

GUIDANCE REGARDING DECLARATIONS TO BE PROVIDED BY APPLICANTS FOR ACCREDITATION

The AATB Accreditation Policies for Transplant Tissue Banks (“Accreditation Policies”) require that applicants for accreditation must provide declarations executed by the Owner(s), Medical Director(s) and person designated as the most senior position for tissue banking operations (“Leadership”) attesting to the absence of criminal history and certain other designated factors that could render the applicant ineligible for accreditation (“Declaration Documents”). This bulletin provides guidance concerning the reasons for, and application of, this requirement.¹

WHAT WAS THE IMPETUS FOR REQUIRING THE DECLARATION DOCUMENT AS PART OF THE ACCREDITATION PROCESS?

There have been several damaging incidents involving illegal and/or unethical activities by a few individuals in the tissue banking industry that were identified by law enforcement authorities and were widely reported at the time the crimes were committed, and resurrected years later, by the media. These events eroded the public’s confidence in tissue banking. More recently, information gathered during AATB accreditation inspections has raised material concerns regarding the practices of some applicants for accreditation and the suitability of some of their leadership.

In response to these events, the AATB Board of Governors undertook a review of the accreditation process, and the tools available to assess an applicant’s practices and suitability for accreditation in light of publicly reported events. As a result of that review, the Board of Governors has adopted accreditation standards that include screening of the Leadership of accreditation applicants. The Board of Governors believes the new screening requirements will help restore and maintain the public’s confidence in tissue banking, including public trust in the tissue donation profession and AATB’s voluntary accreditation process.

The new declaration requirement for criminal background screening requires that the tissue establishment’s Leadership (i.e., its “Owner(s), the Medical Director(s), and the person designated as the most senior position for tissue banking operations” (see Accreditation Policies §II D)) certify that they do not have a criminal history. This requirement is consistent with licensure requirements for tissue establishments (including OPOs that also are tissue banks) in several states (e.g., the Florida Agency for Health Care Administration, and the New York State Department of Health), and we understand many tissue establishments already conduct such investigations consistent with best practices among employers.

¹ See Accreditation Policies, Section II D, which provides: “Each applicant for accreditation will provide with its application, declarations, executed by the *Owner(s)*, the Medical Director(s), and the person designated as the most senior position for tissue banking operations on a form prescribed by the Association, in which the declarant will attest to the absence of criminal history and/or other designated factors that could render the applicant ineligible for accreditation. The Association reserves the right to also perform a criminal records history check regarding such persons. The Executive Committee of the Board of Governors will be informed of any declaration or records check that reflects any past or present criminal or otherwise potentially disqualifying.”

WHAT SECURITY WILL BE MAINTAINED FOR DECLARATION DOCUMENTS, AND WHO, AMONG AATB STAFF, AND FROM OUTSIDE OF AATB, WILL HAVE ACCESS TO THE DECLARATIONS?

Declaration Documents completed by applicants will be maintained by AATB headquarters in a secure facility within a double-locked cabinet that is accessible by only a few designated AATB staff members. Only paper records will be kept; digital files will not be retained. Should an applicant submit completed documents by email, the documents will be printed, the email will be immediately deleted and the email deleted items (trash) folder will be immediately emptied. Electronic versions of completed forms will not be kept or stored on a server. This practice will avoid vulnerability to cyber-attack.

HOW WILL DECLARATION DOCUMENTS, AND ANY SUBSEQUENT BACKGROUND CHECKS, BE USED IN DETERMINING ELIGIBILITY FOR ACCREDITATION?

In considering the suitability of an applicant for accreditation, AATB will review information in Declaration Documents to establish the absence of any questions concerning the lawfulness, honesty and integrity of the applicant's Leadership. Where information provided indicates that one or more of an applicant's Leadership has had prior events that call into question his/her past compliance with laws or ethical requirements, AATB may request additional information from the declarant or his/her employer, and/or may conduct additional screening.. However, it is only where serious issues of past criminal or ethical transgressions are raised by a Declaration Document that AATB will consider further investigation through, e.g., criminal history records checks ("CHRCs") or professional licensure checks. Ultimately, if such issues are of a material nature and are not satisfactorily resolved, they could result in AATB denying or conditioning an applicant's application for accreditation.

WHAT THRESHOLDS WILL BE USED FOR EVALUATING INFORMATION IN DECLARATION DOCUMENTS TO DETERMINE WHETHER AATB SHOULD RUN A BACKGROUND CHECK ON A MEMBER OF AN APPLICANT'S LEADERSHIP?

Information provided in Declaration Documents will be reviewed on a case-by-case basis, and considered along with all other information from the applicant in determining whether matters identified in a Declaration indicate a need to obtain additional information concerning the declarant or warrant rejection of the application.

