IRB APPROVAL/REB ATTESTATION

DATE: Friday, March 6, 2015

TO: Dr. Kenneth Atkinson
Columbia Gastroenterology Management Ltd.
410-301 East Columbia St
New Westminster, BC, V3L 3W5

PROTOCOL: AbbVie Corporation - P15-325
Impact of adalimumab on patient-reported outcomes (PROs) in Canadian patients with moderate-to-severe ulcerative colitis (UCanADA): a prospective observational cohort study (Pro00011211)

SITE APPROVAL: 2015-MAR-06

EXPIRY DATE: 9 Feb 2016

IRB APPROVED DOCUMENTATION

Protocol Version(s):

- P15-325 Version 1.2 dated 2015-JAN-05

Consent Form(s):

- Informed Consent Form Version Date: 2015-FEB-08

Other Material(s):

- Patient Instructions for Questionnaires (undated)
- Patient Module Version Draft 2 dated 2015-JAN-30
- Product Monograph for Pr HUMIRA® adalimumab 40 mg in 0.8 mL sterile solution (50 mg/mL) subcutaneous injection Version dated 2014-JAN-17

The above referenced research was reviewed by the Ontario Institutional Review Board (ON IRB) of Institutional Review Board Services. The IRB approved the research, as described above.

You have been unconditionally approved as the Investigator at your site for the above study.

The consent document(s) referenced are valid for use at your site.

Membership List

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Investigator Responsibilities

Your responsibilities are defined in pertinent regulations, ICH GCP Guidelines as well as the General Guidance: Investigator Responsibilities. You can access a copy of the General Guidance: Investigator

IRB Services, 372 Hollandview Trail, Suite 300, Aurora, Ontario, Canada L4G 0A5
tel. (905) 727-7989 *fax* (905) 727-7990 *e-mail* info@irbservices.com *web* www.irbservices.com

Responsibilities by going to your CIRBI homepage ("My Home") and selecting "Chesapeake IRB Homepage", then selecting the "IRB Services Reference Materials".

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- Prompt Reporting Events (e.g., protocol deviations, serious unexpected adverse reactions, unanticipated problems)
- Continuing review/termination reports (i.e., progress reports)

Compliance Statement/Attestation

IRB Services attests that the protocol and consent document(s) have been approved, as described above, and the membership of the IRB complies with the requirements defined in Health Canada regulations, 21 CFR parts 56 and 312.3 and 45 CFR 46. The IRB carries out its functions in accordance with good clinical practices (e.g., ICH GCP Guidelines) and Health Canada regulations and in compliance with FDA 21 CFR parts 50 and 56, DHHS 45 CFR part 46, and the Tri-Council Policy Statement for Ethical Conduct of Research Involving Humans, as appropriate to the research.

The IRBs of IRB Services are registered with OHRP and FDA as follows:
- ON IRB registration #IRB00000776
- QC IRB registration #IRB00005290

If you have any questions please do not hesitate to contact us at 905-727-7989 or via Contact IRB in CIRBI.

Sincerely,
Institutional Review Board Services

Anna Carnevale
Coordinator
Client Services
(Phase I & Special Projects Team)

IRB Services, 372 Hollandview Trail, Suite 300, Aurora, Ontario, Canada L4G 0A5
tel. (905) 727-7989 *fax* (905) 727-7990 *e-mail* info@irbservices.com *web* www.irbservices.com

Le 28 juillet 2015

Dr Guy Aumais
Gastroentérologie
Hôpital Maisonneuve-Rosemont

Objet: **Évaluation du projet de recherche** « Effets de l'adalimumab sur les résultats signalés par le patient, chez des patients canadiens atteints d'une forme modérée à grave de colite ulcéreuse (étude UCanADA)»

Docteur,

Lors de la réunion du comité scientifique de la recherche et de la convenance institutionnelle (CSRCI) tenue le 28 juillet 2015, votre projet de recherche a été jugé conforme à la convenance institutionnelle. Les membres du comité portent à votre attention qu'il s'agirait d'un projet d'une phase IV.

Dans le but d'obtenir votre lettre d'autorisation de la personne mandatée afin de mener votre étude à l'HMR, vous devrez fournir le contrat signé par toutes les parties lorsque disponible.

