Consent Form Guide

**Study Title**: IoT-Vision Enabled Assistance for Epileptic Patients

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To help you make an informed decision regarding your participation, this letter will explain what the study is about, the possible risks and benefits, and your rights as a research participant. If you do not understand something in the letter, please ask one of the investigators before agreeing to participate in the study.

**What is the study about?**

You are invited to participate in a research study which is about

* The purpose of the study is to make a system that automate the Nursing records and a monitoring system for the patients having some long-term disorders and got troubled in an emergency situation like fall, seizure attacks, heart attack, etc.
* This research is being conducted for the patients who need a permanent caretaker to monitor him. This system would monitor the patient and inform the caretaker at the emergency situation of the caretaker.
* This is a product level research that ends on a cost-efficient, reliable and deployable product.

**Additional Guidance**

* This study aims to improve the patient life standard so that he may live quality life without the dependency of caretaker.
* Nurse/Caretaker only needs to the patient when patient is in situation that he/she can’t handle independently. System would inform about this situation to the caretaker/nurse.

**What does participation involve?**

Participation in this study include the following points:

* 1 or 2 cameras will be installed in the environment of the patient that covers all the sights of the patient.
* These cameras will capture all day activities of the patient.
* All the data of the patient will store in the system.
* Patient has to do nothing, instead just spend all day activities normally without any hesitation.
* Short meetings with caretaker will be arranged with ease of caretaker to get some behavioral information about patient.
* Recordings of the patient will not be treated same as recorded. Instead it will be processed before use, in which skeletons of the patient will be extracted. This process will remove the privacy issues.
* This research will follow the WHO (Would Health Organization) guidelines regarding data collection ethics and privacy issues.

**Additional Guidance:**

* Cameras will be installed by technical team on the roof with some angle inclination that will clearly covers the sight and room activities of the patient.
* Recordings will be collected for several days.
* CS department will provide all required hardware during data collection.
* Short meetings may held with caretakers timely with his/her availability and include some questions like:
  + What is the normal day routine of patient
  + What things that may trigger the patient disorder
  + How patient react during attack
  + What is the situation before and after the attack
* Meetings may held with caretaker in hospital with paper based questionnaire, or telephone call on some online platform like **Skype/MS Teams/Zoom/Google meet** or **WhatsApp** calls.
* The aim for these meetings is to analyze the behavior of the patient with transparency and clarity.
* In any (physical/online) meeting with caretaker, ease of language (English, Urdu, Punjabi) will be taken in consideration.
* After meeting with caretaker, points extracted from the meeting will be confirmed form the caretaker.

**Who may participate in the study?**

Following are some points that define who could participate in this study as a patient:

* This study is irrespective of gender and age.
* The patient mainly targeting the patients having some disorders that are long term with them and need caretaker in episodic attack.
* This study does not include patients having physical body issues like fracture or got cancer of any part

of the body.

**Is participation in the study voluntary?**

Yes, this study is voluntary for the patients. Patients and their caretakers have the following rights in this study:

* It is totally the consent of the patient to participate or deny to participate in this study.
* Patient and his caretaker have the right to leave the study at any time.
* Patient and his caretaker have right to question about privacy issues, clarity regarding questions, questions that win their belief on the system.
* During interview/questionnaire, patient or his caretaker have a right to decline to answer any question that they might prefer not to say.
* Patient can request to remove his/her data during studies until it is not possible to withdraw data once papers and publications have been submitted to the publishers or it in case all anonymous information is removed from the data.

**~~Will I receive anything for participating in the study?~~**

~~Patient will not receive anything from this participation in the study. This research is not funded~~

~~“You will not receive anything for your participation in the study …” or “In appreciation of your time, you will receive …”. “To thank you for your time, you will receive …”. “You will be reimbursed for parking/travel/childcare expenses ...”~~

* ~~If the study has multiple sessions indicate the monetary remuneration for study participation per session as well as whether the remuneration will be pro-rated for partial completion of the study and explain how the pro-rating will be calculated.~~
* ~~For studies that are not pro-rated (i.e., the participant will receive remuneration no matter at what point in the study they decide to withdraw) provide information on how a participant may choose to withdraw from the study, but still receive their remuneration/incentive (e.g., by clicking through to the end of the survey).~~
* ~~Include the appropriate University of Waterloo finance statement for cash or near-cash remuneration (e.g., gift card), refer to~~ [~~Taxable statement for study remuneration~~](file:///\\filed\ofcresearch$\OR-hethic\ORE%20Website\Information%20on%20our%20the%20Website\Samples%20for%20Researchers%20to%20Use%20on%20ORE%20Website_ACTIVE\Information%20-%20Consent%20Samples%20(PDF)\Taxable%20statement%20for%20study%20remuneration) ~~below.~~

