HAAG-STREIT DIAGNOSTICS

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IRB Approved Template
MUST BE APPROVED
FOR SITES BEFORE USE
Mar 18, 2025

RESEARCH SUBJECT CONSENT FORM

TITLE:	Toric Alignment Observational Study 2025-1
PROTOCOL NO.:	9360002 WCG IRB Protocol #20251045
SPONSOR:	Haag-Streit AG
INVESTIGATOR:	Name Address City, State Zip Country
STUDY-RELATED PHONE NUMBER(S):	Phone Number Phone Number (24 hours)

Dear sir, dear madam

We, Haag-Streit, a manufacturer of ophthalmic devices, are conducting a study in collaboration with the study site. As your physician has determined you may be a suitable participant, we would like to ask for your consent to take part in our study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in it. Later sections of this document will provide all relevant details.

Your participation in this study is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled, nor will participation in this study have any effect on the quality of your treatment at the study site.

If you have questions, concerns, or complaints, or think this research has hurt you, talk to the research team at the phone number listed above.

SUMMARY

Why is this study being done?

In this study, we will collect data from voluntary participants who are seeking cataract surgery at the study site. This data will be used to improve the quality of a medical device software that is used to aid ophthalmic surgeons during surgery of patients with astigmatism. The data we collect are:

- the biometric measurements that were taken to plan your surgery, and
- a video recording of the surgical procedure.

The software takes the surgical planning data and maps it to the video images, allowing us to superimpose useful information onto the image.

What happens to me if I agree to take part in this study?
If you decide to participate in this study, the study site will collect your data, anonymise it and provide it to us so we can use it improve the quality of our software.

How long will I be in this study?
Participation in this study does not involve any time commitment. Your participation concludes when the data related to your surgery has been anonymised. This will happen a few weeks after your surgery.

Could being in this study hurt me?
No, participating in this study does not pose any risk of harm to you.

Will being in this study benefit me?
No, participating in this study is not likely to benefit you personally.

What other choices do I have besides taking part in this study?
If you decide not to take part in this study, your treatment at the study site will continue normally, as discussed with your surgeon. There will be no negative consequences to you.

What else should I know about this study?
Your participation is voluntary, and you may decide to withdraw your consent at any time. If you withdraw your consent, your data will be removed from the study. However, it is not feasible to remove your data from the study, if it has already been anonymised. We ask you to consider and accept this fact, before you decide to participate. Your anonymised data will not be used or distributed for future studies.

This study is being conducted in accordance with the Declaration of Helsinki, Good Clinical Practice, ISO 14155, and all applicable regulatory and legal requirements.

The Institutional Review Board WCG IRB has reviewed and approved this study.

DETAILED RESEARCH CONSENT
You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

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- the biometric measurements that were taken to plan your surgery, and
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The software takes the surgical planning data and maps it to the video images, allowing us to superimpose useful information onto the image.

About 100 participants will participate in this study.

What happens to me if I agree to take part in this study?
If you decide to participate in this study, the study site will collect your data, anonymise it and provide it to us so we can use it improve the quality of our software.

How long will I be in this study?
Participation in this study does not involve any time commitment. Your participation concludes when the data related to your surgery has been anonymised. This will happen a few weeks after your surgery.

What are my responsibilities if I take part in this study?
You have no responsibilities related to taking part in this study.

Could being in this study hurt me?
No, participating in this study does not pose any risk of harm to you.

Will being in this study benefit me?
No, participating in this study is not likely to benefit you personally.

Will it cost me money to take part in this research?
No, participating in this study will not cost you money.

What other choices do I have besides taking part in this study?
If you decide not to take part in this study, your treatment at the study site will continue normally, as discussed with your surgeon. There will be no negative consequences to you.

What happens to the information collected for this research?
All the collected data will be anonymised before it is used in this study. However, your private information and parts of your medical record could be shared with individuals and organisations that conduct or watch over this study, including:

- The research sponsor,
- Government agencies, such as the Food and Drug Administration,
- WCG IRB, the Institutional Review Board (IRB) that reviewed this study.

Sharing your private information and parts of your medical record with these individuals and organisations is only permitted to ensure the safety and compliance of this research project and any person handling such information is subject to a duty of confidentiality.

We may publish the findings of this study. However, we will keep your name and other identifying information confidential. We protect your information from disclosure to others to the extent

required by law. However, we cannot promise complete secrecy. Your anonymised data will not be used or distributed for future studies.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Who can answer my questions about this study?
If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number(s) listed in this document.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may contact them at 855-818-2289 or clientcare@wcgclinical.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

What if I am injured because of taking part in this study?
If you are injured or get sick because of being in this study, call the study doctor immediately. The study doctor will provide emergency medical treatment. Your insurance may be billed for this treatment.

Can I be removed from this research without my approval?
The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest
- The research is cancelled by the FDA or the sponsor

We will tell you about any new information that may affect your health, welfare, or choice to stay in this study.

What happens if I agree to be in this research, but I change my mind later?
If you decide to leave this study, please contact the research team as soon as possible so that the investigator can ensure your data is not processed. It is not feasible for us to remove your data from the study, if it has already been anonymised. We ask you to consider and accept this fact, before you decide to participate.

Will I be paid for taking part in this research?
You will not be paid for taking part in this study.

STATEMENT OF CONSENT

Your signature documents your consent to take part in this research.

Signature of subject	Date
Signature of person obtaining consent	Date