PLANNING AND OPERATIONAL CONSIDERATIONS FOR CONDUCTING

Human factors studies with cadavers and tissue samples

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INTRODUCTION

A primary goal when executing a simulated use human factors study is to **create an environment that is as realistic as possible.**

For certain stimuli (e.g., surgical tools), **to achieve the necessary level of realism**, it may be necessary to **involve human or animal tissue samples.**

This poster addresses the **complexities of conducting realistic human factors research with cadaveric and animal tissue samples**, highlighting key logistical, ethical, and technical challenges.

PREPARATION

Choose the right facility

- Traditional market research facility can work for studies involving animal tissue but often lack accommodations needed for cadaver studies.
- "Wet" labs are designed specifically for conducting research and training involving human cadavers.
- They have proper processes and accommodations for receiving, storing, and handling cadaver specimens.
- They are also likely to provide changing rooms and personal protective equipment (PPE).

Logistics of acquiring tissue samples

- Coordinate with your client and/or external vendor to ensure sufficient time is budgeted for acquiring and receiving samples.
- Coordinate to ensure that as few cadavers are required as possible.

  Example: If conducting an orthopedic procedure, use both of the specimen's knees.
- Work with the facility on how tissue samples should be stored.
- Keep in mind that some types of tissue samples have a short shelf life.

  Example: Pig eyes may only be usable for a few days.

Ethical consideration

If working with an external vendor to source human cadavers, ensure they have the necessary license or certification, which vary by location. You want to be certain that any cadavers used in your studies are ethically sourced.

Add realism to the session

- Consider what elements can be added to simulated use setup simulate living bodily functions with your tissue samples.

  Example: Manually pumping blood through a pig heart when testing a cardiac surgical tool.

  Example: Creating negative pressure behind pig eyeballs when testing an ophthalmologic injector.

  Example: Using a CPAP machine to inflate human lungs when testing a bronchoscopy tool.

Prepare your team

- Ensure all team members complete any client, facility, or quality system training.

  Example: Bloodborne pathogen training, hazardous material training, and radiation exposure training.
- Assign and document what roles each team member (internal team and client team) that will be acting as members of surgical team will have.
- Review with the team what they can and cannot do during sessions and ensure that they are not interfering with any critical use tasks.

DATA COLLECTION

Account for time needed to prepare the specimen

- With minimal training, human factors researchers can handle and prepare animal tissue samples.
- Be sure a trained expert is on-site to handle and prepare human cadaver samples.
- Mishandling could impact validity of data.
- Cadavers can take days to thaw and hours to prep before a session.
- Ensure proper placement, positioning, and securing of the tissue, cadaver, or organ.

  Example: If using a pig heart, ensure it is correctly oriented in the manikin chest cavity.

  Example: If using portions of a cadaver, consider that only a portion of the cadaver may be used and will not have the same weight as a living patient.

Ethical consideration

Make sure the use of cadaver and animal specimens is clearly detailed in all recruiting and consent documents.

Wear the proper gear

- When working with cadavers, the proper PPE is necessary to protect you, your research team, and your participant.
- At a minimum:
  - Scrubs (top and bottom)
  - Foot/shoe covers
  - Mask
- Depending on the facility or procedure, head covers and surgical gowns may be required.
- Depending on the situation, you may also need:
  - Gloves (for those directly interacting with the cadaver)
  - Lead vest (if x-rays/imaging being used)
  - Safety glasses (if aerosolized biological matter is possible)
  - Vick's VapoRub under the nose (if specimen odor is present)

Set up your study equipment

- Position your cameras and other study equipment to not interfere with the surgeon's task-completion.

Ethical consideration

Remind the participant that the cadaver was once a living person and should be treated with the same care and expertise that they would use with a living patient.

ANALYSIS AND REPORTING

Acknowledge any specimen limitations or artifacts

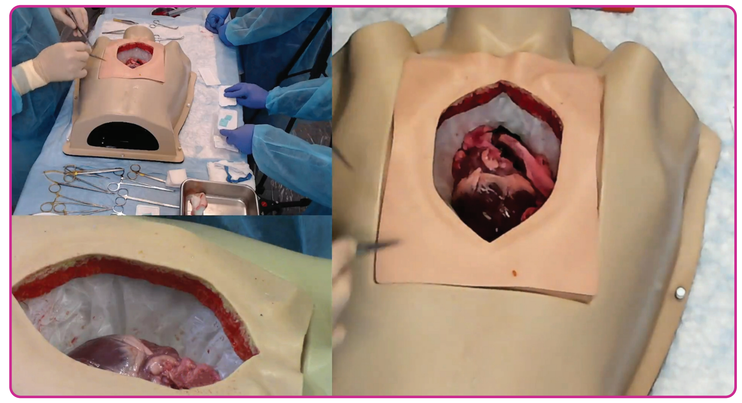
- While animal and cadaveric tissue brings a greater level of realism to a study than using a manikin, it introduces certain test artifacts.
- Be sure to identify if there were any traits or conditions with the cadaver that could impact your test results.

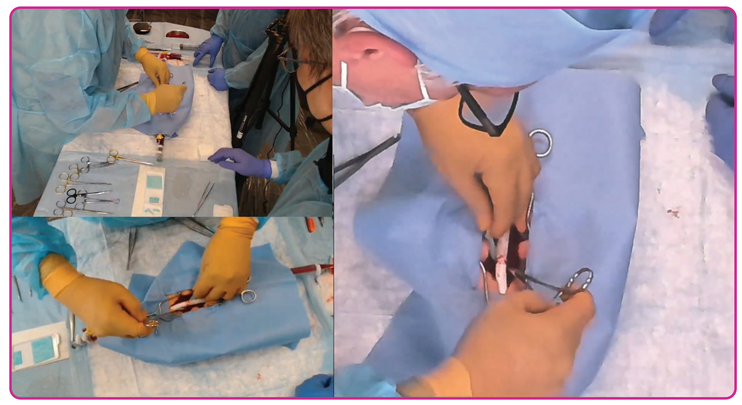
  Example: The age of specimen.

  Example: If the specimen had an illness that could overly impact the specimen tissue quality.
- Be sure to identify ways in which cadaver/animal tissue is different from living tissue and how they may impact your test results.

  Example: Tissue may not be as elastic and may damage easier than regular tissue.

  Example: Refrigerated tissue will be colder than warm living tissue, which could impact participant's dexterity and performance.





Ethical consideration

Be very judicious of omitting data. While it is unavoidable at times, keep in mind that the remains of a human or animal were part of your data collection.

If using a human cadaver, this was their final wish. The families of the deceased may ultimately receive a letter with a list of how their loved one's remains were used for scientific research.

As such, every effort should be made to ensure the specimen is not wasted and is, in fact, used for research purposes.

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