***~~[Cash or near-cash with value less than $300]~~****~~:~~* ~~"The amount received is taxable. It is your responsibility to report this amount for income tax purposes."~~

***~~[Value of $300 or more]:~~***~~"The amount received is taxable. You will be asked to sign a release of personal information form for purposes of remuneration and for issuing a tax slip."~~

* ~~This statement is not required for reimbursement payments (e.g., parking or bus/taxi fare).~~

**~~Additional Guidance~~**

* ~~If using a draw, refer to~~ [~~Language for the information letter when using a draw~~](https://uwaterloo.ca/research/office-research-ethics/research-human-participants/application-process/samples-and-other-supporting-materials/information-consent-samples/information-consent-letters-and-forms#remuneration) ~~for statements to use.~~
* ~~For more information on remuneration to research participants see~~ [~~Remuneration to Research Participants~~](https://uwaterloo.ca/finance-resources/guidance-procedures/procedures-info/remuneration-research-participants)~~.~~

**What are the possible benefits of the study?**

This study has the following benefits:

* Researchers will explore new ways of behavioral analysis with vision input devices.
* This research may end up with a system that provide a monitoring system to the patients and NRS (Nursing record System) to the doctor.
* This system will reduce burden on caretaker, nursing sector and will provide a cost-efficient, reliable and a more accurate system then a human.
* This will ultimately revolutionize the life of the targeted patients.

**Additional Guidance**

* For the personal benefit, caretaker have this opportunity to learn and explore the procedures generally not considered a personal benefit to participants.

**What are the risks associated with the study?**

* There is always a potential risk of data stealing or loss when data transactions require. These risks will be minimized by making multiple local copies of data on local and only use secured server for later use.
* Patient mostly feel uncomfortable in monitoring environment due to their privacy issues. This could be minimizing by individual meetings with them and by telling them the benefits of the research.

**Will my identity be known?**

Only the researcher team and data collecting team will know which data is coming from which patient. Firstly, the data will be preprocessed to remove identity of the patient from the data. Then data will be stored at the central location where team have bulk amount of data but anonymous. This reduces the risk of privacy issues but maintains the consistency of team to work with data. Only the questionnaire team will know the true identity of patient. And this information will purely be limited to the concern of research independent of personal concern.

**Will my information be kept confidential?**

Your information will be kept confidential and secure. Following are the points that explain the way how information will be kept confidential for individual patient.

* The collected data of patient will be stored anonymously. Each patient is assigned a unique patient ID. And all the reports and medical results of particular patient will be displayed with assigned unique ID instead of his/her name. So, any other person, reading patient medical record will not know whom these reports belong to.
* Individual results will not be shared. Only the research team will have access to study data.
* If researchers plan on sharing or publishing de-identified data. The dataset without identifiers may be shared publicly. Your identity will be confidential.
* Patient record will be saved on a secured server in password encrypted format. Only authorized researcher has the access to that data.
* Any data that will be stored on a mobile device will be encrypted.
* Encryption techniques will be used before any transaction of the data.

**Future Data Use**

* Data will be saved for future if this research work extends, same data will be used.
* Data will be used for future project and research of the CS Department that include human behavior modeling with computer vision.
* Data will be saved for future research in the world on Behavior modeling and will be provided on request from research team.

**Additional Guidance**

* Sharing data allows other researchers to easily verify results.
* Sharing data helps to avoid duplicating research efforts and allows existing data to be reused to answer new research questions.
* You are voluntary to the study. You can request to remove your data at any time during the studies before publishing research.
* Any sharing data will include sharing of ID’s and related activities. No one knows the root or source person of that information.
* Once data is deposited to any future research project, this will not possible to remove your data.