Les membres transmettent cette décision au comité d'éthique de la recherche (CÉR) de l'Hôpital Maisonneuve-Rosemont (HMR).

Veuillez agréer, Dr Guy Aumais, mes salutations distinguées.

En remplacement de Dr Michel Vallée, président

Imran Ahmad, M.D., M. Sc.
Membre
CSRCI

c.c. Dr Peter Vavassis, M.D., président du CÉR-HMR

Centre universitaire de santé McGill | McGill University Health Centre

Centre d'éthique appliquée
Centre for Applied Ethics

May 15, 2015

Dr. Talat Bessissow
Montreal General Hospital
1650 Cedar Avenue
Room D16.137
Montreal, Quebec
H3G 1A4

Objet : Approbation des comités d'éthique et scientifique de votre projet de recherche

Re: Approval by the research ethics and science review committees of your research study

Dr. Bessissow,

Le comité d'éthique de la recherche (CER) du Centre Universitaire de Santé McGill (CUSM) qui agit comme CER évaluateur pour le projet de recherche multicentrique suivant, et aux conditions suivantes, confirme que le résultat de l'examen éthique et scientifique est positif.

The McGill University Health Centre (MUHC) Research Ethics Committee (REB) acting as the reviewing REB for the following multi-centered research and with the following conditions confirms the science and ethics reviews received positive results.

# et Titre de la recherche/ # and Research Title:	MP-CUSM-14-478 Impact of Adalimumab on Patient-reported outcomes (PROs) in Canadian Patients Suffering from Moderate-to-severe Ulcerative Colitis (UCanADA)
Nom du promoteur/ Name of sponsor:	AbbVie Corporation
Date CER / REB meeting date:	March 12, 2015 Plénier/Full Board
Évaluation scientifique positive / Favourable science review	par le comité compétant du CUSM/by the competent MUHC Research Ethics Board
Version des documents approuvés / Version of approved documents	Research Protocol including Questionnaires(Version 1.2 January 5, 2015) in English; Revised Information and Consent Form (April 30, 2015) in French and English; Questionnaire Instructions (February 12, 2015) in French and English; Product Monograph (January 17, 2014).
Date expiration de la présente approbation éthique/ Expiry date of ethics approval	May 14, 2016
Renouvellement annuel / Annual renewal Suivi éthique continu / Continuing ethics review	Rapport d'étape annuel doit être déposé un mois avant la date d'expiration (ci-haut) / Annual progress report to be submitted one month prior to expiry date (above) N/A
Attestation du CER / REBA	N/A
FWA	FWA00000840

A) Renouvellement annuel de l'approbation éthique
Si la réalisation de cette recherche se poursuit pendant plus d'un

A) Annual renewal of the ethics approval
If your project lasts more than one year, it is important that

an, notre CER en confirmera à chaque année l'acceptabilité éthique, à condition que vous déposiez auprès du CER, un mois avant la date anniversaire de la présente lettre (tel qu'indiqué plus haut) un rapport d'étape annuel décrivant, dans son ensemble, la réalisation de la recherche.

B) Auprès d'un chercheur dans chaque établissement

Le *Cadre de référence des établissements publics du réseau de la santé et des services sociaux (RSSS) pour l'autorisation d'une recherche menée dans plus d'un établissement* établit, à l'article 11.2, que vous pouvez fournir une copie de la présente lettre à un autre chercheur qui veut demander à son établissement l'autorisation d'y mener la même recherche.

Lorsque vous fournirez ainsi une copie de cette lettre, veuillez également inclure:

- Les versions finales des documents du projet;
- Les lettres émanant de notre CER qui permettent de constater la teneur de l'examen éthique;
- Toute directive de notre CER quant aux modifications purement administratives qui peuvent être apportées à la version finale des documents approuvés.

