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Orientation and Training of New Biobank Personnel

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Summary

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The personnel who operate a biomedical biobank should function as a unit to efficiently manage the numerous types of biospecimens that are to be utilized for both clinical and research purposes. Therefore, new staff must be appropriately trained before becoming fully integrated into the work environment. This chapter focuses on several key aspects to this training that should be completed by all personnel. This first step is an orientation where the new trainee is provided with the priorities and expectations of the biobank. The next and perhaps most important step is training on the various safety precautions. The trainee should learn how to protect patient privacy if human biospecimens are involved. They should gain a basic understanding of different types of biospecimens and their vulnerabilities to suboptimal storage conditions. The trainee must learn the various aspects of the day to day work which encompasses the methods and equipment needed for procuring, labeling, handling, tracking, storing, disbursing, and shipping biospecimens. They should become familiar with aspects of quality assurance.

Keywords

Biobank; Biorepository; Training; Education; Staff; Personnel

1. Introduction

There is little in the way of formal training programs for biobank personnel, necessitating that biobanks train most of their new staff on site. Prior experience from working in another biobank may minimize the required training, but this may not often be the case. Newly hired personnel may have a research laboratory background or may be a recent college graduate with limited laboratory experience. Experience with histopathology techniques and biospecimen processing is desirable but, in the United States, the higher pay scales in clinical laboratories compared to those of academic research biobanks can make recruitment

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difficult. In this chapter, we discuss major elements of bringing in a new person into the biobank.

2. Orientation

2.1 Priorities and expectations

At academic centers and hospitals, trainees may be provided with a list of expectations in regard to behavior and performance. Expectations may vary significantly from institution to institution. It is helpful to review these expectations point by point with the trainee or new employee. In addition, goals, priorities, and expectations specific to the biobank itself should be discussed.

2.1.1 Safety is the highest priority—In our laboratory, at the very beginning of orientation, it is emphasized that the most important priority is safety of the people in the biobank. We emphasize that appropriate safety precautions must be taken at all times. If others in the laboratory are not following appropriate safety precautions, it is incumbent on every person, even the most junior person, to remind their colleague of the appropriate steps. If equipment or material is needed to make processes safer, this should be brought to the attention of the biobank director. We want all personnel to be safe and healthy so that they can perform their vital tasks critical to protecting and leveraging the precious biospecimens in our care. Repeated safety violations may hurt your valued personnel and also can lead to the suspension or closure of the biobank.

2.1.2 The second highest priority: protecting and maximally leveraging the biospecimen—Proper handling of biospecimens is a close second priority to safety. The patient has given their specimen to the biobanker for its care- typically not just for their specific needs but also for potential research and for the general good. So, there is a great responsibility to protect the biospecimen and use it wisely. Biospecimens, whether they are tissue, blood or fluid, are invaluable. For example, a cancer specimen obtained from the patient may contain unique genetic, transcriptomic, and proteomic information that is irreplaceable. A cancer specimen obtained at a later time from the same patient may contain differing genetic, transcriptomic, and proteomic information. It is vitally important that full and accurate labeling of the biospecimens is maintained throughout its sojourn in the biobank. Adequate labeling may include the patient’s research identifier, type of specimen, and the procurement date within the limits of privacy regulations. This accurate labeling cannot be overly emphasized. The ability to link the biospecimen to clinical and investigational data is critical for maximizing the use of the biospecimen. One would not want to be using inadvertently an incorrectly labeled lung cancer specimen in a breast cancer study. Furthermore, stocks of any biospecimen should be carefully conserved and only dispersed when meaningful purposes are properly consented and approved. If fulfilling a biospecimen request and the tissue or fluid is nearing exhaustion, the supervisor or director of the biobank should be notified. The supervisor or director in turn may choose to discuss it with the requester and a tissue oversight committee composed of stakeholders who might provide oversight for use that type of biospecimen. It may be, for example, that use of the

biospecimen for a particular project would prevent sufficient biospecimen being available for entry into a clinical trial.

