

## RECOMMENDATION

### UMBILICAL CORD BLOOD BANKS

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The Hellenic National Bioethics Commission examined within its jurisdiction, the issue that arose by the suspension of cooperation between a private Cord Blood Bank (CBB) and a business group in the health care industry, an event which left pending the biological material that was trusted to the bank by a substantial number of interested parents after the birth of their child.

The Commission deems that this issue is extremely important because of the sensitive nature of this material, the expectations of its potential future use by the interested parents and the urgent need for State intervention.

#### **The demand for safe preservation of the material**

Regardless of the actual probability of Umbilical Cord Blood (UCB) utilization in autologous transplantations (the Commission has examined this issue in a previous Opinion<sup>1</sup> for “The collection of umbilical cord blood”), it is of top priority to secure its storage under conditions that do not jeopardize its suitability for future

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<sup>1</sup> Hellenic National Bioethics Commission. Opinion on “[Umbilical Cord Blood Banking](#)”. Opinion in Greek.

use, for as long as provided by the agreement between the parents and the CBB. There are two reasons for this: a) the material is a source of sensitive personal health data of the child and the parents, and b) the parents expect to use the material for their child's interest or for the benefit of another family member in the future, in case a serious health issue occurs.

The safe preservation of the UCB under proper conditions depends on special facilities, for which the CBBs are responsible, as well as on the stable form of these same banks, either as private enterprises or public entities. The Commission notes that the Greek legislation already provides special guarantees as to the above on which the licensing of the CBBs depends (Articles 54, 55 of the Law No. 3984/2011).

### **Guarantees for safe maintenance in abnormal circumstances**

Especially in the case of private CBBs, which are for-profit units exposed to entrepreneurial risks, the suspension of normal operations is always a possibility. Hence, the preservation of the UCB under proper conditions remains unsafe.

The Commission considers that it is essential to offer immediately two guarantees to protect the biological material in such a case.

- A provision of a special clause in contracts about the future of the biological material in case the bank discontinues its operations must be legally imposed as a necessary condition for bank licensing, so as the concerned parents are informed in advance. More specifically, the contract should: a) mention the new CBB that will store the UCB units, b) guarantee the safe transfer of the sample, and c) explicitly provide the obligation to compensate the parents in case of sample damage during transfer.
- Already licensed banks should be subjected to legal compliance audits for their necessary cooperation with other public or private CBBs. According to the Commission, these initiatives must be urgently considered by the Ministry of Health and the Hellenic Transplant Organization (EOM,

responsible authority according to the Law No. 3984/2011) –regardless of the parents’ compensation rights in case of UCB unit damage– based on the general legislation, and regardless of the licensing status of the banks; this is because the main and most urgent issue at stake is the safety and preservation of the biological material itself.

### **Licensing of CBBs**

The Commission emphasizes that the issue that arose highlights the urgency to implement the statutory procedure for CBB licensing by the Ministry of Health, under the responsibility of EOM. Preventive control of banks before licensing is important to avoid problematic practices, either in the technical or business part of their organization and operation. The Ministry of Health must ensure all necessary means to support EOM, so that this process will be soon completed.

Moreover, the Commission emphasizes that the maintenance of sensitive data records held by the banks is under the competence of the Hellenic Data Protection Authority (HDPa).

It is self-evident that licensing from the HDPa for the management of sensitive data is a prerequisite for bank licensing by the Ministry of Health. Independently of the licensing procedure by the Ministry of Health, the HDPa must initiate an audit on whether already operating CBBs comply with the legal requirements on personal data, especially for CBBS that have been licensed to manage their customers’ sensitive data records.

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