Institutional Review Board
Translator's Declaration

IRB#:
PI:

To the Institutional Review Board:

I, Loki declare that I am fluent in and understand the English language and the Simplified Chinese language. To the best of my knowledge and belief, the attached translation(s) are true, accurate and correct.

Attached are (1) the original documents (In English) and (2) the Simplified Chinese - translated version(s).

Other than my role as a translator, I have no other involvement with the above-referenced research proposal.

Translator's Name (Print): Loki Li

Address: Shenyang, China

Phone No.: +86-24-3141-2317(18) ext. 8019 Fax No.: (____) - _____ - _____

E-mail: keyg@ecinnovations.com

Signature Loki Date 03/22/2017

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简易格式的书面知情同意书

本文档须以实验对象能理解的语言编写，并且应附在口述信息的书面总结之中。

您被要求参与一项研究。

在您同意之前，研究医生应告知您以下内容：

(i) 开展研究的原因、要完成哪些研究事项以及您参与研究的时间；
(ii) 任何实验性试验或治疗；
(iii) 您可以预期的任何风险或副作用，以及该研究可能产生的良好效果；
(iv) 如果决定不参与该研究，您可接受的其他治疗；以及
(v) 如何保存研究结果和可查看研究结果的人。

当任何下列情况适用时，研究医生还应告知您：

(i) 如果您因研究受伤，可获得的赔偿；
(ii) 其他未知的潜在风险；
(iii) 研究医生可能让您退出研究的原因；
(iv) 您参与该研究需要付出的代价；
(v) 如果您决定不再参与该研究，将会发生什么事情；
(vi) 何时告知您有关该研究的新发现，这些发现可能会影响您是否继续参与该研究；以及
(vii) 参与研究的人数。

[Insert if your study is using an investigational drug, device or biologic, otherwise please delete] 根据美国法律的要求，可在 www.clinicaltrials.gov 获取本临床试验的介绍。此网站不会包含能够识别您身份的信息。网站至多包含研究结果的总结。您可随时搜索此网站。

如果您同意参与该研究，研究医生必须给您一份署名的同意书副本和一份书面研究总结。

如果您对此项研究有任何疑问，或者您觉得此项研究已对您造成伤害，
请您随时致电 CONTACT'S PHONE NUMBER 联系 INSERT NAME OF CONTACT 。

[IF THE STUDY INCLUDES A FACULTY ADVISOR, INSERT THE FOLLOWING] 您也可以联系我的指导教授 (INSERT NAME OF FACULTY ADVISOR), 电话号码为 (INSERT FACULTY ADVISOR'S NUMBER)]。

[IF THE STUDY DOCTOR HAS A PAGER, INSERT THE FOLLOWING] 如果您无法联系到研究人员，请呼叫研究医生，传呼号码为 (INSERT INVESTIGATOR'S PAGER NUMBER)]。

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有关同意参与该研究和参与人员权利的更多信息，请联系机构审查委员会办公室 (Institutional Review Board Office)，电话号码是 (615) 322-2918 或免费电话 (866) 224-8273。

您不需要一定参与该研究。您可以选择不参与该研究并获得其他治疗，这将不影响您的医疗保健、服务或其他权利。您可随时退出研究。

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研究参与人员同意声明
已口头向我解释了该研究。我的所有问题都已获得答复，因此我自由且自愿选择参与该研究。

_____		_____	
参与者签名	Signature of Participant	日期	Date
_____		_____	
证人签名	Signature of Witness	日期	Date
_____		_____	
翻译人员签名（如果适用）		日期	Date

Signature of Interpreter (if applicable)

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SHORT FORM WRITTEN INFORMED CONSENT DOCUMENT

This document must be written in a language understandable to the subject and should be attached to a written summary of the information that is presented orally.

You are being asked to take part in a research study.

Before you agree, the study doctor must tell you about:

(i) the reason for doing the study, the things that will be done and how long you will be in the study;
(ii) any tests or treatments that are experimental;
(iii) any risks or side effects you can expect, and good effects that might come from the study;
(iv) other treatments you could get if you decide not to be in the study; and
(v) how the study records will be kept and who can see them.

When any of the following things apply, the study doctor must also tell you about:

(i) payment in case you are injured because of the research study;
(ii) the possibility of other risks that are not known;
(iii) reasons why the study doctor may take you out of the study;
(iv) costs to you if you take part in the study;
(v) what will happen if you decide to stop being in the study;
(vi) when you will be told about new findings which may affect how you feel about staying in the study; and
(vii) how many people will be in the study.

[Insert if your study is using an investigational drug, device or biologic, otherwise please delete] A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

If you agree to be in the study, the study doctor must give you a copy of this form after it is signed along with a written summary of the study.

If you have any questions about this research study or if you feel you have been hurt because of this study, please feel free to contact **(INSERT NAME OF CONTACT)** at **(CONTACT'S PHONE NUMBER).**

[IF THE STUDY INCLUDES A FACULTY ADVISOR, INSERT THE FOLLOWING: You can also contact my Faculty Advisor**, (INSERT NAME OF FACULTY ADVISOR)** at **(INSERT FACULTY ADVISOR'S NUMBER)].**

[IF THE STUDY DOCTOR HAS A PAGER, INSERT THE FOLLOWING: If you cannot reach the research staff, please page the study doctor at **(INSERT INVESTIGATOR'S PAGER NUMBER)]**.

For additional information about giving consent or your rights as a participant in this study, contact the Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

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You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services or other rights. You can stop being in this study at any time.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY
The research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

_____ _____
Signature of Participant Date

_____ _____
Signature of Witness Date

_____ _____
Signature of Translator (if applicable) Date