2.1.3 Expectations in terms of behavior and performance—At orientation, we find it useful to emphasize the importance of courtesy, collegiality and teamwork in terms of daily work or research projects. We emphasize that mundane and perhaps menial tasks such as cleaning or decontaminating workspaces or hoods are a part of the job and a shared responsibility. Timeliness in arriving for work and meetings is discussed. The importance of communication is imparted. We encourage being frank if unable to perform a task and asking for help or more resources. Communication includes raising safety issues without hesitation. Good communication also encompasses timely responses to emails. The new employee is reminded of laws and institutional policies concerning discrimination and harassment. The length of the employee's probationary period may be reiterated, and the understanding imparted that satisfactory behavior and performance are critical to becoming a full employee.

2.2 Introduction to other personnel and to the facilities

The new employee may have already met other staff in the biobank during the interview process but a reintroduction to make sure no one is missed can be helpful. In addition, it may be worthwhile for them to meet end-users of the biobank with whom they might interact with frequently. An email perhaps including a picture of the individual could be sent to a wider circle that might work with the new employee. Paperwork should be submitted so that they can obtain keys for the relevant biobank rooms. The employee should be taken on a guided tour of the facilities. We find it useful at this time to review the locations of nearby emergency exits, fire extinguishers, eyewash stations, and emergency showers.

2.3 Obtaining an identification card and electronic access

The new employee may obtain an identification badge from the security or other relevant office. Some identification cards with magnetic strips or radiofrequency identification (RFID) chips may need to be additionally programmed to allow access to specific secure buildings or areas. Paperwork may be filed for the trainee to get login access to the institution's computer network as well as for their own email account. The Information Technology (IT) department is contacted to get them login access to the appropriate biobank databases and software.

3. Training

3.1 Safety training

Typically, the institution will have mandated safety classes and the new employee may be prohibited from performing certain activities, such as those at the bench, until the training is completed. These may be online classes, in person classes, or an admixture of both. At our institution, relevant training includes biosafety, chemical, electrical, fire, and ergonomic hazards. If handling biospecimens containing radioactive compounds, specific safety training would be required. In the biobank setting, understanding biohazards is critical to the trainee's safety. We like to reemphasize the importance of wearing personal protective

equipment (PPE) including labcoat, pants, and covered shoes. We highlight the importance of not eating or drinking in the laboratory. Personnel are encouraged to remind each other to practice safe habits and to alert colleagues who may have forgotten to wear a specific PPE item. We emphasize the importance of handling all biospecimens as if they are hazardous. Safety techniques to avoid cuts when using blades on samples include using forceps, not hands, to hold tissue specimens and the use of cut-resistant gloves. Eye protection, face shields, and masks provide protection against splash when handling biofluids or laboratory solutions. We note that even the apparently innocuous opening of a freezer can present a splash hazard and that eye and other protection may be warranted when a freezer is used to store biospecimens. As our laboratory supports an AIDS Brain Bank and the biospecimens are at high risk for containing multiple infectious organisms, there is a strong incentive to take basic safety precautions. Biobanks also often use liquid nitrogen and extra care must be taken to review the potential hazards such as burns, tank explosion, and asphyxiation from fumes. Similarly, the ubiquitous dry ice can evaporate into carbon dioxide gas and use of sufficient quantities of dry ice in an enclosed space can result in loss of consciousness or even asphyxiation. Together, the various different hazards that may be present in the biobank, necessitate that the trainee be both proficient and vigilant in safety practices.

3.2 Databases, information systems, and records training

Once oriented and passwords are obtained, trainees can be introduced to the software and log books that facilitate the appropriate allocation and storage of biospecimens. These include biobank databases, pathology information system, freezer maps, and laboratory maps. If a particular software is newly purchased, the software vendor often may provide training. For institutional software or databases, the information technology department may provide the relevant training. Biobanks must carefully store and document access to samples and donor information. Tracking such information is best done via computerized databases, as they can hold vast amounts of data and allow for quicker searches in comparison to paper-based databases. Both specimen annotation and location should be kept in computerized databases. If the databases and software are extant in the biobank, the existing staff can train the incoming personnel. The newcomer should also be familiarized with the backup protocol for the database and also their personal computer. Our data is stored in the internet cloud on redundant servers managed by the university. However, we also make our own weekly backup of lab electronic files onto a local encrypted hard drive.

