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| **Section 2 – Policies and Procedures Manual** | | | |
| ***Standard*** | ***#*** | ***Question*** | ***Eye Bank SOP*** |
| B1.200 | 1 | Reporting requirements following inspections by official agencies? |  |
| C2.000 | 2 | An orientation program for new employees performing eye bank functions? |  |
| C2.000 | 3 | Does the eye bank have a comprehensive and well-defined training program outlining specific job-related tasks that each employee and non-employee is being trained to perform? |  |
| C2.000 | 4 | Documentation of annual competency reviews of skills and job-related knowledge for all employees and non-employees performing eye bank functions? |  |
| C3.200 | 5 | Monitoring, inspection and cleaning procedures and schedules for each piece of equipment? |  |
| C3.200 | 6 | Requiring testing of the refrigerator alarm system on a regular basis? |  |
| C3.600 | 7 | Utilizing Standard Precautions according to applicable regulatory requirements? |  |
| C3.600 | 8 | An exposure control plan that meets OSHA or other applicable regulatory requirements (i.e. reporting needlestick injuries)? |  |
| C3.700 | 9 | Disposing of biohazardous waste? |  |
| D1.000 | 10 | Physical inspection of the donor with special attention to physical signs of HIV disease, infectious hepatitis, and injecting drug use? |  |
| D1.000 | 11 | Routine examination and documentation of prospective donors' medical records and death investigation? |  |
| D1.000 | 12 | Obtaining a medical and social history of each donor? |  |
| D1.000 | 13 | Adequate documentation of donor information/completion of donor files, including medical examiner reports and gross autopsy results? |  |
| D1.100 | 14 | Screening for and listing of exclusion criteria listed in EBAA Medical Standards Section D1.100? |  |
| D1.200 | 15 | Obtaining donor sample for infectious disease testing? |  |
| D1.200 | 16 | Infectious disease (and microbiological, if applicable) testing performed by CLIA certified and FDA registered laboratories? |  |
| D1.200-  D1.220 | 17 | Screening by infectious disease testing in accordance with EBAA Medical Standards and all applicable federal and state laws? |  |
| D1.200 | 18 | Calculating the plasma dilution status of a donor? |  |
| D1.200 | 19 | Not releasing tissue designated for surgical use without documentation of required negative infectious disease testing |  |
| D1.230 | 20 | Handling laboratory reports of non-required tests, whether received before or after tissue distribution? |  |
| D1.300 | 21 | Obtaining a unique identifying number for each donor? |  |
| D1.400 | 22 | Obtaining legal authorization for eye tissue donation consistent with EBAA Medical Standards, federal law, and state law? |  |
| D1.500 | 23 | Donor age exclusion criteria? |  |
| D1.600 | 24 | Recording date and time of death, enucleation, preservation, additional processing, and cooling of ocular tissues for each donor? |  |
| D1.700 | 25 | Eye maintenance prior to ocular tissue removal procedures? |  |
| E1.000 | 26 | Detailing aseptic technique for recovery, processing, and preservation? |  |
| E1.100 | 27 | Special handling of tissue that is hazardous to eye bank personnel (active viral hepatitis, AIDS, HIV seropositivity, etc.)? |  |
| E1.100 | 28 | Examining tissue with a penlight or a portable slit lamp prior to enucleation or in situ removal? |  |
| E1.100 | 29 | Concentration, volume of solution, and duration of ocular surface exposure to povidone iodine? |  |
| E1.100 | 30 | Eye enucleation? |  |
| E1.100 | 31 | In situ corneoscleral disc removal? |  |
| E1.210 | 32 | Preserving whole eyes? |  |
| E1.230 | 33 | Preserving sclera? |  |
| E1.221 | 34 | Laboratory preservation of tissue? |  |
| E1.222, E1.223 | 35 | Other tissue preparation (i.e. pre-cutting for EK, preparation for LAK, etc.)? |  |
| E1.300 | 36 | Storage solution that is manufactured in accordance with U.S. FDA Good Manufacturing Practices and stored in accordance with the manufacturer's recommendations? |  |
| E1.400 | 37 | Long term tissue preservation? |  |
| F1.100 | 38 | A slit lamp examination of the whole eye prior to distribution for surgical use as a whole eye? |  |
| F1.100 | 39 | A slit lamp examination of the corneoscleral disc after excision? |  |
| F1.100 | 40 | Slit lamp examination following additional tissue preparation (i.e.  for EK, LAK, etc.)? |  |
| F1.200 | 41 | Specular microscopic exam of corneas? |  |
| F1.200 | 42 | Specular microscopic exam of corneas following additional tissue preparation (i.e. for EK, LAK, etc.)? |  |
| F1.200 | 43 | Medical Director waiver of specular exam? |  |
| F1.300 | 44 | Appropriate evaluation criteria to determine suitability of all tissues prepared by the bank (penetrating keratoplasty, anterior lamellar keratoplasty, endothelial keratoplasty, keratolimbal allograft, and/or tectonic use)? |  |
| G1.000 | 45 | Soliciting reports of adverse reactions from surgeons? |  |
| G1.000 | 46 | Adverse reaction reporting, investigating, and implementing corrective actions as needed? |  |
| G1.000 | 47 | A quality assurance program which monitors and evaluates activities, identifies problems, and develops plans for corrective action? |  |
| G1.200 | 48 | Reporting positive rim culture results to the transplanting surgeon or receiving eye bank? |  |
| G1.300 | 49 | Tissue recall or withdrawal? |  |
| H1.000 | 50 | Biohazardous labeling of nonsurgical tissue that is not screened with infectious disease testing? |  |
| I1.000 | 51 | Storage conditions for surgical tissue? |  |
| J1.000 | 52 | Labeling tissue? |  |
| K1.300 | 53 | A distribution policy that is just, equitable and fair for all patients served by the bank? |  |
| K1.400 | 54 | Documenting and sharing tissue transportation and storage information to distributing eye banks and transplanting surgeons for corneas returned and redistributed? |  |
| K1.500 | 55 | Investigating and reporting fraudulent activity in the distribution, shipping or labeling of tissue? |  |
| L2.000 | 56 | Packaging tissue individually and sealing it using a tamper-evident seal? |  |
| L2.000 | 57 | Packaging transplantable corneal tissue to maintain cool conditions without freezing, and other tissues (e.g. sclera) with a method appropriate to the method of preservation used? |  |
| M1.100 | 58 | Keeping all donor records for a minimum of ten years from the date of transplantation/ implantation, distribution or whichever is longer? |  |
| M1.200 | 59 | Maintaining records and communications between the eye bank and its donors and recipients as confidential and privileged? |  |
| M1.500 | 60 | Seeking recipient information? |  |
| M1.500 | 61 | When the distributing bank, seeking 3–6-month post-operative outcome information? |  |