## Purpose of this document

The paragraphs in this document shall be used as examples for informed consent, ethical committee applications, or IRB applications.

The paragraphs are intended to assist SMART-TRIAL customers, sponsors or Sites to comply with GCP, best practices for data processing, and information security.

**Limitation of Liability:**

Under no circumstances shall SMART-TRIAL be liable for any indirect, incidental, consequental, special or examplary damages arising out of or in connection with your use of, or inability to use, the example paragraphs below. Whether or not the damages were forseeable and whether or not company was advised of the possibility of such amages.

These examples are intended to be used solely as examples, and should in no way be used without seeking legal advise first.

## Example #1 – paragraph for subject data processing consent

**Processing of your personal identifiable information**

With your participation in this STUDY/PROJECT, the following information will be collected about you; to ensure that general data collection is conducted according to industry regulations and standards of research and clinical studies, and to deliver questionnaires to you that you might need to complete as a part of your participation in this study.

(List personal identifiable information that might be collected, such as email, date of birth, name.

An example list:

* Full name
* Email address
* Birth date or birth year
* Gender
* Address
* Mobile number
* .....

)

The collection and processing of your information is done using a software solution called SMART-TRIAL. All data in SMART-TRIAL is collected, transferred, and stored encrypted in databases, that are hosted on ISO certified servers, that are managed by SMART-TRIAL (<http://www.smart-trial.com/>) within the European Union (Ireland and the Netherlands). For more details on the security of SMART-TRIAL, see <https://www.smart-trial.com/legal/security-service-statement>. DATA CONTROLLER has entered a contractual agreement with SMART-TRIAL which clarifies how SMART-TRIAL complies with regulatory requirements for processing of your information according to applicable regulations, such as the EU GDPR.

**Use of and access to your data**

The personal identifiable information that might be collected about you will solely be used for research or operational purposes, such as 1) to send you an email with a link to a questionnaire that you have to complete or 2) to send you a text message to your personal mobile number with a link to a questionnaire you have to complete.

Analysis of all data is done anonymously, without using or linking results and data with personal identifiable information.

Only a limited number of authenticated staff members will have access to your information for managing the data collection and quality assurance.

You can at any time request access to your data or information on how your data is being processed by contacting DATA CONTROLLER DPO EMAIL .

## Example #2 - Paragraphs for ethical committee or IRB application (or similar applications)

**Methods of data collection and processing**

SMART-TRIAL ([www.smart-trial.com](http://www.smart-trial.com)) will be used as the primary Electronic Data Capture and clinical data management tool in this study.

SMART-TRIAL is designed and developed in compliance with the PIC/S Guidance, PI-011-3 Good Practices for Computerised Systems in Regulated “GxP” Environments, with software validation based on medical device software standards.

SMART-TRIAL is designed to enable DATA CONTROLLER and its users to comply with Good Clinical Practice (such as the ISO 14155:2020 standard), ICH GCP, and other industry requirements, such as FDA 21 CFR Part 11, HIPAA and the EU GDPR. For more information see <https://www.smart-trial.com/legal/gcp-fda-21-cfr-part-11-and-hipaa-compliance-statement>

All data in SMART-TRIAL is collected, transferred, and stored encrypted in databases, which are hosted on ISO certified servers that are managed by SMART-TRIAL within the European Union (Ireland and the Netherlands). Backups are performed continuously throughout the day. For more details on the security, backups, and encryption standards of SMART-TRIAL, see <https://www.smart-trial.com/legal/security-service-statement>

DATA CONTROLLER has entered a contractual agreement with SMART-TRIAL which clarifies how SMART-TRIAL complies with regulatory requirements for processing of personal identifiable information according to applicable regulations, such as the EU GDPR.