

Case History

- Mr. Shalowitz is a 27 year old male with uveitis.
- After standard treatment was unsuccessful, he was referred to the NIH.

Exclusion

- At the NIH, Mr. Shalowitz is offered enrollment on a treatment protocol.
- In the absence of any data on fetal effects, either for safety or toxicity, pregnancy and the intention to conceive a child are listed as exclusion criteria.

Consent

- The consent form states that males and females must agree to use contraception during the study and for 6 months after the experimental treatment ends.
- Mr. Shalowitz signs the consent form and is enrolled on the study.

Response

- Mr. Shalowitz responds well to the drug while on the study, and his uveitis remains under control.
- While on the study, Mr. Shalowitz gets married.

Trial Completion

- Mr. Shalowitz finishes his last treatment on study, and expresses interest in continuing on the drug.
- The drug is not available clinically.

Continued Treatment

- The consent form did not include any statement about continuation of care after the study.
- However, the NIH team has provided continuing treatment to some participants for whom the treatment is effective.

The Couple's Plans

- Mr. Shalowitz states that he and his wife plan to have a child.
- They say they are willing to "take their chances" with potential effects of the drug on any child they might conceive.

Consultation

- The team calls a bioethics consult to assess whether it is ethical to continue to provide the treatment to the patient.

Options

- The consultation team considers the possibility of refusing to provide the treatment unless Mr. Shalowitz promises to use contraception.
- The team also considers the possibility of simply giving Mr. Shalowitz the drug and warning him of possible teratogenic effects.

Alternative Treatments

- The team also considers offering Mr. Shalowitz steroids until his wife conceives.
- Steroid are thought safe to a fetus. However, they have potentially serious side effects, and likely would not be as effective as the experimental drug.