

**THE REPUBLIC OF UGANDA**  
**IN THE HIGH COURT OF UGANDA KAMPALA**  
**CIVIL DIVISION**

**HUMAN RIGHTS PETITION NO. 305 OF 2017**

**HARRIET MUKODA Alias NAIGAGA HANIFA ::::::::::::::::::::PETITIONER**

**VERSUS**

- 1. INTERNATIONAL AIDS VACCINE INITIATIVE**
- 2. UGANADA NATIONAL HEALTH RESEARCH ORGANISATION**
- 3. UGANDA VIRUS RESEARCH COUNCIL**
- 4. MEDICAL RESEARCH COUNCIL**
- 5. MRC/UVRI UGANDA RESEARCH UNIT ON AIDS**
- 6. PROF KALEEBU PONTIANO**
- 7. DR. ANATOLI KAMALI**
- 8. DR. EDWARD KATONGOLE MBIDDE**
- 9. DR. GERSHIM ASIKI**
- 10. DR. MATT PRICE**
- 11. DR. YUNIA MAYANJA**
- 12. DR. GERTUDE NAMALE ::::::::::::::::::::RESPONDENTS**

**BEFORE HON. JUSTICE MUSA SSEKAANA**

**JUDGMENT**

**BACKGROUND**

The petitioner brought this petition against the respondents under Article 50 (1) and 50 (2) of the Constitution of Uganda; alleging violations and threats to four constitutional rights guaranteed under Chapter 4 of the 1995 Constitution, specifically the right to; life (Article 22), health (article 45), freedom from cruel, inhuman and plaintiff filed this suit seeking compensation, general damages, special damages, exemplary damages interest and costs of the suit for the injuries

suffered as a result of the degrading treatment (article 24 and health information (Article 41).

The petitioner's complaints against the respondents as discerned from the affidavit in support thereof are that; prior to enrolment as a study participant, the petitioner was HBV negative. She was persuaded to enroll for the study on the basis of information she believed to be correct that the Hepatitis B vaccine she received would provide her with full immunity and effective protection against HBV infection. On that basis and upon receiving the vaccination, the petitioner "*loosened her grip*" on the use of conventional HBV protection methods such as latex condoms and was subsequently infected with the HBV virus. She attributes her infection to a 'dead' or ineffective Engerix B vaccine that was administered to her which was unable to offer her the protection promised when she was enrolled as a study participant. The petitioner denies granting her 'informed consent' to participate in the study as she claims to not have understood the contents of the consent document written in Luganda which she signed while enrolling because she is unable to read and write in any language and has an understanding of Luganda that is too weak to suffice for informed consent.

Accordingly sought compensation of US\$ 10,000,000 for violation of her rights and Punitive damages and exemplary damages of US\$ 2,000,000

The respondents deny all the claims made against them in the petition and or that the petitioner was ever subjected to a biomedical HIV vaccine trial. The respondents further contend that the petitioner is functionally literate and fully understands Luganda and granted her informed consent before participating in

study. They further contend that she has no locus to seek reliefs on behalf of the study participants.

The petitioner was represented by Mr. Bernard Banturaki whereas the 4<sup>th</sup>, 5<sup>th</sup>, 6<sup>th</sup>, 11<sup>th</sup> & 12<sup>th</sup> respondents were represented by Mr Wamala Dennis, Mr. Kanyemibwa John Fisher and Mr. Andrew Kabombo, the 1<sup>st</sup>, 7<sup>th</sup> and 10<sup>th</sup> respondent were represented by Mr. Phillip Karugaba, the 2<sup>nd</sup>, 3<sup>rd</sup> and 8<sup>th</sup> defendant were represented by the Attorney General and the 9<sup>th</sup> respondent was not represented not did he file any reply to the petition.

The parties filed a joint scheduling memorandum wherein they proposed the following issues for determination by this court.