3.3 Patient consent, privacy, and specimen identification training

3.3.1 Patient privacy and consent—The protection of patient privacy is not only crucial for building trust between donors and researchers, but it is also legally required in many countries. Thus, trainees must undergo a curriculum regarding relevant privacy laws and institutional policies. The Declaration of Helsinki, a document of ethical guidelines developed by the World Medical Association details widely accepted elements of patient consent and is used as a template by many countries (1). As part of patient consent, it is important that patients are aware of procedures, risks, benefits, and alternatives involved in biobanking prior to donating any samples. Therefore, clear consent forms detailing patient rights must be provided. The new biobanker must learn how to track the consent status of the banked biospecimens. To maintain patient privacy, biobanks may code samples- that is, use a

research identification number in lieu of the patient's name, birthdate, medical record number or other identifiers. Access to a patient's personal information and clinical data, therefore, should be tightly controlled.

3.3.2 Biospecimen identification and labeling—The proper labeling and use of patient identifiers impact on several aspects of biobanking, from patient privacy to clinical research integrity. Proper labeling and patient identification techniques have been reviewed previously (2). Briefly, when labeling biospecimens for identification, it is essential to that the trainees understand to exclude the patient's name, initials, biographical data, medical record number, and other traceable identifiers from the label. Solely relying on a single numerical research identifier however may cause confusion, as numbers are prone to transposition or incorrect transcription. Thus, to assure both patient privacy and reliable identification, some labeling principles are worth considering:

1. Use a patient research identifier and a specimen research identifier as the same patient may have more than one specimen over time. Having these two different identifiers on the label also facilitates identification as one identifier may act as a backup in case of typographical error in the other identifier.
2. If dates are placed on the label, it is useful to specify what the date means. A possible schema for specifying the type of date might include: DO=Date of Operation; DA=Date of Autopsy; DR=Date Received; DX=Date of Experiment; DC=Date of Culture; DF=Date Frozen; DP=Date of Procedure; DI=Date Immunostained.
3. Use a letter code in conjunction with a numerical code to mitigate single number transposition errors. For example, 14–1867 may be easily confused with 14–1687. In contrast, 14–1867bin would be difficult to confuse with 14–1687zed where an arbitrary three to four letter alphabetical code is permanently attached to the number.
4. Use labels appropriate for the processing and storage conditions. For example, use freezer-tolerant labels that will not peel off in liquid nitrogen or other frozen storage conditions. The label printer must print numbers and information onto the label that is resistant to the adverse conditions that they might encounter such as solutions and solvents often used in laboratories.
5. Modern laboratories may barcode and less frequently use radiofrequency identification (RFID) tags to label and track their specimens. Barcodes and RFID tags can mitigate many of the human data entry errors and increase speed of processing in high volume centers, but they come at the cost of increased expense related to the computing hardware and software requirements. There is a constant requirement for upgrading as operating systems change as well as a risk of technological obsolescence. Hence, a cost-benefit analysis is a wise step prior to purchasing a bar-code or RFID system.

3.4 Specimen handling: basic principles for trainees

Depending on their prior experience, a trainee may require educational sessions in order to fully understand the rationale behind the various biospecimen handling techniques. In the glossary of the National Cancer Institute Best Practices, a biospecimen is described as a quantity of tissue, blood, urine, or other human-derived material and thus can consist of cells, tissue (e.g. bone, muscle, skin), organs, gametes, embryo, fetal tissue, and waste (3). The term biospecimen can be applied to other organisms in the plant and animal world and to their bio derivatives. There are different modalities by which the biospecimens and their derivatives may be properly procured and conserved. The trainee should understand the differences between these derivatives, as well as how the specimens are procured and prepared.

