Implementation Guidance Document

Uniform Donor Risk Assessment Interview Form (Donor >12 yrs old)

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Dedication

The project to create this *Implementation Guidance Document, Donor Risk Assessment Interview* forms, and support documents is dedicated to all organ, tissue and eye donation professionals involved in communicating directly with donor family members and others to obtain information used to assess a donor's eligibility. These documents have been created to assist with performing this challenging and important part of the donation assessment that requires not only a thorough understanding of technical screening requirements but also compassion, patience, and empathy when interacting with acutely bereaved individuals. Providing this service is personally demanding in a number of ways, and you are recognized for your dedication and sacrifices. The important role you fulfill results in successful transplantation for many.

Respectfully,
Your colleagues

AATB, EBAA, and AOPO recognize the efforts of the following individuals who generously donated their time and expertise to creating and/or advising on the content of this document.

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IMPLEMENTATION GUIDANCE DOCUMENT
UNIFORM DONOR RISK ASSESSMENT INTERVIEW FORM
(Donor >12 yrs old)

I. INTRODUCTION

Organ, tissue, and eye (OTE) donation and transplantation professionals have long understood the value of collecting relevant medical, behavioral risk, and travel history information about potential donors to assess infectious disease risk as well as determine factors that can affect the quality of an organ or utility of the tissue. Testing today is greatly improved and valuable, both for detecting infectious diseases and understanding expected organ function, however, gaps remain (i.e., testing 'window periods,' health history that assists with predicting long term organ functionality) that can be filled by collecting accurate information from a proxy (or proxies) providing information on behalf of the OTE donor. In the past, OTE donor medical and behavioral risk questionnaires have not been studied to assess interviewee comprehension or interviewer perspectives on the functionality of formats, and these are known to be the root cause of mistakes. After reports of the successful development of a qualified blood donor questionnaire, the OTE donation community started a project to develop similar tools for screening donors for transplantation. To develop these tools, lessons learned from the blood donation community's experiences were used as well as knowledge and experience from our own professionals involved with interviewing recently grieving donor family members or others in close relationship to the donor.

This *Implementation Guidance Document* outlines expectations and contains useful descriptions and references for the person administering the *Uniform Donor Risk Assessment Interview* (DRAI) for a donor >12 years old. Following these instructions and utilization of support documents (see Appendices) should promote uniformity in donor screening activities and optimize donation outcomes.

To access components and considerations for developing and implementing an effective quality assurance program for personnel performing the DRAI process, refer to the current version of the AATB-EBAA-AOPO Guidance Document titled "*Effective Quality Assurance of the Donor Risk Assessment Interview*."

A. History and Purpose

The UDHQ-OTE Project was an acronym used for the development of a **U**niform **D**onor **H**istory **Q**uestionnaire for **O**rgan, **T**issue, and **E**ye donors. This project was conceptualized in late 2006 and became a major effort involving experienced professionals from organ, tissue, and eye donation organizations and related associations, as well as government agencies. Its purpose was to create qualified, uniform donor history questionnaires, one for a child donor and one for an adult donor, with supporting documents for use by OTE donation professionals when screening for risks and applying policies used to determine donor eligibility. Supporting documents

include this *Implementation Guidance Document,* references, and a flowchart for each interview question.

Historically, questionnaires used to screen OTE donors in the United States (US) and Canada have had problems similar to those identified at the turn of the century by blood donation professionals in North America. These include:

- content and formats have never been formally evaluated for effectiveness;
- inclusion of unnecessary questions that can act as distracters;
- incorporation of many long, often compound, questions;
- use of terminology and word phrases the general public may not comprehend; and
- lack of standardization among organizations, which affects tissue and eye bank quality program review processes and interpretation of answers by organ transplant professionals.

During 2007, a multi-organizational UDHQ-OTE Task Force was formed to begin work on a consensus questionnaire based on screening requirements of regulations and professional standards, best practices from the vast amount of experiences of members, and new concepts learned from the development in the United States (US) of a universal blood donor questionnaire, as well as one for cellular therapy product donors. This new Task Force met periodically by conference call over the next three years. On December 1, 2010 the Task Force released a draft version of a questionnaire to be used for an OTE donor >12 years old, as well as one for a child donor, and requested constructive comments from professionals and the public. Incorporation of these questionnaires will prove to streamline this critical donor risk assessment process and increase satisfaction of all stakeholders involved in providing donor information (the interviewees), those administering the interviews, and those who review the answers to the donor risk assessment questions. These tools are expected to:

- optimize identification of suitable donors;
- minimize donor loss due to inappropriate rule out;
- accurately identify an organ donor risk designation; and
- reduce complexity to facilitate comprehension by a bereaved interviewee.

