Dr. Lim Teck Onn
ClinResearch Sdn Bhd

Dr Hajjah Rosaida Hj Mohd Said
Dr Sattian Kollanthavelu
Hospital Ampang

Dr Alif Adlan Mohd Thabit
Dr. Wan Mohd Rasis Bin Wan Ahmad Kamil
Hospital Bentong

Dr Ghazali Ahmad
Hospital Kuala Lumpur

Dr Lee Yee Yan
Dr Senamjit Kaur
Hospital Raja Permaisuri Bainun, Ipoh

Dr Tan Soek Siam
Dr Wong Hin Seng
Hospital Selayang

Dr Lim Ee Keng
Dr Rafidah Abdullah
Hospital Sultan Haji Ahmad Shah, Temerloh

Dr Liu Wen Jiun
Hospital Sultanah Aminah

Dato' Dr. Muhammad Radzi Abu Hassan
Dr Ching Chen Hua
Hospital Sultanah Bahiyah, Alor Setar

Dr Suryati Yakob
Hospital Sungai Buloh

Dr Fariz Safhan Bin Mohamed Nor
Dr Mohd Ramli Seman
Hospital Tengku Ampuan Afzan, Kuantan

Dr Mohd Rahim Bin Sulong
Jabatan Kesihatan Negeri Pahang

Dr Morris Wo Chee Yuen
Nobel Dialysis Center Tuaran

Dr Ahmad Fauzi Bin Abdul Rahman
Prima Dialysis (Explorich)

Dear Sir/ Mdm,

AMENDMENTS FOR STUDY: NMRR-16-2391-33614 (IIR)
Protocol No : HR2017-01
Community screening and Prevalence of Hepatitis C and B in Pahang Malaysia based on low cost Point of Care Screening Tests (Community screening using low cost Point of Care tests, Assessment of disease activity using Nucleic Acid Tests and Outcome of patients treated with personally imported generic Anti-virals, for Chronic Hepatitis C and B in Malaysia)

Your amendment submission dated 08-February-2018 is referred.

2. Amendments of the following have been received and reviewed with reference to the above study:

Documents received and reviewed with reference to the above study:
Study Protocol Version 3.2, dated 24th January 2018
Additional of Site and Investigators:
1. Nobel Dialysis Center Kota Kinabalu Sabah - Dr Morris Wo Chee Yuen (Principal Investigator at the site)
2. Nobel Dialysis Center Tuaran Sabah - Dr Morris Wo Chee Yuen (Principal Investigator at the site)
3. Prima Dialysis (Explorich), Kluang, Johor - Dr Ahmad Fauzi Bin Abdul Rahman (Principal Investigator at the site) and Mr Chee Fook Wah (Co-Investigator)

The Medical Research & Ethics Committee, Ministry of Health Malaysia operates in accordance to the International Conference of Harmonization Good Clinical Practice Guidelines.
Comments (if any):

Decision by Medical Research & Ethics Committee:
( √ ) Approved via Expedited Review
(     ) Disapproved

Date of Decision: 23 -February-2018

DR HJH SALINA BT ABDUL AZIZ
Chairperson
Medical Research & Ethics Committee
Ministry of Health Malaysia
Ruj.Kami:(11)KKM/NIH-SEC/P17-66
Tarikh: 21-February-2017

DR. LIM TECK ONN
CLINRESEARCH SDN BHD

DR ALIF ADLAN MOHD THABIT
HOSPITAL BENTONG

DR TAN SOEK SIAM
HOSPITAL SELAYANG

DR RAFIDAH ABDULLAH
HOSPITAL SULTAN HAJI AHMAD SHAH, TEMERLOH

DATO' DR. MUHAMMAD RADZI ABU HASSAN
HOSPITAL SULTANAH BAHYAH, ALOR SETAR

DR CHING CHEN HUA
HOSPITAL SULTANAH BAHYAH, ALOR SETAR

DR FARIZ SAFHAN BIN MOHAMAD NOR
HOSPITAL TENGAU AMPUAN AFZAN, KUANTAN

Dato'/ Tuan/ Puan,

SURAT KELULUSAN ETIKA:

NMRR-16-2391-33614 (IIR)
No Protokol : HR2017-01
Community screening and Prevalence of Hepatitis C and B in Pahang Malaysia based on low
cost Point of Care Screening Tests

Dengan hormatnya perkara di atas adalah dinjuruk.