- 1. Whether the petition discloses any cause of action against the 3<sup>rd</sup> respondent*
- 2. Whether the petitioner was HBV Positive at the date of her enrollment into the study.*
- 3. If the above issue is answered in affirmative, whether this rendered her enrollment into the suit study unlawful.*
- 4. Whether the petitioner's consent to participate in the suit study was unlawfully procured.*
- 5. If the above issue is answered in affirmative, whether the 1<sup>st</sup>, 3<sup>rd</sup>, 4<sup>th</sup> 5<sup>th</sup>, 6<sup>th</sup>, 7<sup>th</sup>, 10<sup>th</sup>, 11<sup>th</sup> and 12<sup>th</sup> respondents violated and or threatened the petitioner's right to life, right to health and right to access to health information contrary to Article 7 of the International Covenant on Civil and Political Rights (ICCPR) and Articles 22, 44(1) (a) and 45 of the Constitution of Uganda.*

6. *Whether the 1<sup>st</sup>, 3<sup>rd</sup>, 4<sup>th</sup>, 5<sup>th</sup>, 6<sup>th</sup>, 7<sup>th</sup>, 10<sup>th</sup>, 11<sup>th</sup> and 12<sup>th</sup> respondents injected the petitioner with a dead Engerix B vaccine and if so, whether this violated the petitioner's rights under Article 7 of the International Covenant on Civil and Political Rights (ICCPR) as well as Article 22, 24, 44 (1)(a) and 45 of the Constitution of Uganda.*
7. *Whether the 1<sup>st</sup>, 3<sup>rd</sup>, 4<sup>th</sup>, 5<sup>th</sup>, 11<sup>th</sup>, and 12<sup>th</sup> respondents subjected the petitioner to verbal threats and or abuse and if so, whether this violated the petitioner's right under Article 7 of International Covenant on Civil and Political Rights (ICCPR) and Articles 24 and 44 (1) a of the Constitution of Uganda.*
8. *Whether the 1<sup>st</sup>, 3<sup>rd</sup>, 4<sup>th</sup>, 5<sup>th</sup>, 6<sup>th</sup>, 7<sup>th</sup>, 10<sup>th</sup>, 11<sup>th</sup> and 12<sup>th</sup> respondents refused to provide the petitioner with optimal HBV care and of so whether and or violated her legal and constitutional rights guaranteed under Article 7 of the International Covenant on Civil and Political Rights (ICCPR) as well as Articles 22, 24, 44 (1) (a) and 45 of the Constitution of Uganda.*
9. *Whether the 1<sup>st</sup>, 3<sup>rd</sup>, 4<sup>th</sup>, 5<sup>th</sup>, 6<sup>th</sup>, 11<sup>th</sup> and 12<sup>th</sup> respondents denied the petitioner access to her medical file and if so whether this violated or threatened her rights as protected under Article 7 of International Covenant on Civil and Political Rights (ICCPR) as well as Article 22, 24, 41 (1), 44(1) a and 45 of the Constitution of Uganda*
10. *Whether the 1<sup>st</sup>, 3<sup>rd</sup>, 4<sup>th</sup>, 5<sup>th</sup>, 6<sup>th</sup>, 11<sup>th</sup> and 12<sup>th</sup> respondents denied the petitioner an honest and comprehensive medical opinion and or assessment of the cause of her chronic HBV infection and if so, whether this violated or threatened her rights as protected under Article 7 of the*

*International Covenant on Civil and Political Rights (ICCPR) as well as Articles 22, 24, 41(1) (a) and 45 of Constitution of Uganda.*

*11. Whether the 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup>, 4<sup>th</sup>, 5<sup>th</sup>, 6<sup>th</sup>, 7<sup>th</sup>, 10<sup>th</sup>, 11<sup>th</sup>, and 12<sup>th</sup> respondents refused or failed to honestly and accurately disclose to the petitioner the benefits of her participation in the suit study.*

*12. If the above issue is answered in the affirmative; whether this violated and or threatened her right to life, health and access to health information contrary to Guidance Point No.12 and 16 of the UNAIDS/ WHO Ethical Guidelines on Biomedical HIV Vaccine Trials and Article 22, 41 (1) and 45 of the Constitution of Uganda.*

*13. What remedies are available to the petitioner?*

**Order 15, Rule 5 of the Civil Procedure Rules SI.71-1** gives this court the power to amend and strike out issues at any time before passing a decree as it thinks fit as may be necessary for determining the matters in controversy between the parties. In the interest of adequate discussion of the legal issues at hand, the court rephrases the issues for determination in accordance with human rights issues to reflect as;

- 1. Whether the fundamental rights and freedoms of the applicant were infringed upon by the respondents.*
- 2. What remedies are available to the parties?*

The parties were ordered to file written submissions; and the parties accordingly filed the same.

