

## Attachment 8D.

### National ALS Biorepository Consent Form Addendum (Postmortem Skin Collection)

#### **Why am I being asked?**

You have agreed to take part in the postmortem tissue collection portion of the National ALS Biorepository.

#### **What is the purpose of this collection?**

We would like to put some of the cells from your skin in a cell bank so that researchers can use them in the future. We don't know what kind of future research will be done but the studies will be ALS related.

#### **What are the procedures involved?**

Small skin samples (postmortem) will be collected from up to 40 participants in order to isolate primary fibroblasts. If you choose to take part in the skin collection, after death a small skin sample about the size of a quarter will be surgically removed from your back. It will be sent to an ATSDR approved laboratory for cell isolation. The lab performing this part of the specimen processing is Zen-Bio Incorporated.

#### **Where will my skin sample be stored?**

After the skin sample is transferred to Zen-Bio the individual skin cells will be separated from the skin tissue. A particular skin cell type called a fibroblast will be grown in the lab to make more of these cells for future ALS research. These cells can be stored at very low temperatures as frozen samples that can be stored forever, if handled properly. These frozen cells can then be thawed and continue to grow in a laboratory to produce more cells for ALS research. Your skin cells will be kept by an ATSDR approved facility.

#### **What about privacy and confidentiality?**

Your skin sample will be coded with an ID number so that your name is not on the sample.

Your skin cells may be shared with researchers in the future. These samples will only be identified by ID numbers. The individual cells contain your genetic information in the form of DNA. There is a very small chance that genetic research in the future could give genetic information that could be used to identify you.

#### **Can I withdraw or be removed from the biorepository?**

Taking part in this biorepository is voluntary. If you choose not to take part or decide to withdraw your consent and stop taking part, this will not affect your relationship with National ALS Registry or other benefits to which you are otherwise entitled.

You have the right to leave this biorepository at any time without penalty. Your family can also refuse to have your tissues collected after your death.

#### **Remember**

Taking part in this biorepository is voluntary. Your decision whether or not to participate will not affect your current or future relations with the National ALS Registry. If you decide to take part, you are free to withdraw at any time without affecting that relationship. Other information about this biorepository can be found on your copy of the consent form you signed earlier.

**Attachment 8D.**

**Subjects' Rights:**

I have read the above information. I have discussed this biorepository with the person obtaining consent, been given an opportunity to ask questions, and my questions have been answered to my satisfaction. I agree to provide a skin specimen. I will be given a copy of this signed and dated form.

\_\_\_\_\_  
Signature of Subject

\_\_\_\_\_  
Date

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If participant is physically unable to sign the consent form, please complete the following

\_\_\_\_\_  
Witness Signature

\_\_\_\_\_  
Date

I, \_\_\_\_\_, witnessed that \_\_\_\_\_ was explained the consent form and has agreed to take part in the skin collection. Due to the progression of the disease, the participant is physically unable to sign the consent form.