



SRI RAMACHANDRA UNIVERSITY

(Established under Section 3 of the UGC Act, 1956)

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INSTITUTIONAL ETHICS COMMITTEE

(Other than Clinical Evaluation of Drugs / Procedures/ Devices/ Diagnostics/Vaccines/
Herbal Remedies)

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Dr.Venkatesan.P

Member Secretary:

Dr.Padmavathi R.

Members:

Dr.Ramesh Hari Hara Iyer

Dr.Darling Chellathai David

Dr.C.D.Narayanan

Dr.T.S.Lokeswari

Dr.S.Nirupa

Dr.Nalini Ganesan

Dr.Ravishankar

Ms.A.G.Shanthi

Mr.S.Rethinakumar –Legal Consultant

Ms.Sheeba Vinod

To
Mr.S.Gopalsamy
Tutor
Dept.of Microbiology
SRU

20.04.09.

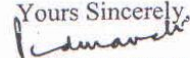
Dear Sir,

REF: IEC-NI/09/APR /09/11

**SUB: Molecular and Immunological characterization of arboviral infections
(Dengue and Chikungunya) – Ph.D.Proposal.**

Thank you for submitting the above proposal to the Institutional Ethics Committee, which was discussed in the meeting, held on 18.04.09. The Institutional Ethics Committee approves the project. You are advised to be familiar with ICMR guidelines on Biomedical Research in human beings and also to adhere to the Principles of good clinical practice. You are required to submit the final report on the completion of study to the Institutional Ethics Committee.

Yours Sincerely,


(DR.R.PADMAVATHI)

Member Secretary

Note: Please quote IEC Reference number in all future communication.

APPENDIX 2

PATIENT INFORMATION SHEET AND INFORMED CONSENT

Title of study	Molecular and Immunological characterization of Arboviral infections (Dengue and Chikungunya)
Name of the principal investigator/Guide	Dr.Padma Srikanth
Name of the investigator	Mr.S. Gopalsamy
Address of principal investigator	Department of Microbiology, Sri Ramachandra University Porur, Chennai - 600116.
Name of participant	_____
Initials of participant	_____/_____/_____ First Middle Last
Study ID of patient	_____

DESCRIPTION OF THE STUDY

Purpose of the Study: Dengue and Chikungunya are important arthropod borne virus that disease characterized by fever, head ache, rash nausea, vomiting, myalgia and arthralgia. It is associated with a fatal haemorrhagic condition. The objective of this study is to determine the Molecular characteristics of Chikungunya virus and Dengue and to study the Immunology of Chikungunya infections and Dengue infections. Profiling of cytokine levels will help in correlating the clinical symptoms, disease stratification and to determine disease severity. This has important implications in developing therapeutic interventions.

Selection of Study Participants: Participation in the study is completely voluntary. Patients suffering from fever for less than 10 days will be included in the study. In addition to the suggestive clinical diagnosis, all patients had the dengue virus and chikungunya virus infection confirmed either by Enzyme –linked immunosorbent (ELISA)-IgM or serotype specific reverse transcription-polymerase chain reaction (RT-PCR for Dengue and Chikungunya). Samples will be collected from healthy individuals those who are not having fever with in last one month.

Role of the Participant: You will be required to make at least one or two visits to the hospital. You will be required to provide information relevant to your disease and/or general health.

Following this 5ml of blood sample will be taken. The procedure does not require overnight hospitalization. All safety precautions will be taken during sampling. You will not be made to incur any additional expenditure for the required investigations. You will have to consent to an unrestricted release of all the information provided and blood samples obtained to the researchers for them to use for the purpose of the study.

Methodology: The information provided by you will be documented by the investigators in a proforma. The blood sample obtained will be used to analyze the presence of viral genetic material in plasma by a RT-PCR technique. This information will be recorded and compared with the results from other participating patients.

Evaluation of Additional Blood Samples (Optional): If you agree, noted by signature on a separate page (Attachment 1. Additional Blood Sample, you will have additional blood samples drawn (5 ml or about one-half table spoon). The serum from these samples will be stored for future testing that may include marker of bone metabolism quality and genetic testing. The serum form these blood samples will be stored at a central laboratory for a period not exceeding 12 years form the conclusion of the study.

