

IN THE COURT OF APPEAL OF THE DEMOCRATIC SOCIALIST REPUBLIC OF SRI LANKA

In the matter of an application for a mandate in the nature of Writs of Certiorari and Mandamus in terms of Article 140 of the Constitution of the Democratic Socialist Republic of Sri Lanka.

Professor Pushpa Lalani Jayawardana,

No: 2A, 6th Lane,

Pagoda Road,

Nugegoda.

**Petitioner**

**Case No: CA/WRIT/265/2011**

**Vs.**

1. Professor A.R. Wickramasinghe,  
The Dean, Faculty of Medicine,  
University of Kelaniya,  
Ragama.
2. Profesor L.S.S. Salgado
3. Dr. A.L. Karunanayake
4. Dr. E.D.P.S. Fernando
5. Professor L.G. Chandrasena
6. Dr. S Chakrawarthy
7. Ms. P.S. Perera
8. Dr. D.C. de Silva
9. Dr. K. Medagoda
10. Dr. W.A.D.L. Amarasiri
11. Dr. W.N.S. Perera
12. Dr. P.A.S. Edirisinghe
13. Dr. Paranitharan

14. Dr. ID.G. Kithulwaththa
15. Dr. R.R.D.P. Perera
16. Dr. M.T. W. Wijesuriya
17. Dr. W.R.P.L.I. Wijesooriya
18. Professor N.R. De Silva
19. Professor W. Abeywickrema
20. Professor T.G.A.N.Chadrasena
21. Dr. H.S.A. Williams
22. Dr. R.M.U.S. Ratnayake
23. Dr. B.A.G.G. Mahendran
24. Professor H.A. De Silva
25. Dr. C.D. Ranasinha
26. Dr. C.N.Wijekoon
27. Dr. S.A. Kurukulasuriya
28. Professor A. Pathmeswaran
29. Dr. M.A. Pinidiya Pathirage
30. Dr. K.T.A.A. Kasturiratne
31. Professor H.J.D e Silva
32. Professor Premawardena
33. Professor B.A.H.R. Premaratne
34. Dr. U.K. Ranawaka
35. Dr. S.T. De Silva
36. Professor P.S. Wijesinghe
37. Dr. B.A. De Silva

38. Mr. D.M.A.B. Dissanayake
39. Professor. D.G.H. De Silva
40. Professor K.A.L.A. Kuruppuarachchi
41. Dr. M.U.R.K. Penis
42. Dr. S.S. Williams
43. Dr. A. Hapangama
44. Professor K.I. Deen
45. Professor M. H. J.Ariyaratne
46. De. C.A.H. Liyanage
47. Ms. L.D. Ileperuma
48. Ms. S. Hettiarachelli
49. Dr. A.A.P.S. Manamperi
50. Dr. Y.I.N.S. Gunawardane
51. Dr. G.P.G.M.D. Hapugoda
52. Mr. T. Ranasinghe
53. Mr. S. Edward Reginold  
All of them Faculty of Medicine,  
University of Kelaniya,  
Ragama.
54. Professor Sarath Amunugama,  
Vice Chancellor,  
University of Kelaniya,  
Kelaniya.
- 54.A Senior Professor Sunanda Madduma  
Bandara  
Vice Chancellor,  
University of Kelaniya,  
Kelaniya.
- 54.B Senior Professor Nilanthi de Silva  
Vice Chancellor,  
University of Kelaniya,  
Kelaniya.

55. University of Kelaniya,  
Kelaniya.
56. Rev. Fr. Roshan Fernando,  
Dept of Christian Culture,  
Faculty of Humanities,  
University of Kelaniya.
57. Mrs. H.K. De Silva,  
SAR/Legal and Documentation,  
University of Kelaniya,  
Kelaniya. 58.
58. Dr. Chrisantha Abeysena
59. Dr. Rizvi Hasan
60. Dr. Rasika Herath
61. Professor J. Hewavisenthi
62. Dr. B. Kumarendran
63. Mrs. P. Shiromi Perera
64. Dr. E.G.D.S. Raj indrajith
65. Professor A.P. De Silva  
All of them,  
Faculty of Medicine,  
University of Kelaniya,  
Ragama.
66. Dr. Priyantha Perera  
Faculty of Medicine,  
University of elaniya,  
Ragama.

**Respondents.**

**Before:** **N. Bandula Karunarathna J.**

**&**

**R. Gurusinghe J.**

**Counsel:** Anil Silva PC with Dileep Bhann, Tharindu Rukshan and Nandana Perera for the Petitioner

Nihal Fernando PC with Harshula Seneviratne instructed by Paul Rathnayaka Associates for the 59<sup>th</sup>, 61<sup>st</sup> and 65<sup>th</sup> Respondents

Kuvera de Zoysa PC with Senaka de Seram for 18<sup>th</sup>, 24<sup>th</sup>, 25<sup>th</sup> and 31<sup>st</sup> Respondents

Milinda Gunathilaka PC, ASG for the 01<sup>st</sup>, 04<sup>th</sup>, 06<sup>th</sup>, 07<sup>th</sup>, 09<sup>th</sup>-11<sup>th</sup>, 13<sup>th</sup>, 16<sup>th</sup>, 17<sup>th</sup>, 19<sup>th</sup>, 23<sup>rd</sup>, 25<sup>th</sup>, 28<sup>th</sup>, 32<sup>nd</sup>, 33<sup>rd</sup>, 36<sup>th</sup>-43<sup>rd</sup>, 45<sup>th</sup>-47<sup>th</sup>, 49<sup>th</sup>-55<sup>th</sup>, 60<sup>th</sup>-63<sup>rd</sup> Respondents

**Written Submissions:** By the Petitioner filed on 07.10.2013, 11.10.2018 & 05.10.2020

By the 59<sup>th</sup>, 61<sup>st</sup> and 65<sup>th</sup> Respondents filed on 08.11.2018 & 28.09.2020

By the 18<sup>th</sup>, 24<sup>th</sup>, 26<sup>th</sup> and 31<sup>st</sup> Respondents filed on 07.10.2013

By the 01<sup>st</sup>, 04<sup>th</sup>, 06<sup>th</sup>, 07<sup>th</sup>, 09<sup>th</sup>, 10<sup>th</sup>, 11<sup>th</sup>, 13<sup>th</sup>, 15<sup>th</sup>, 16<sup>th</sup>, 19<sup>th</sup>-23<sup>rd</sup>, 25<sup>th</sup>, 28<sup>th</sup>, 32<sup>nd</sup>, 33<sup>rd</sup>, 36<sup>th</sup>-43<sup>rd</sup>, 45<sup>th</sup>-47<sup>th</sup>, 49<sup>th</sup>-55<sup>th</sup> and 60<sup>th</sup>-63<sup>rd</sup> Respondents filed on 02-11-2021

**Argued on:** 24.10.2019, 17.07.2020 and 27.04.2021

**Judgment on:** 23.11.2021

**N. Bandula Karunarathna J.**

This is an application for a Writ of Certiorari to quash the decisions of the 01<sup>st</sup> Respondent dated 20.01.2011, to quash the decisions of the 01<sup>st</sup> -53<sup>rd</sup> respondents dated 03.02.2011 and to issue a Writ of mandamus directing the 01<sup>st</sup> -53<sup>rd</sup> Respondents to take steps to approve the standing operating procedure submitted by the Ethics Review Committee on 15.12.2010 and to issue a Writ of Mandamus directing the 01<sup>st</sup> -53<sup>rd</sup> Respondents, the 54<sup>th</sup> Respondent and 55<sup>th</sup> Respondent to appoint Ethics Review Committee by the law.

The Petitioner is a Medical Doctor and join the University of Peradeniya as a Lecturer in the Department of Community Medicine in 1986. She was promoted to a senior Lecture in 1995. In the year 1998, she joined the then Department of Community and Family Medicine, Faculty of Medicine, the University of Kelaniya (which is presently named as Department of Public Health), after which she was promoted as a Professor in the Department of Public Health of the same faculty in the year 2009. Academics in the field of Community Medicine are involved in disseminating knowledge concerning research methodology as well as ethical aspects of human research. She was also the President of the College of Community Physicians in the year 2006 / 2007.

The Petitioner says that the 01<sup>st</sup> Respondent is the Dean of the Faculty of Medicine, University of Kelaniya. The 02<sup>nd</sup> to the 53<sup>rd</sup> Respondents are members of the Faculty Board of the Faculty of Medicine, University of Kelaniya and were present at the meeting of the Faculty Board dated 03.02.2011. All of whom are appointed in terms of the Universities Act No. 16 of 1978. The 54<sup>th</sup> Respondent was the Vice-Chancellor of the University of Kelaniya, and the 55<sup>th</sup> Respondent is the University of Kelaniya a body corporate set up by the Universities Act No.16 of 1978 which can sue and be sued in legal proceedings.

According to the available documents before this court, the 08<sup>th</sup>, 12<sup>th</sup>, 16<sup>th</sup>, 26<sup>th</sup> and 56<sup>th</sup> to 65<sup>th</sup> Respondents were the members of the Ethics Review Committee of the Faculty of the Medicine University of Kelaniya which was appointed by the Faculty Board of the Faculty of the Medicine University of Kelaniya. It was dissolved by the 01<sup>st</sup> Respondent on 20.01.2011. The said 08<sup>th</sup>, 12<sup>th</sup>, 16<sup>th</sup> and 26<sup>th</sup> Respondents are also members of the Faculty Board of the Faculty of Medicine, University of Kelaniya and were present at the Faculty Board Meeting dated 03.02.2011. It is evident that the 02<sup>nd</sup>, 06<sup>th</sup>, 11<sup>th</sup>, 19<sup>th</sup>, 21<sup>st</sup>, 25<sup>th</sup>, 28<sup>th</sup>, 33<sup>rd</sup>, 42<sup>nd</sup>, 48<sup>th</sup>, 50<sup>th</sup> and 66<sup>th</sup> Respondents were the Members of the Ethics Review Committee appointed by the 01<sup>st</sup> Respondent on 20.01.2011 and they are also members of the Faculty Board of the Faculty of Medicine, University of Kelaniya. Except for the 66<sup>th</sup> Respondent, all other members of the new Ethics Review Committee were also present at the Faculty Board Meeting dated 03.02.2011.

The Petitioner states that considering the vulnerability of the subjects who agree to participate in research. various principles have been enunciated to ensure that research using human beings is conducted by the ethical guidelines. Among them is the Nuremberg Code, Declaration of Helsinki on ethical principles for medical research involving Human Subjects and the Belmont Report.

The Petitioner further says that it is the expected norm that before any research involving human beings are conducted, ethical clearance has to be obtained from an. Ethics Review Committee. Accordingly, Ethics Review Committees are set up in Institutions where research is conducted. As there are numerous Ethics Review Committees in Sri Lanka, an umbrella organization named the Forum of Ethics Review Committees, Sri Lanka (FERCSL) has been set up by the Sri Lanka Medical Association with the view of having uniformity in ethical standards that should be applied by the respective Ethics Review Committees.

The Sri Lanka Medical Council has issued guidelines in respect of ethics and medical research which every medical practitioner is bound to follow. According to the Petitioner, the non-following of the medical ethics may make a medical practitioner liable to infamous conduct. The Medical Faculty of the University of Kelaniya has 16 Departments of Study. All such Departments engage in research in addition to teaching and examinations. The Petitioner states that in most instances research is being conducted using human subjects and because of the matters set out, they should get an ethical clearance from an Ethics Review Committee.

The Petitioner states that an Ethics Review Committee has been set up by the Faculty Board of the Faculty of Medicine of the University of Kelaniya in terms of Section 48(3) of the Universities Act No. 16 of 1978. The said Ethics Review Committee deals with the requisite ethical clearance for medical research conducted using human subjects. The Department of Pharmacology is one of the 16 departments which carries out research and in addition, as the

said Department deals with the study of drugs, a Clinical Trials Unit dealing with the testing of new drugs is functional in the said Department. The Faculty Board of the Faculty of Medicine was appointed on 27.08.2010, the Petitioner and 16 members to the Ethics Review Committee of the Faculty of Medicine, University of Kelaniya. The members of the Committee met and elected the Petitioner as the Chairperson of the Ethics Review Committee of the Faculty of Medicine.

The Petitioner states that she has continuously served as a member of the Ethics Review Committees of the Medical Faculty of the University of Kelaniya since 1999 and she had not been found wanting in respect of her conduct in any of the Ethics Review Committees where she was a member. About seven to nine research proposals per month were submitted to the Ethics Review Committee which is the subject matter of this application and all those proposals were given ethical clearance after due consideration except two out of which one was an instance where ethical clearance was sought retrospectively.

The Petitioner further says that it would have nullified the whole purpose of obtaining prior ethical clearance. On 30.11.2010 Five clinical and drug trials were forwarded to the Ethics Review Committee through the Clinical Trials Unit of the Department of Pharmacology of the Faculty of Medicine. These are international multi-centre drug trials for which Sri Lanka has been identified as one of the centres. A Drug Trial means a procedure where the testing of the safety and efficacy of a new drug is considered before it is recommended for use on patients.

It is important to note that to use a drug even for research purposes approval has to be obtained from the National Cosmetics Devices and Drugs Authority set up under the Cosmetics Devices and Drugs Act No. 27 of 1980 as amended by Act No. 25 of 1987 and Act No. 12 of 1993. In terms of the said Cosmetics Devices and Drugs Act, no drug can be used without a license in Sri Lanka. A condition precedent for the granting of approval for the use of any new drug is the ethical clearance granted for the research proposal by the respective Ethics Review Committee.