**~~Has the study received ethics clearance?~~**

~~“This study has been reviewed and received ethics clearance through a University of Waterloo Research Ethics Board (REB~~ ***~~[####][Replace #### with the file number that is listed at the top of your ethics application]~~***~~. If you have questions for the Board, contact the Office of Research Ethics, toll-free at 1-833-643-2379 (Canada and USA), 1-519-888-4440, or~~ [~~reb@uwaterloo.ca~~](mailto:reb@uwaterloo.ca)~~.”~~

* ~~The wording should be inserted exactly as it is presented above.~~

**Who should I contact if I have questions regarding my participation in the study?**

If you have any questions regarding this study or would like additional information to assist you in reaching a decision about participation, please contact **Sayyed Azeem Ali Hashmi** at **(+92 333 4519878)** or by email at [2020cs156@student.uet.edu.pk](mailto:2020cs156@student.uet.edu.pk), or **Muhammad Ali Murtaza** at **(+92 312 4922033)** or by email at [2020cs114@student.uet.edu.pk](mailto:2020cs114@student.uet.edu.pk)

**Additional Guidance**

* Ensure it is clear that the researchers are to be contacted for all general questions regarding the study. Respect and confidence in participation are the main goal for contact and discussion between team and the patient.

**What if the study procedure(s)/topic causes me distress/concern?** (**Optional Section for studies that involve sensitive questions/vulnerable population)**

* If this study causes to security or trust issues, contact the research team asap to above provided contact numbers. Team will council the patient and will try to make the trust level on the system.
* Research team will explain the benefits and impact of the study on society. And also elaborate some examples of related projects in society.
* If this don’t work, doctor will council the patient to relax and will try take patient under confidence.
* Patient at the last stage can post the request to remove his data from research.

# **Consent Form**

By providing your consent, you are not waiving your legal rights or releasing the investigator(s) or involved institution(s) from their legal and professional responsibilities.

**Study Title:** IoT-Vision Enabled Assistance for Epileptic Patients

I have read the information presented in the information letter about a study conducted by University of Engineering and Technology Lahore. I have had the opportunity to ask questions related to the study and have received satisfactory answers to my questions and any additional details.

I was informed that participation in the study is voluntary and that I can withdraw this consent, and any limitations to this withdrawal, by informing the researcher.

~~“This study has been reviewed and received ethics clearance through a University of Waterloo Research Ethics Board (REB~~ ***~~[####][Replace #### with the file number that is listed at the top of your ethics application]~~***~~. If you have questions for the Board, contact the Office of Research Ethics, toll-free at 1-833-643-2379 (Canada and USA), 1-519-888-4440, or~~ [~~reb@uwaterloo.ca~~](mailto:reb@uwaterloo.ca)~~.”~~

For all other questions contact:

**Number:** +92 333 4519878

**Email:** [2020cs156@student.uet.edu.pk](mailto:2020cs156@student.uet.edu.pk)

I agree of my own free will to participate in this study.

Participant Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participant signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Some Permissions related to your data:**

* I agree that my data can be shared in an online repository as described in the information letter.

 Yes  No

* Do you agree to share the information that you provide from this study in an online public repository/database as described in the information letter? The data will be de-identified and will not include names or other identifying information.

 Yes  No

* I agree to allowing my study data to be used for future purposes as described in the information letter.

 Yes  No

* I agree to my questionnairebeing audio recorded for accurate transcription and analysis.

 Yes  No

* I agree to my study session being video recorded for the purpose of situation and expression analysis.  Yes  No
* I agree to allow audio/video clips, digital images, or photographs in which I appear to be used in teaching, scientific presentations and/or publications with the understanding that I will not be identified by name and blur the face so that no one can identify.

 Yes  No

* I agree to the use of anonymous quotations in any thesis or publication that comes from this research.

 Yes  No

* Do you agree to the use of quotations in any paper or publication resulting from this study with the understanding that a pseudonym will be used in place of your real name (e.g., X or Y)?

 Yes  No

**What if I find secondary findings:**

One of the assessments we use in this study is the preventing abnormal activities of the patient. This is an assessment that has been found to be useful to detect abnormality. Although it is not our intent to examine participants for abnormality and we are in no way qualified to make any conclusions about your health status, we do want to give you an opportunity to be informed of your result if you wish. It is your decision if you would like to be notified if we find that your results are below/above what is considered typical for a person your age. If you choose to be notified of your result, we encourage you to share this information with your physician/primary health care provider to discuss

Do you wish to be notified if we find your result is below/above what is considered typical?

I wish to be notified