All parties' submissions were considered by this court.

### **Preliminary point:**

The respondents raised a preliminary point of law as;

*Whether the petition discloses any cause of action against the 3<sup>rd</sup> respondent.*

### **Submissions**

Counsel for 4<sup>th</sup>, 5<sup>th</sup>, 6<sup>th</sup>, 11<sup>th</sup>, and 12<sup>th</sup> respondent raised a preliminary objection that the petitioner's cause of action under Article 41 of Constitution is misconceived as the said article only provides for the right of access to information in the possession of the state or any other organ or agency of the state. He stated that pursuant to Article 41 (2) of the Constitution, parliament enacted the access to Information Act (Act 6 of 2005) where in the act states under section 2 that it applies to all information and records of government ministries, departments, local governments, statutory corporations and bodies, commissions and other government organs and agencies unless specifically exempted by this Act. Counsel stated that the respondents are certainly not organs or agencies of the state. Counsel therefore prayed that court finds that Article 41 of the Constitution does not apply to the said respondents.

Counsel further stated that the petitioner's affidavit in support is prolix and argumentative. He states that the petitioner effectually argues rather than state facts. The said affidavit is fatally defective as it offends the mandatory provisions of Order 19, Rule 3 of the Civil Procedure Rules as interpreted in various judicial precedents. Counsel relied on the decision of *Male H Mbirizi K. Kiwanuka v*

*the Attorney General Misc. Applic. No. 7 of 2018* where court stated that affidavits are meant adduce evidence and not argue the application.

Counsel therefore prayed that court strikes off the petitioner's affidavit on grounds that the same is prolix, argumentative and non-compliant with Order 19, Rule 3 of the CPR.

Counsel further stated that the petitioner's affidavit is defective on further ground that the averments therein are not from the petitioner's knowledge under paragraphs;6,12,34,35,36,37,41,42,43,47,53,54,55,57,58,59,62,63,64,65,66,67,68,69,70,71,72,73,74 and 75 of the said affidavit are expressed based on advice from her lawyers thus offending Order 19, Rule 3 of CPR and should be struck out.

Counsel further submitted that the consequences of striking out the affidavit in support is that there is no competent petition before court as there would be no evidence adduced in support thereof which as required under Rule 6 of Judicature (Fundamental Rights and Freedoms) (Enforcement Procedure) Rules, 2008. He invited court to strike out the petition altogether. He prayed that in the alternative, paragraphs;6,12,34,35,36,37,41,42,43,47,53,54,55,57,58,59,62,63,64,65,66,67,68,69,70,71,72,73,74 and 75 and all other paragraphs of the said affidavit which are deemed to be prolix and or argumentative should be expunged from court record.

The respondents led evidence through affidavits in reply deposed by Dr. Pontia Kaleebu, Dr. Yunia Mayanja, Dr. Gertrude Namale, Prof Ponsiano Ocama, Rebecca Nabukenya, Catherine Nankabira, Ochola Willy Fred, Joan Namayanja and Nadia Ngabire. The whole of the said evidence adduced in the affidavits of

the said deponents was neither challenged nor rebutted by any affidavits in rejoinder thereto. He submitted that legally, the petitioner is taken to have accepted the said evidence as was held in *David Kato Luguzu & Anor v Evelyn Nakafeero & Anor HCA No. 37 of 2011*. The evidence adduced in affidavits of the said witnesses was not controverted through cross examination. Only one deponent was subjected to cross examination on the contents of his affidavit. Counsel therefore prayed that court hold that the petitioner accepted the said evidence of the said witnesses.