The Petitioner states that three members of the Ethics Review Committee are assigned as Reviewers for the evaluation of each proposal and their comments are discussed at the Ethics Review Committee before finally granting ethical clearance for same. The Petitioner was one of the reviewers in respect of one of the Drug Trials titled as follows;

"A Phase 2, Randomized, Open-label (with Blinded Plasminogen Activator and Placebo Control Groups) Study to Evaluate the Effects of Different Intra-thrombus Infusion Regimens of Plasmin (Human) Compared to Plasminogen Activator and Placebo in Patients with Acute Lower Extremity Native Artery or Bypass Graft Occlusion".

After reviewing the aforesaid proposal put forward by the applicant all three reviewers were of the view that there were serious ethical issues that needed clarification by the Ethics Review Committee before granting ethical clearance. The Ethics Review Committee was to deliberate the granting of ethical clearance for this proposal on 13.01.2011 and two of the investigators who were a renowned Vascular Surgeon and a Radiologist were invited to be present. Out of them Dr. Ruwan Fonseka the Vascular Surgeon was present. After the said meeting, as the ethical issues identified by the three reviewers remained unanswered, the Committee decided to call for a second opinion from Professor Sherif Deen.

The Petitioner further says that similarly the other four Drug Trials were taken up for consideration at the meeting held on 18.01.2011. There too the Committee invited the main investigators to be present to explain certain ethical issues that arose. They have not participated but they were represented by Professor H. Asitha De Silva, who is the coordinator of the Clinical Trials Unit of the Department of Pharmacology of the Faculty of Medicine. At the said meeting the ethical issues arising in these four drug trials were considered and as those too remained unanswered it was decided to seek second opinions. The Guidelines on Ethical Conduct of Medical & Dental Practitioners Registered with The Sri Lanka Medical Council categorically state that if the Ethics Committee does not feel competent to consider difficult scientific data or the difficult ethical issues, it should seek appropriate advice or co-opt people with the necessary expertise.

The Petitioner states that the 01<sup>st</sup> Respondent was present at the meeting of the Ethics Review Committee on 18.01.2011 and tried to persuade the Ethics Review Committee to accept the proposals without adhering to guidelines set out by Sri Lanka Medical Council and Forum of Ethics Review Committees of Sri Lanka (FERCSL). The petitioner contended that the 01<sup>st</sup> Respondent is a member of the Clinical Trials Unit of the Department of Pharmacology which coordinated these drug trials and therefore was an interested party in these drug trials. The Petitioner further states that in terms of the said guidelines the 01<sup>st</sup> Respondent was not entitled to interfere with the decision-making process of the said Committee.

The Petitioner says that, while trying to persuade the Ethics Review Committee to grant ethical clearance to these drug trials, the 01<sup>st</sup> Respondent tried to mislead the Committee by saying that the Ministry of Health had given clearance and therefore the Committee should follow suit. The Petitioner further says that this was false. The members of the Ethics Review Committee considering the ethical issues that arose thought, it was in the best interest of the human subjects who would be involved in the research to seek further opinions. The 01<sup>st</sup> Respondent being angered by the refusal of the Ethics Review Committee to accede to his unreasonable and illegal demand and with a view of getting the requisite approvals for the drug trials purported to dissolve the Ethics Review Committee by letter dated 20.01.2011 with immediate effect. The Petitioner or any of the members of the Ethics Review Committee was not informed of any reason as to why suddenly the said Committee was dissolved.

The Petitioner argues that the said decision of the 01<sup>st</sup> Respondent is ultra-vires. The powers of the 01<sup>st</sup> Respondent, made for a collateral purpose, mala-fide and contrary to law. The members of the Ethics Review Committee acted by the guidelines of the FERCSL and in the best interests of the human subjects that were to be subjected to invasive procedures. The Petitioner further states that this was by the Guidelines set out by the Sri Lanka Medical Council about granting ethical clearance. The Petitioner believes that the investigators had informed the Sub Committee on Clinical Trials of the Cosmetics Devices and Drugs Authority that the Ethics Review Committee of the University of Kelaniya had already granted ethical clearance for these proposals and therefore when they became aware that second opinions were sought in respect of the said proposals, the Investigators became agitated.

The Petitioner states that the Management Committee of the Faculty of Medicine was held on 20.01.2011. At the said meeting the Dean announced that the said committee was dissolved and the reasons given by the Respondent for the dissolution of the said Committee is



contained in the minutes of the meeting of the Management Committee of the Faculty of Medicine dated 20.01.2011.

The minutes of the said Management Committee meeting dated 20.01.2011, inter-alia as follows;

#### 2011 - 01 -03 Deans Announcements

##### 03.01 Ethics Committee (EC)

The Dean informed the Committee that he has dissolved the Ethics Committee with immediate effect in the best interests of the faculty. Prof. P.L. Jayawardena and Dr. Deepthi de Silva wanted to know the reasons for the dissolution. The Dean apprised the committee of the following:

1. The Dean has received a document with signatures of 47 academic staff members complaining about the conduct of the Ethics Committee.
2. The Dean has received resignations of 4 academic staff members of the Ethics Committee stating that it is difficult and unpleasant to render their services to the Ethics Committee.
3. The Dean has received numerous complaints from consultants of the high handedness of the Ethics Committee. He indicated that he has received a letter from Dr. Chalukya Gunasekara regarding the treatment meted out to one of her SRs.
4. The Dean informed the Committee that he attended the Ethics Committee meeting held on 18<sup>th</sup> January at 11:00 am in the Board Room of the Faculty of Medicine, University of Kelaniya and informed the Committee of his observations given below
  - a. The Dean believed that the Ethics Committee was disregarding the mandate given by the Faculty Board of Medicine about only considering ethical issues as opposed to scientific issues unless there are gross issues concerning the scientific merit of a proposal.
  - b. The Dean believed that the Ethics Committee was conducting its business in a very haughty way assuming that it was the ivory tower of research in the faculty. He stated that this should not be the attitude of the Ethics Committee that reflects poorly on the faculty.
  - c. The Dean thought that the Ethics Committee was unable to articulate ethical issues.

- d. The Dean believed that the Ethics Committee lacked insight into understanding issues of multi-centre clinical trials. He stated that the Ethics Committee was trying to modify outcomes and methodology which cannot be done in multi-centre trials if results are to be pooled. A basic understanding of these fundamental issues was a major drawback of the Ethics Committee.
- e. The Dean also stated that the Ethics Committee was reluctant to make a decision and was referring everything for second opinions. He stated that he felt that it appeared to be a delaying tactic or that the Ethics Committee was incompetent.

During the ensuing discussion, the following was also highlighted;

- a Some academic staff members were submitting proposals for ethical clearance to other committees to avoid undue delays and hassles.
- b The Ethics Committee in the past has instructed researchers to change titles of projects and even use alternate scales to measure outcomes which are well beyond the mandate of the committee.

Dr. Deepthi de Silva alleged that the dissolution of the Ethics Committee is related to 5 commercial trials proposals submitted for ethical clearance. It was pointed that these proposals have been approved by the Ministry of Health in Sri Lanka and other countries such as the USA, Belgium etc and that these proposals are not isolated ones that have been rejected by other ethics committees.

Prof. Pushpa Jayawardena and Dr. Deepthi De Silva requested for an inquiry by an independent person. The Dean stated that he would look into the matter.

Dr. Chrishantha Abeysena requested that the minutes be recorded ad verbatim.

The Dean announced the new committee comprising the following members;

- |                                  |                             |
|----------------------------------|-----------------------------|
| 1. Prof. L.S.S.Salgado           |                             |
| 2. Dr. Sureka Chakrewarthy       | 9. Prof. A. Pathmeswaran    |
| 3. Dr. Nirmala Perera (Convenor) | 10. Prof. W. Abeyewickreme  |
| 4. Dr. Channa Ranasinha          | 11. Prof. Ranjan Premaratne |
| 5. Dr H.S.A. Williams            | 12. Dr. Shehan Williams     |
| 6. Dr. Shyamini Hettiarachchi    | 13. Dr. Priyantha Perera    |
| 7. Mrs. Kumari Perera            | 14. Dr. Nilmini Gunawardena |
| 8. Prof. K. Karunathileke        | 15. Rev. Roshan Fernando    |

The Petitioner states that the matters set out by the 01<sup>st</sup> Respondent for dissolving the committee is erroneous and is contrary to the guidelines issued by the FERCSL and Sri Lanka Medical Council. The decision to dissolve the Committee was taken by the 01<sup>st</sup> Respondent without allowing any of the members of the Committee to explain their position and none of the alleged documents referred to therein was shown to the members. Thus, the basic norms of fairness were grossly violated. The Petitioner verily believes that some of these documents were fabricated by interested persons to dissolve the Ethics Review Committee and get those Drug Trials approved. The Petitioner complained about this unjust treatment meted out to her by bringing this to the notice of FERCSL the umbrella organization named Forum of Ethics Review Committees, Sri Lanka by letter dated 27.01.2011. It was copied to Director Drug Regulatory Authority, President Sri Lanka Medical Council and Chairpersons of Ethics Review Committees of Colombo, Sri Jayawardenapura, Peradeniya and Ruhuna Medical Faculties to bring to their notice the scandalous affairs happening at the Faculty of Medicine, University of Kelaniya and also to ensure that the proper guidelines relating to the ethical dimension in using human subjects are adhered to.

The Petitioner further states that a meeting of the Faculty Board of the University of Kelaniya was held on 03.02.2011. In the agenda sent to the Members of the Faculty Board, it was not mentioned that there was anything related to the Ethics Review Committee being discussed at that meeting. The faculty Board consists of about 88 members. At the said meeting only the 01<sup>st</sup> to 53<sup>rd</sup> Respondents as well as the Petitioner participated and the 01<sup>st</sup> Respondent intimated to them that the Ethics Review Committee had been dissolved and a new committee had been appointed. The Faculty Board approved the said decision of the 01<sup>st</sup> Respondent.

The Petitioner's argument was, that the said decision of the Faculty Board is contrary to law, unreasonable based on misrepresentations. It is null and void and of no force or avail in law.

The Petitioner states that after the Ethics Review Committee was dissolved by letter dated 20.01.2011 the 01<sup>st</sup> Respondent purported to appoint another Committee. Normally an opportunity is given to persons who are interested to apply to be members of the Ethics Review Committee. The Faculty Board should appoint suitable persons from them. But in this instance, the impugned appointments did not follow the criteria of transparency and the 01<sup>st</sup> Respondent purported to appoint the said Ethics Review Committee on his own. Thereafter the five drug trials referred to above in respect of which second opinions had been called for by the dissolved Ethics Review Committee, had been once again reviewed by the new Ethics Review Committee. The Petitioner says that she reliably understands that the new Ethics Review Committee acted in post-haste and approved the said drug trials unconditionally thereby jeopardizing the health of the human subjects that would be subjected to serious health risks which cause concern to the dissolved Ethics Review Committee.

The petitioner further states that the said ethical clearance had been granted without considering and contrary to the specific mandatory guidelines set out by the FERCSL and the Sri Lanka Medical Council. The Petitioner states that without addressing the ethical issues raised by the dissolved Ethics Review Committee, the ethical clearance could not have been granted in respect of those five drug trials under the prevailing ethical clearance regime. The Petitioner by letter dated 24.01.2011 brought this matter to the notice of the Vice-Chancellor and subsequently by letter dated 26.02.2011 her Counsel also requested the 54<sup>th</sup> Respondent

(Vice-Chancellor) to look into this matter and grant relief and ensure that proper procedure is followed. But the 54th Respondent (Vice-Chancellor) failed and neglected to look into the matter.

The Petitioner states that non-compliance with strict guidelines applicable to granting of ethical clearance in respect of research projects wherein human subjects are used, can cause serious risks to lives and limbs of the said human subjects and the authorities concerned have a public and constitutional duty to ensure that research using human subjects is properly carried out. The 01<sup>st</sup> to 54<sup>th</sup> Respondents who have a public duty as aforesaid has failed and neglected to ensure that due compliance is made in respect of this Statutory and Public duty. The Petitioner states that the Senate of the University of Kelaniya has a statutory right to control the research that is being done at the university and with that in view to ensure duly constituted Ethics Review Committee is functional and also that the proper procedures in granting ethical clearance is observed.

The Petitioner further argues that she has always acted by the guidelines issued by the FERCSL and the Sri Lanka Medical Council in discharging her duties as the Member and the Chairperson of the Ethics Review Committee. The dissolution of the Ethics Review Committee presided by her cause's grave repercussions as far as her integrity and her career in the University is concerned and therefore, she seeks mandates like Writs of Certiorari to quash the decisions of the 01<sup>st</sup> Respondent, dated 20.01.2011 and the decisions of the Faculty Board consisting the 01<sup>st</sup> to 53<sup>rd</sup> Respondents, dated 03.02.2011. The Petitioner further states that in the circumstances this is a fit and proper case where this Court should issue mandates like Writs of Certiorari quashing the decisions of the 01<sup>st</sup> Respondent dated 20.01.2011 dissolving the Ethics Review Committee and appointing a new Ethics Review Committee and the decisions of the Faculty Board consisting the 01<sup>st</sup> to 53<sup>rd</sup> Respondents of the Medical faculty of the University of Kelaniya dated 03.02.2011 dissolving the said Ethics Review Committee and appointing a new Ethics Review Committee.

