

§482.45(a)(2) - Incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement;

Interpretative Guidelines §482.45(a)(2)

The hospital must have an agreement with at least one tissue bank and at least one eye bank. The OPO may serve as a “gatekeeper” receiving notification about every hospital death and should notify the tissue bank or eye bank chosen by the hospital about potential tissue and eye donors.

It is not necessary for a hospital to have a separate agreement with a tissue bank if it has an agreement with its OPO to provide tissue procurement services; nor is it necessary for a hospital to have a separate agreement with an eye bank if its OPO provides eye procurement services. The hospital is not required to use the OPO for tissue or eye procurement but is free to have an agreement with the tissue bank or eye bank of its choice. The tissue banks and eye banks define “usable tissues” and “usable eyes.”

The requirements of this regulation may be satisfied through a single agreement with an OPO that provides services for organ, tissue and eye, or by a separate agreement with another tissue and/or eye bank outside the OPO, chosen by the hospital. The hospital may continue current successful direct arrangements with tissue and eye banks as long as the direct arrangement does not interfere with organ procurement.

Survey Procedures §482.45(a)(2)

Verify that the hospital has an agreement with at least one tissue bank and one eye bank that specifies criteria for referral of all potential tissue and eye donors, or an agreement with an OPO that specifies the tissue bank and eye bank to which referrals will be made. The agreement should also acknowledge that it is the OPO’s responsibility to determine medical suitability for tissue and eye donation, unless the hospital has an alternative agreement with a different tissue and/or eye bank.