Agreement Form
GENOTYPE 1
Sofosbuvir/Ledipasvir Treatment Outcome – Observational Report
Principal Investigator: Brian McMahon, M.D.
Flesch-Kincaid Reading Level = 8.9

You have given your permission to be in a study on hepatitis C infection. In the study, information is collected about response to treatment for hepatitis C. This study helps us learn more about hepatitis C treatment in Alaska Native and American Indian persons.

You are a person whom treatment for hepatitis C is recommended. Treatment with sofosbuvir/ledipasvir has been recommended to you. You have agreed to be treated.

Sofosbuvir/ledipasvir is approved by the United States Food and Drug Administration (FDA) for treating genotype 1 hepatitis C. Gilead Sciences makes sofsobuvir/ledipasvir. Gilead is giving sofosbuvir/ledipasvir to the Alaska Native Medical Center for up to 200 persons.

Why is this being done?
Sofosbuvir/ledipasvir was licensed by the FDA because of high cure rates in people with hepatitis C who participated in research studies. It is recommended for treating hepatitis C in all persons with genotype 1 virus. However, very few Alaska Native and American Indian people were able to participate in these studies. This study is being done to see how well this treatment works in Alaska Native and American Indian persons for hepatitis C infection. More needs to be learned about how well these drugs work in Alaska Native and American Indian persons.

What is the goal?
To better understand how well sofosbuvir-containing drugs work in Alaska Native and American Indian persons with hepatitis C.

Why am I being asked?
You are being asked for your permission because you:

- Are already enrolled in a study of hepatitis C
- Are eligible and ready for hepatitis C treatment

What will I be asked to do?
You have given us permission to review your medical records. We are asking your permission to share your information with Gilead Sciences. Information that is shared will not have anything that will identify you like your name, date of birth or address. We will share medical information related to the hepatitis infection and your body's response to the treatment.

Is there any risk?
The drugs you receive for treatment have been approved by the Food and Drug Administration and ANMC. The treatments you receive for hepatitis C will be recommended by your doctor.

How many people will be participating?
About 200 adults.

How will I benefit?
There may be no direct benefits to you.

Will I have to pay?
Gilead Sciences will provide the sofosbuvir/ledipasvir medications. You will not be billed for these medications.

Who do I call if I have any questions?

If you have any questions about the study, please contact one of the study nurses at (907) 729-1560, or toll-free at 1-800-655-4837. For questions about your rights as a study participant contact Dr. Shanda Lohse, Alaska Area Institutional Review Board Co-Chair (slohse@southcentralfoundation.com; 907-729-4130) or Terry Powell, Alaska Area Institutional Review Board Administrator (tjpowell@anthc.org; 907-729-3924; will accept collect calls).

Can I refuse?
Yes. If you choose to not give your permission, the health benefits that you are getting now at ANMC will not be affected. The medication that will be used is the licensed drug sofosbuvir/ledipasvir that ANMC has at no cost. If you do not want to use the free medication from Gilead, you will be treated with the very same medications that will be purchased by the ANMC pharmacy.

You will receive a signed copy of this consent form.

I have been informed about possible risks and benefits. I have read and understand this form. I understand that I am free to withdraw at any time, even after signing this form.

I give my permission to share my medical information with Gilead Sciences.

Print Participant Name _____

Signature of Individual _____ **Date**_____

I administered and observed the process of consent. The prospective participant read this form, was given the chance to ask questions, appeared to accept the answers, and signed to enroll in the study.

Signature of Person Conducting Review of Consent_____ **Date**_____