The Petitioner states that the dissolved Ethics Review Committee prepared Standard Operating Procedures for the functioning of the Ethics Review Committee of the Faculty of Medicine University of Kelaniya and presented it to the Faculty Board for approval on 15.12.2010. This is a fit and proper case where this Court should issue mandates in the nature of Writs of Mandamus directing the members of the Faculty Board to take steps to approve the said Standard Operating Procedures and to direct the Vice-Chancellor and the members of the Faculty Board of the Faculty of Medicine, the University of Kelaniya to take steps to appoint a new Ethics Review Committee by the law.

The Petitioner states that all her endeavours to ensure that the University of Kelaniya adhered to the proper procedures especially in granting approvals to international multi-centre drug trials had fallen on deaf ears. The authorities in the Faculty of Medicine in the University of Kelaniya have failed to ensure that medical research and drug trials are conducted under applicable laws, rules and guidelines as set out above and they have neglected to perform their public duty. Therefore, the Petitioner was compelled to seek relief from this Court in her capacity as well as in the Public Interest.

the Petitioner prays inter-alia that;

- I. Grant and issue a mandate in the nature of a Writ of Certiorari quashing the decision of the 01<sup>st</sup> Respondent dated 20.01.2011 dissolving the Ethics Review Committee of the Medical faculty of the University of Kelaniya,
- II. Grant and issue a mandate in the nature of a Writ of Certiorari quashing the decision dated 03.02.2011 approving the dissolution of the Ethics Review Committee made by the members of the Faculty Board of the Medical faculty of the University of Kelaniya consisting of the 01<sup>st</sup> to 53<sup>rd</sup> Respondents,
- III. Grant and issue a mandate in the nature of a Writ of Certiorari quashing the decision dated 20.01.2011 of the 01<sup>st</sup> Respondent appointing a new Ethics Review Committee.
- IV. Grant and issue a mandate in the nature of a Writ of Certiorari quashing the decision dated 03.02.2011 of the members of the Faculty Board of the Faculty of Medicine of the University of Kelaniya appointing a New Ethics Review Committee.
- V. Grant and issue a mandate in the nature of a Writ of Mandamus directing the members of the Faculty Board of the Faculty of Medicine of the University of Kelaniya to take steps to approve the Standard Operating Procedures submitted by the dissolved Ethics Review Committee on 15.12.2010.
- VI. Grant and issue a mandate in the nature of a Writ of Mandamus directing the members of the Faculty Board of the Medical faculty of the University of Kelaniya and the Vice-Chancellor the 54<sup>th</sup> Respondent and the University of Kelaniya the 55<sup>th</sup> Respondent to appoint an Ethics Review Committee by the law,

Objections of the 18<sup>th</sup>, 24<sup>th</sup>, 26<sup>th</sup> and 31<sup>st</sup> Respondents, Objections of the 59<sup>th</sup>, 61<sup>st</sup> and 65<sup>th</sup> Respondents and Objections of the 01<sup>st</sup>, 04<sup>th</sup>, 06<sup>th</sup>, 07<sup>th</sup>, 09<sup>th</sup>, 10<sup>th</sup>, 11<sup>th</sup>, 13<sup>th</sup>, 15<sup>th</sup>, 16<sup>th</sup>, 17<sup>th</sup>, 19<sup>th</sup> to 23<sup>rd</sup>, 25<sup>th</sup>, 28<sup>th</sup>, 32<sup>nd</sup>, 33<sup>rd</sup>, 36<sup>th</sup> to 43<sup>rd</sup>, 45<sup>th</sup>, 46<sup>th</sup>, 47<sup>th</sup>, 49<sup>th</sup> to 53<sup>rd</sup>, 54<sup>th</sup>, 55<sup>th</sup>, 60<sup>th</sup> and 63<sup>rd</sup> Respondents filed separately in 3 occasions.

The 18<sup>th</sup>, 24<sup>th</sup>, 26<sup>th</sup> and 31<sup>st</sup> Respondents says that they are raising preliminary objections.

- (a) The Petitioner is guilty of laches.
- (b) The Petitioner has misrepresented facts.
- (c) The application of the Petitioner is an action of private nature and therefore not governed by any statutes of the Democratic Socialist Republic of Sri Lanka. As such the Petitioner is not entitled to invoke the writ jurisdiction.
- (d) The Petitioner has failed to make a prior demand of the relief prayed for in paragraphs (f) and (g) of the petition. These Respondents state further that the Petitioner has no

statutory right to obtain the relief prayed for in paragraphs (f) and (g) of the petition of the Petitioner.

(e) The Petitioner has failed to make necessary parties as Respondents to this Application.

#### Ethics Review Committees of Sri Lanka

These Respondents state in Sri Lanka there exists no statutory or any other regulatory framework which regulates the creation, functioning, governance or dissolving of Ethics Review Committees; and have been created and run based on the needs of the institutions concerned. These Respondents state that in the said circumstances Ethics Review Committees in Sri Lanka including the Ethics Review Committee which is the subject matter of this application have,

- (a) not been created by statute,
- (b) are informal,
- (c) have no statutory powers and
- (d) have no regulatory framework which governs their conduct.

These Respondents state that Ethics Review Committee has been appointed and dissolved by the Dean of the Faculty of Medicine. Traditionally and historically the Faculty Board of the Faculty of Medicine, University of Kelaniya ratifies the decisions of the Dean. The appointment and dissolution of the Ethics Review Committees were done by the Dean as the Head of the Faculty and the head of the Faculty Board of the University.

The Ethics Review Committee which is the subject matter of this application has no regulatory framework which is uniformly accepted which governs their conduct. As such, each Ethics Review Committee adopts, rules and regulations of their choice to regulate their affairs. Generally, Ethics Review Committees comprise persons of the medical profession and laypersons. These Respondents state that the Ethics Review Committee which is a subject matter of this application also consisted of laypersons not qualified in the medical professions such as the 56<sup>th</sup> and 57<sup>th</sup> Respondents. An Ethics Review Committee requires to act professionally and with competence in discharging their duties and not delegate their role to any other body of persons.

These Respondents state that accordingly the Petitioner, 8<sup>th</sup>, 12<sup>th</sup>,16<sup>th</sup>, 26<sup>th</sup>, 56<sup>th</sup> to 65<sup>th</sup> Respondents were nominated by the 01<sup>st</sup> Respondent to the Ethics Review Committee on the 06.07.2010. The Petitioner, 8<sup>th</sup>, 12<sup>th</sup>,16<sup>th</sup>, 26<sup>th</sup>, 56<sup>th</sup> to 65<sup>th</sup> Respondents nomination by the 01<sup>st</sup> Respondent to the Ethics Review Committee was ratified by the Faculty Board of the Faculty of the Medicine University of Kelaniya on 05.08.2010. These Respondents state that the said Ethics Review Committee is an informal committee appointed by the Dean.

These Respondents state that thereafter the Petitioner was selected by the 8<sup>th</sup>, 12<sup>th</sup>,16<sup>th</sup>, 26<sup>th</sup>, 56<sup>th</sup> to 65<sup>th</sup> Respondents to function as the chairperson of the said Ethics Review Committee.

These Respondents state that the Ethics Review Committee of the Faculty of the Medicine University of Kelaniya is also

- (a) created not by statute,

- (b) is informal,
- (c) has no statutory powers,
- (d) has no regulatory framework which governs their conduct.

These Respondents state that traditionally and historically the Ethics Review Committee of the Faculty of the Medicine University of Kelaniya was thus appointed and dissolved by the Dean of the Faculty of Medicine of the University of Kelaniya. The said decision was thereafter ratified by the Faculty Board of the Faculty of the Medicine University of Kelaniya.

Process of obtaining ethical clearance from an Ethics Review Committee for a drug to be used for clinical research as standard practice when there is a proposal submitted to the Ethics Review Committee for ethical clearance the committee would assign 3 members of the said Committee as Reviewers for the evaluation of the proposals submitted. The findings of the Reviewers and their comments are thereafter discussed at the Ethics Review Committee meeting before final ethical clearance is to be granted. With the appointment of the Petitioner and 8<sup>th</sup>, 12<sup>th</sup>, 16<sup>th</sup>, 26<sup>th</sup>, 56<sup>th</sup> to 65<sup>th</sup> Respondents as the Ethics Review Committee of the Faculty of Medicine, the 01<sup>st</sup> Respondent received the following complaints and resignations about the said Ethics Review Committee due to its incompetence and dysfunctional behaviour.

The 01<sup>st</sup> Respondent and the 26<sup>th</sup> Respondent received many complaints about the Ethics Review Committee's dysfunctional behaviour from consultants and also complaints from some members of the Faculty Board, concerning their disappointment in the attitudes and actions of the said Ethics Review Committee. By complaint dated 17.01.2011, there were 57 members of the Faculty Board of the Faculty of Medicine, highlighted the inefficiency, arbitrary, over-intrusive and obstructions in its dealings with the study investigations and adjudications of study protocols of the said Ethics Review Committee. The said members of the Faculty Board have also stated that the said Ethics Review Committee appears to be biased against the sanction of multicentre, international clinical trials which is based on ideological rather than scientific reasons, and is dysfunctional, which threatens to discourage the spirit of inquiry and destroy the culture of research in the Faculty of Medicine. The said faculty board members had also requested the 01<sup>st</sup> Respondent to address the said issue urgently.

By letter dated 18.01.2011 the Consultant of the Dermatology Unit of the Colombo North Teaching Hospital, Ragama, Dr. Chalukya Gunasekera complained of how a research project which was sent to the said Ethics Review Committee for approval was disallowed, even though the said research project was approved by the Board of Study in Dermatology of the Post Graduate Institute of Medicine. In the said letter Dr. Chalukya Gunasekera also stated that the said research project involved obtaining of skin biopsy which is considered to be the most basic tool of investigation to a dermatologist. The research applicant was repeatedly summoned by the said Committee to give explanations and was instructed to make erroneous modifications which resulted in the researcher abandoning the said research project in disgust. Dr. Chalukya Gunasekera in the said complaint had informed that the said Committee failed to understand the subject put forward to them.

It is important to note that the 01<sup>st</sup> Respondent received four letters of resignation from 26<sup>th</sup> Respondent, 59<sup>th</sup> Respondent, 61<sup>st</sup> Respondent and the 65<sup>th</sup> Respondents who were members

of the said Ethics Review Committee due to the undue delays, a trend of vacillation, the lack of smooth functioning of the Committee and the state of dysfunction.

The 26<sup>th</sup> Respondent while functioning in the said Ethics Review Committee found that;

- (a) the Petitioner was stultifying the approval being granted for clinical and drug trials due to her incompetence and lack of knowledge,
- (b) the Petitioner was unduly delaying all approvals for clinical and drug trials,
- (c) there were several complaints about the Petitioner by consultants and researchers whereby the researchers had given up their respective research assignments,
- (d) the Ethics Review Committee was on numerous occasions postponing approval for clinical and drug trials and considering extraneous factors which are not within the preview of the Ethics Review Committee,
- (e) even though clinical and drug trials had received approval from the regulatory authorities in reference countries the Petitioner refused to grant approval for such clinical and drug trials,
- (f) the Petitioner was not acting in the best interest of the Ethics Review Committee.

These Respondents state that on or around 30.11.2010 five clinical and drug trials were forwarded to the said Ethics Review Committee from the Clinical Trials Unit of the Department of Pharmacology. The said clinical and drug trials were to be carried out internationally, performed simultaneously and were multicenter drug trials which Sri Lanka was also chosen as one of the trials centres. In the event the clearance for the said clinical and drug trials are unduly delayed, Sri Lanka will not be allowed to participate in the said clinical and drug trials. The nonparticipation results in Sri Lanka losing out in scientific research, the free infrastructure provided to the hospitals where the trials are performed and grants were given for carrying out the said clinical and drug trials.

The said clinical and drug trials have received approval from the regulatory authorities in reference countries such as the United States of America, United Kingdom, countries governed by the European medical authority, Japan, Canada, New Zealand, Singapore, Malaysia, South Korea, South Africa and Taiwan. One of the aforesaid trials, A Phase 2 Randomized Open-label (with Blinded Plasminogen Activator and Placebo Control Groups) Study to Evaluate the Effects of Different Intra-thrombus Infusion Regimens of Plasmin (Human) Compared to Plasminogen Activator and Placebo in Patients with Acute Lower Extremity Native Artery or Bypass Graft Occlusion which was referred to the said Ethics Review Committee was referred by the said committee to the Petitioner, 63<sup>rd</sup> and 64<sup>th</sup> Respondents for considerations. Out of the Petitioner, 63<sup>rd</sup> and 64<sup>th</sup> Respondents, the 64<sup>th</sup> Respondent approved and cleared the said clinical trial while the 63<sup>rd</sup> Respondent has indicated that the application is in proper order and complete but did not possess sufficient knowledge to make a clear decision as she was a non-medical person.



The 24<sup>th</sup> Respondent and Dr. Ruwan Fonseka, Consultant Vascular Surgeon, the coordinating principal investigator in one of the drug trials who attended an Ethics Review Committee meeting on invitation on the 13.01.2011 and 18.01.2011 explained all queries relating to the study of the trial satisfactorily.

Concerning the other clinical and drug trials, out of the 3 Reviewers appointed by the said Ethics Review Committee, the 65<sup>th</sup> and 16<sup>th</sup>, Respondents have approved and cleared the said clinical trials while the 58<sup>th</sup> Respondent has not approved or disapproved the said clinical trials. Despite the above, the Petitioner as chairperson continuously postponed the decision to clear or reject the said clinical and drug trials. These Respondents state that due to the said postponements, Sri Lanka was to lose the opportunity to conduct the said clinical and drug trials which were to take place internationally, simultaneously in multi centres. In the said circumstances at the Ethics Review Committee meeting held on 18.01.2011, the 01<sup>st</sup> Respondent has requested the said Ethics Review Committee to decide about the aforesaid clinical and drug trials without postponing the decision making. These 18<sup>th</sup>, 24<sup>th</sup>, 26<sup>th</sup> and 31<sup>st</sup> Respondents state that the Petitioner as chairperson did not consider the said request. The Ministry of Health has independently approved for the said clinical and drug trials.

