The University of Iowa Dezii Translational Vision Research Group

TITLE: Personnel Responsibilities

SOP Number: D-GLO-PRO-005 Revision Number: 0

Effective Date: 09 Aug 2015

Author: _____ Date: _____

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A. OBJECTIVE

This SOP is to define the responsibilities for all of The University of Iowa DTVR personnel.

B. APPLICABILITY

This SOP shall be performed by all DTVR personnel.

C. REFERENCES

21 CFR 211.28
D-GLO-PRO-004, Dress Code and Cleanroom Gowning for DTVR

D. PROCEDURE

1. All personnel engaged in the manufacture, processing, packing or holding of any Human Cell, Tissue, and Cellular or Tissue Based Materials (HCT/P) product shall wear clean clothing appropriate for the duties they perform. Protective apparel will be worn as required by DTVR SOPs to protect (HCT/P) products from contamination.

2. All personnel must practice good sanitation habits and health habits as well as common laboratory safety.

   2.1. Thoroughly wash and dry your hands before entering any laboratory or processing area, and wash and dry them again frequently during work and before exiting the laboratory into a public area.

   2.2. Dry your hands with clean towels, disposable paper towels or under an air dryer.

   2.3. Never smoke, chew gum, spit, eat or drink in any laboratory or processing area.

   2.4. Never cough or sneeze over HCT/P's or where HCT/P's are prepared or stored.

   2.5. Wear clean appropriate clothing, as described in the Section H.1. of this SOP.

   2.6. Keep your street clothes and other personal items away from where HCT/P's are stored and prepared.

   2.7. Hair, especially when it is long, attracts dust and provides a potential source of contamination. Consider tying it back or using a hair cover or cap.

   2.8. Keep your nails short so they are easy to clean, and don't wear nail polish as it can chip into the HTC/P's.

   2.9. Avoid wearing jewelry, or only wear plain banded rings and sleeper earrings.

   2.10. If you have cuts or wounds, make sure they are completely covered by a waterproof wound strip or a bandage. Use brightly colored wound strips, so they can be seen easily if they fall off.

   2.11. Wear disposable gloves over the top of the wound strip if you have wounds on your hands.

2.12. Change disposable gloves regularly.

2.13. Advise your supervisor if you feel unwell and don't handle any HCT/P's.

2.14. Pipetting by mouth is strictly forbidden.

2.15. Materials must not be placed in the mouth. Labels must not be licked.

2.16. All technical procedures should be performed in a way that minimizes the formation of aerosols and droplets.

2.17. The use of hypodermic needles and syringes should be limited. They must not be used as substitutes for pipetting devices or for any purpose other than parenteral injection or aspiration of fluids from laboratory animals.

2.18. All spills, accidents and overt or potential exposures to infectious materials must be reported to the laboratory supervisor. A written record of such accidents and incidents should be maintained.

2.19. A written procedure for the clean-up of all spills must be developed and followed.

2.20. Consider wearing clean gloves during aseptic procedures. Flakes of dry skin are loaded with bacteria. The gloves provide a measure of personal protection as well.

2.21. Caution should be taken when handling sharp instruments such as needles, scalpels, scissors and glass pipettes. Sterile disposable plastic supplies should be preferentially used to avoid the risk of broken or splintered glass.

2.22. Be careful doing cell culture after baking or brewing with yeast. Even after thorough washing and a change of clothing, home bakers and brewers sometimes shed substantial quantities of yeast for at least a day or two later.

2.23. Written documents that are expected to be removed from the laboratory need to be protected from contamination while in the laboratory.

3. Only personnel authorized by supervisory personnel will enter those areas of the building designated as limited-access.

4. Any person shown at any time by medical examination or supervisory observation to have an apparent illness or open lesions that may adversely affect the safety or quality of (HCT/P) products shall be excluded from direct contact with components, (HCT/P) product containers, closures, in-process materials, and (HCT/P) products until the condition is corrected or determined by competent medical personnel not to jeopardize the safety or quality of (HCT/P) products. All personnel are required to report to supervisory personnel any health conditions that may have an adverse effect on (HCT/P) products.

E. History

Effective Date	Revision	Change
09 Aug 2015	0	Original document