3.4.1 Procurement and processing of biospecimens—It is important that the new biobanker understands several key principles in the procurement process. Most importantly, they must be vigilant in minimizing the time from procurement to stabilization, as this may result in tissue ischemia and degradation (4). Typically, stabilization is considered to occur when tissue is snap frozen or to begin when placed into formalin. The time period in which a biospecimen is at room temperature after removal from the body, but prior to being stabilized is known as *warm ischemia time*. To limit warm ischemia effects, biobank facilities either send a technician into the operating room with a liquid nitrogen container or place tissue sample containers on wet ice in the interim. By keeping the tissue on ice until further stabilization, cellular changes are limited, and degradation is slowed. The time period in which tissue is kept on ice or in a refrigerator (4°C) after being resected but prior to being frozen or formalin-fixed is known as *cold ischemia time*. During cold ischemia, cellular changes and degradation is markedly reduced compared to warm ischemia but is still ongoing. The ischemia times prior to delivery to the biobanker are out of the biobanker's control. However, once in our hands, ischemia times must be minimized as much as feasible. Regardless, warm and cold ischemia times are to be documented fastidiously. In the future, methods to assess the quality of the biospecimens after collection and stabilization may obviate the necessity to track these times. Until then, these times may be valuable for researchers in understanding deviations in data relevant to particular biospecimens.

It is helpful for the trainee to understand that the method by which a biospecimen is procured is dependent on intended testing. This is especially true for blood, where different types of tubes are required for different purposes, e.g. DNA collection vs serum collection. Furthermore, some blood analytes are better preserved at room temperature while others are more stable on ice. For blood collections then, they should know to ask what tubes to collect and the handling conditions after procurement.

The trainee should learn the various preparation processes that biospecimens undergo after procurement and prior to storage. These processes are necessary so that the biospecimen can be appropriately aliquoted and stored for efficient clinical and research testing. While each process will require specific training, the basic differences in techniques will be briefly summarized.

Blood samples for DNA extraction can be frozen. Blood samples where white cells and serum or plasma are desired should be fractionated and aliquoted immediately after collection. It has been recommended that all samples should be frozen within 24 hours after collection. Tissue specimens may undergo formalin fixation before they are processed into paraffin (wax) blocks that can be stored at room temperature and used for making histologic or immunohistochemical slides. Tissue is placed into a 10% formalin solution that cross-links proteins and nucleic acids while inactivating most enzymes and microorganisms. It takes approximately 6–18 hours for formalin to adequately penetrate and fix tissue cut to a 3–5 mm thickness. The tissue is then processed in a tissue processor through alcohol cycles to dehydrate the tissue and through xylene cycles to remove alcohol and facilitate paraffin infiltration. The tissue processor then goes through wax steps to permeate tissue with paraffin. The tissue is then molded into a formalin-fixed paraffin embedded (FFPE) block also known as a paraffin block. Formalin fixation, tissue processing, and embedding cross-links and fragments nucleic acids rendering FFPE samples suboptimal for whole exome and whole genome sequencing (5). However, some molecular analyses including PCR and RT-PCR assays generally work well. Also, FFPE tissue allows for room temperature storage and superior preservation of cellular detail for microscopy compared to frozen tissue. Numerous immunohistochemical studies to evaluate protein expression at the cellular level can be performed on FFPE tissue. The biobank technician may train in microtomy, the practice of cutting extremely thin slices of paraffin-embedded tissue with a microtome. The resultant ribbons of tissue can be placed into tubes for molecular analyses. Alternatively, a single slice of tissue may be laid on a slide for staining or immunostaining.

Assuming the tissue is procured properly, frozen tissue typically maintains enzymatic activity and produces high yields of well-preserved DNA and RNA. These frozen samples may be useful for enzymatic assays, nucleic acid extraction for next generation sequencing, immunohistochemistry, and immunofluorescence studies. A biobank technician may also find it useful to learn cryotomy whereby unfixed, but frozen samples of biological tissue are sectioned into thin slices via the cryotome. Most importantly, as cryotomes utilize incredibly sharp blades, all personnel must be trained appropriately in their use to ensure personal safety.

3.4.2 Room Temperature Biospecimen Storage—The most common biospecimens that can be stored at room temperature is the FFPE block and stained or immunostained FFPE slides (5). Slides and blocks can be stored in cabinets with narrow drawers suitable for their dimensions. Sections can be cut from the FFPE block for years to decades after preparation and produce excellent histologic sections. Proteins exhibit variable rates of degradation such that immunohistochemistry typically works but may produce increasingly weak signals over time. As FFPE blocks age, nucleic acids may decline in yield and fragment size leading to higher quality assurance failure rates. RNA is particularly vulnerable to degradation. Use of FFPE samples for molecular studies should be carefully validated given biological changes that occur in the creation of FFPE materials (6,7). Blood applied to matrices can preserve the blood DNA for years at room temperature for basic genetic or forensic analyses. The matrices may have a paper, tube, or titer plate format. Tissue samples placed into some commercial solutions can reportedly preserve the tissue or

cells at room temperature for 6 months such that high-quality DNA can be extracted. Some solutions can preserve tissue and cells such that RNA can be extracted after one week of room temperature storage. Freeze drying of tissue has been reported to reduce but not prevent nucleic acid degradation and remains experimental.