The 18<sup>th</sup>, 24<sup>th</sup>, 26<sup>th</sup> and 31<sup>st</sup> Respondents state that the 1st Respondent thereafter dissolved the said Ethics Review Committee and on the 20th of January, 2011 considering the following factors.

- a. The petition was signed by 47 members of the Faculty Board, and members of the said Committee.
- b. The resignation of 4 key members of the Ethics Review Committee.
- c. Complaints made by consultants and members of the Faculty Board.
- d. The Committee was disregarding the mandate given by the Faculty Board of Medicine where only ethical issues were considered and not scientific issues beyond the expertise of an Ethics Review Committee.
- e. The Ethics Review Committee was conducting its business in a very haughty way with an assumption that it was the ivory tower of research of the faculty.
- f. The Ethics Committee was unable to articulate ethical issues.
- g. The Committee lacked insight into understanding issues relating to clinical research of multi-centre clinical trials, and the said committee was trying to modify outcomes and methodology which cannot be done in multi-centre trials.
- h. The lack of basic understanding of fundamental issues.
- i. The inability of the Committee to make decisions and to send proposals for second opinions habitually gives a clear glimpse of the committee being incompetent.

The 1<sup>st</sup> Respondent's decision to dissolve the said Ethics Review Committee was endorsed by the members of the Faculty Board of the Faculty of Medicine, including members of the Faculty Board who were members of the said Ethics Review Committee such as the 08<sup>th</sup>, 12<sup>th</sup>, 16<sup>th</sup>, 26<sup>th</sup> and 63<sup>rd</sup> Respondents. Even after the 01<sup>st</sup> Respondent had dissolved the said Ethics Review

Committee, the 01<sup>st</sup> Respondent has received numerous complaints from certain consultants of the high-handedness of the said Ethics Review Committee.

These Respondents state that concerning query raised by the Sri Lanka Medical Council the 01<sup>st</sup> Respondent by letter dated 07.04.2010 has given reasons as to why the aforesaid Ethics Review was dissolved. Thereafter the 01<sup>st</sup> Respondent has appointed the 2<sup>nd</sup>, 6<sup>th</sup>, 11<sup>th</sup>, 19<sup>th</sup>, 21<sup>st</sup>, 25<sup>th</sup>, 28<sup>th</sup>, 33<sup>rd</sup>, 42<sup>nd</sup>, 48<sup>th</sup>, 50<sup>th</sup>, and 66<sup>th</sup> Respondents as members of the Ethics Review Committee.

The 59<sup>th</sup>, 61<sup>st</sup> and 65<sup>th</sup> Respondents say that the Ethics Review Committee of the Faculty of Medicine, University of Kelaniya, was lawfully dissolved on 20.01.2011. The dissolution was approved and endorsed and ratified by the Faculty Board after the Petitioner was heard. For the said meeting the Petitioner, 08<sup>th</sup>, 12<sup>th</sup>, 16<sup>th</sup>, 26<sup>th</sup>, 63<sup>rd</sup> Respondents, who are members of the said Ethics Review Committee, were present. At the Faculty Board Meeting of 01.03.2011, at which meeting the 08<sup>th</sup>, 26<sup>th</sup>, 56<sup>th</sup>, 58<sup>th</sup>, 61<sup>st</sup>, 63<sup>rd</sup>, 64<sup>th</sup> and 65<sup>th</sup> Respondents who are members of the said Ethics Review Committee were present. The decision to dissolve the Ethics Review Committee was lawfully approved and ratified and endorsed by the Faculty Board. Hence the said dissolution of the Ethics Review Committee is valid in law.

Answering the averments contained in paragraph 9 of the Petition these respondents only admit that the 02<sup>nd</sup>, 06<sup>th</sup>, 11<sup>th</sup>, 19<sup>th</sup>, 21<sup>st</sup>, 25<sup>th</sup>, 28<sup>th</sup>, 33<sup>rd</sup>, 42<sup>nd</sup>, 48<sup>th</sup>, 50<sup>th</sup> and 66<sup>th</sup> Respondents are members of the present Ethics Review Committee. They are also members of the Faculty Board. The Ethics Review Committee was lawfully appointed and was approved or endorsed and ratified by the Faculty Board at its meeting held on 03.02.2011 and 01.03.2011. The 02<sup>nd</sup>, 06<sup>th</sup>, 11<sup>th</sup>, 19<sup>th</sup>, 21<sup>st</sup>, 25<sup>th</sup>, 28<sup>th</sup>, 33<sup>rd</sup>, 42<sup>nd</sup>, 48<sup>th</sup> and 50<sup>th</sup> Respondents were present at the faculty board meeting on that day. The appointment of the present Ethics Review Committee is valid in law.

The 59<sup>th</sup>, 61<sup>st</sup> and 65<sup>th</sup> Respondents state that the powers, duties and functions of the Faculty Board are set out in section 48(3) of the Universities Act including the power to appoint committees. These Respondents state that during the period the Petitioner was the Chairperson of the Ethics Review Committee several complaints were made concerning the conduct of the said Committee.

The Petitioner was the chairperson of the Ethics Review Committee and was unable to carry out the duties assigned to it and was dysfunctional in as much as vacillation and indecisiveness, undue delays in making decisions related to the applications submitted and hostile and unreceptive conduct of some members of the committee, the 59<sup>th</sup> and 65<sup>th</sup> Respondents tendered their resignation by letters dated 18.01.2011 and 17.01.2011 respectively. Further, the 61<sup>st</sup> Respondent too resigned from the said committee, due to the lack of smooth functioning of the said committee. The 26<sup>th</sup> Respondent who was the secretary of the said committee also tendered her resignation by letter 14.01.2011.

The 59<sup>th</sup>, 61<sup>st</sup> and 65<sup>th</sup> Respondents state that Dr. Ruwan Fonseka, Consultant Vascular Surgeon Coordinating principal investigator of the study and Professor Asita de Silva, National coordinator of the study, were present at the said meeting and clarified all issues raised by some members of the Ethics Review Committee. Dr. Ruwan Fonseka and Professor Asita de Silva further informed the committee that the same trial had already received approval from

ethic committees and regulatory authorities in many countries governed by the European Medicines Authority including Spain and Germany. The evidence of these approvals had been submitted with the application form. In addition to the verbal explanation provided by Dr. Ruwan Fonseka at the said meeting, he also submitted to the committee a detailed written submission dated 13th January 2011.

These Respondents annexed certified copies of the approvals granted by various countries for the Phase II, Randomized, Open-Label (With blinded Plasminogen Activator and Placebo Control Group) Study to evaluate the effects of different intra-thrombus infusion regimens of Plasmin (Human) compared to plasminogen activator and placebo in patients with acute lower extremity native artery or bypass graft occlusion. Subject to the above these Respondents deny the averments contained in paragraph 31 of the Petition.

Also, 59<sup>th</sup>, 61<sup>st</sup> and 65<sup>th</sup> Respondents state that Prof Asita de Silva, of the Clinical Trials Unit, Faculty of Medicine, University of Kelaniya, was present at the meeting held on 18.01.2011 and answered all queries raised, most of which did not relate to any ethical issues related to the trials. At the said meeting Prof Asita de Silva informed the committee that the same trials have received approval from ethics committees and regulatory authorities in many countries governed by the European Medicines Authority including the United Kingdom.

The said Ethics Review Committee was dissolved and the present Ethics Review Committee was appointed and that said dissolution and appointment was approved and endorsed and ratified by the faculty board at the faculty board meetings of 03.02.2011 and 01.03.2011. This 59<sup>th</sup>, 61<sup>st</sup> and 65<sup>th</sup> Respondents state that the Ethics Review Committee of which the Petitioner was chairperson was dissolved inter alia for reasons of several complaints received about the conduct and attitude of the committee, the inability to decide without referring for a second opinion, resignation by four members of the ethics review committee for the reason that it was difficult and unpleasant to render their services to the committee and the conduct and attitude of some members of the committee and the signed petition of over 45 members of the Faculty Board requesting the Dean to take appropriate action.

These 59<sup>th</sup>, 61<sup>st</sup> and 65<sup>th</sup> Respondents state that;

- (a) the Petitioner is guilty of delay and aches.
- (b) the Petitioner has suppressed material facts;
  - i. the Petitioner has wilfully suppressed from this Court that the said dissolution of the Ethics Review Committee and the appointment of the new Ethics Review Committee was approved and endorsed and ratified by the Faculty Board at the Faculty Board Meeting of 01.03.2011.
  - ii. the Petitioner has wilfully suppressed from this Court the material fact that these Respondents resigned from the said Ethics Review Committee and the reasons for such resignation.

(c) The application of the Petitioner seeking Writs in the nature of Writ of Certiorari and Mandamus is misconceived in fact and law.

(d) The Petitioner is not entitled to the relief prayed for.

the 01<sup>st</sup>, 04<sup>th</sup>, 06<sup>th</sup>, 07<sup>th</sup>, 09<sup>th</sup>, 10<sup>th</sup>, 11<sup>th</sup>, 13<sup>th</sup>, 15<sup>th</sup>, 16<sup>th</sup>, 19<sup>th</sup>- 23<sup>rd</sup>, 25<sup>th</sup>, 28<sup>th</sup>, 32<sup>nd</sup>, 33<sup>rd</sup>, 36<sup>th</sup> to 43<sup>rd</sup>, 45<sup>th</sup> to 47<sup>th</sup>, 49<sup>th</sup> to 55<sup>th</sup> and 60<sup>th</sup> to 63<sup>rd</sup> Respondents state that the petitioner was attached to the University of Kelaniya as a Professor in Public Health.

The Dean of the Faculty of Medicine, members of the Faculty Board, Vice-Chancellor and the University of Kelaniya have been named as Respondents to this application. The members of the Ethics Review Committee, which was dissolved and the present members of the said Ethics Review Committee have also been named as Respondents to this application.

Universities Act, No. 16 of 1978

48. (1) Each Faculty of a University shall consist of the Departments of Study assigned to that Faculty under the provisions of this Act. Faculties of the University. [S 48(1), 7 of 1985]

(1A) Each Faculty of a University shall have a Faculty Board which shall consist of the following persons: - [Inserted a new section as 48(1A), 7 of 1985]

(a) the Dean of that Faculty;

(b) all permanent Senior Professors, Professors, Associate Professors, Senior Lecturers and Lecturers of the Departments of Study comprising the faculty; [S 48(1A)(b), 57 of 2009]

(c) two members elected by the Lecturers (Probationary) of the faculty from among such Lecturers; [S 48(1A) (c), 57 of 2009]

(d) two members of the permanent staff attached to the faculty and who are imparting instructions, other than those referred to in paragraphs (b) and (c), elected from among such staff members; [S 48(1A) (d), 57 of 2009]

(e) two students elected by the students of the faculty from among their number; and

(f) three persons not being members of the staff of the University elected by the Faculty Board from among persons of eminence in the areas of study relevant to the faculty.

(2) A member elected under paragraph (e) of subsection

(1) shall hold office as a member for one year, and any other elected member for three years, reckoned from his date of the election and shall be eligible for re-election.

(3) Subject to the provisions of this Act, a Faculty Board shall exercise, perform and discharge the following powers, duties and functions- [S 48(3), 7 of 1985]

(i) to consider and report on any matter referred to it by the Senate;

(ii) subject to the control of the Senate, to regulate matters connected with teaching, examinations and research in the Departments of Study in the Faculty;

(iii) to present recommendations and reports to the Senate on all matters connected with the courses of study and examinations in the faculty;

(iv) to appoint committees, which may include persons other than members of the faculty, to consider and report on any special subject or subjects; and

(v) to recommend to the Senate persons suitable for appointment as examiners.

(4) (i) The Dean shall preside at all meetings of the Faculty Board; [S 48(4), 7 of 1985]

(ii) The members elected under paragraph (e) of subsection (1A) shall be excluded from the proceedings of any meeting of the Faculty Board relating to the election of the Dean under section 49 of this Act, and to examinations and connected matters and any such meeting shall, notwithstanding such exclusion, be deemed to have been duly held.

48A (1) Any University may with the concurrence of the Commission establish a Faculty of Graduate Studies to promote research and provide courses of study leading to higher degrees and other academic distinctions in the several Faculty of Graduate Studies of the University and the Dean thereof. [Inserted a new section as

branches of learning within such University; 48A, 7 of 1985]

- (2) The Commission shall determine by Ordinance the structure, powers, duties and functions of the faculty and the procedure for the appointment of the election of the Dean of such Faculty;
- (3) The Dean of the Faculty of Graduate Studies shall be a full-time officer of the University and the academic and administrative Head of such Faculty.
49. (1) There shall be a Dean of each Faculty who shall be a full-time officer of the University and the academic and administrative Head of that Faculty. The Dean shall be elected by the Faculty Board from among the Heads of the Departments of Study comprising such Faculty, and shall, when so elected, cease to be the Head of the Department of Study concerned. The Dean of the Faculty.  
[S 49(1), 7 of 1985]
- (2) The Dean shall, subject to the provisions of any appropriate Instrument, hold office for three years reckoned from the date of his election and shall, unless removed from office, be eligible for re-election.
- (3) Where owing to leave of absence, illness or other cause, the Dean of a Faculty is temporarily unable to perform the duties of his office for a period not exceeding three months, the Vice-Chancellor shall appoint another Head of a Department of that Faculty to act in the post of Dean, for such period. Where however a Dean of a Faculty retires or resigns, or is for any other reason unable to perform the duties of his office for a period exceeding three months, the post of Dean of that Faculty shall be deemed to be vacant, and a new Dean shall be elected by subsection (1). [S 49(3), 7 of 1985]  
[Deans of Universities to cease to hold office on the coming into operation of this section. This section was effective till 18.02.1985, 7 of 1985]

Notwithstanding anything in this Act any Dean of a University of University College holding office at the time of coming into operation of this Act, shall hold office for the unexpired

portion of the term of his office.