The questions were designed to meet requirements and expectations of state, national and international regulations, laws, policies and/or standards. The concept surrounding how the interview can be done has been optimized by use of broad-based *filter questions*, a process that assists with a respondent's understanding of the questions. Further questioning to identify specific risk is only performed when indicated. Sub-questions were developed to gather appropriate, supportive information about the risk being evaluated.

In April 2011, a steering committee, the "UDHQ Stakeholder Review Group," was formed to review more than 500 comments received during the comment period and to finalize the forms. This group included representatives from appropriate government agencies such as FDA/CBER, HRSA, CDC and NCHS, as well as two OPTN/UNOS committees (DTAC, and the OPO

Committee), and professional societies, namely, AATB, AOPO, EBAA, NATCO, AST, and ASTS. A few members of the UDHQ Task Force completed the membership of this review group. They finalized a new draft version of the Uniform DRAI for a Donor >12 years old after careful consideration of comments received. Officials from FDA/CBER offered a few final comments for improvement that were incorporated so the form was sure to meet federal expectations when screening donors of human cells and/or tissues. This next version was made available for use on May 7, 2012 by the professional donation and transplantation societies above. Updates to questions occurred in early 2013 to ensure the Uniform DRAI for a Donor >12 years old met expectations of the "*PHS Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation*."

The Uniform DRAI for a Donor >12 years old was further scrutinized throughout 2013 by the foremost authority for development of effective public health and behavioral history surveys in the US. A professional from the CDC's National Center for Health Statistics (NCHS) performed a series of cognitive interviewing studies using a final draft version of the 'adult' donor questionnaire. This science-based, qualitative evaluation of the questions was funded by the Office of Blood, Organ and Other Tissue Safety at CDC, via an Interagency Agreement. The final version was made available during September 2014 along with this *Implementation Guidance Document*, references and flowcharts, and an online portal hosted by AATB will be opened to collect constructive suggestions from users. This information will be reviewed periodically by the Stakeholder Review Group and changes made where appropriate.

B. Abbreviations

The following abbreviations are used in this Guidance Document:

AOPO – Association of Organ Procurement Organizations
AATB – American Association of Tissue Banks
AST – American Society of Transplantation
ASTS – American Society of Transplant Surgeons
CBER – Center for Biologics Evaluation and Research
CAN/CSA – Canada/Canadian Standards Association
CDC – Centers for Disease Control and Prevention
CTO – cell, tissue, and organ
DRAI – Donor Risk Assessment Interview
DTAC – Disease Transmission Advisory Committee
EBAA - Eye Bank Association of America
FDA – US Food and Drug Administration
HHS – Health and Human Services
HRSA – Health Resources and Services Administration
LEP – Limited English Proficiency
NATCO – "The organization for transplant professionals"
NCHS - National Center for Health Statistics (a division within CDC)
OPO – organ procurement organization
OPTN – Organ Procurement and Transplantation Network
OTE – organ, tissue, and eye

PHS – Public Health Service
UDHQ – Uniform Donor History Questionnaire
UNOS – United Network for Organ Sharing
US – United States
yrs - years

C. Definitions

As used in this Guidance Document, the following definitions apply:

Donor Risk Assessment Interview (DRAI) – (aka Medical History Interview - FDA) A documented dialogue in person or by telephone with an individual or individuals who would be knowledgeable of the donor's relevant medical history and social behavior (i.e., a *knowledgeable person*). Alternatively, a living donor may complete a written questionnaire. The relevant social history is elicited by questions regarding certain activities or behaviors that are considered to place such an individual at increased risk for a relevant communicable disease agent or disease (RCDAD).

Filter question – A question asked in order to determine if further questioning is necessary to assess risk.

Knowledgeable person – a person interviewed who would be familiar with the donor's relevant medical history and social behavior, which can be: the donor, if living; a next of kin; the nearest available relative; a member of the donor's household; other individual with an affinity relationship (e.g., caretaker, friend, significant life partner); and/or, the primary treating physician.