Bersama dengan surat ini dilampirkan surat kelulusan saintifik dan etika bagi projek ini. Segala rekid
dan data subjek adalah SULIT dan hanya digunakan untuk tujuan kajian dan semua isu serta
prosedur mengenai data confidentiality mesti dipatuhi. Kebenaran daripada Pengarah
Hospital/Institusi di mana kajian akan dijalankan mesti diperolehi terlebih dahulu sebelum kajian
dijalankan. Dato'/ Tuan/ Puan perlu akur dan mematuhi keputusan tersebut:

2. Penyelidik- penyelidik yang terlibat ialah:
   ClinResearch Sdn Bhd
   Dr. Lim Teck Onn (Penyelidik Utama)

   HOSPITAL BENTONG
   Dr Alif Adlan Mohd Thabit (Penyelidik Utama)
HOSPITAL SELAYANG
Dr Tan Soek Slam (Penyelidik Utama)

HOSPITAL SULTAN HAJI AHMAD SHAH, TEMERLOH
Dr Lim Ee Keng
Dr Rafidah Abdullah (Penyelidik Utama)

HOSPITAL SULTANAH BAHYAH, ALOR SETAR
Dato' Dr. Muhammad Radzi Abu Hasen (Penyelidik Utama)
Dr Ching Chen Hua (Penyelidik Utama)

HOSPITAL TENGKU AMPUAN AZAFAN, KUANTAN
Dr Fariz Salhan bin Mohamad Nor (Penyelidik Utama)


i. **Continuing Review Form** selewat-lewatnya dalam tempoh 1 bulan (30 hari) sebelum tamat tempoh kelulusan ini bagi memperbaharui kelulusan etika.

ii. **Study Final Report** pada penghujung kajian.

iii. Mendapat kelulusan etika sekiranya terdapat pindaan ke atas sebarang dokumen kajian/lokasi kajian/penyelidik.

iv. Kajian berkenaan intervensi klinikal sahaja: Laporan mengenai **all Serious Adverse Events (SAEs)**, **Suspected Unexpected Serious Adverse Reaction (SUSARs)** dan **Protocol Deviation/Violation** di lokasi kajian yang diluluskan oleh JEPP jika berkenaan. SAE perlu dilaporkan dalam tempoh 15 hari kalender dari kesedaran kejadian (awareness of event) oleh penyelidik. Laporan awal SUSAR perlu dikemukakan seawal mungkin tapi tidak melewat 7 hari kalender dari kesedaran kejadian oleh penyelidik, disusuli dengan laporan lengkap dalam tempoh tambahan 8 hari kalender.


4. Sila ambil maklum bahawa sebarang urusan surat-menyurat berkaitan dengan penyelidikan ini haruslah dinystakan nombor rujukan surat ini untuk melicinkan urusan yang berkaitan.

Sekian terima kasih.

BERKHIDMAT UNTUK NEGARA

Saya yang menurut perintah,

Dato' Dr Chang Kian Meng
Pengerusi
Jawatankuasa Etika & Penyelidikan Perubatan
Kementerian Kesihatan Malaysia
Ref: (12)KKM/NHSEC/ P17-66
Date: 21-February-2017