Veuillez rappeler au chercheur qu'il doit, si ce n'est déjà fait :

- s'identifier et identifier son établissement auprès de notre CER;
- fournir à notre CER les documents démontrant sa compétence pour la réalisation du projet (confirmation de son privilège de recherche);
- fournir à notre CER l'information utile au sujet des populations et des conditions locales qui serait susceptible d'avoir une incidence sur l'évaluation de l'acceptabilité éthique du projet de recherche;
- déposer à chaque année, à la date indiquée ci-haut, un rapport d'étape sur le déroulement de la recherche dans son établissement. L'omission par le chercheur d'un établissement de déposer ce rapport ne compromettra pas le renouvellement annuel de l'approbation éthique couvrant l'ensemble de ce projet de recherche. Notre CER évaluateur pourra cependant demander à la personne mandatée dans cet établissement de suspendre l'autorisation donnée à un chercheur qui n'a pas déposé le rapport d'étape demandé.

you submit an annual progress report for review by the evaluating REB one month prior to the anniversary date of this letter (see above) for continuation of the project.

B) To the Principle Investigator at each site

In accordance with article 11.2 of the *Cadre de référence des établissements publics du réseau de la santé et des services sociaux (RSSS) pour l'autorisation d'une recherche menée dans plus d'un établissement*, you can provide another researcher with a copy of the REB approval letter to conduct the same research at another institution.

When you provide a copy of this letter please also include the following documents:

- The final versions of all study documents;
- The REB letters indicating the changes required thus reflecting the scope of ethics review;
- Any of our directives pertaining to the administrative modifications brought to the final version of the approved documents.

Please remind the researcher(s) that he or she must provide us as soon as possible with the following:

- His or her name, title and the name of the institution where the research will be conducted;
- Documents to show that the researcher has the appropriate qualifications to conduct the research (confirmation of his or her research privileges);
- All relevant information about the local populations and circumstances that may have a bearing on the ethics review;
- An annual progress report from his or her institution to be filed with us every year by the date indicated above. Failure of the researcher(s) to submit an annual progress report from that institution will not compromise the annual ethics approval of the research. Our reviewing REB may, however, ask the Personne Mandatée in that institution to suspend the authorization of the researcher to conduct research who has not submitted the required annual report.

C) Responsabilités du chercheur

L'approbation éthique du projet de recherche pourrait être suspendue si les conditions suivantes ne sont pas respectées :

- obtenir l'autorisation écrite de notre CER de toute modification substantielle à la recherche, incluant tout changement dans le déroulement de l'étude, les arrangements financiers et/ou l'utilisation de ressources avant d'effectuer les changements; à moins qu'une action immédiate et urgente est nécessaire pour éliminer tout danger pouvant compromettant le bien-

C) Duties of researchers

Ethics approval may be withdrawn if the following stipulations are not met:

- to obtain prior written approval from the REB for any substantive modification to the research, including changes to the study procedures, financial arrangements and/or resource utilization, before initiating the change; except where urgent action is required to eliminate an immediate hazard to a study subject;

être d'un participant;

- maintenir confidentiellement à jour le registres des participants pendant tout le temps requis par les lois et règlements et les politiques institutionnelles;
- vous conformer à toutes les lois, politiques et règlements qui gouvernent la recherches impliquant des êtres humains ainsi que les exigences du CER;
- vous conformer à toutes les demandes du CER notamment la nécessité de notifier le CER de toute réaction indésirable graves (RIG) inattendues ou pattern alarmant dans les RIG envisageables selon les politiques et procédures de chaque institution où la recherche s'est déroulée;
- aviser le CER ainsi que tous les participants à la recherche de nouvelles données émergentes significatives;
- vous conformer aux exigences de l'assurance de la qualité comme défini dans chaque institution;
- maintenir les dossiers et les données de la recherche selon les lois et règlements applicables.

- to maintain confidentially the updated Research Subjects Registry to be retained for the length of time required by regulations, and in accord with institutional policy;
- to comply with all relevant regulations and guidelines governing the conduct of research involving human subjects and the requirements of the REB;
- to comply with all REB requests to report study information including prompt reporting of unexpected or serious adverse events (SAEs) or alarming trands in expected SAEs, according to the policies and procedures of each institution where the study is conducted;
- to advise the REB and all study subjects of new significant findings emerging during the course of the study;
- to comply with quality assurance assessment as defined by each institution's policy,
- to maintain study records according to regulatory requirements.

