Consent Form, Key Information Section

Informed consent document for a clinical investigation | Final specimen

https://www.editfast.com/editing-services/informed-consent-documents

The opening section of a consent form rebuilt against the sponsor's own study record, with one sentence referred back to the board.

FINAL TEXT

SPECIMEN, PREPARED BY EDITFAST FOR ILLUSTRATION. NOT A REAL RECORD.

Halloway Therapeutics (fictitious), consent form for protocol HT-214, page 1

EXTRACT FROM THE SPONSOR'S STUDY RECORD (reproduced unchanged in both panels)

SR-1 Protocol HT-214 is an applicable clinical trial under 42 U.S.C. 282(j)(1)(A).

SR-2 Expected duration of a participant's involvement: 18 weeks, including 6 clinic visits.

SR-3 Purpose approved by the sponsor's medical and regulatory reviewers: to compare an investigational tablet with the standard tablet for adults with moderate seasonal rhinitis.

SR-4 Alternative approved for disclosure: continuing the standard tablet outside the study.

SR-5 The study is conducted under an FDA-regulated investigational new drug application and is supported by HHS.

SR-6 The sponsor has not authorized any statement about payment for research-related injury beyond the institution's standard wording.

KEY INFORMATION You are being asked to take part in research. Taking part is voluntary, and you may stop at any time.

This research compares an investigational tablet with the standard tablet for adults with moderate seasonal rhinitis. If you take part, you are expected to be in the study for 18 weeks and to come to the clinic 6 times.

You do not have to take part. You may continue the standard tablet outside the study instead.

[Query to the sponsor and the board: the sentence beginning "I waive any possibility of compensation" is listed by OPRR as an example of unacceptable language. SR-6 records no authorized alternative beyond the institution's standard wording. Please supply that wording, or confirm the substitution proposed here: "This hospital is not able to offer financial compensation nor to absorb the costs of medical treatment should you be injured as a result of participating in this research."]

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.