DR. LIM TECK ONN
CLINRESEARCH SDN BHD

DR ALIF ADLAN MOHD THABIT
HOSPITAL BENTONG

DR TAN SOEK SIAM
HOSPITAL SELAYANG

DR RAFIDAH ABDULLAH
HOSPITAL SULTAN HAJI AHMAD SHAH, TEMERLOH

DATO' DR. MUHAMMAD RADZI ABU HASSAN
HOSPITAL SULTANAH BAHYIAH, ALOR SETAR

DR CHING CHEN HUA
HOSPITAL SULTANAH BAHYIAH, ALOR SETAR

DR FARIZ SAFHAN BIN MOHAMAD NOR
HOSPITAL TENGKU AMPUAN AFZAN, KUANTAN

Dear Sir/ Mdm,

ETHICS INITIAL APPROVAL:

NMRR-16-2391-33614 (IIR)
Protocol No: HR2017-01
Community screening and Prevalence of Hepatitis C and B In Pahang Malaysia based on low
cost Point of Care Screening Tests

This letter is made in reference to the above matter.

2. The Medical Research and Ethics Committee (MREC), Ministry of Health Malaysia (MOH) has
provided ethical approval for this study. Please taken note that all records and data are to be kept
strictly CONFIDENTIAL and can only be used for the purpose of this study. All precaution are be
taken to maintain data confidentiality. Permission from the District Health officer/Hospital
Administrator/ Hospital Director and all relevant heads of departments /units where the study will be
carried out must be obtained prior to the study. You are required to follow and comply with the
decision.

3. The investigators involved in this study are:
   ClinResearch Sdn Bhd
   Dr. Lim Teck Onn (Penyelidik Utama)
4. The following study documents have been received and reviewed with reference to the above study:

**Documents received and reviewed with reference to the above study:**

1. Study Protocol version 1.7 08/02/2017
2. Case Report Form
3. Patient Information Sheet (PIS) and Informed Consent for the sub-study to evaluate the accuracy of the Point of Care tests to be used in the Hepatitis screening campaign in
   - English Version 1.1 dated 08/02/2017
   - Chinese Version 1.1 dated 08/02/2017
   - Bahasa Malaysia Version 1.1 dated 08/02/2017

Approval for Waiver from informed consent from the subjects who responded to the Screening Campaign and come forward for the screening tests. (prevalence / cohort study)

4. Investigators

<table>
<thead>
<tr>
<th>Name of Investigator(s)</th>
<th>Investigator's Establishment / Institution</th>
<th>Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Lim Teck Onn</td>
<td>ClinResearch Sdn Bhd</td>
<td>Principal / Coordinating Investigator</td>
</tr>
<tr>
<td>Dato' Dr Muhammad Radzi Abu Hassan</td>
<td>Hospital Sultanah Bahiyah, Alor Setar</td>
<td>Principal / Coordinating Investigator</td>
</tr>
<tr>
<td>Dr Rafidah Abdullah</td>
<td>Hospital Sultan Haji Ahmad Shah, Temerloh</td>
<td>Principal Investigator at the site</td>
</tr>
<tr>
<td>Dr Tan Soek Slam</td>
<td>Hospital Selayang</td>
<td>Principal Investigator at the site</td>
</tr>
<tr>
<td>Dr Alif Aclan Mohd Thabit</td>
<td>Hospital Bentong</td>
<td>Principal Investigator at the site</td>
</tr>
<tr>
<td>Dr Ching Chen Hua</td>
<td>Hospital Sultanah Bahiyah, Alor Setar</td>
<td>Principal Investigator at the site</td>
</tr>
<tr>
<td>Dr Fariz Saifan bin Mohamad Nor</td>
<td>Hospital Tengku Ampuan Afzan, Kuantan</td>
<td>Principal Investigator at the site</td>
</tr>
</tbody>
</table>
Please note that the approval is valid until 20-February-2018. The following are to be reported upon receiving ethical approval. Required forms can be obtained from the Medical Research Ethics Committee (MREC) website (http://www.nih.gov.my/mrec).

i. **Continuing Review Form** has to be submitted to MREC within 1 month (30 days) prior to the expiry of ethical approval.

ii. **Study Final Report** upon study completion to the MREC.

iii. Ethical approval is required in the case of amendments/changes to the study documents/study sites/study team.

iv. Applicable for Clinical Interventional Studies only: Report occurrences of all Serious Adverse Events (SAEs), Suspected Unexpected Serious Adverse Reaction (SUSARs) and Protocol Deviation/Violation at all MREC approved sites to MREC. SAEs are to be reported within 15 calendar days from awareness of event by investigator. Initial report of SUSARs are to be reported as soon as possible but not later than 7 calendar days from awareness of event by investigator, followed by a complete report within 8 additional calendar days.

