

Survey consent and patient questionnaire, in person

Study of long-term impact of RMSF

Flesch-Kincaid (grade level 5.2)

Date of Interview \_\_\_\_\_

Our records show that you/your child had RMSF in (mm/yyyy).

We are members of the tribal health department, working with the Centers for Disease Control and Prevention to conduct a study looking at the long-term effects of Rocky Mountain spotted fever with a special focus on nervous system problems. We would like to ask you a few questions about you (your child's) Rocky Mountain spotted fever illness. Your answers will help us better understand how people are impacted by Rocky Mountain spotted fever years later. The questions should take about 10 minutes to complete. You do not have to participate in the study. You can stop answering questions at any time, and your decision to do so will not affect any care you normally receive. All information will remain private. Only study staff will have access to your responses. If we identify that you have nervous system problems, we may ask you to take part in an additional medical exam to research these issues more closely.

I have been told about the study. I have been allowed to ask questions. I had all of my questions answered. I would like to be in the study. By signing this form, I agree to be in the study.

Participant's signature: \_\_\_\_\_ DATE: \_\_\_\_\_

NAME (print): \_\_\_\_\_

Survey consent and patient questionnaire, telephone

Study of long-term impact of RMSF

Flesch-Kincaid (grade level 5.2)

Date of Interview \_\_\_\_\_

Our records show that you/your child had RMSF in (mm/yyyy).

We are members of the tribal health department, working with the Centers for Disease Control and Prevention to conduct a study looking at the long-term effects of Rocky Mountain spotted fever with a special focus on nervous system problems. We would like to ask you a few questions about you (your child’s) Rocky Mountain spotted fever illness. Your answers will help us better understand how people are impacted by Rocky Mountain spotted fever years later. The questions should take about 10 minutes to complete. You do not have to participate in the study. You can stop answering questions at any time, and your decision to do so will not affect any care you normally receive. All information will remain private. Only study staff will have access to your responses. If we identify that you have nervous system problems, we may ask you to take part in an additional medical exam to research these issues more closely.

Would it be alright if I asked you a few questions about your illness, and your subsequent recovery?

Yes / No

--If yes, proceed

--If no, ask if there is a better time to contact them.

--If they refuse, state, “Thank you for your time. We hope that you have experienced recovery from your illness. If you change your mind, you can reach me at (phone number)”.

Verbal consent/permission obtained from \_\_\_\_\_ Date \_\_\_\_\_

Verbal consent/permission obtained by \_\_\_\_\_ Date \_\_\_\_\_

## Neurological exam consent

### Consent/Permission for physical exam

#### Flesch-Kincaid (Grade 8.1)

**TITLE:** Study of long-term impact of RMSF

**PRINCIPAL INVESTIGATOR (PI):** Naomi Drexler, MPH

**DATE:** \_\_\_\_\_

**PARTICIPANT'S NAME:** \_\_\_\_\_

We are with the: local tribal healthcare facility/Indian Health Service /Centers for Disease Control and Prevention (note: PI will select provider agency) and are conducting a research study on the long term affects Rocky Mountain spotted fever has on the nervous system. You (or your child) have been invited to take part in this study because you (or your child) had Rocky Mountain spotted fever (RMSF). We would like to see how this illness has affected your (or your child's) health.

#### I. Purpose of investigation

The purpose of this investigation is to learn if and how often RMSF causes neurologic damage.

#### II. Your rights

- You do not have to participate in this study.
- You (or your child) may decide not to take part or to quit the study at any time without any penalty.

#### III. Procedures

We will do a physical exam to test your (your child's) alertness, strength, sensation, reflexes, and coordination. This will be done by having you (your child) answer questions, having you (your child) follow commands and show your (your child's) strength; we will test your reflexes by touching your (your child's) skin and gently tapping your (your child's) muscles with a reflex hammer. The exam should take about 30 minutes.

#### IV. Risks and Benefits

1. **BENEFITS:** You may benefit by having the results of your exam shared with you and your medical providers. Also, by taking part, you (or your child) will help us improve understanding and treatment of RMSF in Arizona.
2. **RISKS:** Only study staff will have access to your (or your child's) personal information. However, since we are keeping this information, there is a small risk that your (or your child's) identity could be revealed. There may also be some slight discomfort with strength or reflex testing. However, this is rare, and the exam would be stopped if you asked.

**V. Compensation**

A \$10 gift card will be given to those who participate in the physical exam. But otherwise you will not be paid to participate in the study.

**VI. Costs**

There should be no costs to you (or your child) for being part of this study.

**VII. Confidentiality**

Your (or your child’s) study records will be kept private to the best of our ability. The study records and answer sheets will contain information on your name and date of birth. However, this information is kept in a locked, secured space. No one other than the study staff will have access to this material. We will use this information only to contact you about the study. Your (or your child’s) name will not be used in any reports or articles that are written about the results of this study.

**VII. Questions**

Please feel free to ask any questions you may have about the study. If you have other questions later, you may contact Naomi Drexler, (404) 718-4669 or Paige Armstrong (404) 639-8450 with the Centers for Disease Control and Prevention or \_\_\_\_\_ at your tribal health facility.

The purpose and procedures of this study have been explained to me. I have been told about all of the potential risks that might result. I agree to participate (or for my child to participate) in this investigation. I have been told that this is voluntary, and I may end my (my child’s) participation at any time. I give consent (permission) for the following:

Yes       No      Neurologic examination

Yes       No      I would like any and all results relayed directly to my (my child’s) physician.

Participant’s signature: \_\_\_\_\_ DATE: \_\_\_\_\_

NAME (print): \_\_\_\_\_

Name of Primary/Personal Physician: \_\_\_\_\_

Contact information for Primary Physician: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Signature of investigator providing consent: \_\_\_\_\_ Date: \_\_\_\_\_

Neurological exam assent

**Child assent for examination (for children 8 years or older)**

(Flesch-Kinkade Grade Level 6.0)

**TITLE:** Study of long-term impact of RMSF

**PRINCIPAL INVESTIGATOR (PI):** Naomi Drexler, MPH **DATE:** \_\_\_\_\_

**PARTICIPANT'S NAME:** \_\_\_\_\_

We are with the: local tribal healthcare facility/Indian Health Service /Centers for Disease Control and Prevention (note: PI will select provider agency) and are doing a study about Rocky Mountain spotted fever (RMSF). This study looks back at people who had Rocky Mountain spotted fever in the past, to see if they are having any problems since their illness. This study will help us better understand the disease and how it could affect people in your community. You can say you don't want to participate for any reason and at any time. If you decide that you want to be part of this study, you will be asked to take part in an exam by a doctor or nurse. In the exam we will ask you to show how strong you are, check your reflexes, and see how you walk, among other things. We expect the exam to take about 30 minutes.

There might be some slight discomfort with the exam. But if that happens, just tell us, and we will stop. There are no needles or shots involved in this exam.

You might benefit from knowing the results of your exam. A benefit means that something good happens to you.

When we are finished with this study, we share with you and your parents what we have learned and the results will be included in a summary of all persons in the study. This report will not include your name.

You do not have to be in this study if you do not want to be. If you decide to stop after we begin, that's okay too. Your parents know about the study and can be present if you want during the exam.

If you decide you want to be in this study, please tell the investigator your name, and that you agree to participate.

NAME (print): \_\_\_\_\_

Age: \_\_\_\_\_ (years)

Assent provided

Assent not provided

Signature of investigator providing consent: \_\_\_\_\_ Date: \_\_\_\_\_