After all analyses are done, your samples will be destroyed. The information obtained from the analysis of your samples may be used scientifically, and the analysis of your samples may contribute to the greater understanding of the pathogenesis of CHIKV and dengue infection Furthermore, you may not receive any compensation, royalty, or other financial benefit that may result from any product, procedure, or other work product that may be developed from studying your samples.

You are still eligible to participate in the study even if you choose not to have these additional samples taken.

Possible risk to the participant:

During drawing of blood, mild discomfort and minimal bleeding will occur at the site where blood is drawn. The samples will be collected by only trained people and allow minimizing the occurrence of complications.

Possible Benefits to the medical profession:

Development of Multiplex PCR will help in rapid and specific diagnosis of Chikungunya, Dengue and Dengue sub typing. To understand the evolution of these current circulating chikungunya viruses and to study the molecular epidemiology sequencing of the viruses is required. The cytokine profile of CHIKV infection will be correlated with dengue infection and may favour early identification of patients with poor prognosis and may contribute to the establishment of more directed therapeutic procedures than the present one.

Cost and Payments to the participant: There is no cost for participation in this study. Participation is completely voluntary and no payment will be provided.

Confidentiality: Information obtained in this study is strictly confidential. Your name will not be used in reporting of information in publications or conference presentations.

Participants' right to withdraw from the study: You have to right to refuse to participate in this study, the right to withdraw from the study and the right to have your data destroyed at any point during or after the study, without penalty and without affecting the medical care provided to you.

Voluntary consent by the participant: Participation in this study is completely voluntary, and your consent is required before you can participate in this study.

PATIENT'S DECLARATION

I have read this consent form (or it has been read to me) and I fully understand the contents of this document and voluntarily consent to participate in the study. All of my questions concerning this study have been answered. If I have any questions in the future about this study they will be answered by the investigators. I understand that this consent ends at the conclusion of this study.

By signing this form, I agree to participate in this study. A copy of this form has been given to me.

Date

Name of the Patient

Signature / Thumb impression

Name of Witness

Signature / Thumb impression

CERTIFICATION OF INFORMED CONSENT

I certify that I have explained the nature and purpose of this study to the above named individual, and I have discussed the potential benefits of this study participation. The questions the individual had about this study have been answered, and we will always be available to address further questions.

Date

Name of the Investigator

Signature of the Investigator

PATIENT INFORMATION SHEET AND INFORMED CONSENT

Additional Blood Samples

Attachment 1

Signature Page

To have additional blood samples drawn for future testing, you must sign on this page.

By signing this page, you are confirming the following:

1. You have read the information in Additional Blood Samples (Optional) section
2. All of your questions have been answered to your satisfaction.
3. You voluntarily agree to have additional blood samples drawn and stored by the investigators.
4. You may refuse to participate or freely choose to stop being a part of this study at any time without penalty or loss of benefits.
5. You will receive a copy of this signed and dated Patient Information Sheet and Consent Form to keep for yourself.

_____	_____	_____
Date	Name of the Patient	Signature / Thumb impression
	_____	_____
	Name of Witness	Signature / Thumb impression

Certification of informed consent for additional blood samples (optional)

I hereby certify that the study procedures in detail were explained and all questions were fully and clearly answered to the above mentioned participant.

_____	_____	_____
Date	Name of the Investigator	Signature of the Investigator

ASSENT FORM FOR (CHILDREN 12-18 YEARS)

Why are we meeting with you?

We want to tell you about something we are doing called a research study. A research study is when doctors collect a lot of information to learn more about something. My

self and other members of the team are doing a study to learn more about children with chronic kidney disease. After I tell you about it, we will ask if you'd like to be in this study or not.

Why are we doing this study?

What will happen to you if you are in this study?

Will this study hurt?

Will you get better if you are in this study?

Do you have any questions?

You can ask questions any time. You can ask now. You can ask later. You can talk to me or you can talk to someone else.

Do you have to be in this study?