100000 number of subjects/patients/respondents are targeted to enroll this study in Malaysia.

Please take note that the reference number for this letter must be stated in all correspondence related to this study to facilitate the process.

Comments (if any):

Project Sites:
- ClinResearch Sdn Bhd
- HOSPITAL BENTONG
- HOSPITAL SELAYANG
- HOSPITAL SULTAN HAJI AHMAD SHAH, TEMERLOH
- HOSPITAL SULTANAH BAHYAH, ALOR SETAR
- HOSPITAL TENGGU AMPUAN AFZAN, KUANTAN

Decision by Medical Research & Ethics Committee:
( □ ) Approved
( □ ) Disapproved

Date of Approval: 21-February-2017

DATO' DR CHANG KIAN MENG
Chairperson
Medical Research & Ethics Committee
Ministry of Health Malaysia
Dear Sir/ Mdm,

AMENDMENTS FOR STUDY: NMRR-16-2391-33614 (IIIR)
Protocol No: HR2017-01
Community screening and Prevalence of Hepatitis C and B in Pahang Malaysia based on low cost Point of Care Screening Tests

Your amendment submission dated 27-March-2017 is referred.

2. Amendments of the following have been received and reviewed with reference to the above study:
Documents received and reviewed with reference to the above study:

Addition of investigators:

**HOSPITAL TENGGU AMPUAN AFZAN, KUANTAN**
- Dato' Dr Mohd Ramli Bin Seman (Principal Investigator at the site)
- Dr Kiren Kaur AVP Bhajan Singh (Co / Sub Investigator at the site)
- Lim Bee Chiu (Co / Sub Investigator at the site)
- Fatihah Binti Mahmud (Co / Sub Investigator at the site)

**HOSPITAL BENTONG**
- Dr Wan Mohd Rasis Bin Wan Ahmad Kamil (Principal Investigator at the site)

**HOSPITAL SELAYANG**
- Dr Wong Hin Seng (Principal Investigator at the site)
- Lee Fei Yee (Co / Sub Investigator at the site)
- Dr Suryati Binti Yakob (Co / Sub Investigator at the site)

**HOSPITAL SULTANAH AMINAH JOHOR BAHRU**
- Dr Liu Wen Juin (Principal Investigator at the site)
- Dr Tee Shin Kuan (Co / Sub Investigator at the site)

The Medical Research & Ethics Committee, Ministry of Health Malaysia operates in accordance to the International Conference of Harmonization Good Clinical Practice Guidelines.

Comments (if any):

Decision by Medical Research & Ethics Committee:
( √ ) Approved via Expedited Review
(    ) Disapproved