On the preliminary objection raised by the respondents, counsel for the 1<sup>st</sup>, 7<sup>th</sup> and 10<sup>th</sup> respondents concurred with the submission of the 4<sup>th</sup>, 5<sup>th</sup>, 6<sup>th</sup>, 11<sup>th</sup> and 12<sup>th</sup> respondents in relation to the fact that the defects in the petitioner's affidavit as being bad for prolixity, argumentative and for failure to disclose the sources of information from which it is deponed and failure of the petitioner to file an affidavit in rejoinder or otherwise to challenge the evidence of the several respondents. Counsel also submitted that indeed Article 41 of the Constitution is inapplicable to the current case. He therefore prayed that the affidavit in support of the application should be struck out entirely or in the alternative, the offending paragraphs in it severed.

### **Ruling**

Counsel for the respondents submitted that the affidavit in support of the application is prolix and argumentative as the petitioner effectively argues the petition rather than state the facts in the circumstances as seen in several paragraphs of the said affidavit. Counsel further relied on the case of Male H.



Mabirizi v Attorney General (supra) where court observed that affidavits are meant not adduce evidence and not argue the application.

I concur with the submissions of the counsel as regards to principles governing affidavit evidence where by an affidavit should contain facts and not arguments or matters of law. From the court record, it is indeed true that the affidavit in support of the application is prolix and argumentative rather than stating the evidence in support of the matter before court.

Court therefore finds the petitioner's affidavit is prolix, argumentative and non-compliant with Order 19, Rule 3 of the Civil Procedure Rules all those paragraphs that offend this rule are accordingly expunged (6,12,34,35,36,37,41,42,43,47,53,54,55,57,58,59,62,63,64,65,66,67,68,69,70,71,72,73,74 and 75).

However, this court will now determine this application on its merits to entirely dispose of the matter.

## **DETERMINATION OF ISSUES**

### **Issue 1**

*Whether the fundamental rights and freedoms of the applicant were infringed upon by the respondents.*

Submissions:

**For the applicant:**

It was submitted that the applicant maintained that according to the laboratory results communicated to her on the 12/8/2014 prior to her vaccination with Engerix B, she was HBV negative. It was stated that this was corroborated by the petitioner's study eligibility form which was personally filled by the 11<sup>th</sup> respondent. The said report indicated that the petitioner was free of any acute illnesses and any chronic diseases. Counsel submitted that the impugned laboratory results of 23/9/2014 that indicated a case of chronic hepatitis B were a forgery conjured by the respondents to hoodwink this court.

Counsel submitted that the enrollment of the petitioner into the study was unlawful, null and void ab initio. He stated that this study was governed by the provisions of Protocol Version 1.3: 2<sup>nd</sup> April, 2014 where it stated under section 4.2 that persons with chronic diseases were not supposed to be recruited/enrolled into the study. Counsel argued that if at the date of her enrollment onto the study the petitioner had chronic HBV, then her enrollment contravened, offended and or violated the express provisions of the study protocol hence manifestly illegal.

Counsel further submits that the petitioner's consent to participate in the study was procured from her upon a clear and unequivocal promise that she would personally benefit by acquiring effective vaccination against HBV using an effective drug known as Engerix B and that she would not have consented to participate if she had been told that the vaccine would not work for her. He stated that the petitioner's consent was obtained through misrepresentation which goes to the root and inevitably negatives and vitiates it. He stated that it

was the duty of the respondents to provide accurate information to ensure that the petitioner's consent was based on this.

Counsel further submitted that the petitioner's consent was unlawfully obtained from her and is ineffective as informed consent since it was not administered in the her native language, Lusoga but in was administered in Luganda which is too weak to suffice as she is functionally illiterate and unable to read and comprehend written words in any language.

The petitioner also stated that the continued non-disclosure of the facts of her file is a violation of her rights to health information and health and is indeed an affront on her right to life.

**4<sup>th</sup>, 5<sup>th</sup>, 6<sup>th</sup>, 11<sup>th</sup> and 12<sup>th</sup> Respondents' submissions;**

Counsel for the 4<sup>th</sup>, 5<sup>th</sup>, 6<sup>th</sup>, 11<sup>th</sup> and 12<sup>th</sup> respondent submitted that the issue before court relates to a technical matter concerning the HBV status of the petitioner at the time of enrollment as a study participant. He stated that the resolution of this issue requires an evaluation of evidence of laboratory tests conducted on the petitioner's blood sample and court cannot rely on speculation or submissions of counsel at the bar.