3.4.3 Cold and Frozen Biospecimen Storage—Refrigeration can maintain samples at temperatures of approximately 4°C. To avoid warm ischemia, we sometimes place surgical specimen containers that are on wet ice into a refrigerator while waiting for a pathologist to verify the diagnosis and to release research tissue for stabilization. Instant snap freezing after resection of a tissue specimen is the ultimate goal; however, this may not be achievable given that a biobank may not have the resources to send a technician to the operating room on every case to wait and to procure the specimen. As a rule of thumb, time to stabilization should be less than 20 minutes from the time of specimen excision (4, 8). Times less than that are desirable to mitigate changes in gene expression or protein phosphorylation that can occur rapidly within a few minutes. Refrigeration is not appropriate or ideal for long term storage of tissue specimens. In the clinical setting, blood is often refrigerated for a week in case further chemical analyses need to be performed. While suboptimal, PCR analyses can be conducted on refrigerated blood after months to years. For best analytical results, blood or blood derivatives should be frozen for long term storage or stabilized in room temperature matrices depending on the anticipated downstream testing.

In terms of storing frozen biospecimens, cells and tissues are best stored at −80°C or −150°C (9, 10). The −20°C freezer, common a few decades ago, has been shown to be inadequate for preserving tissue biospecimens over the long-term. The −20°C freezer is now mostly used for storage of enzymes or select antibodies as specified by the relevant vendors. Most modern mechanical freezers maintain a temperature of −80°C but some can hold temperatures of −150°C. Most modern liquid nitrogen tanks are vapor phase; that is, they are designed to hold the biospecimen containers in the vapor phase above the liquid nitrogen. Vapor phase storage avoids the risk of contamination from cellular material floating in the liquid nitrogen. While the liquid phase temperature is −196°C, the vapor phase temperature of liquid nitrogen fluctuates but averages approximately −150°C which is below the glass transition temperature of water (−137°C) where molecular movement essentially stops, and enzymes are incapacitated. A number of studies suggest that −80°C is adequate for storage of biospecimens to be used for next generation sequencing analyses. Studies comparing tissue biospecimen storage at −80°C or at −150°C are limited and have shown mixed results as to the relative superiority of one temperature over the other. In our estimation, the cost-benefit ratio currently favors using −80°C freezers for storing tissue biospecimens, including avoiding liquid nitrogen hazards (4).

It is important to note that living cells (e.g. cell lines, embryos, eggs, sperm) should be frozen at a controlled rate in cryoprotective media to optimize their survival as these are intended to be thawed back to a viable state at a later time. Storage is typically in liquid nitrogen. In contrast, tissue specimens, where the ultimate aim is to analyze nuclei acids, proteins, or other analytes, can be instantly (“snap”) frozen by placing the specimen container in liquid nitrogen prior to storage in a freezer or liquid nitrogen tank. Consideration should be given to the best aliquot size for biospecimens. If a large sample is

repeatedly removed from the freezer, it will undergo repeated thawing and freezing which is known to result in nucleic acid degradation. Aliquoting the specimen into multiple containers (typically cryovials) limits this problem in that only a small portion needs be taken out of the freezer at any one time. However, a balance must be achieved in that excessive aliquoting can result in too many containers that take up a lot of space in the freezer.

