Celularity Inc.
170 Park Avenue
Florham Park, NJ 07932

**Re: Interfyl®** Human Connective Tissue Matrix

**FDA Tracking Requirements for Human Tissue-based Products**

Dear Healthcare Practitioner,

Thank you for choosing **INTERFYL®**, an allogeneic decellularized particulate human placental connective tissue matrix, which is regulated by the United States Food and Drug Administration (FDA) as a human tissue-based product.

The FDA requires that a record-keeping system be used to track human cellular and tissue-based products from the donor to the consignee or any other final disposition and vice versa (21 CFR 1271.290). In accordance with this regulation, Celularity Inc., the manufacturer of **INTERFYL®**, has established a tracking system for this human placental product.

For each syringe or vial of **INTERFYL®** that is applied, the Healthcare practitioner must create and maintain a record sufficient to permit prompt identification of the recipient. The **INTERFYL®** Tracking System utilizes unique bar code labels enclosed in each **INTERFYL®** package.

To effect the tracking process, the Healthcare Practitioner must:

1. Affix the unique **INTERFYL®** tracking bar code label that comes in the package to the recipient's medical records and/or other pertinent records, if any, for each syringe or vial of **INTERFYL®** that is applied to a patient.
2. Maintain the records to permit prompt tracking of each syringe or vial of **INTERFYL®** to its recipient or other final disposition.
3. Ensure all such records are legible, accurate, indelible, and secure.
4. Ensure all such records are readily available to allow Celularity Inc. and any authorized government officers prompt access to such records to the extent required by law.
5. Ensure that security systems are adequate to protect the confidentiality of **INTERFYL®** recipients.
6. Retain the records referenced in this document for at least ten (10) years after the date of the application of the syringe or vial of **INTERFYL®** to the recipient or, if the application date is not known, the date the product is received, disposed of, or expired–whichever is the latest (21 CFR 1271.270).
7. Refrain from further distribution of **INTERFYL®** to any other Healthcare Providers without including a copy of this letter, so that they are informed of the tracking process.

If the requirements regarding the **INTERFYL®** Tracking System change, we will inform you. Thank you in advance for your cooperation. Please contact us at Celularity Inc. (1-844-963-2273) if you have any questions.

Sincerely,

Celularity Inc.