Informed Consent Form Key Review Items Checklist

Case No.:

Number of types of Informed Consent Forms for this case: types.

□Informed Consent Form for the Main Study □Informed Consent Form for Sample Collection □Informed Consent Form for Pharmacogenetic Study □Informed Consent Form for Pharmacokinetic Study □Informed Consent Form for Pregnant Partner Data Collection

□Other

|  |  |  |  |
| --- | --- | --- | --- |
|  | Key review item | Assessment outcome | Review criteria |
| Number of subjects | Expected number of subjects to be enrolled for the entire trial? | \_ subjects |  |
| Expected number of subjects to be enrolled in Taiwan? | \_ subjects |
| Storage and use of samples and residual samples | Will samples be exported to other countries for analysis? | □Yes □No | * The final disposal for the residual samples should be stated, e.g. to be immediately discarded after completion of the trial. If samples are to be retained for a certain period of time after completion of the trial, and will only be used within the scope of this trial, the retention period and restrictions on the scope of usage should still be stated. * If the residual samples are to be retained for use in other research in future, subjects should be provided with the option to agree/disagree to the retention of residual samples for other uses. In addition, it should be stated that the new research must be reviewed and approved by the IRB, and if it is determined that the original scope of consent is exceeded, consent from the subjects must be obtained again. * The maximum retention period is **20 years** after the completion of the trial; samples must be discarded after the retention period has passed. |
| Is the final disposal for the residual samples stated? | □Yes □No |
| Will residual samples be retained after the completion of the trial? | □Yes □No |
| Is there a checkbox that allows subjects to select whether to retain or discard their samples? | □Yes □No |
| Are the names and addresses of retention facilities for the samples and residual samples stated? | □Yes □No |
| Retention period for the residual samples? | years |
| Pharmacogenetic study (PGx) | Will a pharmacogenetics study be conducted? | □Yes □No | * If genetic testing is a required item for the trial, the test items or methods should be clearly explained in the Informed Consent Form for the Main Study, and it should be stated that subjects cannot participate in the trial if they do not wish to provide samples. * If participation is optional, there should be a separate section providing an explanation, and a checkbox should be provided for subjects to select whether to participate; alternatively, a separate Informed Consent Form for Pharmacogenetic Study should be established. If an Informed Consent Form for genetic study is established, the contents must comply with the requirements of the Official Announcement. |
| Are subjects allowed to select whether to participate in the pharmacogenetics study? | □Yes □No |
| If participation is optional, is there a checkbox for subjects to select whether to participate, or is there a separate Informed Consent Form for Pharmacogenetic Study? | □Yes □No |
| If genetic testing is a required item for the trial, (1) Are the test items or methods clearly explained in the Informed Consent Form, and (2) Is it stated in the Informed Consent Form that subjects cannot participate in the trial if they do not wish to provide samples? | □Yes □No  □Yes □No |
| Is the explanatory content compliant with regulations? | □Yes □No |
| Pharmacokinetic study (PK/Population PK) | Will a PK or PPK study be conducted concurrently during this trial? | □Yes (□PK  □PPK)  □No | * A separate Informed Consent Form is not mandatory for a PK or PPK study. * If a separate Informed Consent Form is not established, it must be clearly stated in the Informed Consent Form for the Main Study that a PK or PPK study will be conducted, and a specific explanation on whether participation is mandatory must be provided. * If participation is optional, a checkbox must be provided. * The time of sample collection and volume of blood to be drawn should be clearly documented. |
| Are subjects allowed to select whether to participate? | □Yes □No |
| Is there a separate Informed Consent Form? or  Is there an explanation provided in the main Informed Consent Form? | □Yes □No  □Yes □No |
| Are the time of sample collection and volume of blood to be drawn fully documented? | □Yes □No |
| Compensation for damages | Is the full text from the template shown? | □Yes □No | * The full text from the template must be shown, and the text must be identical. * Words or sentences that limit or change the text from the template shall not be added. * The "Sponsor/Pharmaceutical Company" shall be listed as the responsible party for damage compensation. The "Sponsor/Pharmaceutical Company" which is responsible for initiating and managing the trial should be stated in the full Chinese name of the certified teaching hospital or the pharmaceutical company with a domestic pharmaceutical company license. |
| Has any text other than that of the template been added? | □Yes □No |
| Has the text of the template been changed? | □Yes □No |
| Is the "Sponsor/Pharmaceutical company" listed as the responsible party for damage compensation? | □Yes □No |