Le CER du CUSM est structuré et fonctionne selon les directives publiées de *L'Énoncé de politique des trois Conseils : Éthique de la recherche avec des êtres humains2-2014*, du *Plan d'action ministériel en éthique de la recherche et en intégrité scientifique*, et en conformité avec la *Loi sur les aliments et drogues* incluant les règlements sur les aliments et drogues, sur les instruments médicaux et sur les produits de santé naturelle ainsi que les lois applicables au Québec et au Canada, les standards énoncés par le *Code of Federal Regulations* Américain qui régit la recherche sur les êtres humains, et selon les principes des bonnes pratiques cliniques (BPC) reconnues mondialement. Nous souhaitons vous aviser que les modes opératoires du CER du CUSM satisfait aux exigences de l'Attestation du comité d'éthique pour la recherche comme stipulé par Santé Canada.

The REB of the MUHC is organized and works under the published guidelines of the *Tri-Council Policy Statement 2 - 2014*, and *Plan d'action ministériel en éthique de la recherche et en intégrité scientifique*; and in compliance with the *Food and Drugs Act*, including the *Food and Drug Regulations*, *Medical Devices Regulations*, and *Natural Health Products Regulations*, and the applicable provisions of Quebec and Canadian law; and act in conformity with standards set forth in the (US) *Code of Federal Regulations* governing human subjects research, and functioning in a manner consistent with internationally accepted principles of good clinical practice (GCP). We wish to advise you that the MUHC REB working procedures completely satisfies the requirements for Research Ethics Board Attestation (REBA) as stipulated by Health Canada.

En espérant le tout à votre entière satisfaction.

Bien à vous

We trust this meets with your complete satisfaction.
Sincerely

Bertrand Lebouché M.D.
Lic 1-11755

Bertrand Lebouché, PhD, MD
Co-Président
CER du CUSM
MP-CUSM-14-478

Cc: Personne Mandatée CUSM / Mandated Person MUHC

IRB APPROVAL/REB ATTESTATION

DATE:	2015-OCT-16
TO:	Dr. Rahman Bacchus Dr. Rahman Bacchus Medicine Corporation 1275 Walker Road, Unit 7 Windsor, ON, N8Y 4C9
PROTOCOL:	AbbVie Corporation - P15-325 Impact of adalimumab on patient-reported outcomes (PROs) in Canadian patients with moderate-to-severe ulcerative colitis (UCanADA): a prospective observational cohort study (Pro00011211)
SITE APPROVAL:	2015-OCT-16
EXPIRY DATE:	2016-FEB-09

IRB APPROVED DOCUMENTATION

Protocol Version(s):

- P15-325 Version 2.0 dated April 8, 2015

Consent Form(s):

- Informed Consent Form Version Date: 2015-FEB-08

Other Material(s):

- Patient Instructions for Questionnaires (undated)
- Patient Module Version Draft 2 dated 2015-JAN-30
- Product Monograph for Pr HUMIRA® adalimumab 40 mg in 0.8 mL sterile solution (50 mg/mL) subcutaneous injection Version dated 2014-JAN-17
- Patient Module Version 2 dated 5 May 2015 (English)
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The above referenced research was reviewed by the Ontario Institutional Review Board (ON IRB) of Institutional Review Board Services. The IRB approved the research, as described above.

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Membership List

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- ON IRB registration #IRB00000776
- QC IRB registration #IRB00005290

If you have any questions please do not hesitate to contact us at 905-727-7989 or via Contact IRB in CIRBI.

Sincerely,
Institutional Review Board Services

Anna Carnevale
Coordinator
Client Services

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IRB APPROVAL/REB ATTESTATION

DATE: 2015-SEP-01

TO: Dr. Andrew Bellini
Bellini Medicine Professional Corporation
470 Chrysler Dr., Unit 11
Brampton, ON, L6S 0C1

PROTOCOL: AbbVie Corporation - P15-325
Impact of adalimumab on patient-reported outcomes (PROs) in Canadian patients with moderate-to-severe ulcerative colitis (UCanADA): a prospective observational cohort study (Pro00011211)

SITE APPROVAL: 2015-SEP-01

EXPIRY DATE: 2016-FEB-09

IRB APPROVED DOCUMENTATION

Protocol Version(s):

- P15-325 Version 2.0 dated April 8, 2015

Consent Form(s):

