

## Formation of the UDHQ-OTE Project

The UDHQ-OTE Project is an acronym for the development of a uniform donor history questionnaire for organ, tissue, and eye donors. This is a newly formed, multi-organizational endeavor with a primary goal to create a donor history questionnaire and materials for use by organ, tissue, and eye donation organizations that will be modeled after the donor history questionnaire and related materials developed for blood donation in the United States (U.S.).

There is a wealth of information that transplant professionals involved in eye banking, tissue banking, and organ transplantation can garner from the well organized development of a questionnaire and donor materials for blood donation. In 2000, at the request of the Food and Drug Administration (FDA), a Task Force was formed to create a uniform blood donation questionnaire. The membership included representatives from the blood and plasma industry, professional trade organizations, an ethicist, statistician, experts in survey design and cognitive methods, and liaisons from the Centers for Disease Control and Prevention (CDC) and FDA. Goals of the task force included reducing the complexity of the questionnaire and the educational materials to assure that donors will better comprehend the information and provide more accurate responses. Components of this formal evaluation of a redesigned questionnaire included: careful review of the requirements and recommendations of FDA regulations; application of the principles of questionnaire design; recommendations derived from experiences with focus groups who reviewed the materials; results of testing the materials using cognitive interviewing techniques; surveys directed to blood donor screening personnel who critiqued the new screening materials versus current materials; and finally, review for acceptability by the Center for Biologics Evaluation and Research (CBER) at the FDA. The result of the FDA review, which was published in April of 2004, can be found in the “Draft Guidance for Industry, Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Use in Screening Human Donors of Blood and Blood Components.” This can be accessed at <http://www.fda.gov/cber/gdlns/donorhistques.htm>. A second version (v1.1) may be published as a Final Guidance Document. It's apparent that extensive work by many dedicated individuals resulted in the culmination of these qualified materials. The incorporation of these as screening tools for blood donation will prove to streamline the process and satisfy both the donor and the screener/interviewer, but will also be more likely to correctly identify donors who qualify as well as those who do not – adding an increased measure of safety to the blood donation pool.

The questionnaires being used today to screen organ, tissue, and eye donors in the U.S. have many parallel problems that were identified 6 years ago in the blood donation industry. These include that the questionnaire(s): 1) content and formats have never been formally evaluated for effectiveness; 2) contain questions that are not necessary; 3) contain many, long, often compound questions; 4) use terminology and word phrases that the general public may not comprehend; and 5) are not standardized in any way from organization to organization. The UDHQ-OTE Project Team has been organized to explore the applicability of the blood UDHQ and materials to these donor screening processes. Members currently include representatives from the AATB, AABB, AOPO, EBAA, NATCO, CDC, FDA, HRSA, UNOS, and Health Canada. These types of donors pose unique challenges. There are living organ and tissue donors who will be their historian, but most donors of tissues and organs are deceased/brain dead. Generally, a historian is identified and expected to participate in completion of a questionnaire to supply relevant medical history and behavioral risk information soon after a life-changing event has occurred. This Project will require participation by many constituents of transplantation.