To whom it may concern
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CURELINE HBS REGULATORY POLICIES AND PATIENT CONSENT STATEMENT

Cureline Group is a global translational and precision medicine CRO specializing in preclinical services including human biospecimen (HBS) procurement and analysis since 2003. Throughout our scientific and commercial activities, Cureline, Inc., offers access to elements derived from the human body. We maintain a worldwide clinical network, with operations in the USA, Europe, Central Asia, China, India, South-Pacific Asia, South and Central America. The biospecimens we procure are consented by donors for transfer to third parties engaged in commercial research and development. Our commitment lies in adhering to legal and ethical principles governing the extraction, collection, donation, shipment, and use of human body elements. Our clinical team ensures that:

- Prior to extraction or collection, donors provide written, free, and informed consent.
- Donors do not receive any financial incentives in exchange for the extraction or collection.
- Biospecimens are collected, processed, tracked, stored, deidentified, and transported in compliance with applicable laws and regulations. We work with protocols for human specimen collection/extraction approved by qualified Ethical Committees (IRBs).
- Biospecimens are properly consented, de-identified, and selected with accurate clinical diagnoses by certified clinical experts.

Donor Consent. Our ethical policies have always adhered to the highest standards relevant to the project requirements.

- For surgical/diagnostic disease-specific tissue removal, we work under IRB/EC approval and obtain a standard consent form signed by patients (*Attachment A*).
- All international collection protocols align with our Human Biospecimens Procurement protocol, approved in the USA by Western IRB (you can find a current renewed approval in *Attachment B*). Local EC approvals are obtained for this umbrella protocol outside of the United States for the Cureline biobanking activities.
- For certain remnant oncology samples (usually archival FFPE blocks), clinical centers may use a shortened version of the consent (*Attachment C*).
- For custom collection protocols (molecular diagnostics, biomarker assay development, special processing protocols, etc.), we can obtain specific protocol approval from the local EC/IRB, often using a Sponsor's template ICF for regulatory package submission (extra charges may apply).
- *Normal tissue samples* are obtained either from consented living donors or post-mortem with

the next of kin's consent (*Attachment D*). We collect these tissues within 2 – 12 hours post-mortem interval (PMI) from accidental death cadavers or unrelated-cause-of-deaths patients. These biospecimens are sourced from State-licensed facilities allocating parts and unwanted organs for research purposes.

All specimens are consented under the laws and regulations of the country of acquisition. Please note that Cureline provides human biospecimens solely for biomedical research and not for use in humans.

Biospecimens, Clinical Data and Personal Data Protection. All specimens and clinical data delivered to Cureline customers are fully de-identified or anonymized. We operate in compliance with updated Common Rule (USA, effective July 19, 2018) and General Data Protection Regulations (EU, effective May 25, 2018). We guarantee that we will not transfer or provide access to any "Protected Health Information" ("PHI") as defined in 45 C.F.R. Section 164.501 or Personal Data as defined in the General Data Protection Regulation (EU) 2016/679

Infectious Materials. To the best knowledge of Cureline, and as a part of our standard collection protocol requirements, *all samples are collected from HIV1/2- and HepB/C-free individuals*, unless otherwise is required by a collection protocol. A clinical report form (CRF) for each case is signed by a clinical site PI to confirm this statement. All original documents are on file at clinical sites and local Cureline offices.

Quality Management. Cureline Biorepository works under the guidelines of the College of American Pathology (CAP) Biorepository accreditation program, verifying all biospecimens management processes. We have established a comprehensive Quality Management Program that addresses all aspects of Biorepository operations, ensuring quality of human biospecimens for clinical research, drug discovery, and personalized medicine and maintain an ISO9001 certificate (#1109996).

I hope that this overview is helpful. Please, let me know if you have any additional questions, I'd be happy to address them. We are looking forward to establishing an effective business relationship with your organization.

Most sincerely,

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