No, you don't. No one will be mad at you if you don't want to do this. If you don't want to be in this study, just tell us. Or if you do want to be in the study, tell us that. And, remember, you can say yes now and change your mind later. It's up to you.

If you don't want to be in this study, just tell us.

Your treatment will not be affected in anyway by non-participating in this study.

If you want to be in this study, just tell us.

The doctor will give you a copy of this form to keep.

I, _____ understand that my parents (mom and dad)/guardian have/has given permission (said it's okay) for me to take part in a project.

I am taking part because I want to. I have been told that I can stop at any time I want to and nothing will happen to me if I want to stop.

Signature

APPENDIX 3

SRI RAMACHANDRA UNIVERISITY, CHENNAI – 600 116.

DEPARTMENT OF MICROBIOLOGY

CHIKUNGUNYA/DENGUE PROFORMA

Name		Age/Sex:		Date
Address				
Contact No.				
Post illness day		Date of onset of fever		
Specimen		Lab No.		
OPD/IPD No:		Ward:		
History of Current illness				
S.No	Symptoms	Yes	No	Duration
1	Abrupt onset of fever			
2	Fever			
3	Intermittent fever			
4	Chills			
5	Head Ache			
6	Severe joint pain			
7	Joint inflammation			
8	Low back pain			
9	Hemorrhage			
10	Rash			
11	Maculo-papular rash on trunk and limbs			
12	Myalgia			
13	Arthralgia			
14	Suffusion of Conjunctiva			
15	Slight photophobia			
16	Convulsions			
17	Hepatomegaly			
18	Splenomegaly			

APPENDIX 4

SEQUENCES RETRIEVED FROM GENBANK DATA BASE

Accession Number	Country	Year
AF339485	Tanzania	1953
HM045811	Tanzania	1953
HM045792	South Africa	1956
HM045810	Thailand	1958
HM045809	Congo	1960
HM045823	Angola	1962
HM045803	India	1963
HM045813	India	1963
EF027140	India	1963
HM045821	Senegal	1963
HM045788	India	1973
EF027141	India	1973
HM045814	Thailand	1975
HM045795	South Africa	1976
HM045805	South Africa	1976
HM04582	Central African Republic	1978
HM045808	Thailand	1978
HM045791	Indonesia	1983
HM045790	Philippines	1985
HM045797	Indonesia	1985
HM045800	Philippines	1985
HM045806	India	1986
HM045789	Thailand	1988
HM045820	Cote d'ivoire	1993
HM045796	Thailand	1995
HM045802	Thailand	1995
HM045787	Thailand	1995
EF0271394	India	2000
KF283986	Grande Island	2005
KP702297	Grande Island	2005
FR717337	La Reunion	2005
KF283987	Comoros	2005
FR717336	Reunion	2005
EF452494	USA	2006
EU703759	Malaysia	2006
EU703760	Malaysia	2006
EU703761	Malaysia	2006
EU703762	Malaysia	2006
FN295483	Malaysia	2006
FN295484	Malaysia	2006
AB455493	Srilanka	2006
AB455494	Srilanka	2006
DQ443544	Reunion	2006
EF012359	Mauritius	2006

EF210157	Mauritius	2006
EU037962	Mauritius	2006
EU372006	India	2006
EU564334	Mauritius	2006
EU564335	India	2006
FJ000062	India	2006
FJ000063	India	2006
FJ000065	India	2006
FJ000066	India	2006
FJ000067	India	2006
FJ807896	Singappore	2006
FJ959103	Mauritius	2006
GU18906	Srilanka	2006
KP003807	France	2006
KP003808	Madagaskar	2006
KP003809	Mayotte	2006
EF027134	India	2006
GQ428210	India	2006
EU192142	Singapore	2006
JX442959	India	2006
HM159384	India	2006
KM673291	Indonesia	2006
KJ941050	India	2006
EF027136	India	2006
EF027137	India	2006
JF274082	India	2006
EF027138	India	2006
EF027135	India	2006
EU192143	Indonesia	2007
FJ807887	Indonesia	2007
FJ807886	Indonesia	2007
EF452493	Thailand	2007
EU192143	Indonesia	2007
FJ807897	Indonesia	2007
L37661	USA	2007
KM923918	Malaysia	2007
KM923917	Malaysia	2007
KM923919	Malaysia	2007
KM923920	Malaysia	2007
EU244823	Italy	2007
DQ443544	Reunion	2006
EF012359	Mauritius	2006
EF210157	Mauritius	2006
EU037962	Mauritius	2006
EU372006	India	2006
EU564334	Mauritius	2006
EU564335	India	2006
FJ000062	India	2006
FJ000063	India	2006
FJ000065	India	2006