The review process will be conducted in a fair and consistent manner, focusing only on issues of past misconduct that would be likely to have an impact on a person's suitability – from a legal, ethical and/or character standpoint – to serve in a senior leadership position of an accredited tissue establishment and, therefore, that bear on an applicant's suitability for accreditation. The evaluation of such matters is conducted in an objective manner, guided by the same exercise of judgment that is applied in assessing an applicant's satisfaction of all other requirements for accreditation. In considering any such matter, factors that are considered include, e.g., the nexus between the offense or activities in question and the individual's role at the applicant, the nexus between the offense and tissue banking/processing generally, the severity of the offense, how long ago the misconduct occurred, extenuating circumstances, the person's conduct thereafter, and any action by another licensing or accrediting body regarding the matter. The final decision regarding any such matter will be made by AATB's Chief Executive Officer based on consideration of the

recommendation of the Vice President of Accreditation and, if necessary, advice from the Association's attorneys.

WHAT OPPORTUNITY WILL A DECLARANT AND THE ACCREDITATION APPLICANT HAVE TO RESPOND TO AATB CONCERNS REGARDING CRIMINAL HISTORY OR ETHICAL ISSUES THAT ARE IDENTIFIED IN A DECLARATION?

In most cases, when a declaration reflects a criminal history or ethical issue of a material nature, AATB will contact the declarant and the accreditation applicant to provide him/her an opportunity to submit additional information that satisfactorily resolves the issue and rebuts any indication of unsuitability. If the declarant or applicant fails to do so, and the applicant does not remove the unsuitable declarant from management of the tissue establishment, then the application for accreditation could be denied. If the declarant is removed and replaced with a substitute that completes an acceptable declaration, then the application for accreditation could continue to be processed. If the applicant disagrees with a finding of unsuitability of a declarant that results in a denial of accreditation, then such finding can be addressed in the applicant's appeal from the denial of accreditation.

DOES THE DEFINITION OF "OWNER", AS USED IN ACCREDITATION POLICY II D (WHICH PROVIDES THAT EACH APPLICANT FOR ACCREDITATION WILL PROVIDE DECLARATIONS EXECUTED BY, AMONG OTHERS, ITS "OWNER(S)"), INCLUDE BOARD MEMBERS OF AN INDEPENDENT NON-PROFIT ORGANIZATION RUN BY A BOARD OF DIRECTORS?

Owner includes any person who has a ten (10) percent or greater ownership interest in, or who has voting control over, a tissue establishment. The definition of Owner is not intended to include Board members of a non-profit organization as a class of persons. However, a Board member who is an Owner, Medical Director, or the person designated as the most senior position for tissue banking operations, will be included within the class of persons who must submit a declaration.

WHAT IS THE CONSEQUENCE OF AN APPLICANT'S FAILURE TO SUBMIT A REQUIRED DECLARATION, AN INCOMPLETE DECLARATION, OR A DECLARATION CONTAINING FALSE OR INCOMPLETE INFORMATION?

Failure to submit Declaration Documents that contain all required information, or that are found to be inaccurate in any material respect, may result in further investigation, including a CHRC or professional licensure check, or in denial or conditioning of accreditation.

DOES THE FAIR CREDIT REPORTING ACT APPLY TO AATB'S DECLARATION REQUIREMENT?

AATB does not believe that the Fair Credit Reporting Act ("FCRA") applies to the requirement that applicants for accreditation submit Declaration Documents for the designated members of their senior management. Moreover, even if FCRA were found to apply, use of the Declaration Document and any CHRC would be found to comply with the law's requirements.

- FCRA applies generally to (1) the provision by a consumer reporting agency ("CRA") (2) of a consumer report (3) that contains information concerning a consumer (4) that is to be used for any of a number of permitted purposes, including where the CRA has been authorized by the consumer to provide such information. The information included in a consumer report can concern, among other things, a person's character, general reputation and personal

characteristics. The Declaration Documents that an applicant for AATB accreditation is required to submit are not “consumer reports” within the meaning of FCRA, and therefore the Act does not apply to them.

- Even if the Act did apply, acquisition of Declaration Documents or CHRCs would still comply with the law because, in executing the Declaration, the Declarant will have authorized AATB to obtain such information² and, therefore, the information will have been obtained for a permissible purpose and no “adverse action notice” would be required. See 15 U.S.C. 1681b(a)(2), 1681a(k).
- Finally, any non-public personal information contained in a Declaration or a CHRC will be treated by AATB as confidential, in accord with AATB’s confidentiality policy.

If you have any questions regarding AATB’s use of Declaration Documents, or the guidance provided above, please contact Frank Wilton, AATB’s CEO, at WiltonF@aatb.org .

² The Declaration provides: “I consent to AATB conducting a criminal records history check. I agree to provide information for, and execute any additional documents required by AATB to conduct, such a search.”