Automated alarm systems should be used to continuously monitor freezers and the room temperature (9, 10). These alarm systems may have the capability to automatically send a phone, email, page, or text message. Some alarm systems alert a call center whose personnel then alerts the biobank personnel. Contingency plans are vital should power outages or natural disasters occur. Freezers may be plugged into special outlets that are connected to backup power generators. For sites lacking that luxury, backup coolant supplies like CO^2 or liquid nitrogen connected to the freezers can give extra time to handle the emergency. In the situation of a power outage, do not open the freezers if possible; they will maintain their temperature for many hours if unopened. However, if the power is not likely to be restored, then moving the samples to sufficiently cold storage is necessary. A spare freezer is ideal, but this is not always possible and costly to maintain. Current knowledge of extra freezer space in a consortium of freezer owners at your institution may facilitate identifying temporary storage space. A cooler box with dry ice is another possibility. Written standard operating procedures (SOPs) that are tested on a routine basis should be in place to respond to freezer failures, weather emergencies, and other disaster recovery/emergency situations (9, 10). Despite remote monitoring, we require a walk-through inspection of the freezers and freezer rooms.

3.4.4 Shipment of biospecimens—Many institutions offer specific training to personnel for biohazard shipping. When shipping biospecimens, it is essential that temperature, mode of transportation, shipping time, climate, and distance are considered in packaging the biospecimen. Slides can be shipped in slide boxes with adequate padding. FFPE blocks may require nothing other than a sturdy container if shipped in temperate climes. However, where temperatures are likely to be above the melting point of wax as in the tropics or desert regions, sealed small plastic bags to hold each individual block can trap tissue if the block melts. In addition, the wrapped FFPE blocks can be taped to cold packs. Inclusion of a temperature-measuring device with the biospecimen shipment has been suggested though this seems rarely to be done. Frozen biospecimens will need to be shipped in insulated shipping containers that have dry ice. Sufficient refrigerant must be included with the shipment to allow for at least a 24-hour delay in transport. A courier may be necessary for handling shipments containing temperature-sensitive material. Triple packaging of blood or fluid shipments is recommended or required in many jurisdictions. Sufficient absorbent material should be included within the secondary container to soak up spilled blood or other fluid. Governmental regulations that specify requirements for shipping of biohazards should be observed. Biobank personnel must be aware that, when shipping specimens, a Material Transfer Agreement (MTA) is recommended. An MTA governs the transfer of research materials in addition to specifying the rights and obligations of provider and recipient with respect to materials, timelines, third-party transfers. Shipping must occur

via authorized personnel. The biospecimen resource should notify the recipient of the incoming package prior to shipping shipping to ensure that someone will be present to accept the samples. Shipment tracking must occur in a written or computerized log, including invoice number, sample description, date shipped/received, condition on arrival, study name, key investigator's name, and signature of recipient. Additionally, sample identification numbers, descriptions of the samples, and standard operating procedure specifics should accompany all shipments. International Air Transport Association (IATA) rules, governmental regulations, and National Cancer Institute (NCI) or International Society for Biological and Environmental Repositories (ISBER) Best Practices regarding shipment should be satisfied depending on the type and location of your biobank.

3.4.5 Quality Assurance—Quality assurance (QA) helps to promote patient and researcher satisfaction as well as effective use of limited biospecimens. Therefore, formalized QA policies should be developed by biobanking facilities (9, 10). While policies should be customized to each individual biorepository, there are several overarching QA guidelines that should be understood by the trainee. Personnel must always have access to the standard operating procedures that they are required to follow. Additionally, documentation of adherence to SOPs is necessary. Constant documentation of inventory, lengths of processing times, incidents, and shipments must be present. Recording lengths of processing times can provide information regarding efficiency as well as specimen quality. Periodic testing of representative biospecimens should occur. To provide an example, each year, a percentage of samples might be tested for RNA integrity although this data can be collected from end-users to minimize costs. Maintenance and certification of equipment should be regularly scheduled and documented (e.g. certification of fume and biohazard hoods). As part of accreditition of the biobank, an auditing entity, separate from the institution, may conduct audits to monitor biobanking processes. Regular internal audits for accuracy of annotation data (e.g. biospecimen location), patient data, and SOPs are necessary. A system must be put into place to share audit findings with all biobank staff members.

4. Conclusion

As the responsibilities within a biobank are numerous, appropriate orientation and training can smooth integration of the new trainee into the laboratory. Learning and following best practices recommended by the NCI or ISBER will enhance the quality of the lab and trainees are encouraged to read through these documents (9, 10). Learning about teamwork, personnel safety, patient privacy, biospecimen quality, and best practices in the form of carefully implemented SOPs will provide a solid base for the new biobanker to grow into a productive member of the biobank.

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