Counsel stated that the petitioner under section 106 of the Evidence Act bears the burden of proving her alleged negative HBV vaccine at the time of her enrolment through laboratory results of her blood samples to discharge the said burden. The failure to do so injures that petitioner's claim as various records from experts

that swore affidavits in reply to the petition proves that the petitioner was HBV positive at the time of enrolment into the study on the 12<sup>th</sup> of August 2014.

Counsel submitted that the petitioner does not provide any results on which she claims that the laboratory results communicated to her prior to the vaccination proved her to be HBV negative.

Counsel submitted that the applicant's claim that the laboratory test results are forged is misleading and founded a pure conjecture and not be taken seriously by court. He stated that these allegations were not pleaded and cannot lawfully be raised during the stage of submissions and should be disregarded by court.

Counsel further submitted that the full study eligibility criteria cannot be discerned only from one form read in isolation of the study protocol. He stated that the volunteer's HBV status at the time of enrolment was not relevant or material in their inclusion as study participants under para 2 of pg. 10 of the protocol. Counsel stated that the petitioner was informed that she would be eligible for enrolment if her test results showed that she was not infected with HIV and no mention was made of ineligibility on the ground of HBV status. The applicant cannot therefore argue that the HBV positive status rendered her enrolment into the study unlawful.

He therefore submitted that the petitioner's submission that her enrolment as a participant violated her right to life and right to access to information under Articles 22 and 41 of the Constitution is far-fetched and that no plausible grounds are disclosed for enforcement by court and should accordingly be struck out.

In respect of the petitioner's consent being procured unlawfully, counsel submitted that the petitioner admitted appending her signature on the consent document worded in Luganda and that before signing the same, she was provided information in Luganda relating to the study which was signed in the presence of Christine Nankabirwa , a senior nursing officer employed by the 5<sup>th</sup> respondent. The petitioner granted her informed consent to participate in the study voluntarily with a clear understanding of the benefits and risks associated therewith.

On whether the respondents refused the petitioner access to her medical file, counsel submitted that no evidence was adduced showing to whom the alleged request for her personal file was made and thus the complaint ought to fail for being frivolous and vexatious.

**The 1<sup>st</sup>, 7<sup>th</sup> and 10<sup>th</sup> respondents' submissions;**

Counsel for the respondents argued that the study eligibility form is a preliminary form in the course of enrolment in the study to establish eligibility for prospective volunteers and at the point it was made out, no diagnostic tests had been made on the prospective candidate. He stated that the form was filled placing reliance solely on the information as given by the study participant and in this case, the petitioner.

On the petitioner's submission being unlawful as she was HBV negative at the time, counsel stated that Protocol under section 4.2 states that hepatitis B status was not exclusion criterion for enrolment into the study and that therefore, the petitioner's enrolment was not unlawful since it did not violate the protocol.

## **Determination**

I have analyzed the evidence before this court and the submissions of counsel in regard to this issue.

The applicant alleges that the respondents violated her rights under Article 24 that guarantees freedom from torture, cruel, inhuman degrading treatment or punishment

The **Constitution of the Republic of Uganda, 1995** under **Article 24** guarantees freedom from torture, cruel, inhuman degrading treatment or punishment. **Article 44 (a)** of the Constitution and also under Section 3 of the Prevention and Prohibition of Torture Act of 2012 state that this right is non-derogable under The Constitution under **Article 20** also stipulates that human rights are inherent and not granted by the state. One whose rights have been violated is entitled to petition to the court for redress under Article 50(1).

Freedom from torture is one of the most universally recognized human rights. Torture is considered so barbaric and incompatible with civilized society that it cannot be tolerated. Torturers are seen as the 'enemy of mankind'.

The ban on torture is found in a number of International treaties, including Article 2 of the United Nations Convention Against Torture and Article 3 of the Human Rights Convention and Article 5 of the Universal Declaration of Human Rights and Article 5 of the African Charter on Human and People's Rights.

