UNILEVER INDEPENDENT ETHICS COMMITTEE
HINDUSTAN UNILEVER LTD., R & D

INFORMED CONSENT FORM (ICF)

Study No. & Title: EVALUATION OF DOMESTIC PRACTICES, WATER USE AND HEALTH IN RURAL BIHAR, INDIA

Name of the Subject (Volunteer):

Subject No. /ID: **Date of Birth:**

You have been invited to participate as a volunteer in a human research study. Before you decide to take part in this study, it is important that you read and understand the contents of this document carefully. This informed consent form explains the nature, purpose and other relevant details of this study.

Please take time to read and understand the following information. Please ask any questions you may have, regarding your participation in this study.

By signing this document, you acknowledge having received all the relevant study information and agree to take part in this study on your own free will, without any coercion or inducement.

Information to the Volunteer

1. **Introduction**

This is a research study. It is being conducted by the London School of Hygiene & Tropical Medicine from the United Kingdom, and is sponsored by the Child Investment Fund Foundation in the United Kingdom. The purpose of this study is to learn more about domestic and child care practices and to study the amount of water used by families in villages in Bihar. We are further interested in studying the water and sanitation situation in this part of Bihar and how it affects daily life. The study will be conducted in 320 villages across Bihar and will last for about one year involving about 6000 families. In each village the study will be done during three to four days.

2. **Pre-screening criteria**

This study includes families with children under 5 years and school aged children. You have been chosen for invitation to take part in this study because you have a child under 5 years and a school aged child in your household.

3. **Procedural Details**

If you agree to take part in the study I will ask you some more questions about your family. I will arrange for a lady field worker to visit your household this week for 3 hours in the early morning to observe ordinary household activities. I will arrange for this to happen on a day that is convenient for you and I will introduce you to the fieldworker in advance. You will not be expected to do anything, just to carry on your activities as normal. The lady field worker will take some notes while she is there. She may also observe how water is used for different activities. I or another supervisor may also come to check that she is doing her work correctly. After that day either I or another supervisor may come to your house to ask some final questions relating to your family, including water, sanitation and daily activities. Thus the study will take place during three visits to your household. First visit today (now), second visit to observe daily activities in your household, and third visit to ask a few further questions. If you agree, we may visit your house a few months later and repeat the same study.

4. Foreseeable or unforeseeable risk

Researchers are always asked to explain any risks to people who take part in the study. The study team does not know of any risks to you from participating in the study. We will only observe daily household activities as they normally take place in your household, without interfering. However, some members of your household may find it uncomfortable to be observed in their daily activities or to be asked questions on their daily activities.

5. Benefits from participation

There will be no direct medical or health benefits to you due to your participation in the study since it is of non-therapeutic nature. Being a part of this study is a chance to provide information which at a later date may help to improve child health in your community and in other places. There is no direct benefit to you from participating in this study. There is no direct compensation to you for participating in the study.

6. Safety Information:

Any significant new and/or important information, which is discovered during the study and may influence your willingness to continue in this study, will be made available to you as soon as possible.

7. Contact details in case of adverse effects (Name, Address , Telephone Numbers, Mobile Numbers) and any study related information

For any trial related queries or in the event of any injury please contact:			
Designation	*Name*	*Telephone Number*	*Address*

Principal Investigator	*Dr. Wolf-Peter Schmidt*	*09790608319*	*Dept., of Emergency Medicine, Christian Medical College, Vellore 632004, Tamil Nadu*
Study Manager	*Dr. Sweta Patnaik*	*022-1231234 / 9876556789*	*Water Aid India, CNI Bhavan, 16, Pandit Pant Marg, Pandit Pant Marg Area, Sansad Marg Road Area, New Delhi, Delhi 110001*

For any queries regarding your rights as a clinical trial Subject, please contact the ethics committee at the address below			
Designation	*Name*	*Telephone Number*	*Address*
Ethics Committee Secretary	*Dr. Vaishnav*	**9611899412**	UNILEVER INDEPENDENT ETHICS COMMITTEE, HURC, BANGALORE
Ethics Committee Secretary	Professor John DH Porter	*+44*-20 7636 8636	INTERVENTIONS RESEARCH ETHICS COMMITTEE London School of Hygiene and Tropical Medicine, Keppel Street, WC1E 7HT, London, UK

8. Other Details:

- **<u>Confidentiality</u>:**

Any information that is gathered about you and your family will be kept anonymous. The study team might use information from the study to make recommendations to health care providers and policy-makers. What they learn from the study may be used in articles, books, and for teaching. With your permission they may use quotes, stories and excerpts from your interview in their work, but they will never identify you or your family by name or provide any other information that would allow you or your family to be identified.

- **<u>Subject Responsibilities</u>**

During the observation of daily household activities, we ask you and other family members not to interact with the lady observer more than necessary. This will be explained in more detail on the day of the observation. You do not need to offer her anything during her visit.
You are entirely free to participate or refuse to participate in this study. Refusal to participate or discontinuation from the study will not involve any penalty to you, or loss of any benefits to which you would otherwise be entitled. Your refusal will not affect your selection for future studies. You are free to refuse to answer any question that you don't like, and to leave the study at any time that you feel like without having to give a reason.
You are free to ask any question related to the study at any time.

<u>Acknowledgement by the Volunteer</u>

a. **I have fully understood the information pertaining to the human study in which I have been asked to participate. I have understood the activities required of me as I participate.**

b. **I have been fully made aware of the foreseeable risks and the possibility of unforeseeable risks. In the event of unexpected effects, I have been made aware of the persons to contact and their telephone numbers.**

c. **I have had an opportunity to ask questions, and my questions have been satisfactorily answered.**

d. **I agree that I will not seek to restrict the use, to which, the results of the study may be put, and in particular, I accept that they may be disclosed to the regulatory authorities in India and elsewhere or published, but not in a form by which I may be identified unless my explicit written permission is obtained.**

e. **I will be able to follow the procedures required of me, including visits for assessment, and agree to follow instructions as required.**

f. **I am willing to take part in this study on my own free will without any coercion or inducement.**

g. **I confirm that I have been given a signed original copy of this ICF.**

Signature Section:

Please initial the box (Subject)

(i) I confirm that I have read and understood the information sheet (Consent form) dated DD/MM/YYYY for the above study and have had the opportunity to ask questions. [ ]

(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reasons, without my medical care or legal rights being affected. [ ]

(iii) I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at the data from my household in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s) [ ]

(v) I agree to take part in the above study. [ ]

Signature of the Subject: _____

Date: _____/_____/_____

Subject's Name: _____

Signature of the Investigator(s): _____

Date: _____/_____/_____

Investigator (s) Name:_____