These Respondents further state that;

- (a) as stipulated in section 48(1A) of the Universities Act, each Faculty of a University has a Faculty Board which consists of the Dean of the Faculty, all permanent Professors, Associate Professors, Senior Lecturers and Lecturers of the Departments of Study comprising the said Faculty, two members elected by the permanent Assistant Lecturers, two members of the permanent staff, two students elected by the students of the Faculty and three persons, who are not members of the staff of the University, elected by the Faculty Board.
- (b) The powers, duties and functions of the Faculty Board are stipulated in section 48(3) of the Universities Act, including the power to appoint committees.
- (c) it is further stipulated in section 48(4) (i) of the University Act that the Dean is required to preside at meetings of the Faculty Board.
- (d) As stipulated in section 49(1) of the said Act, the Dean of a Faculty is the Academic and Administrative Head of the Faculty and is elected by the Faculty Board from the Heads of Departments of a Faculty.

The petitioner was intimated in writing of the decision to appoint the petitioner as a member of the Ethics Review Committee by way of a document marked as P6 by the petitioner and the persons mentioned therein too were appointed as members of the said Ethics Review Committee. Consequent to the appointment of the members of the Ethics Review Committee, the said members had elected the petitioner as the Chairman of the said Ethics Review Committee. The number of complaints was received during the tenure of office of the petitioner as the Chairman of the said Ethics Review Committee about how the said Committee was conducting itself and discharging its duties and responsibilities.

The aforementioned sentiments were expressed at the Faculty Board Meeting held on 15th December 2010 as well and the petitioner was allowed to explain the delay in approving certain research proposals and was also given an opportunity of answering queries raised by the members of the Faculty Board. Though the proposals submitted in that regard were given clearance by the Ethics Review Committee, the said clearance had been given after much prolongation and after causing much inconvenience to the proponents of the research proposals.

These Respondents further state as follows;

- (a) As per the Ethics Review Committee Guidelines (P4), an Ethics Review Committee is required to review and evaluate the ethical nature of all medical research involving human participants, tissue & data and animals and is also required to safeguard the dignity, rights, safety and well-being of actual and potential research participants.

- (b) In doing so, an Ethics Review Committee is required to review and evaluate such proposed research based on social value, scientific validity, fair participant selection, favourable risk and benefit ratio etc...
- (c) To engage in any biomedical research involving human participants, tissue & data or animals, it is essential to seek and obtain prior ethical clearance.
- (d) Such proposed research is considered justified and valid only when the design of the research is scientifically sound and the method to be used is appropriate to the objectives of the research and the field of study and includes a thorough knowledge of scientific literature and other relevant sources of information, which ought to be reflected in the application submitted in that regard seeking ethical clearance.
- (e) In reviewing and evaluating such research proposals, an Ethics Review Committee is required to provide independent, competent and timely reviews and are also required and expected to ensure that all applications submitted seeking ethical clearance are reviewed in a systematic manner.
- (f) The Ethics Review Committee is also required to review and evaluate all research proposals submitted for ethical clearance and review including those submitted by students. If there is an inordinate delay in approving research proposals, the purpose of having an Ethics Review Committee would be defeated.

Answering the averments contained in paragraphs 23, 29 and 30 of the petition, these Respondents state that;

- (a) The proposed research had been designed to assess the superiority of intra-clot injection of plasmin compared to plasminogen-activator and 'no treatment' about clots in the leg following clot formation in Artery or Bypass Graft. In Sri Lanka, due to lack of facilities, the current standard of care for such patients is conservative management with lifestyle changes and anti-platelet therapy.
- (b) This is not the internationally-accepted 'best' therapy and does not produce a significant benefit to most patients thus requiring surgical bypass grafting. Occlusion of the bypass graft may result in amputation. Plasmin (human), a substance that dissolves clots, has the potential to have a lower major bleeding event profile than currently used thrombolytics (clot busters). Thus, plasmin delivered via catheter directly into a thrombus (clot) is not expected to induce internal bleeding as observed with currently available plasminogen activators.
- (c) The main investigators who submitted the aforementioned proposed research were Dr.Ruwan Fonseka (Vascular Surgeon) and Dr.Asitha de Silva.
- (d) Two Reviewers had approved the research proposal submitted in that regard and deny the remaining averments contained therein.



- (e) Two of the main investigators had been invited by the Ethics Review Committee to participate at meetings held in that regard by the said Committee on 13.01.2011 and 18.01.2011. According to participating at the said meeting, by way of a letter dated 13.01.2011, Dr. Ruwan Fonseka had tendered a further analysis of the proposed research.
- (f) At the meeting held on 18.01.2011, Dr. Nirmala Wijekoon, who was the Secretary of the said Ethics Review Committee, had resigned from the said post and Committee.

As of 18.01.2011, four members of the Ethics Review Committee had resigned from the said Committee chaired by the petitioner. They were Dr. Nirmala Wijekoon, Prof. Arjuna De Silva, Dr. R. Hasan and Prof. Hewavisenthi. The said Committee was dissolved because of the complaints that were received of how the said committee was functioning and because of the spate of resignations that occurred.

On 20.01.2011, the Management Committee and petitioner were apprised of the decision to dissolve the said Committee and the reasons for doing so and of the appointment of the new Committee. The Faculty Board was informed of the said decision and that decision was approved by the Faculty Board. The Ethics Review Committee had approved the said proposed research subject to the observations made in that regard, following the Guidelines. Such research projects have received approval from regulatory authorities and Ethics Review Committees in many countries including the USA, UK and European countries. The Guidelines are based on the Guidelines introduced in the aforementioned countries.

These Respondents state that they have acted in good faith and in compliance with the relevant provisions contained in the Universities Act and Ethics Review Committee Guidelines. The application of the Petitioner seeking Writs of Certiorari and Mandamus is misconceived in law and ought to be dismissed and in any event, the Petitioner is not entitled to the relief prayed therein.

The Petitioner has gone through the objections filed by all the Respondents and decided to reply by filling a counter objection by an affidavit on 30.03.2012. She has denied all and singular the several averments contained therein, except those that are specifically admitted by her. The main contention of the Petitioner is that the Statements of Objections filed on behalf of the 04<sup>th</sup>, 06<sup>th</sup>, 07<sup>th</sup>, 09<sup>th</sup>, 10<sup>th</sup>, 11<sup>th</sup>, 13<sup>th</sup>, 15<sup>th</sup>, 16<sup>th</sup>, 18<sup>th</sup>, 19<sup>th</sup> to 23<sup>rd</sup>, 25<sup>th</sup>, 28<sup>th</sup>, 31<sup>st</sup>, 32<sup>nd</sup>, 33<sup>rd</sup>, 36<sup>th</sup> to 43<sup>rd</sup>, 45<sup>th</sup>, 46<sup>th</sup>, 47<sup>th</sup>, 49<sup>th</sup> to 53<sup>rd</sup>, 54<sup>th</sup>, 55<sup>th</sup>, 60<sup>th</sup>, 61<sup>st</sup>, 63<sup>rd</sup> Respondents were not supported by Affidavits and therefore not by the Supreme Court Rules and Therefore the objections filed by those Respondents should be rejected in limine.

The Petitioner states that the Statement of Objections filed on behalf of the 59<sup>th</sup> Respondent was not supported by an Affidavit when the said Objections were tendered to this Court but subsequently on 14.03.2012 the 59<sup>th</sup> Respondent submitted an affidavit to this Court and therefore the statement of objections, is not in compliance with the Supreme Court Rules and should be rejected. Not only that, when this application was mentioned on 21.02.2012 in this Court, the counsel appearing for the 18<sup>th</sup>, 24<sup>th</sup>, 26<sup>th</sup> and 31<sup>st</sup> Respondents stated that they will be filing their Objections on or before 28.02.2012. But contrary to the undertaking given to this Court and without permission from this Court the said Respondents have filed their Objections

on 01.03.2012 and therefore the Objections of the said 18<sup>th</sup>, 24<sup>th</sup>, 26<sup>th</sup> and 31<sup>st</sup> Respondents should be rejected.

Answering averments contained in Paragraph 14 of the affidavit of the 01<sup>st</sup> Respondent the Petitioner states that on 30.11.2010 which was the last day for accepting research proposals for ethical clearance, the Ethics Review Committee received live voluminous proposals requesting ethical clearance. As the documents are voluminous, the Petitioner seeks the indulgence of the Court to produce these five boxed files when the case is taken up for argument. These proposals were forwarded through the Clinical Trials Unit of the Faculty of Medicine of the University of Kelaniya.

As this is the usual practice on receipt of these five proposals, they were distributed among three appointed Reviewers to review the proposals. The Ethics Review Committee meets on the second or third week of every month and the Ethics Review Committee meeting for December had already been fixed for 09.12.2010 and these proposals were included in the agenda. Some of the Reviewers had brought along with them completed evaluation forms. As it was not possible to carry out a comprehensive evaluation during the short time available it was decided to postpone the consideration of these five proposals for the next meeting which was scheduled for 13.01.2011.

The Petitioner states that the Faculty Board meeting was held on 15.12.2010 and at the said meeting the 15<sup>th</sup> Respondent only stated that there were certain representations made to him about delays regarding obtaining ethical clearance. He further stated that the mandate of the Ethics Review Committee is to review only ethical issues unless there are gross scientific issues involved regarding the proposals submitted to the Committee. The Petitioner states that there were no undue delays. She further states that she was never informed before this that there were any complaints regarding the functioning of the Ethics Review Committee.

The Petitioner says that at the next meeting of the Ethics Review Committee held on 13.01.2011 the proposals referred to above were considered and one of the five voluminous proposals were also taken up and Dr. Ruwan Fonseka who had been invited to be present at the meeting. explained certain matters. As some of the ethical issues raised were unanswered. it was decided to seek a second opinion from Prof. A.H. Sheriff Deen. As there wasn't sufficient time the Ethics Review Committee meeting was adjourned to 18.01.2011 to consider the other four proposals.

On 17.01.2011 the collective disappointment letter against the Ethical Review Committee, signed by 57 signatories (1 R 2) had been handed over to the 01<sup>st</sup> Respondent. The Petitioner states that up to November 2010 out of the 57 signatories whose names appear in 1 R 2 only 17 had submitted proposals to the Ethics Review Committee. A list of persons who had submitted proposals to the Ethics Review Committee from August to November 2010 is marked as P17.

The Petitioner specifically states that the letters marked 1 R 2 and 1 R 3 were not copied to her and she was not allowed to explain these allegations before the Ethics Review Committee was dissolved. Thereby 01<sup>st</sup> Respondent has violated rules of natural justice. The Petitioner further states that when the decision to dissolve the Ethics Review Committee was conveyed to the

Management Committee of the Faculty of Medicine, the Petitioner and Dr. Deepthi De Silva objected to the said dissolution and requested that an inquiry by an independent person be held in respect of this matter. But no such inquiry was held.

Again on 18.01.2011, the Ethics Review Committee met and the other four Clinical Trial Proposals were taken up for consideration. The Petitioner says that in respect of the said clinical trial proposals too, there were ethical issues to be clarified and the Committee appointed Professor Anoja Fernando and Dr. Lilani Panangala Consultant Rheumatologist Rehabilitation Hospital Ragama to report to the Committee on the ethical issues raised. On 20.01.2011 the 1st Respondent arbitrarily, capriciously, mala-fide. unreasonably and contrary to law dissolved the said Ethics Review Committee.

The Petitioner further says that Dr. Chalukya Gunasekare had submitted a research proposal titled "Clinical & Histopathological study of periorbital Hyperpigmentation" in August 2010. The Ethics Review Committee appointed Dr. Deepthi De Silva, Professor Hewawisenthani and Professor A.P. De Silva as the Reviewers of this proposal. Dr. Deepthi De Silva is a Senior Lecturer in the Department of Physiology. Professor J. Hewawisenthani is the Professor of Pathology in the Department of Pathology and Professor A.P. De Silva is a Physician in the Department of Medicine of the Faculty of the Medicine University of Kelaniya. They are the 08<sup>th</sup>, 61<sup>st</sup> and 65<sup>th</sup> Respondents to this application respectively. The said proposal was considered at the Ethics Review Committee meeting held on 17.08.2010 and as the Reviewers were of the view that approving a biopsy of the tissues surrounding, the eye was un-ethical in as much as the risk-benefit ratio was not in favour of performing a biopsy of the tissues surrounding the eye, clearance of that part of the project was not granted by the Ethics Review Committee.

