Examples of Well-Written Protocols: Section G.1 (Lay Description)

Background on the Lay Description

Federal regulations (PHS Policy IV.A.3.b.3) require that the IACUC have at least one non-scientific member. One of the DFCI IACUC's non-affiliated members serves as a lay member, as do several other committee members. These non-scientists volunteer their time to review every protocol submitted to the IACUC, so the lay descriptions must be appropriate. If the lay members do not understand your study, the protocol may be rejected. Following are requirements and suggestions for the lay descriptions.

A Well-Written Lay Description

Writing the lay (non-scientific) description in your protocol involves thinking in a whole new way. It is important not only to remove scientific terms, but also to simplify the overall concepts used in your protocol. The language of this section must be understandable by the general public. Imagine explaining your protocol to your mail carrier or the server at your local coffee shop: you are writing for the *Boston Globe*, not *Cell*.

Consider the following excerpt, which might be part of the introduction to a research study about music cognition:

In music, timbre...is the quality of a musical note or sound which distinguishes different types of sound production or musical instruments. The physical characteristics of sound which are used in the determination of timbre are spectrum and envelope with psychoacoustics or human perception also determining the perceived quality of a sound.

--from Wikipedia (http://en.wikipedia.org/wiki/Timbre)

1. Define technical terms

The description above is not terribly scientific; however, it is also not in lay language, so it is likely that the average person on the street will not understand it easily. One option is to define any technical terms used. (We've also added a comma before 'with' to make the paragraph slightly more understandable.):

In music, timbre...is the quality of a musical note or sound which distinguishes different types of sound production or musical instruments. The physical characteristics of sound which are used in the determination of timbre are spectrum ("the amount of vibration at

each individual frequency") and envelope ("the change in over-all amplitude of a sound over the course of its duration"), with psychoacoustics (how sound affects the human brain) or human perception also determining the perceived quality of a sound.

--Definition of 'spectrum' borrowed from
http://www.phys.unsw.edu.au/~jw/sound.spectrum.html
--Definition of 'envelope' borrowed from
http://music.arts.uci.edu/dobrian/digitalaudio.htm

2. Replace technical terms

Although the second description includes only words that most college-educated adults would understand, the paragraph is cumbersome, and it is likely that the reader will need to refer to the definitions several times over while reading the rest of the protocol.

Another option is to remove technical terms and replace them with lay terms (or, when no lay term exists, remove the technical terms and replace them simply with definitions, as we've done). Use this cautiously, however, because many times the overall concept is still out of reach to the non-scientist. The above paragraph without the technical terms 'spectrum,' 'envelope' and 'psychoacoustics' would read as follows:

In music, timbre...is the quality of a musical note or sound which distinguishes different types of sound production or musical instruments. The physical characteristics of sound which are used in the determination of timbre are the amount of vibration at each individual frequency and the change in over-all amplitude of a sound over the course of its duration, with how sound affects the human brain or human perception also determining the perceived quality of a sound.

3. Simplify complex concepts

This is not much easier to read. In addition, now that the unfamiliar vocabulary is out of the way, the reader is more likely to struggle over relevance of slighly more common concepts such as 'frequency' and 'amplitude.' If timbre is still be a difficult concept to wrap your mind around, consider the following:

One of the basic elements of music is called color, or timbre (pronounced "TAM-ber"). Color includes all the aspects of a sound that do not have anything to do with how high or low it is, how loud or soft, or how long or short. In other words, if a flute plays a note, and then an oboe plays the same note, for the same length of time, at the same loudness, you can still easily tell the two notes apart, because a flute sounds different from an oboe. This difference is the color of the sound.

Timbre is caused by the fact that each note from a musical instrument is made up of more than one sound wave. These sets of sound waves, called harmonics, are basically the same for every instrument. Small differences in the balance of these waves - how many you can hear, and how loud they are compared to each other - create the many different musical colors. The harmonics at the beginning of each note - the attack - are especially important for timbre, so it is actually easier to identify instruments that are playing short notes with strong articulations than it is to identify instruments playing long, smooth notes.

--from https://cnx.org/contents/8wb7KfA0@15/Timbre-The-Color-of-Music, a description written for students in grades pre-K to 5

Even though it is longer than any of the preceding descriptions, this final excerpt is far less technical in both terminology and *overall concept*, and therefore it is much more informative. Although it was written for young children, an adult who is not familiar with music terminology would probably find this excerpt a better introduction to the music cognition study. In the same way, the lay members on the IACUC are not scientists, and thus need a non-technical description of your work. It is better to err on the side of too much simplicity; it is not likely that anyone will complain if you make their job too easy!

Where to go for help

The IACUC Coordinators are available via email or in person during regular business hours to review and comment on your lay objectives and procedures. Additionally, you may know another non-scientist who can provide constructive feedback on the understandability of your lay description.

In the future we hope to have a glossary of scientific terms and their preferred non-scientific equivalents/definitions. If a term has you stumped and you need a non-scientist's input, or if you have a particularly good definition, please email it to the IACUC Office.

Examples of Well-Written Protocols

G.1 (Lay description)

Lay Description of Objective(s)
*Please describe the overall objective(s) of your research **in lay terms**.*

We have learned a great deal about immune protection against viral diseases through the previously approved thymic vaccination project. Now, we would like to apply the knowledge and expertise gained through these efforts to explore the possibility of T cell vaccination against influenza virus infection, a devastating acute respiratory infection that may kill millions of people if a new influenza pandemic occurs. Unlike the conventional "flu shot" vaccine which induces antibodies produced by B cells, this approach will focus on the disease-fighting T cells, another type of cell which is an important arm of the immune system to defend against viral infections. We will continue to use the mouse model of the influenza virus infection approved in the previous animal protocol to test the efficacy of this new vaccination strategy.

Lay Description of Procedures
*Please briefly describe **in lay terms** all procedures (surgical and non-surgical, including breeding, if applicable), that will be performed on the animals requested for this protocol.*

In order to induce an immune response to the new experimental vaccines under examination in this animal protocol, HLA*0201 H2-K-/-/H2-D-/- mice will be injected with different concentrations of the vaccines bound to the carrier cells called dendritic cells (DCs) through the skin of abdomen directly into the abdomen cavity. As controls, another group of mice will be injected through the same route but only with the DCs. The difference of the immune responses between the vaccine-injected and control-injected mice will be examined.

To study the immune responses to the influenza virus itself, wild-type C57BL/6 mice sometime need to be infected with the live virus itself. To this end, the animals will be given the live influenza viruses in a small volume (30 ul) directly into the nostril. After a variable period of time (1 to 3 months), immune response-related organs will be harvested as described for further analysis.

After injection with the vaccines or the live influenza viruses, mice will be euthanized using CO2. Immune response-related organs of the animals, such as lung, spleen and lymph nodes, will be dissected out. In some cases, the lungs need to be washed (termed bronchoalveolar lavage) in order to collect and analyze the immune cells accumulated in the airways of the lung tissues after injection or virus infection. To this end, the mice will first be injected with an anesthetic combination called ketamine/xylazine through the same route as described above. The cells accumulated in the lung airways will be washed out using saline solution administered through a

plastic needle inserted into the large bronchia of a mouse (termed trachea). The animals will die during this procedure under anesthesia and without any pain.

HLA*0201 H2-K-/-/H2-D-/- mice will be bred to maintain the mouse strain. The genetic make-up of these animals will be routinely examined by taking a small drop of the blood from the tail and a small ear punch from these animals. All of these procedures will be done off-site at Taconic Farms, a professional experimental animal vendor, following their rules and guidelines.