Date of Decision: 21-April-2017

**DATO’ DR. CHANG KIAN MENG**
Chairman
Medical Research & Ethics Committee
Ministry of Health Malaysia
Dear Sir/ Mdm,

Dr. Lim Teck Onn
Clinresearch Sdn Bhd

Dr. Alif Adlan Mohd Thabit
Hospital Bentong

Dr. Wan Mohd Rasis Bin Wan Ahmad Kamil
Hospital Bentong

Doctor Ghazali Ahmad
Hospital Kuala Lumpur

Dr. Lee Yee Yan
Hospital Raja Permaisuri Batin, Ipoh

Dr. Tan Soek Siam
Hospital Selayang

Dr. Wong Hin Seng
Hospital Selayang

Dr. Rafidah Abdullah
Hospital Sultan Haji Ahmad Shah, Temerloh

Dr. Liu Wen Jiun
Hospital Sultanah Aminah

Dato' Dr. Muhammad Radzi Abu Hassan
Hospital Sultanah Bahiyah, Alor Setar

Dr. Ching Chen Hua
Hospital Sultanah Bahiyah, Alor Setar

Dr. Suryati Yakob
Hospital Sungai Buloh

Dr. Fariz Safhan Bin Mohamad Nor
Hospital Tengku Ampuan Afzan, Kuantan

Dr. Mohd Ramlil Seman
Hospital Tengku Ampuan Afzan, Kuantan
AMENDMENTS FOR STUDY: NMRR-16-2391-33614 (IIR)
PROTOCOL NO.: HR2017-01
COMMUNITY SCREENING AND PREVALENCE OF HEPATITIS C AND B IN PAHANG MALAYSIA
BASED ON LOW COST POINT OF CARE SCREENING TESTS

Your amendment submission dated 05-June-2017 is referred.

2. Amendments of the following have been received and reviewed with reference to the above study:

<table>
<thead>
<tr>
<th>Documents received and reviewed with reference to the above study:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Additional of Investigators and Sites:</td>
</tr>
<tr>
<td>1. Hospital Kuala Lumpur:</td>
</tr>
<tr>
<td>- Datuk Dr Ghazali Bin Ahmad (Principal Investigator at the site)</td>
</tr>
<tr>
<td>- Dr Izzaty Binti Dalawi (Co / Sub Investigator at the site)</td>
</tr>
<tr>
<td>- Dr Karina Koh (Co / Sub Investigator at the site)</td>
</tr>
<tr>
<td>- Dr Murninina Binti Abdul Malek (Co / Sub Investigator at the site)</td>
</tr>
<tr>
<td>- Dr Nurul Asyiqin (Co / Sub Investigator at the site)</td>
</tr>
<tr>
<td>2. Hospital Raja Permaisuri Bainun, Ipoh: Dr Lee Yee Yan (Principal Investigator at the site)</td>
</tr>
<tr>
<td>- Dr Loh Chek Loong (Co / Sub Investigator at the site)</td>
</tr>
<tr>
<td>- Dr Sridhar Ramanaidu (Co / Sub Investigator at the site)</td>
</tr>
<tr>
<td>3. Hospital Sungai Buloh:</td>
</tr>
<tr>
<td>- Dr Suryati Yakob (Principal Investigator at the site)</td>
</tr>
</tbody>
</table>

The Medical Research & Ethics Committee, Ministry of Health Malaysia operates in accordance to the International Conference of Harmonization Good Clinical Practice Guidelines.

Comments (if any):

Decision by Medical Research & Ethics Committee:

( √ ) Approved via Expedited Review
( ) Disapproved

Date of Decision: 05-June-2017

DATO' DR. CHANG KIAN MENG
Chairman
Medical Research & Ethics Committee
Ministry of Health Malaysia
Ref: (18) KKM/NIHSEC/ P17-66
Date: 17-July-2017