II. ORGANIZATIONAL CONSIDERATIONS

A. Compliance Expectations

Users of the Uniform DRAI for a Donor >12 years old are strongly discouraged from changing the content or order of any questions, preambles to questions, or the format designed to enhance flow and mental time travel. Adulteration of the form removes the ability to apply qualitative analysis findings by NCHS because the interview tool is different from the tested version. Versions with revisions outside the scope listed below may not be presented as the "Uniform DRAI." Only the following changes are considered acceptable for an organization to title their DRAI as the "Uniform DRAI:"

- The name/title of the form can be changed, however, the establishment's policies and/or procedures should contain a reference that describes the new title's link to the "Uniform Donor Risk Assessment Interview for a Donor >12 yrs old" form.
- There is space provided in the header on page one to insert the logo of the program using the form as well as their address. Alternative styles can be used to document this

information, but provision of the identity of the program is required. Adding information to the area before the first preamble is allowed.

- Information on page one that provides the name of a second person interviewed and their contact information can be adjusted to meet local needs.
- The sequence of questions must remain unaltered, however, individual questions can be removed if not required for that donation. For example;
    - if eye tissue only can be donated and no organs or other tissues, questions not required for eye donation can be selectively removed; and
    - if a test kit being used for HIV-1 **Ab** testing is labeled to include HIV-1 Group O, the questioning associated with HIV-1 Group O risk can be removed.
- If any new questions are added, they can only be inserted before the first numbered question or after the last numbered question.

Compliance with published updates of the Uniform DRAI is expected within the deadline announced.

B. Local Policies/Procedures

1. Living Donation
   The category of "living donor" may include (but is not limited to) a living organ donor or organ donation from an individual in the context of imminent death (e.g., mechanical ventilation willingly discontinued by the patient being treated), reproductive tissue donors, and other tissue donation (e.g., placenta for amnion, skin from abdominoplasty, surgical bone donation, etc.). For these donations, the donor would provide directly their medical, behavioral and travel history. Local policy should dictate how current the living donor's DRAI must be, relative to the donation event, but it is recommended that this donor screening step occurs close to the donation date. Procedural considerations should include how the interview with a living donor must be conducted. If a prospective donor is allowed to self-administer the DRAI questionnaire, consultation with professional staff (such as a donation coordinator) must occur to ensure a dialogue so questions are understood and answers are interpreted correctly.

2. When to Stop the Interview Process
   Policy should be established with consideration of written agreements/contracts of local organizations involved in the donation and procurement/recovery process. Direction needs to be clear for organs versus tissue/eye and/or research scenarios. If individual local policy allows, the interview may be stopped for a tissue or eye donor if a definitive risk is identified that indicates the donor is not eligible.

3. Alternative Languages
   In order to collect accurate relevant medical, behavior risk and travel history information about the potential donor the *knowledgeable person* must be able to understand and respond to the questions being asked. If it is determined during the

conversation with the *knowledgeable person* that they have a Limited English Proficiency (LEP), every reasonable effort should be made to ensure the opportunity for donation is provided such as utilization of:

- a professional interpreter service;
- staff fluent in the language; and/or
- a family member or friend of the family to translate.

Regarding use of an alternative language form, see section III., part B. Format and Use.

C. Electronic Use of the Form

The Uniform DRAI can be formatted as an electronic file, however, the software program used must be capable of providing an audit trail to account for any revisions to the original, concurrent documentation. Note: A fillable PDF (Adobe® Systems Incorporated) version does not meet this expectation. As with all electronic records, the DRAI tool should be programmed to the same security and verification standards. Version identification should be visible on the electronic system (or printed, if applicable) on the screen (or paper). Programming of questions and response choices (e.g., "yes", "no", "N/A") should include audit capabilities for verification of the documenter. If built within an existing electronic documentation system, the DRAI will carry the same expectation for validation of any modifications or enhancements. Policies must be in place if the electronic system is not used and a backup plan must be in place if the electronic system is not working.

D. Form Acceptance

To be sure of compliance to regulations, laws, standards and policies, any changes to the Uniform DRAI must be approved prior to use by the entity determining donor suitability (e.g., tissue processor).

E. Document Control

Organizations should implement a plan consistent with their management of internal forms and documents. This may include, but not be limited to:

1. naming the document;
2. identifying an implementation date;
3. assigning a version number;
4. approving each version with signatures;
5. requiring regular review and training of the form; and
6. archiving former versions.

Organizations must have a method to ensure that staff has access to the current version of the form, whether electronic or paper.