The Ethics Review Committee also allowed Dr. Chalukya Gunasekare's Registrar to re-submit the proposal which was submitted in September 2010 for the second time, including the component on biopsy which was rejected earlier. On this occasion too due to the said reasons the Ethics Review Committee did not approve the said part of the proposal. Prof. Hewawisenthani and Prof. A.P. De Silva who resigned from the committee stating that they cannot work in the committee also refused to approve the said proposal. The Petitioner states that in the circumstances, not granting ethical clearance to the proposal submitted by Dr. Chalukya Gunasekare was justifiable and she for co-lateral purposes has submitted the letter marked 1 R 3 to the 01<sup>st</sup> Respondent.

The Petitioner says that the Ethics Review Committee of the Colombo University seeks a minimum of 2 months to review a project proposal. Dr. Ruwan Fonseka did not clear all the ethical issues that arose, a second opinion had to be sought from Professor A. H. Sheriff Deen. The Petitioner believe that even the Sub Committee on Clinical Trials of the Ministry of Health before approving the said proposal had sought an opinion from Professor A. H. Sheriff Deen.

Dr. Nirmala Wijekoon was a member of the Clinical Trials Unit of the Faculty of Medicine of the University of Kelaniya which submitted the five (5) clinical trial proposals. According to the guidelines of the FERCSL, members of the Ethics Review Committee should not have any conflict of interest and if there is a conflict of interest, they should declare the conflict of interest and refrain from participating in the said deliberations. That was the procedure

followed by the members of the Ethics Review Committee before this. When her Research proposals were being considered the Petitioner too left the meeting enabling the other members of the Ethics Review Committee to make an independent decision whether to grant ethical clearance to her research proposals or not. But Dr. Nirmala Wijekoon participated in the Ethics Review Committee meeting on 13.01.2011, where the ethical issues of the said clinical trials were considered. When members of the Ethics Review Committee including the Petitioner expressed certain reservations regarding Dr. Nirmala Wijekoon's participation as there was a conflict of interest in her participation, having deliberated on the situation, the legal officer who is the 57<sup>th</sup> Respondent stated that Dr. Nirmala Wijekoon can participate in the meeting to attend to secretarial functions as the Secretary of the Ethics Review Committee, but should not deliberate in the proceedings on the proposals on the five clinical trials as there was a conflict of interest.

On 13.01.2011 after the said meeting Dr. Nirmala Wijekoon telephoned the Petitioner and expressed her dissatisfaction in remaining on the committee and I requested her to be on the Ethics Review Committee as suggested by the 57<sup>th</sup> Respondent. At the next meeting held on 18.01.2011 notwithstanding her desire to resign, Dr. Nirmala Wijekoon came and participated in the meeting. The Petitioner apprised the committee what transpired whereupon Dr. Nirmala Wijekoon reiterated her desire to resign.

Although Dr. Nirmala Wijekoon is alleged to have written a letter of resignation on 14.01.2011, where she has stated that she will resign with effect from 31st January, it was not tabled at the meeting of the Ethics Review Committee which was held on 18.01.2011 nor did the 1st Respondent forward to the Petitioner such a letter before 18.01.2011 thereby depriving the opportunity of explaining the factual situation.

The Petitioner stated that Dr. R. Hassan who was a member of the Ethics Review Committee had attended only the first two meetings held in August and September 2010, whereas Prof. Hewawisanthi had stated in her letter of resignation that she was resigning from the Ethics Review Committee as she was unable to devote the time required to carry out duties satisfactorily as a member of the Ethics Review Committee. Therefore, I state that the letters of resignation have been orchestrated and has been obtained to facilitate the granting of approval to the five clinical trials even though there were serious ethical issues and before a proper appraisal of the ethical issues were considered.

The Petitioner believe that the Ethics Review Committee was dissolved to enable the clinical trials to proceed as the 1<sup>st</sup> Respondent was also a member of the Clinical Trials Unit through which these proposals were submitted. The Petitioner specifically states that even before the decision of the 1st Respondent was ratified by the Faculty Board, the newly appointed Ethics Review Committee had met on 26.01.2011 and granted approval to the five clinical trials.

The Petitioner further states that before the Ethics Review Committee was dissolved, she was not given an opportunity of explaining matters. She also stated that before this decision was conveyed to the Faculty Board, at a meeting of the Management Committee of the Faculty of Medicine University of Kelaniya held on 20.01.2011, the 01<sup>st</sup> Respondent informed the said Management Committee that the Ethics Review Committee of the Faculty of Medicine had been dissolved and a new committee had been appointed. Although he gave certain reasons,

the Petitioner objected and requested for an independent person to be appointed to investigate the matters before the Ethics Review Committee was dissolved. Although the 01<sup>st</sup> Respondent undertook to look into that matter no such steps were taken by the 01<sup>st</sup> Respondent.

The Petitioner states that the ethical standards considered by the Ethics Review Committees in developed countries where there is a much greater patient care system could not be unquestionably applied to the system prevailing in Sri Lanka.

Answering the averments contained in paragraph 25 of the 01<sup>st</sup> Respondent's affidavit, The Petitioner states that after she came before this Court, the steps to implement the "Standard Operating Procedure" for the Ethics Review Committee of the Medical faculty of the University of Kelaniya is being pursued by the 01<sup>st</sup> Respondent. The Petitioner says that she is entitled to bring this application in the public interest as this is a situation where the 01<sup>st</sup> Respondent has tried to jeopardise the lives and limbs of the Sri Lankan patients without following the guidelines in which he has a public duty to adhere to.

Answering averments contained in objections and affidavits of the Respondents, the Petitioner states that there are no 'aches on my part in making this application to Court and deny that she has misrepresented facts to Court in making this application. The Petitioner says that this application is not Merely of a private nature. It has been made in the interest of the voiceless patients who are unaware of the serious risks they are sought to be subjected to. The appointment of the Ethics Review Committee derives its legitimacy from statutory power granted under the Universities Act and is designed to further the constitutional rights of patients who may be subjected to cruel inhuman degrading treatments and punishments in the guise of medical research.

The Petitioner further says that she is entitled to invoke the writ jurisdiction of this Court. Since an Ethics Review Committee is appointed in terms of statutory power conferred on the appointing authority, the principal function of the Ethics Review Committee is to ensure that the medical research using human subjects are conducted strictly following the internationally accepted ethical standards and for the benefit of the public. The conduct of medical research in Sri Lanka is also governed by an international legal regime that Sri Lanka has agreed to abide by. Medical Research using human subjects is usually conducted by Medical Practitioners who are bound by the statutory regime governing their conduct and should adhere to rules, regulations and conduct governing the medical profession.

Therefore, the appointment of members, the dismissal and the procedure of the Ethics Review Committee should be following the public interest and in compliance with the public trust reposed on statutory functionaries. The said committees are performing a public duty for and on behalf of the public and have a statutory underpinning and of statutory flavour. The Ethics Review Committees are appointed by the Dean of the Faculty and is ratified by the Faculty Board under the powers granted by the Universities Act. The Petitioner further state that the Faculty Board cannot abdicate their statutory functions. If the necessity arises an Ethics Review Committee is required to obtain opinions from experts in the said fields and the said procedure has been sanctioned by the Sri Lanka Medical Council guidelines on Ethical Conduct for Medical and Dental Practitioners.

The Petitioner specifically denies that she was stultifying the approval been granted for Clinical and Drug trials due to her incompetence and her lack of knowledge. Further answering the averments contained in the objections filed by the Respondents the Petitioner says that herself or the members of the former Ethics Review Committee had never unduly delayed approvals for Clinical and Drug trials. Any researcher has not complained stating that he or she had to give up his or her research due to inaction of the Ethics Review Committee before 17.01.2011. The Ethics Review Committee has not postponed the granting of approvals for Clinical and Drug trials considering extraneous factors. She was acting in the best interest of the Ethics Review Committee.

The Petitioner argued that, even though some of the clinical and drug trials are alleged to have received approvals from the regulatory authorities in reference countries, the ethical standards applicable to Ethics Review Committees in developed countries where there is a much greater patient care system could not be unquestionably applied to the system prevailing in Sri Lanka. Answering the averments contained in paragraphs 23 and 29 of the affidavits of the 24<sup>th</sup> and 26<sup>th</sup> Respondents, I state that the approval of the Ministry of Health for licensing the import of the drug to be used in clinical trial titled -A Phase 2 randomized, open-label (with blinded plasminogen activator and placebo control groups) study to evaluate the effects of different intra-thrombus infusion regimens of plasmin (human) compared to plasminogen activator and placebo in patients with acute lower extremity native artery or bypass graft occlusion- was granted only on 12.08.2011. Therefore, even if the Ethics Review Committee rushed in and granted approval notwithstanding the serious ethical issues involved, the clinical trials could not have been held simultaneously with the other countries. She specifically denies that she continuously postponed the decision to clear or reject the said research proposals. I state that the Ministry of Health independently raised the same concerns expressed by the Ethics Review Committee as regards this proposal as evident by the document marked X24 submitted with the affidavits of the 24<sup>th</sup> and 26<sup>th</sup> Respondents.

Although the 64<sup>th</sup> respondent signed and approved the evaluation form submitted to the Ethics Review Committee meeting held on 09<sup>th</sup> December 2010, when the ethical aspects of the proposal were further discussed, he also agreed to call for a second opinion having realised that there were serious ethical issues involved.

Dr. Ruwan Fonseka the Coordinating Principal Investigator in one of the aforesaid five clinical trial proposals appeared before the Ethics Review Committee on 13<sup>th</sup> January 2011 and explained his position as regards certain queries raised. But I specifically state that the Ethics Review Committee was not fully satisfied with his explanations regarding the ethical issues raised by the Committee. The evaluation forms were submitted to the Ethics Review Committee and in some evaluation forms, the Reviewers had made their comments.

The 01<sup>st</sup> Respondent tried to pressurise the Committee to approve the said clinical trials notwithstanding the ethical issues the Committee was considering because the proposals were submitted through the Clinical Trials Unit in which he too was a member, but as there were serious ethical issues to be considered the Committee was not in a position to accede to his unreasonable request. The Petitioner further state that it is unethical for the appointing authority to actively take part at the meetings of the Ethics Review Committee as articulated in the FERCSL guidelines. In any event in the circumstances of this case, there is a serious conflict

of interest as regards the 01<sup>st</sup> Respondent is concerned and it was unethical on his part to have tried to pressurise the Committee.

Answering the averments contained in paragraph 31 of the affidavits of the 24<sup>th</sup> and 26<sup>th</sup> Respondents, the Petitioner admitted that the Ministry of Health had approved Four Proposals on 11<sup>th</sup> February 2011 and approval to import the drugs for research was granted on 01<sup>st</sup> March 2011. The fifth proposal titled "A Phase 2 randomized, open-label (with blinded plasminogen activator and placebo control groups) study to evaluate the effects of different intra-thrombus infusion regimens of plasmin (human) compared to plasminogen activator and placebo in patients with acute lower extremity native artery or bypass graft occlusion- which was reviewed by me was granted approval on 12<sup>th</sup> August 2011 and approval to import the drug was granted by letter dated 14<sup>th</sup> September 2011. To approve by Cosmetics Drugs and Devices Act No. 27 of 1980 and the regulations made thereunder coupled with the legal regime governing medical research it is a sine qua non that ethical clearance should be obtained. At the meeting held on 18.01.2011, the 01<sup>st</sup> Respondent intimated to the Ethics Review Committee that the Ministry had approved the proposals. The Petitioner states that this is factually incorrect as on that date the approval for that proposal had not been granted by the Ministry of Health and the Respondent made this incorrect statement with a view of persuading the Ethics Review Committee to approve the said proposal in which he was also personally interested.

Prof. A. Pathmeswaran (28<sup>th</sup> Respondent) who is a member of the newly appointed Ethics Review Committee is also a member of the Clinical Trials Unit through which the said clinical trial proposals were submitted to the Ethics Review Committee. Prof. A. Pathmeswaran has reviewed and approved four out of five of the proposals. The Petitioner further state that there is a clear conflict of interest but notwithstanding that Prof A. Pathmeswaran had been appointed by the 01<sup>st</sup> Respondent to the said Ethics Review Committee and he had approved the said proposals.

Therefore, the Petitioner denies that the Ethics Review Committee in which she was the Chairperson was lawfully dissolved, she was given an opportunity of being heard before the decision was ratified by the Faculty Board and the dissolution of the Ethics Review Committee was valid in law.

Thus, the dissolution of the Ethics Review Committee by the 01<sup>st</sup> Respondent and the ratification of the said decision by the Faculty Board is contrary to law, unreasonable, mala-fide and done for a collateral purpose. The appointment of the present Ethics Review Committee is ultra vires the powers of the 01<sup>st</sup> Respondent and is null and void and of no force or avail in law.

The Petitioner admits that Professor Asitha De Silva and Dr. Ruwan Fonseka was present at the Ethics Review Committee meeting held on 13.01.2011 and that Professor Asitha De Silva was present at the meeting held on 18.01.2011. The members of the Ethics Review Committee inquired from them about various ethical issues that confronted the members of the Ethics Review Committee. The Petitioner specifically denies that the members of the Ethics Review Committee asked any questions from Professor Asitha De Silva that did not relate to ethical issues. As the concerns of the members of the Ethics Review Committee was not fully

explained further clarifications were sought from Professor A. H. Sheriff Deen, Professor Anoja Fernando and Dr. L. Panangala.

If the decision to dissolve the Ethics Review Committee was to be considered at the Faculty Board meeting the aggrieved parties should have been given appropriate notice to defend themselves in respect of unfounded allegations which has serious repercussions on their competence and integrity. The Petitioner states that the failure to do so violates the rules of natural justice.

