# SLEEP STUDY INFORMATION SHEET

**Principal Investigator(s):** Eric Zhou, PhD and Kira Bona, MD, MPH

## INTRODUCTION AND KEY INFORMATION

We are inviting you to take part in a research study called "Insomnia prevention in children with Acute Lymphoblastic Leukemia" also called The Sleep Study Aim 2. The goal of this research study is to understand the acceptability and feasibility of the Sleep ALL Night intervention among children with Leukemia in hopes of improving their quality of sleep.

All research is voluntary. It is your choice whether you take part in this research or not. If you decide to participate in this research study we will give you a copy of this information sheet that you can refer to at any time. The following is a short summary of this research study to help you decide whether you would like to be a part of this study.

### 1. Why am I being invited to take part in a research study?

You are invited to take part in in this research study because you are receiving maintenance therapy for ALL on or as per Dana-Farber Cancer Institute Protocol 16-001.

### 2. Why is this research being done?

1in 3 children with ALL has problems with his or her sleep either during ALL treatment, or once their ALL treatment has ended. We know from families that sleep problems are very disruptive for both the child and family. This research study is a Pilot Study, which means that study doctors hope to:

- Learn more about what sleep is like for you during one chemotherapy cycle for your ALL treatment and how you think we could improve your sleep
- Assess the acceptability and feasibility of the intervention to help prevent children from having sleep problems during ALL therapy.

### 3. Who is supporting this research?

The National Cancer Institute is supporting this research study ***with funding***.

### 4. What does this research study involve and how long will it last?

It is expected that about 30 people will take part in this research study. You will be in this research study for about 3-months. Study components:

- **Baseline Survey:** A study team member will ask you to complete the baseline survey (parent-completed). The survey will take approximately 5 minutes and will include questions about your sleep habits and your interest to learn more about improving sleep. You may skip any questions or stop completing the survey at any time.
- **Orientation to the Sleep Study:** An Oncology Nurse Navigator will introduce you to the sleep action plan. If you decided to move forward a study team

member will review the intervention website with you.

- **From the time of first study visit until the end of the study (12-weeks):** You will review the information provided on the website and complete the sleep diary.
- **Intervention survey (*administered at Week-3*):** A study team member will ask you to complete the Intervention survey (administered at Week-3) (parent-completed). The survey will take approximately 10 minutes and will include questions about your sleep habits, sleep efficacy, and sleep knowledge. You may skip any questions or stop completing the survey at any time.

**Medical Record Review:** The study team will gather information about your ALL and ALL treatment from your medical record.

**Token of appreciation:** You will receive a $20 gift card after completing the baseline survey and a $40 gift card after completing the intervention assessment survey (administered at Week-3) to thank you for your time and participation in the study.

**1. What are the benefits, risks, or discomforts of this study?**

We do not know if taking part in this study will benefit you. It is possible that learning more about your sleep will be informative. We hope that this study will help researchers to develop an intervention to prevent sleep problems during cancer treatment for other children in the future. There are no physical risks to participating in this study. It is possible that you may find questions about your sleep habits on the surveys upsetting or difficult to answer. If this happens, you can skip any questions that you do not wish to answer. You can also stop being on the study at any point. A system of psychosocial support is in place at your institution. Drs. Zhou and Bona will be responsible for coordinating psychosocial referrals if necessary and ensuring adequate follow-up. There is also a small risk of loss of confidentiality. We will use several security measures to protect confidentiality.

**2. Confidentiality**

We will take measures to protect the privacy and security of all your personal information, but we cannot guarantee complete confidentiality of study data. To minimize the risk of any privacy violations, we will record all of your responses using a unique study ID number, not your name or other identifying information. Your personal information and/or data collected during this study may be stored and used for future research. Data will be used for research and teaching purposes only and may be shared in the future. Any personal identifiers will be removed, before the data are shared, so that the information cannot be linked back to you.

To help protect your privacy, we have been issued a Confidentiality Certificate from the National Institutes of Health (NIH). With this Certificate, the researchers on this study cannot be forced (for example, by court subpoena) to disclose information that may identify you in federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary upon request of a United States federal or

state government agency sponsoring the project that will be used for audit or program evaluation purposes or to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family or even the research doctor from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or employer learns about your participation, and obtains your consent to receive research information, then we cannot use the Certificate of Confidentiality to withhold this information. This means that you and your family must actively protect your own privacy. The Certificate of Confidentiality cannot be used to prevent disclosure to state or local authorities when there is a duty to report concerns of abuse, neglect, self-harm, or a danger to others.

**3. What are my options?**

Instead of being in this research study, you may decide not to participate in this research study. If you choose not to participate, are not eligible to participate, or withdraw from this research study, this will not affect your present or future care and will not cause any penalty or loss of benefits to which you are otherwise entitled.

**Whom do I contact if I have questions about the research study?**

If you have questions about the study, please contact the research doctor or study staff as listed below:

- Eric Zhou, PhD (Head of study): (617) 632-6162
- Kira Bona, MD, MPH (Head of study): (617) 632-4688
- Lucille Lokko (Research Coordinator): sleepallnight@dfci.harvard.edu

For questions about your rights as a research participant, please contact a representative of the Office for Human Research Studies at Dana-Farber Cancer Institute (617) 632-3029. This can include questions about your participation in the study, concerns about the study, a research related injury, or if you feel/felt under pressure to enroll in this research study or to continue to participate in this research study.