- Informed Consent Form Version Date: 2015-FEB-08

Other Material(s):

- Patient Instructions for Questionnaires (undated)
- Patient Module Version Draft 2 dated 2015-JAN-30
- Product Monograph for Pr HUMIRA® adalimumab 40 mg in 0.8 mL sterile solution (50 mg/mL) subcutaneous injection Version dated 2014-JAN-17
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Sincerely,
Institutional Review Board Services

Anna Carnevale
Senior Coordinator
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IRB INSTITUTIONAL REVIEW BOARD SERVICES

IRB APPROVAL/REB ATTESTATION

DATE:	20 Sep 2016
TO:	Dr. Edmond-Jean Bernard EJ Bernard MD Inc.
PROTOCOL:	AbbVie Corporation - P15-325 Impact of adalimumab on patient-reported outcomes (PROs) in Canadian patients with moderate-to-severe ulcerative colitis (UCanADA): a prospective observational cohort study (Pro00011211)
SITE APPROVAL:	20 Sep 2016
EXPIRY DATE:	15 Jan 2017

IRB APPROVED DOCUMENTATION

Protocol Version:

- P15-325 Protocol Version 3.0, April 4, 2016
- P15-325 Protocol Administrative Change 01 dated 15 December 2015

Consent Forms:

- Informed Consent Form Version Date: 2015-FEB-08 (Fr. & Eng.)

Product Information:

- Product Monograph for Pr HUMIRA® adalimumab 40 mg in 0.8 mL sterile solution (50 mg/mL) subcutaneous injection Version dated 2014-JAN-17

Recruitment Material:

- Your Trial Pamphlet (undated) (Fr. & Eng.)
- Nice to meet you (Visit 1) Brochure (undated) (Fr. & Eng.)
- Well Done (Visit 5) Brochure (undated) (Fr. & Eng.)
- Good to see you (Visit 3) Brochure (undated) (Fr. & Eng.)
- Your Condition Pamphlet (undated) (Fr. & Eng.)
- Website Information Notice Email (undated) (Fr. & Eng.)
- Welcome Back (Visit 4) Brochure (undated) (Fr. & Eng.)
- Hello Again (Visit 2) Brochure (undated) (Fr. & Eng.)
- Postcards Series (Visit 1, Visit 2, Visit 3, Visit 4, Visit 5) Rev. June 1, 2015 (Fr. & Eng.)
- Newsletter - Theme A Version dated July 8, 2015 (Fr.)
- Newsletter - Theme A Version dated July 3, 2015 (Eng.)
- Newsletter - Theme B Version dated July 8, 2015 (Fr.)
- Newsletter - Theme B Version dated July 3, 2015 (Eng.)
- Newsletter - Theme D Version dated July 8, 2015 (Fr.)
- Newsletter - Theme D Version dated July 4, 2015 (Eng.)

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tel. (905) 727-7989 *fax* (905) 727-7990 *e-mail* info@irbservices.com *web* www.irbservices.com

- Newsletter - Theme E Version dated July 8, 2015 (Fr.)
- Newsletter - Theme E Version dated July 4, 2015 (Eng.)

Other Material:

- Patient Instructions for Questionnaires (undated)
- Patient Module Version Draft 2 dated 2015-JAN-30
- Patient Module Version 2 dated 5 May 2015 (English)
- Patient Module Version 2 dated 5 May 2015 (French)
- Patient Information Form (English & French) (undated)

The above referenced research was reviewed by the Ontario Institutional Review Board (ON IRB) of IRB Services. The IRB approved the research, as described above.

You have been unconditionally approved as the Investigator at your site for the above study with the above referenced modifications.

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- QC IRB registration #IRB00005290

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Thank you for selecting IRB Services to review your research project.