The Petitioner states that the University of Kelaniya is an institution where medical research is conducted by academic staff members who are mostly Medical Practitioners. Therefore, if acceptable research is to be conducted, it is a sine qua non that an Ethics Review Committee should be in existence and ethical clearance be obtained. To satisfy this requirement an Ethics Review Committee of the Faculty of Medicine of the University of Kelaniya was set up in terms of Section 48(3) of the Universities Act No. 16 of 1978. The Conduct of the Doctors in Sri Lanka is regulated by the Medical Ordinance of the Sri Lanka Medical Council and to ensure that the Medical Practitioners adhere to the law, the Sri Lanka Medical Council has been set up by Statute. The Medical Council has formulated guidelines as to how research should be done by doctors using human subjects.

Concerns about the ethics of the practice of medicine have a long history. But until the middle of this century, they were mostly centred around the practice of therapeutic medicine, not research medicine. In 1946, there were 23 Nazi Physicians who went on trial at Nuremberg for crimes committed against prisoners of war. These crimes included exposure of humans to extremes of temperature, the performance of mutilating surgery, and deliberate infection with a variety of lethal pathogens. During the trial, fundamental ethical standards for the conduct of research involving humans were codified into the Nuremberg Code, which set forth 10 conditions that must be met to justify research involving human subjects. The two most important conditions were the need for voluntary informed consent of subjects and scientifically valid research designs that could produce fruitful results for the good of society.

The World Health Organization recognized a need for guidelines that were broader in scope than the Nuremberg Code and the Declaration of Helsinki. Recommendations Guiding Medical Doctors in Biomedical Research involving Human Subjects was adopted by the World Medical Association in 1964. These guidelines have been revised several times, most recently in 1989, and currently are in use throughout the world.

Thus, there arose the necessity while researching for the development of medicine also to take into consideration the safety and well-being of the human beings subjected to research. The mechanism of balancing these two countervailing policy considerations was the establishment of Ethics Review Committees in all institutions doing research using human subjects and making it compulsory to obtain ethical clearance from such committees. The importance of these Ethics Review Committees cannot be underestimated. Because for the sake of money given by Pharmaceutical Companies the safety of the vulnerable section of the society who are used for research projects would be at stake. They are the voiceless persons from whom sometimes informed consent for using them in research is not properly obtained.



An umbrella organization named Forum of Ethics Review Committees of Sri Lanka (FERCSL) has also been formed consisting of all the Ethics Review Committees of all the institutions which conduct human research. They too have adopted guidelines as to how the Ethics Review Committees should function. Thus, a carefully designed legal mechanism is set up to balance the countervailing policy considerations. The proper and unbiased functioning of the Ethics Review Committees is essential to carry out these principles. Therefore, unless strict parameters are not set out when issues arise severe difficulties would arise to unsuspecting Citizens and patients during the drug trials.

The Reconstituted Ethics Review Committee of the Faculty of Medicine of the University of Kelaniya for the period under consideration had been appointed by the Faculty Board of the Faculty of Medicine, University of Kelaniya. The Petitioner was a member of that committee. The said appointment was conveyed to her by letter dated 27.08 2010. Thereafter the members of the said Committee elected the Petitioner as the Chairperson of the said Committee. The Petitioner says that she has considerable experience as being a member of the Ethics Review Committee as she had continuously served as a member of the Ethics Review Committees of the Medical Faculty of the University of Kelaniya since 1999. On 20th January 2011, the said Ethics Review Committee was dissolved by the Dean of the Faculty of Medicine, University of Kelaniya. The Petitioner states that the said decision was illegal, mala-fide, in violation of the rules of natural justice and for extraneous and collateral reasons. It is against this dissolution that the Petitioner is seeking a Writ of Certiorari from this Court.

Before I analyse the submissions of the present case, it would be interesting to shed a light regarding the concept of prerogative Writs.

If any wrongful act is committed or injustice has been done to anybody then it will spread like a virus and can't be tolerated. Therefore, all the justice is done will be spoiled and everyone else has to wonder, what it would take for that same injustice to be done with them. There arises a need to provide justice to all and remove the bias from the system. Hence the concept of the writ was introduced in Common Law for keeping a judicial eye on the work of administration.

A writ is a written official order issued by the court. The formal order may be in form of a warrant, direction, command. Writs can only be issued by the Court of Appeal Under Article 140 of our Constitution. We have adopted the concept of prerogative writs from English common law. Writs were first used to describe a written command of the King. Whereas, these writs are now available to a person aggrieved by the decision of the inferior courts or administrative body in England.

When we consider the distinction between writs and orders, it can be said that writs can be issued to provide an extraordinary remedy. That is in cases where the aggrieved person is seeking an extraordinary remedy usually against an administrative action, whereas, orders can pass in any matter. A writ of mandamus is a command given by the Court of Appeal to the lower court or any tribunal or board or to any other public authority to perform their public duty imposed upon them by law. Its primary objective is to supply defects of justice and prevent the rights of the citizen.

The writ of certiorari has been defined as one of the most effective and efficient remedies taken from common law. Certiorari means "to certify". It is an order issued by the Superior

Court to an inferior court or any authority exercising judicial or quasi-judicial functions. The main object of this writ is to keep the inferior courts, judicial and quasi-judicial authorities within their limits of jurisdiction and if they act over their jurisdiction, their decision will be quashed by the Court of Appeal by issuing a writ of certiorari.

Lord Atkin stated that writ of certiorari may be issued "wherever anybody or person having legal authority to determine questions affecting the rights of subjects and having the duty to act judicially, act over their legal authority." This statement has been approved by the Supreme Court in many cases like in Province of Bombay vs Kusaldas S. Advani and Others 1950 SCR 621 and held the four components of this writ are as follows;

- 1) Body of persons
- 2) Such a body is having some legal authority
- 3) The legal duty for determining the question affecting the rights of the subjects
- 4) Duty to act judicially

It is a great corrective writ by which a superior court may exercise supervisory power on inferior courts and judicial or quasi-judicial tribunals. By exercising such power their records and proceedings are brought under review and the sole object become to prevent abuse of law. Earlier writ of certiorari was used as a writ of error. It was invoked only in criminal matters and later on, was also used in civil cases.

Writ of certiorari may not be issued against

- 1) an individual
- 2) company
- 3) Private authority
- 4) An association or tribunals have no judicial or quasi-judicial powers.
- 5) Also, can't be issued for making a declaration that an act or statute is ultra-virus or unconstitutional.

It is important to note that a Writ of Certiorari can be issued on the following grounds;

- (a) Want or Excess of Jurisdiction

When an inferior court or tribunal act over jurisdiction or act without jurisdiction or fails to act then, the Writ of Certiorari come into the picture for correcting the errors of jurisdiction.

Wherever there is a defect in jurisdiction or power, a writ of certiorari must be issued.

In the case of Rafiq Khan and Another vs State Of Uttar Pradesh AIR 1954 All 3, a divisional Magistrate does not have the power to modify the order or sentence. Whereas, he can either quash the order or cancel the jurisdiction. In this case, the sub- Division Magistrate has modified the order by maintaining the conviction of the accused in one of the offences and quashed his conviction in respect of the other offences, in this manner the order passed by the Magistrate Court Panchayati Adalat has been modified by sub- Division Magistrate.

It was held in Allahabad High Court that the order of sub- Divisional Magistrate is contrary to the provision of section 85 and quashed the same order by issuing a writ of certiorari.

Therefore, by reviewing this case it is clear that want of jurisdiction may arise from the nature of the subject matter of the proceeding and the court can't decide some of its parts and let the other be untouched. Enquiry of the whole case should be conducted together. Similarly, in cases where the inferior courts have wrongfully denied to exercise jurisdiction vested in it, writ of certiorari may be issued to quash the decision of the inferior court and decide the case falling within their jurisdiction.

In cases of conditional powers, there are certain powers vested in the court that can be exercised only when certain jurisdictional facts exist otherwise if the court or tribunal exercised those powers without the availability of those jurisdictional facts, even the assumption of jurisdiction by the court that such facts exist would not be supported and can be removed by a writ of certiorari.

In the case of Express newspaper Ltd. v Workers and Staff 1963 SCR (3) 540, the question on which the jurisdiction industrial tribunal decided was whether the dispute is an industrial dispute or a non-industrial one? The Supreme Court held that if the industrial tribunal assumes to have jurisdiction over a non-industrial dispute, then it can be challenged before Court and the Court has the power to issue a writ of certiorari for the same question. Power to issue an appropriate Writ by Court is not subject to any question.

If it is a violation of procedure or disregard of the principle of natural justice, a writ of certiorari can be issued. To set aside any decision given in violation of the principle of natural justice, a writ of certiorari will always be issued.

There are two principles of natural justice recognised by law;

- 1) Audi alteram partem (hear the other side) means that both sides must be given equal opportunity of hearing. Both sides should be given a full and fair chance to present their side of the case. Every judicial or quasi-judicial body must give an equal and reasonable opportunity to the parties to make their representation. In other words, it can be said that the party whose civil rights are affected in any proceeding before the court must have reasonable notice of the case he has to meet with and be given an opportunity of stating his case. This rule commands the authority deciding the case to give both the parties to the case an equal opportunity for presenting their case and to correct and contradict any relevant statement.

In the case of Collector of Customs v A.H.A. Rahiman AIR Mad 496; The collector of customs, in this case, passed an order of confiscation of goods without any notice and enquiry, The Madras Court held that the order passed by the collector was without hearing and knowing all the key points of the case and held that the same is contrary to the principles of natural justice and hence, the court issued a writ of certiorari to quash the order of customs collector.

Supreme Court held in Gullapalli Nageswara Rao v A.P. SRTC SCR Supl. (1) 319, that fundamental principle of natural justice states that both the parties to the case be given equal opportunity to make their representation but where it is expressly provided in the act a right to a personal hearing, then the authority deciding the case must hear the case personally.

At the same time, it is to be noted that further a sub-rule to this principle states that every decision of tribunal must be accompanied with a reason for giving such decision whereas this

rule does not apply in English Common- Law and this rule is not universally established though in certain cases is rigidly followed. Where a rule or any provision is laid down in the foregoing reasons then the judicial or quasi-judicial authority must provide the same and give reasoned decisions in all the cases.

Usually, reasoned decisions or duty to give reasons arise where the statute provides an appeal, review or revision against the order passed. But those reasons given by the tribunal or inferior court would become easier for the court to make a further decision and the reason will make or give a clear picture of the authority given the said decision.

- 2) Bias and interest– the second principle of Natural Justice states that no one should be a judge in his case. Elaborating the statement means that the judge deciding the case does not have any interest in the case in which he is providing his decision because it is a human tendency that a person can be wrong in his own eyes. Therefore, the business will emanate and aim for fair justice to all could not be reached.

There are two principles for governing this doctrine of bias and interest

- 1) No one shall be a judge in his case.
- 2) Just should be manifestly and undoubtedly seen to be done.

Any judicial entity is "subject to bias" when he is in favour or against any party to the dispute or where it can be assumed that bias exists, then he should not take part in the decision. Also, where there exists any pecuniary interest (or any other interest) of the person sitting to provide justice to all will become the reason for his disqualification in giving a decision in that case.

The reason given for this principle in the case of A.P. SRTC v Satyanarayana Transport 1965 AIR(SC) 1303 by The Supreme Court is that while delivering judgement and providing justice to the parties, the person delivering the judgment must give his adjudication with a free and independent mind without any indication of bias towards either side of the case. Neither there should be any pressure on him that will divert him from delivering justice and mislead him while fulfilling the purpose of his seat.

In the case of Manik Lal v Prem Chand Singhvi 1957 SCR 575, the appellant was an advocate, who was alleged of misconduct for which bar council tribunal was appointed to enquire, tribunal consists of 3 members, one of them was the chairman who has given his Vakalatnama on behalf of the opposite party in proceeding under section 145 of Criminal Procedure Code and argued the case on the same date on behalf the opposite party only and appellant act as a pleader to the proceedings.

The appellant raised the point that the tribunal was not properly constituted as the chairman of the tribunal conducting the inquiry of his case is arguing the matter on behalf of the opposite party and will be assumed and believed that there must be some bias. The tribunal gave its judgment on which appellant was convicted and therefore he filed an appeal before the supreme court for issuing a writ of certiorari to quash the judgment of the tribunal.

After going through the facts of the case supreme court issued a writ of certiorari for quashing the decision of the tribunal on the ground of violation of the principle of Natural Justice.

On an application to the Supreme Court, in the case of Syed Yakoob v Radhakrishnan SCR (5) 64, it is found that the question raised in the case before the high court was a pure question of facts and The High Court has no jurisdiction to interfere in the matters decided on facts by the tribunal. If there is a failure in considering the material evidence by the tribunal then that will become an error on the face of the record.

It was held in this case by Justice Gajenderagadkar that by way of a writ of certiorari error on the face of the record can be correct but not an error of fact.

It is important to note that Cases where an error of fact might be impugned on the ground of error of law;

- (a) Mistakenly refuse to admit material evidence, those can be admitted.
- (b) Admitted evidence that is not admissible and the same influenced the findings of the case.
- (c) There was a finding of facts without any evidence.

The writ of mandamus is a judicial remedy in the form of an order from a superior court to any government body, court, corporation or public authority to do or not to do some specific act. They are bound to perform or not to perform under law, as the case may be. These acts must be performed as a part of their public duty or statutory duty. The writ of mandamus cannot be issued by the higher authority to force their lower departments to act or do something which is against the law.

The writ of mandamus can only be issued when there exists a legal right and without a legal right, it can't be issued. A person is called an aggrieved person only when he is denied a legal right by any person, court or board who has a legal duty to do something and abstains from doing it.