III. THE INTERVIEW FORM

A. Important Concepts and Expectations

1. The Uniform DRAI is a tool designed to optimize the process used to gather relevant information from the *knowledgeable person*(s) identified to provide medical, behavioral, and travel history for a deceased donor. This tool can also be adapted for use with a living donor of an organ or tissue.

2. This interview tool is not intended to assist with policy decisions in all scenarios. For example, actions to take after answers and information have been provided in the Final Questions are at the discretion of the users.

3. The Uniform DRAI form must be completed concurrently while performing the interview in the order provided and according to local policies and procedures.

4. The questions are designed to meet requirements and expectations of state, national and international regulations, laws, policies and/or standards. If donor criteria between users differ, this can promote confusion, and jeopardize the process uniformity to which donation and transplantation stakeholders have agreed is best.

5. Each question is constructed to be as short as possible but with the ability to gather necessary information to cover requirements. Although kept to a minimum, there are a few questions where screening redundancy occurs. Entirely restricting screening for risk to one possibility does not always occur and this is deliberate (i.e., risks related to travel). This allows for interviewees to remember diseases, surgeries, procedures etc. that they may not have thought of with the initial question.

6. Use of "she/he*" in the questions is intentional to consistently remind the interviewer to mix the appropriate pronoun with other terms with which the interviewee can relate: the donor's given name; their nickname; or by inserting "your" father, mother, husband, wife, sister, brother, daughter, son, or child (as indicated). By using this approach, the interviewer is afforded real-time instructions throughout administration of the questionnaire, versus simply using "the donor" or "the deceased" to lead off questions.

7. The Uniform DRAI uses the *filter question* approach which covers a broad topic initially, and when an affirmative answer is given, provides follow-up sub-questions that must also be asked to elicit additional, necessary information/details. Since specific donor eligibility criteria may vary from one facility to another, an affirmative response to some questions may require consultation with the facility's policies.

8. A few questions and preambles include examples to educate the interviewee regarding risk being assessed. For instance, after communicating with officials at FDA, a *filter question* can be used to initially assess sexual risk but only when "sexual activity" and "sex" has first been defined for the interviewee. An acceptable

preamble and question were developed for the Uniform DRAI that considers the sensitive nature of the topic. Additionally, providing examples of these terms aids in reducing the number of questions considered intrusive.

9. Our nation's foremost authority on health history and behavioral risk surveys, the National Center for Health Statistics (NCHS), a division of the CDC, analyzed the Uniform DRAI form. Their qualitative evaluation used cognitive interviewing techniques that included bereaved persons. Users are strongly discouraged from changing any questions, preambles to questions, or question order because doing so removes the ability to apply findings by NCHS to an adulterated form. If any questions are added, they can only be inserted before the first question or after the last question. The name of the form can be changed and users are encouraged to identify the form with their name, address, and logo. Refer to section II., part A. Compliance Expectations above.

10. Questioning begins with current and recent history, and sequentially proceeds through the past 12 months, past 5 years, then EVER. This mental time travel order is known to enhance the interviewee's recall.

B. Format and Use

A format was selected for the Uniform DRAI from a variety of styles. The following points are considered to enhance use, and concepts described in the *Effective QA of the DRAI Guidance Document* and garnered from the *Cognitive Evaluation of the Donor Risk Assessment Interview (DRAI): Results of Interviews Conducted April – December, 2013* apply:

- A quiet area for both the interviewer and interviewee(s) is desired so questions and responses can be clearly heard, and privacy is preferred to maintain confidentiality.
- All *filter questions* are designed to be asked first. In paper format, they appear in the left-hand column.
- Questions must not be skipped unless directed to do so by the questionnaire.
- To optimize interviewee recall, questions are designed to be read in numbered order.
- Questions should be read in their entirety and as written. Specific word choices were intentionally made and further developed after the Uniform DRAI was tested using cognitive interviewing techniques. Reading questions verbatim is not a requirement unless directed by your internal policy and procedures, but it is highly encouraged.
- The Uniform DRAI is intended to be an interactive conversation (dialogue) designed to collect and document pertinent information, but a consistent intent of the questions regarding specific risk must be communicated to interviewees if not read verbatim. Rephrasing questions is discouraged and may miss the intent of a question's assessment of risk.
- In paper format, the No - Yes answer selections are arranged in the middle column vertically instead of horizontally to avoid confusion. If a Yes response is received, sub-

questions that must be asked next appear directly across from the Yes selection to promote ease of flow.