Sincerely,
Institutional Review Board Services

Anna Carnavale
Senior Coordinator
Client Services

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IRB APPROVAL/REB ATTESTATION

DATE: 2015-JUN-10

TO: Dr. Ian Bookman
Kensington Screening Clinic
340 College St., Suite 601
Toronto, ON, M5T 3A9

PROTOCOL: AbbVie Corporation - P15-325
Impact of adalimumab on patient-reported outcomes (PROs) in Canadian patients with moderate-to-severe ulcerative colitis (UCanADA): a prospective observational cohort study (Pro00011211)

SITE APPROVAL: 2015-JUN-10

EXPIRY DATE: 9 Feb 2016

IRB APPROVED DOCUMENTATION

Protocol Version(s):

- P15-325 Version 2.0 dated April 8, 2015

Consent Form(s):

- Informed Consent Form Version Date: 2015-FEB-08

Other Material(s):

- Patient Instructions for Questionnaires (undated)
- Patient Module Version Draft 2 dated 2015-JAN-30
- Product Monograph for Pr HUMIRA® adalimumab 40 mg in 0.8 mL sterile solution (50 mg/mL) subcutaneous injection Version dated 2014-JAN-17
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tel. (905) 727-7989 *fax* (905) 727-7990 *e-mail* info@irbservices.com *web* www.irbservices.com

Investigator Responsibilities

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- Modifications to research (e.g., protocol amendments, revised consent forms, new or revised subject recruitment materials, change of site information, change of investigator)
- Prompt Reporting Events (e.g., protocol deviations, serious unexpected adverse reactions, unanticipated problems)
- Continuing review/termination reports (i.e., progress reports)

Compliance Statement/Attestation

IRB Services attests that the protocol and consent document(s) have been approved, as described above, and the membership of the IRB complies with the requirements defined in Health Canada regulations, 21 CFR parts 56 and 312.3 and 45 CFR 46. The IRB carries out its functions in accordance with good clinical practices (e.g., ICH GCP Guidelines) and Health Canada regulations and in compliance with FDA 21 CFR parts 50 and 56, DHHS 45 CFR part 46, and the Tri-Council Policy Statement for Ethical Conduct of Research Involving Humans, as appropriate to the research.

The IRBs of IRB Services are registered with OHRP and FDA as follows:
- ON IRB registration #IRB00000776
- QC IRB registration #IRB00005290

If you have any questions please do not hesitate to contact us at 905-727-7989 or via Contact IRB in CIRBI.

Sincerely,
Institutional Review Board Services

Anna Carnevale
Coordinator
Client Services
(Phase I & Special Projects Team)

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tel. (905) 727-7989 *fax* (905) 727-7990 *e-mail* info@irbservices.com *web* www.irbservices.com

IRB APPROVAL/REB ATTESTATION

DATE: 2015-MAY-19

TO: Dr. Marc Bradette
Centre de Recherche Saint-Louis
3165 Chemin Saint-Louis
Quebec, QC, G1W 4R4

PROTOCOL: AbbVie Corporation - P15-325
Impact of adalimumab on patient-reported outcomes (PROs) in Canadian patients with moderate-to-severe ulcerative colitis (UCanADA): a prospective observational cohort study (Pro00011211)

SITE APPROVAL: 2015-MAY-19

EXPIRY DATE: 9 Feb 2016

IRB APPROVED DOCUMENTATION

Protocol Version(s):

- P15-325 Version 1.2 dated 2015-JAN-05

Consent Form(s):

- Informed Consent Form Version Date: 2015-FEB-08

Other Material(s):

- Patient Instructions for Questionnaires (undated)
- Patient Module Version Draft 2 dated 2015-JAN-30
- Product Monograph for [Pr] HUMIRA® adalimumab 40 mg in 0.8 mL sterile solution (50 mg/mL) subcutaneous injection Version dated 2014-JAN-17

The above referenced research was reviewed by the Ontario Institutional Review Board (ON IRB) of Institutional Review Board Services. The IRB approved the research, as described above.

You have been unconditionally approved as the Investigator at your site for the above study.

The consent document(s) referenced are valid for use at your site.

The French version of the consent form is currently not available but will be forwarded to you once it becomes available.

Membership List

You can access a copy of the most recent IRB membership list by going to your CIRBI homepage ("My Home") and selecting "Chesapeake IRB Homepage", then selecting the "IRB Services Reference Materials".

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tel. (905) 727-7989 *fax* (905) 727-7990 *e-mail* info@irbservices.com *web* www.irbservices.com

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If you have any questions please do not hesitate to contact us at 905-727-7989 or via Contact IRB in CIRBI.