FJ000066	India	2006
FJ000067	India	2006
FJ807896	Singapore	2006
FJ959103	Mauritius	2006
GU18906	Srilanka	2006
KP003807	France	2006
KP003808	Madagascar	2006
KP003809	Mayotte	2006
EF027134	India	2006
GQ428210	India	2006
EU192142	Singapore	2006
JX442959	India	2006
HM159384	India	2006
KM673291	Indonesia	2006
KJ941050	India	2006
EF027136	India	2006
EF027137	India	2006
JF274082	India	2006
EF027138	India	2006
EF027135	India	2006
EU192143	Indonesia	2007
FJ807887	Indonesia	2007
FJ807886	Indonesia	2007
EF452493	Thailand	2007
EU192143	Indonesia	2007
FJ807897	Indonesia	2007
L37661	USA	2007
KM923918	Malaysia	2007
KM923917	Malaysia	2007
KM923919	Malaysia	2007
KM923920	Malaysia	2007
EU244823	Italy	2007
FJ445427	Srilanka	2007
FJ445428	Srilanka	2007
KP003810	Italy	2007
KP003811	Italy	2007
KP003812	Gabon	2007
GQ428211	India	2007
GQ428213	India	2007
HM045799	Srilanka	2007
KP164570	Italy	2007
KF578457	Srilanka	2007
KF578458	Srilanka	2007
KF578459	Srilanka	2007
JX442960	India	2007
JX442961	India	2008
JX442962	India	2008
GU199353	India	2008
GU199351	India	2008
GU199350	China	2008

HQ848080	India	2008
FJ807891	Indonesia	2008
FJ807890	Indonesia	2008
FJ807888	Indonesia	2008
KJ796848	Thailand	2008
KJ796849	Thailand	2008
KJ796851	Thailand	2008
FJ807891	Indonesia	2008
FJ000068	India	2008
FJ000069	India	2008
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FJ445431	Singapore	2008
FJ445432	Singapore	2008
FJ445433	Singapore	2008
FJ445443	Singapore	2008
FJ445463	Singapore	2008
FJ445484	Singapore	2008
FJ445502	Singapore	2008
FJ513628	Srilanka	2008
FJ445511	Singapore	2008
FJ513629	Srilanka	2008
FJ513632	Srilanka	2008
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FJ513645	Srilanka	2008
FJ513654	Srilanka	2008
FJ513657	Srilanka	2008
FJ513673	Srilanka	2008
FJ513675	Srilanka	2008
FJ513679	Srilanka	2008
FJ807898	Bangladesh	2008
FJ807899	Malaysia	2008
FN295487	Malaysia	2008
GU013528	Srilanka	2008
GU013530	Srilanka	2008
GU301780	Thailand	2008
GQ428212	India	2008
GQ428214	India	2008
GQ428215	India	2008
FN295485	Malaysia	2008
FJ445510	Srilanka	2008
FJ513635	Srilanka	2008
FJ807892	Malaysia	2008
FJ807894	India	2008
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JX276647	India	2008
FJ807889	Indonesia	2008
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HM067743	Singapore	2009

HQ848081	India	2009
JN558834	India	2009
JN558835	India	2009
JN558836	India	2009
KF151174	Myanmar	2009
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KJ796844	India	2009
KJ796847	Thailand	2009
KJ796850	Thailand	2009
KJ796852	Thailand	2009
KP164869	Thailand	2009
GQ905863	Thailand	2009
GU013529	Srilanka	2009
GU301779	Thailand	2009
GU301781	Thailand	2009
GU908223	Thailand	2009
HM045801	Srilanka	2009
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KJ796846	India	2009
HM038418	India	2009
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HM067744	Thailand	2009
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KC862329	Indonesia	2010
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JQ065890	China	2010
JQ065891	China	2010
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AB857731	Thailand	2010

