Informed Consent Form

Project Name： The Development of New Functions of Esculin and Digitalis glycosides Eye Drops: A Study on the Treatment of Presbyopia

Project Leader: Zhang Yu

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Informed Consent Form

Dear patient (subject):

We sincerely invite you to participate in the research on "The Therapeutic Study of Digitalis Disglycoside Eye Drops on Presbyopia". Before you decide whether to participate in this research, please read the following content as carefully as possible. It can help you understand this therapeutic research, the reasons for conducting this research, the procedures and duration of the research, as well as the potential benefits, risks and discomforts that may result from your participation. If you wish, you can also discuss it with your relatives or friends, or ask your doctor for an explanation to help you make a decision on whether to participate in this clinical research. If you have any questions, please raise them to the doctor or researcher in charge of this project.

I. Introduction to the Research Project Situation

Accommodation is one of the important functions of the human eye. With age, the lens gradually hardens and the contraction ability of the ciliary muscle decreases, eventually leading to presbyopia. The main components of Digitalis-Scutellarin Eye Drops are scutellarin and digitalis glycosides. Digitalis glycosides can directly inhibit acetylcholinesterase in the ciliary muscle, enhance the physiological release of the parasympathetic vagal neurotransmitter ACH, and increase the contraction ability of the ciliary muscle, thereby improving accommodation. Scutellarin can promote the production of prostaglandins in the ciliary muscle vessels, increase blood flow to the ciliary muscle, and enhance the vitality of the ciliary muscle, effectively regulating the contraction and relaxation of the ciliary muscle. This project explores the related effects of Digitalis-Scutellarin Eye Drops on presbyopia based on its mechanism of action. The project compares and analyzes various indicators such as visual acuity, accommodation function, and aberration before and after treatment for the subjects, and finally evaluates the therapeutic effect. The risk to the subjects in this project is extremely small. Adverse reactions such as eye irritation and foreign body sensation may occur as described in the drug instructions. If any adverse event occurs, you must inform the researchers in detail. The project members will do their best to prevent possible harm and strictly keep the patient information confidential. If you have any questions or problems, please contact the project researchers. Participation and withdrawal from this project are voluntary and will not result in any punishment or unfair treatment.

II. Patient (Subject) Consent Statement

I have read the above introduction about this research and discussed it with the researcher, raising questions. All the questions I raised have been answered satisfactorily.

I am aware that participating in this research may involve risks and benefits. I understand that my participation in the study is voluntary. I confirm that I have had sufficient time to consider this and am aware that:

I can consult information about the research issues at any time.

I can withdraw from this study at any time without discrimination or retaliation, and my medical treatment and benefits will not be affected.

I agree ☐ or refuse ☐ that my personal biological specimens collected for this research can be used for other research projects.

I will receive a copy of the informed consent form that is signed and dated.

I have decided to agree to participate in this research and will do my best to cooperate with the researchers.

Patient (Subject) Signature _____

Date of Signature _____ year ____ month ___ Sun. Contact number _____

III. Guardian Proxy Consent Statement (When the subject lacks the capacity to provide informed consent)

I have read the above introduction about this research and discussed it with the researcher, raising questions. All the questions I raised have been answered satisfactorily.

I understand the potential risks and benefits to my guardian from participating in this study. I am aware that participation in the study is voluntary. I confirm that I have had sufficient time to consider this and understand that:

I can consult information about the research issues at any time.

My ward can withdraw from this study at any time without discrimination or retaliation, and their medical treatment and benefits will not be affected.

I, as the legal representative, agree ☐ or refuse ☐ to allow the use of my ward's biological specimens in research projects other than this one.

I will receive a copy of the informed consent form that is signed and dated.

Finally, I have decided to act on behalf of my ward to consent to participation in this study and will do my best to cooperate with the researchers.

The relationship between guardians and wards _____

Guardian's signature _____

Date of Signature: Year Month Day Contact Number: _____

IV. Researcher's Statement

I confirm that I have explained the details of this study to the subjects (or their guardians when the subjects lack the capacity to give informed consent), including their rights and the possible benefits and risks, and have provided them with a copy of the signed informed consent form.

Name of the researcher _____ Signature _____

Date of Signature: Year Month Day Contact Number: _____