model Ministry 1
Form EC-1

Request [] Acceptance [] Renew acceptance The Ethics Review Committee in people who consider clinical research programs on drugs
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Write at ....
Date ..... Month ..... Year .....

I (Mr / Mrs / Ms.) .... Position …… .....
(Name of the Chairman of the Board Applicant)
On behalf of Research ethics committee in people who consider the research project About medicine of
[] Institute [] Agency Name ....
Under the jurisdiction of .... Is on the number ..... Moo .....
(Department / Ministry of affiliation)
Alley / Soi .... Road ..... District / District ..... District / Region ..... Province ..... . Phone .....
Intending to request acceptance from the Food and Drug Administration
In this regard , I have attached evidence Available data on the memory card (CD) number. 1 series As follows
1. 1. The book appointing a research ethics committee to consider the clinical research program
2. About medicine
3. 2. Education and training of the Ethics Committee members in person Consider clinical research projects on drugs
4. 3. Documents showing sources of income and the regulations for receiving and paying money for research ethics committees in people who consider clinical research programs on drugs
5. 4. Quality system documents of the Ethics Review Committee in people who consider the project Clinical factors related to medicines include Quality guide Work Procedure Guide
6. 5. Documents for meeting of the Ethics Review Committee in people considering the annual clinical research program (number of times / year)
7. 6. A list of research projects involving experimental drugs in people's Transportation Committee consider (not less than 10. Project)
8. 7. Certificate of action that follows the guidelines of good clinical practice of International Conference on Harmonization-Good Clinical Practice (ICH-GCP) and supervision throughout the research project
9.
10. I hereby certify and agree. As follows
11. 1. The proposed research project must be considered as science. Medical field And ethics Using the same criteria in all research projects And summarize written comments that identify research projects and documents that the committee considers review Review date And the opinion of the Board of Directors
12. 2. The Research Ethics Committee in the people who consider the clinical research program on drugs will be responsible for monitoring clinical research that is approved. To ensure
13. 2. 1 Conducting clinical research According to the research outline that has been Approve all Without deviating or changing from the research ethics committee in people who consider the clinical research program about medicine to consider approving Unless it is specified in accordance with the ICH-GCP guidelines
14. 2. 2 The research subjects are protected rights. Safety And well-being such as In the event of adverse events In the case of charges from volunteers and others etc.
15. 3. The Research Ethics Committee in the person who considers the clinical research program about drugs will report the results of operations / amendments About the research ethics committee in people who consider clinical research programs on drugs To the Food and Drug Administration according model Mon Dec. 3
16. 4. The Research Ethics Committee in the person who considers the clinical research project about the drug will allow the Food and Drug Administration Drug monitoring in case of suspicious reason
17. 5. The agency of the research ethics committee in the person who considers the clinical research project about the drug agrees to be responsible for the costs of the actual inspection.
18. 6. Research ethics committee in people who consider the structure Clinical research about drugs is welcomed. Rules method And conditions for acceptance of the research ethics committee in people who consider clinical research programs related to drugs prescribed by the Food and Drug Administration in all respects However, if found later that they are unable to follow the principle Such criteria Welcomed the Food and Drug Administration Can cancel the acceptance
19.
20.
21. (Signature) .... Applicant
22. (..... .....)
23.
24.
25.
26.
27. (This section is for staff)
28.
29. Staff opinion
30. [] Accept
31. [] To inspect before bringing the examination results for consideration, acceptance or renewal of acceptance

[] Not accepted because ……
...
……..

(Signature) .....
.....
Position .....
Dated .....

study Director of Drug Administration
For your consideration If agreeing to the staff opinion Please continue to propose the Secretary-General.
Will be your king
(Signature) .....
.....
Position .....
Supervisory group leader before entering the market
Dated .....

study Secretary-General of the Food and Drug Administration
For your consideration If agreeing to offer Please consider signing
[] Letter of Acceptance / Renewal of Adoption of Ethics Committee Research to determine the clinical research on drugs (a. Ministry 2)
[] Approved to inspect before bringing the examination results for consideration, acceptance or renewal of acceptance.
[] Notice of acceptance of the research ethics committee

(Signature) .....
.....
Position .....
Dated .....

Competent Order
[] Accept
[] Approved to inspect before bringing the examination results for consideration, acceptance or renewal of acceptance.
[] Not accepting Because .....

(Signature) .....
.....
Position .....

Staff
Dated .....