ph.D, M.Sc.Hyg.). Christine Densmore, M.A., was the original Project Coordinator at the NIDDK, a position replaced by Carolyn Miles, Ph.D., Project Scientist.

LABS will select one or more laboratories for central assessments of various measures. Biospecimens, to be obtained and processed in standardized manners, will be stored at the NIDDK-supported Biosample Repository, where they will be available for future studies. Dr. David Kleiner, who is at the National Cancer Institute, will read all liver biopsies obtained for LABS.

The primary goal of this consortium is to conduct research that advances our understanding of bariatric surgery, including the mechanisms through which different procedures affect energy regulation and obesity-related comorbid conditions, and to identify metabolic predictors of response to surgery. To accomplish this goal, LABS brings together researchers with expertise in bariatric surgery and other relevant scientific disciplines, including medicine, metabolism, neuropsychiatry, nutrition, laboratory science, genetics, health economics, epidemiology, and biostatistics to plan and conduct studies that will ultimately lead to better understanding of bariatric surgery and its impact on the health and well-being of patients with extreme obesity. The consortium will enable collaborative studies in clinical, and more basic areas, including energy balance, nutrient absorption, genetics, physiology, and metabolism.

LABS investigators aim to standardize definitions of data items and data collection procedures. Common protocols will include data collection timepoints, data collection instruments, and methods for computerizing data. There will be detailed instructions on how to collect each data item. The data items will comprise a comprehensive core database for LABS participants. The database will enable us to investigate the impact of bariatric surgery on important clinical outcomes including mortality, complications (e.g., surgical leak, wound infection) and others (e.g., weight rebound, comorbidity improvement, quality of life) and to identify factors predictive for these outcomes.

LABS is organized around a series of committees, subcommittees, and working groups. The governing body is the Steering Committee, comprised of the Principal Investigators and another investigator (at least one of whom is a surgeon) from each clinical site; the

Coordinating Center Principal Investigator; and the NIDDK Project Scientist. Each clinical site, the coordinating center, and the NIDDK have one vote. The Steering Committee provides oversight in planning and implementing LABS. The committee votes on all important decisions and will approve the final core database and protocols for both the Core database and all sub-studies. The Steering Committee is co-chaired by Bruce Wolfe, M.D. and David Kelley, M.D. (co-Investigator from the University of Pittsburgh Medical Center clinical site). In the planning year, the Steering Committee met monthly— 6 times in person and 6 times by conference call. There are also weekly updates with information available on the study website.

The Executive Committee, comprised of the Steering Committee co-chairs, the Coordinating Center Principal Investigator, and the NIDDK Project Scientist, meets weekly by conference call. This committee makes decisions about study conduct in-between Steering Committee meetings, sets the agendas for Steering Committee meetings, and provides oversight to the study.

The working groups are proposing measures to collect in the core database, and suggesting short- and long-term sub-studies that will be carried out on a subset of LABS participants. To facilitate these tasks, there are 11 working groups, each responsible for a specific area of scientific endeavor related to bariatric surgery (surgical measures and operative risk, behavioral assessment, nutrition, laboratory measures, body composition, diabetes, cardiovascular disease, liver disease, health services and economics, quality of life, and biospecimens). Over 70 experts participate in these workgroups, with overlapping expertise assuring that the working groups function as a network, rather than as a series of independent bodies.

There are 4 active subcommittees. The Protocol subcommittee is charged with developing protocols, with the input of the working groups, and proposing data elements for the LABS core database for submission to the Steering Committee for final approval. The Ancillary Studies subcommittee has developed procedures for investigators who are seeking additional funds proposing to study LABS' patients, data, or biospecimens. The Publications and Presentations subcommittee has drafted policies regarding preparation of manuscripts, assigning writing groups, authorship policy, and other issues related to publications, abstracts, and presentations. The Website subcommittee is responsible for reviewing material that is on the study website, which is password-protected and available only to LABS personnel and workgroup members. A public website has been developed (http://www.niddklabs.org).

LABS is funded for 5 years, starting September 30, 2003. During the first year-and-a-half, the core database will be developed, protocols will be written, and appropriate regulatory documents created. Enrollment into the core database is expected to begin in Spring, 2005. Over the following 3 years, participants will be enrolled and followed with data collected according to a common protocol implemented at each of the clinical centers and monitored at the Coordinating Center. Short- and long-term studies of important aspects of bariatric surgery will be designed and implemented. Analyses will be performed and results presented

at scientific meetings and in the literature. In the final year, we envision follow-up continuing to enable investigations of long-term outcomes.

This Consensus Conference is happening just as LABS is working towards developing protocols, policies, and procedures. The information presented here may help LABS investigators to make informed decisions regarding inclusion criteria, data elements, and design issues to enhance our ability to provide clinically useful, and scientifically sound, data on patients with extreme obesity undergoing bariatric surgery.

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