- The format provides more space in the column to the right for documenting detailed information for the sub-questions.
- Lines can be added to facilitate documentation for sub-questions and spacing between questions can be adjusted to meet local needs.
- Documentation of answers to sub-questions can be provided in a horizontal fashion instead of vertically. Example: when documenting "What kind?, Where?, and When?" for travel or residency outside the US or Canada, documentation methods can align across the answer area. This may only be practicable for some questions.
- Questions periodically contain instructions to the interviewer that are not read to the interviewee. These appear as text in *italics*.
- The preambles appear in bold type to enhance visibility to the interviewer. The preambles are part of the Uniform DRAI and were studied when qualifying the form's comprehension.
- Time periods (i.e., past 12 months, past 5 years, and EVER) appear in bold type to stress relevance to the interviewer.
- When relevant risk history is known by the interviewee, it must be captured, but there can be instances when an "I don't know" answer is initially given to a question. It's important to remind the interviewee(s) to answer to the best of their knowledge. If the answer is again "I don't know," then ask "Do you have actual knowledge of...." (be sure to repeat the question in a format that fits the question). Local policies and training should describe how to handle this scenario.
- In cases where the interviewee repeatedly answers "I don't know" the interviewer needs to assess if this person is knowledgeable or if someone else needs to be interviewed.
- If more than one *knowledgeable person* is interviewed, refer to local policy for documenting answers to questions.
- If it is determined that an additional person is needed to answer specific questions, document that determination in the "Additional Notes" section. Document which question(s) the second person answered.
- When interviewing one *knowledgeable person* for two or more donors, or for more than one history (i.e., interviewing a parent about her/his children, or interviewing a child about her/his parents), the interview can be conducted simultaneously, if consistent with organizational policy/procedure.
- Responses should be documented with sufficient detail. Local policies and procedures must define how responses to sub-questions will be documented on the Uniform DRAI.
- Use of a translated form (alternative language) is encouraged when indicated and Compliance Expectations must be met. Refer to section II., part A. on page 9, and section II., part B., listing 3. on page 10.

IV. APPENDICES AND REFERENCES

A. Flowcharts

Flowcharts are provided for each question on the Uniform DRAI to guide the interviewer through the interview process and they can also be used for quality assurance purposes. They are intended as a resource that, where indicated, may be revised by programs to reflect local policy as long as eligibility decisions are not made less strict than those indicated by relevant requirements. Users of the Uniform DRAI should have policies and procedures that describe acceptable methods for gathering necessary information when a response to a question indicates follow-up is needed. The flowchart for each question can be tailored to meet local policy, when applicable.

Each question is formatted in a separate flowchart, and each one contains the following information:

- Question: Question number and the question.
- Donor Eligibility: Provides additional information regarding eligibility considerations
- Note: an optional field related to the specific question.
- Flowchart: Uses standard flow-charting symbols.
    - Square/Rectangle = statement
    - Diamond = question/decision point (Uniform DRAI questions are within red diamonds)
    - Oval = action
    - Arrow = move to next question

Each question ends with an arrow that indicates to "move to the next question," however, programs must follow their own policies and procedures concerning eligibility determinations based on information collected (which may indicate the donor is not eligible). A condition or history that is not an absolute rule-out can be directed to "Consult your policy."

B. Uniform DRAI Requirements Crosswalk

A *Uniform DRAI Requirements Crosswalk* document is available that provides the relationship between questions on the Uniform DRAI for a Donor >12 years old and donor screening expectations from applicable federal regulations, guidance and policies, as well as state laws and professional standards. This document is updated when any requirements change or when the Uniform DRAI form is updated.

C. Effective Quality Assurance of the DRAI (AOPO-EBAA-AATB Guidance Document)

This multi-agency guidance document provides expectations and describes best practice for managing an effective Quality Assurance Program that provides a high level of assurance the

DRAI process is being performed consistently as intended. It contains direction regarding components of the program such as: standard operating procedures; staff qualifications, training and competency; sampling plans for quality control measures; auditing examples; and corrective and preventive action including timely notification. The current version can be accessed on the websites of AOPO, EBAA, and AATB.

D. References

Uniform Donor Risk Assessment Interview for a Donor >12 years old 9-10-14

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Note: For a final version of this report, periodically check the Q-Bank website at
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