A person is said to be aggrieved, only when his legal rights have been denied by someone who has a legal duty to do something or denied from doing something. The denied legal right must be a legally enforceable right as well as a legally protected right, before one suffering a legal grievance can ask for a mandamus. Any person seeking for writ of mandamus must show that he has a legal right to overpower the opponent, against whom writ will be issued, to do or not to do some specific act. The legal right of the petitioner is a condition precedent. Legal rights must be a legally enforceable right as well as a legally protected right, before claiming for mandamus. The existence of a legal right is the foundation of jurisdiction of a writ court, to issue mandamus.

It was pointed out by the court in the case of Umakant Saran v State of Bihar AIR 1973 SC 964 that the purpose of mandamus is to force the authorities to do something, it must be shown that the statute imposes a legal duty and the aggrieved person had a legal right under the Statute to enforce its performance. Therefore, the appeal was dismissed by the court and a writ of mandamus was not issued.

Supreme court of India held in State of Madhya Pradesh vs G. C. Mandawar 1955 SCR 158 that the applicant must have a legal right to compel the performance of some duty cast on the opponent by The Constitution or any other statute. And the duty must possess three qualities;

- 1) Duty must be of Public Nature
- 2) Must not be a discretionary one
- 3) And duty if discretionary then the power must have been conferred by the authority and statutory provisions are made for it.

It is important to note that a Writ of Mandamus will not lie against a private individual or any private company

In the case of Pragya Tools Corporation v C.A. Immanuel 1969 SCR (3) 773, Justice Shelat held that an application for mandamus will not lie for an order of reinstatement to an office which is essential of a private character, nor can such an application be maintained to secure performance of an obligation owed by a company registered under the Companies Act, 1956 towards its workmen or to resolve any private dispute.

Court held that if a writ of mandamus could not lie against a company which is neither a statutory company nor one having public duties or responsibilities imposed upon it by a statute, no relief could also be given by granting a declaration on the court of the agreement between the company and its workman being illegal.

For issuance of a writ of mandamus, one of the essential requirements is that there must be a demand by the person seeking relief and the same demand must have been refused by the concerned authority.

In "Halsbury's Law of England" it is stated that;

As a general rule party seeking a writ of mandamus must know that what was the actual requirement, for considering whether or not he should comply, and it must be proved by evidence that the demand was distinct by the part and that demand is met with a refusal, therefore, the prerequisite for mandamus is the acknowledgement of the person seeking mandamus is must, about what he was required to do.

The writ of mandamus is not a writ of right and a person invoking the special jurisdiction of the court, for the extraordinary remedy by way of a writ was required to be diligent. Therefore, it was held in Kamini Kumar Das Chaudhary v State of West Bengal 1973 SCR (1) 718 that the writ of mandamus is a discretionary writ and the charges against the petitioner was such that even if he shows any technical flaw then also one would refuse to interfere.

Mendis V Seema Sahitha Panadura Janatha Santhaka Pravahana Sevaya 1995 (2) SLR 284, held that it is in this context that the view has been firmly held that relationships that are based on contract, without anti statutory underpinning and actions of companies and private individuals and bodies, are not subject to judicial review by way of the Writs of Certiorari and Prohibition.

In the case of Weligama Multipurpose Co-operative Society Ltd. v.Chandradasa Daluwatta 1984 (1) SLR 195, where the petitioner-respondent, the Manager of the appellant society, was interdicted and served with a charge sheet, sought a Writ of Mandamus to compel the appellant society to pay him half a month's salary after the sixth month of interdiction in terms

of Circular No.18 of 1975 dated 23.7.75 issued by the Secretary of the Co-operative Employees' Commission, it was held by five Judges of the Supreme Court that there was no public or statutory duty cast on the appellant society and dismissed the application.

"Mandamus lies to secure the performance of public duty, in the performance of which an applicant has sufficient legal interest to be enforceable by mandamus; the duty to be performed must be of a public nature and not of a merely a private character. A public duty may be imposed by statute, charter or the common law or custom."

In the English case of R v East Berkshire Health Authority, ex parte Walsh [1984] 3 All ER 425 which was relied on by learned counsel for the respondent, it was held that the question of whether a dismissal from employment by a public authority was subject to public law remedies depended on whether there were special statutory restrictions on dismissal which underpinned the employee's position. It was held that the remedy of judicial review is only available when an issue of public law is involved. In the said case reference was made to the case of Malloch vs. Aberdeen Corp. 1971 S.C.CH.L.85 where Lord Wilberforce said that it was the existence of statutory provisions which injects the element of public law necessary to attract the remedies of administrative law.

It was decided in Jayasuriya v Consumer Affairs Authority CA WRIT Application No. 1590/2006 dated 20.11.2008 that, the Petitioner claimed to be entitled to the remedies in public law, based on the principles of natural justice, unreasonableness and consideration of the other relevant factors.

"The counter-argument advanced by the respondents represented by the Senior State Counsel is that the Act does not set out the procedure under which the Director-General can be removed. According to him, the Act does not even specify the Director-General shall hold the post for a specified number of years, unlike in the case of the Chairman or certain other Members of the Authority. As regards the Chairman and certain other members of the Authority, the Act, specifically provides for their removal before the expiration of the time limit fixed by the Act. Under section 4 of the Act, the Chairman and the three full-time Members shall hold office for three years. In terms of clause 2 of the schedule to the Act, the Minister may by order published in the Gazette remove the Chairman or any one of the full-time Members of the Authority, for misconduct or physical or mental incapacity, in terms of section 3 (1) of the schedule to the Act, the Minister may by an order published in the like manner remove any member of the Authority, for misconduct or physical or mental incapacity."

"On the strength of the above provisions of the law, regarding the removal of the Chairman or the other Members of the Authority, the learned Senior State Counsel has persistently argued that the clear intention of the legislature in doing so was to grant statutory protection to the Chairman, full-time Members and other Members of the Authority by specifying the ground on which they can be removed and by laying down the procedure to be followed for their removal. It goes without saying that if any one of them is removed contrary to these statutory provisions, a writ of certiorari would undoubtedly lie to quash such a decision."

"Looking at the plight of the Director-General within the four corners of the relevant Statute, it is crystal clear that the Legislature in its wisdom has consciously refrained from granting any such statutory protection to the office of Director-General. In the premise, those of the respondents who opposed the application, have vigorously argued that the service of the petitioner with the Authority came to be terminated in terms of the contractual power the Authority exercised and enjoyed by the Authority, over the petitioner, in terms of the letter of appointment marked as X3. The enabling clause in the letter of appointment which gave rise to the dismissal of the petitioner, based on a simple contract of employment between master and servant will be reproduced in this judgment at the appropriate stage."

"For reasons set forth, the contesting respondents take up the position that employment by Public Authority does not per se introduce any elements of public law, unless there were the statutory underpinning of the employment with such statutory restrictions on dismissal, which would support the claim of ultra vires or statutory duty to incorporate certain conditions in terms of employment which could be enforced by mandamus as has been commented in the treatise on Administrative Law 8th edition, at page 658 by Wade and Forsyth."

"In other words, as has been laid down in decided cases, when an employee is dismissed from service by a Statutory body, it is not inherent in the decision to dismiss, that the employment of the person so dismissed would be governed by conditions different from an ordinary contract of employment between master and servant. In the like manner, there is no condition- precedent to the dismissal of the employee, requiring the employer to follow a procedure involving the holding of an inquiry or to grant an opportunity to the employee to hear."

In the case of Chandradasa Vs Wijeratne 1982 1 Sri Lanka Law Report 412, the petitioner sought a writ of certiorari to quash the order dismissing him from service on the ground of malafides and bias and also on the ground of not being given a fair opportunity of being heard and total lack of evidence to support the charge brought against him.

Court held that where the order of dismissal was in the exercise of a private contractual right, no writ would lie.

"No doubt the competent authority was established by statute and is a statutory body. But the question is when the respondent as competent authority dismissed the petitioner, did he do so in the exercise of any statutory power? The Act does not deal with the question of the dismissal of employees at all. It does not specify when and how an employee can be dismissed from service - the grounds of dismissal or the procedure for dismissal. So that, when the respondent made his order of dismissal, he did so in the exercise of his contractual power of dismissal and not by any statutory power. If the petitioner's dismissal was in breach of the terms of the employment contract, the proper remedy is an action for declaration or damages. The Court will not quash the decision on the ground that natural justice has not been observed,"

Justice Thambiah quoted a relevant portion from the judgment in R Vs electricity commissioners - 1924 KB 171 at 204, which is worth being re-quoted in this judgement;



"The writ of certiorari was declared to be available against anybody or persons having legal authority to determine questions affecting the rights of subjects, and having the duty to act judicially. In other words, certiorari lies only against persons or tribunals the source of who's Authority to make decisions or orders affecting the rights of subjects is legal."

The period during which the chairperson of the Ethics Review Committee shall hold office is determined not by the statute by the letter of appointment issued by the Dean of the Faculty as the Academic and Administrative Head. Unlike in the case of the Vice-Chancellor, or the Dean, no protection has been afforded to the post under consideration against arbitral dismissal. Since there are no statutory provisions either the director by a necessary implication suggesting how the chairperson of the Ethics Review Committee, should be removed from office or underpinning the position of chairperson of the Ethics Review Committee by restricting the freedom of the Dean to be dismissed, in my opinion, the public law rights are not available to the Petitioner.

The 01<sup>st</sup> Respondent's decision to dissolve the said Ethics Review Committee was endorsed by over 60% of the members of the Faculty Board of the medical faculty of the University of Kelaniya including members of the faculty board, who were members of the said Ethics Review Committee such as the 8<sup>th</sup>, 12<sup>th</sup>, 26<sup>th</sup> and 63<sup>rd</sup> Respondents. It should be noted that even after the 01<sup>st</sup> Respondent had dissolved the said Ethics Review Committee, the 01<sup>st</sup> Respondent has received numerous complaints from certain consultants of the highhandedness of the said Ethics Review Committee.

Thereafter queries were raised by the Sri Lanka Medical Council about the status quo, the 01<sup>st</sup> Respondent by letter dated 07.04.2010 has given reasons as to why the aforesaid Ethics Review was dissolved. The 01<sup>st</sup> Respondent had no choice and decided to appoint the said 02<sup>nd</sup>, 6<sup>th</sup>, 11<sup>th</sup>, 19<sup>th</sup>, 21<sup>st</sup>, 25<sup>th</sup>, 28<sup>th</sup>, 33<sup>rd</sup>, 42<sup>nd</sup>, 48<sup>th</sup>, 50<sup>th</sup> and 66<sup>th</sup> Respondents as members of the Ethics Review Committee. Accordingly, it should be noted that the said Ethics Review Committee had not served its purpose but only had drawn considerable criticism for its dysfunctional approach amongst its members. The 01<sup>st</sup> Respondent upon considering all aspects had sought to dissolve the said Ethics Review Committee whilst allowing the Petitioner and other members of the said Ethics Review Committee had sought to dissolve the said Ethics Review Committee.

Hence the application of the petitioner to impugn the decision to discontinue her from services has been misconstrued in law and the proper remedy lies not in the area of jurisdiction of this court, as invited to be exercised by the Petitioner.

The application of the Petitioner seeking Writ of Certiorari and Mandamus is misconceived in fact and law. The Faculty Board of the Faculty of Medicine of the University of Kelaniya has duly ratified the dissolution of the Ethics Review Committee headed by the Petitioner and the appointment of a new Ethics Review Committee. Therefore, the decisions challenged by the Petitioner are in fact decisions made within the legal parameters and there were compelling reasons to make the said decisions. The Petitioner has failed to seek a writ of certiorari to quash the decision of the Faculty Board ratifying the decision of the 01<sup>st</sup> Respondent to appoint a new Ethics Review Committee.

The Writ of Mandamus sought by the Petitioner seeking to direct the Faculty Board to appoint a new Ethics Review Committee is redundant and nugatory in as much as a new Ethics Review Committee has already been appointed by the Faculty Board.

The Writ of Mandamus sought by the Petitioner directing the Faculty Board to adopt the purported Standard Operating Procedures submitted by the dissolved Committee cannot be granted in law as there is no justification to adopt such standards without same being duly reviewed and discussed by the experts and scholars involved in such field and such expert technical matters. The decisions of the Faculty Board will only be subject to the writ jurisdiction of this Court in an instance, where the decision is ultra vires, irrational, unreasonable or arbitrary, none of the grounds which the Petitioner has established in the instant matter before this Court. In any event, the Petitioner has also failed to identify any statutory duty in seeking the said writ of mandamus which is a necessary condition precedent in seeking writs of mandamus.

For the foregoing reasons, it is my considered view that the type of proceedings initiated by the petitioner to challenge the propriety of the decision of the Dean to terminate her services has been wrongly chosen from and out of the available remedies and thus misconstrued in law. In another word, the petitioner has boarded into a vehicle that cannot take her to the desired destination at all and therefore she is yet to identify an appropriate vehicle for her journey, to ensure that she is safely made to reach her desired destination.

The application of the Petitioner is an action of private nature and therefore not governed by any statutes of the Democratic Socialist Republic of Sri Lanka. As such the Petitioner is not entitled to invoke the writ jurisdiction of this Court.

The merits of the case also do not warrant the issuance of the writs prayed for. As such the Petitioner's application warrants dismissal.

Application Dismissed with Cost.

**Judge of the Court of Appeal**

**R. Gurusinghe J.**

**I agree.**

**Judge of the Court of Appeal**