*In Ireland vs United Kingdom ECHR Application No.5310/71, Court explained the distinction between Torture and inhuman or degrading treatment lies in the difference in*

*the intensity of suffering inflicted. In deciding whether certain treatment amounts to torture, the court takes into account factors of each individual case, such as the duration of treatment, its physical and mental effects, and age, sex, health and vulnerability of the victim.*

The courts should apply a very strict test when considering whether there has been a breach of an individual's right to freedom from torture or inhuman or degrading treatment. Only worst examples are likely to satisfy the test.

There are no exceptional circumstances whatsoever to justify torture.

The petitioner alleges that her right to freedom from cruel, inhuman and degrading treatment under Article 24, right to life, health and health information was violated by the respondent.

It was submitted that the petitioner was unlawfully subjected to a study where at enrolment, she was HBV negative but later tested positive with chronic hepatitis B having been led to believe that upon vaccination, she would not be vulnerable to the infection.

According to the evidence on record, the applicant was already Hepatitis B positive. Nabukenya stated in her Paragraph 8; The petitioner's blood sample (SiV00007) was tested for Hepatitis B on 23<sup>rd</sup> September, 2014 and the laboratory test results revealed that the petitioner was Hepatitis B positive.

Ponsiano Ocama (Assoc. Prof) and an expert in hepatology in his affidavit stated that; "I know that the vaccine can be administered even if infection with hepatitis B has been confirmed or not and vaccine does not have any negative effect even

if the person had already been exposed to the infection or not. Therefore the vaccine may be administered irrespective of the hepatitis B status. I know that there is absolutely no risk to a chronically or acutely infected person who receives the vaccination.”

The petitioner tries to deny that she was positive by contending that she started on the vaccination when she was clearly HBV negative. Her annexure D to the application shows that Hepatitis B viral load was ticked as such. She alleges that the vaccine was not perfectly effective and she would not have consented to participate in the project. There is evidence on record from her other co-participants who confirm that she is conversant with the luganda language

It is clear that the petitioner consented to the study and the claims of not knowing the luganda language is an afterthought in order to make a case in court.

Informed consent has been explained in different *Guidelines in Helsinki Declaration (1964) and Belmont Report (1979)* to be understood as follows;

In any research on human beings, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely-given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed.

- 1.) Information: Most codes of research establish specific items for disclosure



intended to assure that subjects are given sufficient information. These items generally include: the research procedure, their purposes, risks and anticipated benefits, alternative procedures (where therapy is involved), and a statement offering the subject the opportunity to ask questions and to withdraw at any time from the research.

2.) Comprehension: The manner and context in which information is conveyed is as important as the information itself. For example, presenting information in a disorganized and rapid fashion, allowing too little time for consideration or curtailing opportunities for questioning, all may adversely affect a subject's ability to make an informed choice.

3.) Voluntariness: An agreement to participate in research constitutes a valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence. Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance. Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance.

No investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

I find the consent of the petitioner complied with the above standards set under those guidelines.

The petitioner claims that because of the respondents' actions and failure to disclose all necessary information, her said rights were violated.

The petitioner alleges that she was HBV negative at the time of enrollment into the study and not positive as the test results show. This argument is lacks basis as the petitioner has not provided this court with any evidence to show that indeed her status was positive at the point of enrollment. The issue as to the petitioner's status at the time of enrollment into the study is one that requires scientific evidence and explanation. This court can therefore do so little where such evidence is not provided by the petitioner seeking judgment on the same in her favour. The petitioner failed to adduce any cogent evidence to prove that she was negative at the time of carrying out the tests.

The *Evidence Act, Cap 6 under Section 101* provides that whoever desires any court to give judgment as to any legal right or liability dependent on the existence of facts which he or she asserts must prove that those facts exist. The petitioner in the circumstances has not proved that she was indeed negative at the time of enrollment into the study. It is therefore hard for court to find otherwise with no basis.

