SPECIBIO

A Celltech Discovery Solutions Brand

KRISHGEN BioSystems

OUR REAGENTS, YOUR RESEARCH

Ethically Sourced. Fully Traceable.

Informed consent, IRB oversight and chain-of-custody records, with documentation ready for your regulatory submissions.



Six Commitments Behind Every Sample

Informed Consent

Documented, freely given, taken by trained clinical staff

IRB Oversight

All human collections under IRB-approved protocols

Donor Privacy

De-identified, barcode-tracked, HIPAA and GDPR aligned

3Rs Welfare

Replace, Reduce, Refine, with veterinary monitoring

GLP Processing

Sterile, controlled Good Laboratory Practice conditions

Chain of Custody

Documented from collection point to final shipment

Available on request for regulatory submissions

- **IRB protocol numbers**
- **Proof of ethical collection**
- **Redacted consent language**
- **Certificate of Analysis**

www.specibio.com

In India: Krishgen Biosystems Private Limited | (022)-49198700 | kbiinfo@krishgen.com

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Aligned With Global Standards

Ethical Frameworks We Follow



Year each framework was first adopted. Also guided by the Nuffield Council on Bioethics.

Donor Privacy by Design



Jurisdiction-Specific Compliance

United States

- FDA-licensed facilities
- OHRP 45 CFR 46
- FDA 21 CFR 606 & 610
- HIPAA data handling
- CLIA-certified testing

EU & UK

- EU Directive 2004/23/EC
- UK Human Tissue Act
- GDPR data handling
- Ethics committee approval

International

- ISBER Best Practices
- ICH-GCP E6(R2)
- CITES permits for NHP
- WHO biological standards

Animal

- USDA Animal Welfare Act
- EU Directive 2010/63/EU
- UK ASPA
- NC3Rs & ARRIVE

Need documentation for a submission?

Ask for IRB numbers, consent language and CoA with your quote.

Scan for our ethics policy

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