

INFORMED CONSENT TO TAKE PART IN RESEARCH
(Suggested use: Minimal Risk research Involving In-Vitro Device)

Study Title: REALTIME water pipe tobacco smoke sampling device

Study Sponsor: Device Company

Principal Investigator: John Smith, MD, Professor, Internal Medicine, UTHealth

Study Contacts: Jane Doe, PhD, Research Assistant, 713-500-0000

The purpose of this research study is to test a device called REALTIME that will sample tobacco smoke from a water pipe.

You do not have to participate in this study. If you choose to participate you may stop at any time without any penalty. You may also choose not to answer particular questions that are asked in this study.

You will be asked questions about your general health, smoking history, and marijuana and alcohol use. If you are a woman you will need to provide a urine sample that will be tested immediately for pregnancy. If you are pregnant you cannot participate.

All information will be confidential. There is always a small risk of accidental disclosure.

Your participation will require three, 2-hour sessions separated by at least 48 hours. You may not use any tobacco products or nicotine containing products (like gum or the patch) for at least 12 hours before each session. You will take a simple breath test to make sure that you have complied with these restrictions.

We will also ask you to stop eating 1 hour before each session.

In each session you will be asked to smoke a water pipe in the laboratory. We want you to smoke as you normally would and we will use your preferred brand/ flavor of tobacco. The water pipe will be loaded only once in each session, and we ask that you use it for at least 45 minutes, though you may take as many or as few puffs as you like during that period. The water pipe will be started with a single charcoal disk, but you may add additional ½ disks as you like.

You will receive \$30 after the first session, \$70 after the second, and \$100 after the third session.

You can contact Dr. Smith with any questions about the study at <XXX-XXX-XXXX>

If you have any complaints, suggestions, or questions about your rights as a research volunteer, contact the Committee for Protection of Human Subjects at <XXX-XXX-XXXX>.