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AB857762	Thailand	2010
AB857763	Thailand	2010
AB857764	Thailand	2010
AB857784	Thailand	2010
HM159387	India	2010
AB857777	Thailand	2010
AB857780	Thailand	2010
JX276649I	India	2010
JX442965I	India	2010
HQ846356	China	2010
HQ846357	China	2010
HQ846358	China	2010
HQ846359	China	2010
KJ679578	India	2011
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JQ861253	Cambodia	2011
JQ86125	Cambodia	2011
JQ861258	Cambodia	2011
JQ861259	Cambodia	2011
JQ861260	Cambodia	2011

KC614648	Yemen	2011
KP003813	Congo	2011
JQ861256	Cambodia	2011
JQ861257	Cambodia	2011
JX442967	India	2011
JX442968	India	2011
KF425514	India	2011
KF818475	India	2011
HE806461	New Caledonia	2011
JX276650	India	2011
KT336779	India	2012
KT336780	India	2012
KC488650	China	2012
KF318729	China	2012
HM045784	Srilanka	2012
HM045812	Uganda	2012
HE806461	New Caledonia	2012
KF818472	India	2012
KF818473	India	2012
AB860301	Philippines	2013
KF872195	Russia	2013
KJ579184	Thailand	2013
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KT336782	India	2013
KT58102	Brazil	2014
KP164567	Brazil	2014
KP164572	Brazil	2014
KP164571	Brazil	2014
KP851710	Mexico	2014
KP851709	Mexico	2014
KR559495	Puretico Rico	2014
KR559485	Virgin Island	2014
KR559483	Puerto Rica	2014
KR559482	Virgin Island	2014
KR046227	Trinidad	2014
KR046228	Trinidad	2014
KR046230	Trinidad	2014
KR046232	Trinidad	2014
KR046233	Trinidad	2014
KR046234	Trinidad	2014
KR559470	Puerto Rico	2014
KT449801	Reunion	2014
KJ451624	British Virgin Island	2014

KR046229	Trinidad	2014
KR264949	Puerto Rico	2014
KR264951	Puerto Rico	2014
KR559471	Salvador	2014
KR559472	Salvador	2014
KR559474	Puerto Rico	2014
KR559475	Salvador	2014
KR559476	Haiti	2014
KR559477	DOMINICANREPUBLIC	2014
KR559478	Haiti	2014
KR559479	DOMINICANREPUBLIC	2014
KR559480	Virgin Island	2014
KR559481	Guatemala	2014
KT336781	India	2014
KT336782	India	2014
KT58102	Brazil	2014
KP164567	Brazil	2014
KP164572	Brazil	2014
KP164571	Brazil	2014
KP851710	Mexico	2014
KP851709	Mexico	2014
KR559495	Puerto Rico	2014
KR559485	Virgin Island	2014
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KR559482	Virgin Island	2014
KR046227	Trinidad	2014
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KR046230	Trinidad	2014
KR046232	Trinidad	2014
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KR046234	Trinidad	2014
KR559470	Puerto Rico	2014
KT449801	Reunion	2014
KJ451624	British Virgin Island	2014
KR046229	Trinidad	2014
KR264949	Puerto Rico	2014
KR55948	Salvador	2014
KR559486	Panama	2014
KR559487	Honduras	2014
KR559488	Honduras	2014
KR559489	Jamaica	2014
KR559490	Guyana	2014
KR559491	Colombia	2014
KR559492	Saint Lucia	2014
KR559493	American Soma	2014
KR559496	Guyana	2014
KR559498	Dominic	2014
KT327163	Mexico	2014
KT327164	Mexico	2014
KT327165	Mexico	2014

KT327166	Mexico	2014
KP164568	Brazil	2014
KP164569	Brazil	2014
KT581023	Brazil	2014
KP164567	Brazil	2014
KR559479	French Polynesia	2014
KT327166	Mexico	2014
KR559473	French Polynesia	2015
FJ445430	Singapore	2016