DR. LIM TECK ONN
CLINRESEARCH SDN BHD

DATO' DR. MUHAMMAD RADZI ABU HASSAN
HOSPITAL SULTANAH BAHYAH, ALOR SETAR

DR ALIF ADLAN MOHD THABIT
HOSPITAL BENTONG

DR. WAN MOHD RASIS BIN WAN AHMAD KAMIL
HOSPITAL BENTONG

DOCTOR GHAZALI AHMAD
HOSPITAL KUALA LUMPUR

DR LEE YEE YAN
HOSPITAL RAJA PERMAISURI BAINUN, IPOH

DR TAN SOEK SIAM
HOSPITAL SELAYANG

DR WONG HIN SENG
HOSPITAL SELAYANG

DR LIM EE KENG
HOSPITAL SULTAN HAJI AHMAD SHAH, TEMERLOH

DR RAFIDAH ABDULLAH
HOSPITAL SULTAN HAJI AHMAD SHAH, TEMERLOH

DR LIU WEN JIUN
HOSPITAL SULTANAH AMINAH

DR CHING CHEN HUA
HOSPITAL SULTANAH BAHYAH, ALOR SETAR

DR SURYATI YAKOB
HOSPITAL SUNGAI BULOH

DR FARIZ SAFHAN BIN MOHAMAD NOR
HOSPITAL TENGKU AMPUAN AFZAN, KUANTAN

DR MOHD RAMLI SEMAN
HOSPITAL TENGKU AMPUAN AFZAN, KUANTAN
DR MOHD RAHIM BIN SULONG
JABATAN KESIHATAN NEGERI PAHANG

Dear Sir/ Mdm,

AMENDMENTS FOR STUDY: NMRR-16-2391-33614 (IIR)
Protocol No : HR2017-01
Community screening and Prevalence of Hepatitis C and B in Pahang Malaysia based on low cost Point of Care Screening Tests

Your amendment submission dated 13-July-2017 is referred.

2. Amendments of the following have been received and reviewed with reference to the above study:

<table>
<thead>
<tr>
<th>Documents received and reviewed with reference to the above study:</th>
</tr>
</thead>
<tbody>
<tr>
<td>i. Additional of Investigators and Sites:</td>
</tr>
<tr>
<td>- Site: Hospital Raja Permaisuri Bainun, Ipoh</td>
</tr>
<tr>
<td>Co / Sub Investigator at the site : Dr Chang Chee Tao</td>
</tr>
<tr>
<td>- Site : Jabatan Kesehatan Negeri Pahang</td>
</tr>
<tr>
<td>Principal Investigator at the site : Dr Mohd Rahim bin Sulong</td>
</tr>
<tr>
<td>ii. Change of role from Co / Sub Investigator to Principal Investigator at the site</td>
</tr>
<tr>
<td>Site : Hospital Sultan Haji Ahmad Shah, Temerloh</td>
</tr>
<tr>
<td>Principal Investigator at the site : Dr Lim Ee Keng</td>
</tr>
</tbody>
</table>

The Medical Research & Ethics Committee, Ministry of Health Malaysia operates in accordance to the International Conference of Harmonization Good Clinical Practice Guidelines.

Comments (if any):

Decision by Medical Research & Ethics Committee:

( √ ) Approved via Expedited Review

(    ) Disapproved

Date of Decision: 17-July-2017

DATO’ DR. CHANG KIAN MENG
Chairman
Medical Research & Ethics Committee
Ministry of Health Malaysia
DR. LIM TECK ONN
CLINRESEARCH SDN BHD

Dear Sir/ Madam,

AMENDMENTS FOR STUDY: NMRR-16-2391-33614 (IIR)
Protocol No : HR2017-01
Community screening and Prevalence of Hepatitis C and B in Pahang Malaysia based on low cost Point of Care Screening Tests

Your amendment submission dated 07-August-2017 is referred.

2. Amendments of the following have been received and reviewed with reference to the above study:

<table>
<thead>
<tr>
<th>Documents received and reviewed with reference to the above study:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Study Protocol Version 3.1, dated 07 August 2017</td>
</tr>
<tr>
<td>2. Patient Information Sheet and Consent Form English Version 2.0, dated 07 August 2017</td>
</tr>
<tr>
<td>3. Patient Information Sheet and Consent Form Bahasa Version 2.0, dated 07 August 2017</td>
</tr>
<tr>
<td>4. Patient Information Sheet and Consent Form Chinese Version 2.0, dated 07 August 2017</td>
</tr>
<tr>
<td>5. Additional of Investigator (IA-HOD-IA and CV): Dr Senamjit Kaur, Hospital Raja Permaisuri Bainun, Ipoh Principal Investigator at the site</td>
</tr>
</tbody>
</table>

The Medical Research & Ethics Committee, Ministry of Health Malaysia operates in accordance to the International Conference of Harmonization Good Clinical Practice Guidelines.