In respect of the petitioner not giving informed consent, she gave evidence admitting that she appended her signature on the consent document worded in Luganda and that before signing the same, was provided information about the study in Luganda. It does not seem like the petitioner did not understand the contents of the information given at the time. She does not claim not knowing

Luganda, she however claims that her knowledge of Luganda is insufficient for informed consent. This is quite absurd as the petitioner has failed to prove to this court that indeed she did not have informed consent due to language used being insufficient. Merely alleging to be functionally illiterate does not suffice and prove the same without any background information.

According to the affidavit of Yunia Mayanja paragraph 11; the petitioner was availed with appropriate information about the study; she was given information sheet and consent form written in luganda. She was allowed appropriate time to read and consider the information therein. She demonstrated clear ability to read and understand the contents; she was assessed to determine whether she had understood contents information and she scored 10 out of 10. See annexure YM2.

The petitioner was a peer facilitator and this means she was teaching her peers who were all participants in the study in the language she is conversant with which is luganda. This evidence was not denied apart from the statement that she was not conversant with luganda and she would have preferred Lusoga. Atleast one of her fellow participant would have clarified on her inability to understand luganda.

The petitioner stated in paragraph 50, that the respondent's betrayed her trust and instead misled her to believe the vaccination with Engerix B offered her protection against the Hepatitis B virus. Dr Ponsiano Ocama explained the effects of Engerix and confirmed that there is absolutely no risk to a chronically or

acutely infected person who receives the vaccination. The vaccine can be administered irrespective of the Hepatitis B status.

The petitioner's counsel argued in the alternative, that if it is true that the petitioner was positive then she was ineligible since she was chronic hepatitis. There is no evidence that has been lead to prove that she was chronic. The doctor (Ponsiano Ocamá) explained paragraph 8; Hepatitis B infection can either be acute or chronic. Acute Hepatitis B virus infection is a short term illness that occurs within six months after someone is exposed to the Hepatitis B Virus. Acute infection can-but does not always-lead to chronic infection. Chronic Hepatitis B virus infection is a long term illness that occurs when the Hepatitis B virus remains in a person's body for more that 6 months.

Under the Protocol, section 4.2 it is provided; that Hepatitis B status will not be an exclusion criterion for enrolment.

This point was equally not explored or proved through evidence since the petitioner denied ever being negative. The evidence does not show that she was Chronic in order not make her eligible for the study.

I find that the petitioner's lawyer tried to interrogate the process of carrying out medical research and trying to find any fault in the process. The petitioner's case can be deduced from her affidavit was about being infected with a dead Engerix B vaccine/drug but later it changed or transformed to challenging the entire process. It was neither here nor there but it tries to find every possibility of getting liability by interrogating every step taken.

This court shall not determine the matter on science assumptions or guidelines as set out in the WHO Guidelines and Protocols but on the evidence available or adduced to prove the violation of the petitioner's rights. The evidence available is about her word against the respondents and it is highly technical in medical research which she was explained too together with other participants. But the procedural steps taken seemed to be the basis of her challenge like lack of consent etc. The research was not about herself alone, there are other participants (Commercial Sex workers) and at least she has not said they were affected or that they were not availed all the necessary information.

That is why the affidavit is couched in terms of the Study protocol like...."if the volunteer is functionally illiterate, the consent document may be read to them in a language they best understand in the presence of a literate witness who will not be evaluating the volunteer directly. She stated that she was functionally illiterate in order to fit herself in the exception envisaged under the protocol and yet she was a peer facilitator in the Luganda language to other participants in the study.

The petitioner has failed to adduce any evidence to show that the study was not conducted in accordance with the protocol.

In the result I therefore find that the petitioner has not proved any violations to her constitutional rights under Article 22, 45, 24, 41 and Chapter 4 of the Constitution of Uganda.

I therefore find this issue in the negative.

## **Issue 2**

*What remedies are available to the parties?*

Having found that the petitioner's rights were not violated, I find the application to be lacking in merit.

This application is therefore dismissed with costs.

I so order.

***Dated, signed and delivered be email and whatsApp at Kampala this 8<sup>th</sup> day of May 2020***

**SSEKAANA MUSA  
JUDGE**