Disaster Recovery Plan for human reproductive cell/tissue cryobanks

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Summary

A biobank is a type of biorepository that stores biological samples for use in research and in potential clinical applications. Some biorepository services cater specifically for human reproductive cells and tissues that are cryostored for potential future reimplantation (human reproductive cell/tissue cryobanks). In addition to high-standard working procedures, biobanks need to have in place an efficient back-up plan to identify, prevent and reduce risks in order to guarantee activity continuity in the event of unexpected natural disasters or other emergencies.

KEY WORDS: biobank, biorepository, stem cells, cryopreservation, cryobank.

Introduction

A biobank is a systematic collection of biological specimens and information on participants’ health (1) which are essential raw materials for the advancement of biotechnology, human health, and research and development in life science (2). The establishment and maintenance of biobanks is an activity that requires a high degree of expertise in the implementation of reliable preservation technologies and appropriate quality assurance in order to ensure that recovered cultures and other biological materials perform in the same way as the originally isolated culture or material. Once they have arrived in a biobank, samples are collected, processed and stored according to state-of-the-art technology. In order to guarantee safe storage, workflow procedures are carefully designed to protect biological samples at each single step, following the best standards and back-up systems available.

Disaster Recovery Plan

a) Emergency plan and crisis management
Despite extensive quality control and high-standard procedures, disruptive and unexpected events which threaten biorepository services may occur. In order to prevent damage to stored specimens, biobanks need to implement an efficient emergency plan that focuses on identifying, preventing and reducing risks in order to guarantee business continuity. First, information regarding biological material and structure of the biobank must be collected. Then, the biobank team must establish a model of intervention, assign decision-making responsibilities and use the available resources (staff, space, tools, etc.) effectively.

b) Transport off site
If emergency conditions affect the biorepository site, transport to other premises with adequate capacity must be carried out within a predetermined time by specialized personnel, in order to minimize the time taken for extraction of liquid nitrogen tanks and their collection from the biobank. The specific route must be decided in
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advance, and staff must be able to provide remote monitoring and control of all the critical parameters, such as nitrogen levels and inside temperatures, in addition to maintenance of the tanks themselves. At the end of the critical event the biological samples must be transferred back from the emergency tank room to the original storage biobank and replaced in their previous positions. This activity must guarantee the same safety conditions as the first move, with predefined timeline and logistical operations. Finally, all biobanks should have a back-up container for any emergency specimen transfer. Obviously all the premises used in these operations must satisfy minimum requirements, have adequate equipment, monitoring systems and maintenance plans: liquid nitrogen vessels, liquid nitrogen distribution system, monitoring and control system of critical parameters, emergency air and electrical power supply units.

Biobanking in human Assisted Reproduction (AR)

Some biorepository services are dedicated specifically to human reproductive cell/tissue: cumulus cells, seminal plasma, spermatozoa, oocytes, follicular fluid, spent embryo culture media, etc. Infertility is estimated to affect almost 50 million patients of reproductive age and in vitro fertilization (IVF) and assisted reproductive technique (ART) procedures are well established with the need for freezing and storing increasing numbers of gametes and embryos (3). Assisted Reproduction procedures must guarantee the maximal integrity and preservation of reproductive samples, in order to provide the highest chance of success of the technique (Figures 1-3). Therefore, disaster recovery plans for reproductive material biobanks must be even more rigorous than those for research biobanks.

Directives

ISO 22301 is the international standard for business continuity management to minimize the risk of disruption (4). European Directive 2004/23/CE also establishes standards of quality and safety for the donation, supply, testing, processing, preservation, storage and distribution of human tissues and cells (5). This Directive defines the role of a back-up plan to cope with the temporary unavailability of laboratories and/or storage areas in the case of natural disasters or permanent/severe damage to one or more nitrogen tanks, or the interruption of liquid nitrogen

Figure 1 - Cryogenic room provided with Chart tanks and Sapio liquid hydrogen storage system.
Conclusion

The establishment and maintenance of human reproductive cell/tissue cryobanks is an activity that requires a high degree of expertise in order to ensure that biological specimens perform optimally at reimplantation after thawing. In order to guarantee safe storage, workflow procedures must be designed to protect biological samples throughout by following the best standards and back-up systems available.

Figure 2 - Liquid nitrogen supply and control system. Each tank is equipped with three independent monitoring probes.

Figure 3 - Cryogenic room remote monitoring and control system.
References