Comments (if any):

Decision by Medical Research & Ethics Committee:
( √ ) Approved via Expedited Review
(    ) Disapproved

Date of Decision: 08-August-2017

DATO’ DR. CHANG KIAN MENG
Chairman
Medical Research & Ethics Committee
Ministry of Health Malaysia
DR. LIM TECK ONN
CLINRESEARCH SDN BHD

DR HAJAH ROSAIDA HJ MD SAID
HOSPITAL AMPANG

DR SATTIAN KOLLANTHAVELU
HOSPITAL AMPANG

Dear Sir/Mdm,

AMENDMENTS FOR STUDY: NMRR-16-2391-33614 (IIR)
Protocol No.: HR2017-01
Community screening and Prevalence of Hepatitis C and B in Pahang Malaysia based on low cost Point of Care Screening Tests

Your amendment submission dated 08-September-2017 is referred.

2. Amendments of the following have been received and reviewed with reference to the above study:

Documents received and reviewed with reference to the above study:

Addition of Site and Investigators:
Site: Ampang Hospital, Selangor

Principal Investigator at the site:
Dr Hajah Rosaida Hj Md Said (IA-HOD-IA, CV, GCP Certificate enclosed)
Dr Sattian Kollanthavelu (CV, GCP Certificate enclosed)

The Medical Research & Ethics Committee, Ministry of Health Malaysia operates in accordance to the International Conference of Harmonization Good Clinical Practice Guidelines.

Comments (if any):

Decision by Medical Research & Ethics Committee:
( ) Approved via Expedited Review
( ) Disapproved

Date of Decision: 11-September-2017

DATO' DR. CHANG KIAN MENG
Chairman
Medical Research & Ethics Committee
Ministry of Health Malaysia
Dr. Lim Teck Onn  
Clinresearch Sdn Bhd

Datuk Dr. Muhammad Radzi Abu Hassan  
Hospital Sultanah Bahiyah, Alor Setar

Dato'/Tuan,

Annual Ethical Renewal for 2018: NMRR-16-2391-33614 (IIR)  
Protocol No: HR2017-01  
COMMUNITY SCREENING AND PREVALENCE OF HEPATITIS C AND B IN PAHANG MALAYSIA BASED ON LOW COST POINT OF CARE SCREENING TESTS (COMMUNITY SCREENING USING LOW COST POINT OF CARE TESTS, ASSESSMENT OF DISEASE ACTIVITY USING NUCLEIC ACID TESTS AND OUTCOME OF PATIENTS TREATED WITH PERSONALLY IMPORTED GENERIC ANTI-VIRALS, FOR CHRONIC HEPATITIS C AND B IN MALAYSIA)

With reference to the ‘Continuing Review Form’ submitted 25-January-2018, we are pleased to inform that the conduct of the above study has been granted approval (via Expedited Review by Chairperson) for a year by the Medical Research & Ethics Comittee, Ministry of Health Malaysia. Please note that the approval is valid until 4-Feb-2019. To renew the approval, a completed ‘Continuing Review Form’ has to be submitted to MREC within 1 month before the expiry of the approval.

The MREC, Ministry of Health Malaysia operates in accordance to the International Harmonization Good Clinical Practice Guidelines.

Thank you.

“BERKHIDMAT UNTUK NEGARA”

Yours sincerely,

........................................................

( DR HAJAH SALINA BINTI ABDUL AZIZ)  
Chairperson  
Medical Research & Ethics Committee  
Ministry of Health Malaysia
DR. LIM TECK ONN
CLINRESEARCH SDN BHD

DR HAJJAH ROSAIDA HJ MOHD SAID
HOSPITAL AMPANG

DR SATTIAN KOLLANTHAVELU
HOSPITAL AMPANG

DR ALIF ADLAN MOHD THABIT
HOSPITAL BENTONG

DR. WAN MOHD RASIS BIN WAN AHMAD KAMIL
HOSPITAL BENTONG

DOCTOR GHAZALI AHMAD
HOSPITAL KUALA LUMPUR

DR LEE YEE YAN
HOSPITAL RAJA PERMAISURI BAINUN, IPOH

DR SENAMJIT KAUR
HOSPITAL RAJA PERMAISURI BAINUN, IPOH

DR TAN SOEK SIAM
HOSPITAL SELAYANG

DR WONG HIN SENG
HOSPITAL SELAYANG

DR LIM EE KENG
HOSPITAL SULTAN HAJI AHMAD SHAH, TEMERLOH

DR RAFIDAH ABDULLAH
HOSPITAL SULTAN HAJI AHMAD SHAH, TEMERLOH

DR LIU WEN JIUN
HOSPITAL SULTANAH AMINAH

DATO’ DR. MUHAMMAD RADZI ABU HASSAN
HOSPITAL SULTANAH BAHIYAH, ALOR SETAR

DR CHING CHEN HUA
HOSPITAL SULTANAH BAHIYAH, ALOR SETAR

Ref : KKM.NIHSEC.P17-66 ( 30 )
Date: 04-June-2018
Dear Sir/ Mdm,

AMENDMENTS FOR STUDY: NMRR-16-2391-33614 (IIR)
Protocol No : HR2017-01
Community screening and Prevalence of Hepatitis C and B in Pahang Malaysia based on low cost Point of Care Screening Tests (Community screening using low cost Point of Care tests, Assessment of disease activity using Nucleic Acid Tests and Outcome of patients treated with personally imported generic Anti-virals, for Chronic Hepatitis C and B in Malaysia)

Your amendment submission dated 18-May-2018 is referred.
2. Amendments of the following have been received and reviewed with reference to the above study:

<table>
<thead>
<tr>
<th>Documents received and reviewed with reference to the above study:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. New site and Investigator:</td>
</tr>
<tr>
<td>a. Dr Lam Swee Win Pusat Dialysis NKF- Yayasan Sultanah Bahiyah, Kulim, Kedah as the Principal Investigator at the site</td>
</tr>
<tr>
<td>2. Co-Investigator for the approved sites:</td>
</tr>
<tr>
<td>a. Fanny Bt Paukin as Co-Investigator from Nobel Dialysis Center Tuaran Sabah</td>
</tr>
<tr>
<td>b. Kumutham A/P N.Raman as Co-Investigator from Nobel Dialysis Center Kota Kinabalu Sabah</td>
</tr>
<tr>
<td>c. Sr Siti Fatimah bt. Basir as Co-Investigator from Pusat Dialisis NKF - Dato Dr. G.A.Sreenivasan</td>
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<td>d. Sr Salma bt. Mahmud as Co-Investigator from Pusat Dialisis NKF - Superkids Trinity-Dr Eason Chang.</td>
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<td>e. Sr Wan Suriyani bt. Abdullah as Co-Investigator from Pusat Dialisis NKF - Yayasan Buah Pinggang Kemaman</td>
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<tr>
<td>f. Sr Chuah Bee Bee as Co-Investigator from Pusat Dialisis NKF - Yayasan Dialisis Pertubuhan Pendidikan Akhlak, Taiping (Moral Uplifting Society(MULS) - NKF Taiping, Perak)</td>
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<td>g. SN Suraya Abd Rasep as Co-Investigator from Pusat Dialisis NKF - Yayasan Dialisis Pertubuhan Pendidikan Akhlak, Taiping (Moral Uplifting Society(MULS) - NKF Taiping, Perak)</td>
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<tr>
<td>h. Sr Zainon Sarinin as Co-Investigator from Pusat Hemodialysis Darul Ta'zim</td>
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</tbody>
</table>

The Medical Research & Ethics Committee, Ministry of Health Malaysia operates in accordance to the International Conference on Harmonization Good Clinical Practice Guidelines.

Comments (if any):

Decision by Medical Research & Ethics Committee:
(√) Approved via Expedited Review
( ) Disapproved

Date of Decision: 04-June-2018

DR HJH SALINA BT ABDUL AZIZ
Chairperson
Medical Research & Ethics Committee
Ministry of Health Malaysia