Sincerely,
Institutional Review Board Services

Anna Carnevale
Senior Coordinator
Client Services
(Phase I & Special Projects Team)

IRB Services, 372 Hollandview Trail, Suite 300, Aurora, Ontario, Canada L4G 0A5
tel. (905) 727-7989 *fax* (905) 727-7990 *e-mail* info@irbservices.com *web* www.irbservices.com

IRB APPROVAL/REB ATTESTATION

DATE:	2015-JUN-10
TO:	Dr. Brian Bressler Gastrointestinal Research Institute 1190 Hornby Street, Suite 770 Vancouver, BC, V6Z 2K5
PROTOCOL:	AbbVie Corporation - P15-325 Impact of adalimumab on patient-reported outcomes (PROs) in Canadian patients with moderate-to-severe ulcerative colitis (UCanADA): a prospective observational cohort study (Pro00011211)
SITE APPROVAL:	2015-JUN-10
EXPIRY DATE:	9 Feb 2016

IRB APPROVED DOCUMENTATION

Protocol Version(s):

- P15-325 Version 2.0 dated April 8, 2015

Consent Form(s):

- Informed Consent Form Version Date: 2015-FEB-08

Other Material(s):

- Patient Instructions for Questionnaires (undated)
- Patient Module Version Draft 2 dated 2015-JAN-30
- Product Monograph for Pr HUMIRA® adalimumab 40 mg in 0.8 mL sterile solution (50 mg/mL) subcutaneous injection Version dated 2014-JAN-17
- Patient Module Version 2 dated 5 May 2015 (English)
- Patient Module Version 2 dated 5 May 2015 (French)

The above referenced research was reviewed by the Ontario Institutional Review Board (ON IRB) of Institutional Review Board Services. The IRB approved the research, as described above.

You have been unconditionally approved as the Investigator at your site for the above study.

The consent document(s) referenced are valid for use at your site.

Membership List

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Sincerely,
Institutional Review Board Services

Anna Carnevale
Coordinator
Client Services
(Phase I & Special Projects Team)

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tel. (905) 727-7989 *fax* (905) 727-7990 *e-mail* info@irbservices.com *web* www.irbservices.com

IRB APPROVAL/REB ATTESTATION

DATE:	2015-SEP-01
TO:	Dr. Daniel Green Oshawa Clinic 117 King Street East Oshawa, ON, L1H 1B9
PROTOCOL:	AbbVie Corporation - P15-325 Impact of adalimumab on patient-reported outcomes (PROs) in Canadian patients with moderate-to-severe ulcerative colitis (UCanADA): a prospective observational cohort study (Pro00011211)
SITE APPROVAL:	2015-SEP-01
EXPIRY DATE:	2016-FEB-09

IRB APPROVED DOCUMENTATION

Protocol Version(s):

- P15-325 Version 2.0 dated April 8, 2015

Consent Form(s):

- Informed Consent Form Version Date: 2015-FEB-08

Other Material(s):

- Patient Instructions for Questionnaires (undated)
- Patient Module Version Draft 2 dated 2015-JAN-30
- Product Monograph for Pr HUMIRA® adalimumab 40 mg in 0.8 mL sterile solution (50 mg/mL) subcutaneous injection Version dated 2014-JAN-17
- Patient Module Version 2 dated 5 May 2015 (English)
- Patient Module Version 2 dated 5 May 2015 (French)

The above referenced research was reviewed by the Ontario Institutional Review Board (ON IRB) of Institutional Review Board Services. The IRB approved the research, as described above.

You have been unconditionally approved as the Investigator at your site for the above study.

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Anna Carnevale
Senior Coordinator
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RÉSEAU DE SANTÉ
Horizon
HEALTH NETWORK

Research Ethics Board
Horizon Health Network, SDN SIRH,
400 University Avenue, Saint John, New Brunswick, Canada E2L 4L2
Research Office - 506-648-6094 Tel 506-648-6173 Fax

September 17, 2015

Dr. Mark MacMillan,
471 Smythe Street
Atlantic SuperStore, 2nd floor
Fredericton, NB E3B 3E3

Dear Dr. MacMillan:

Re: Impact of adalimumab on patient-reported outcomes (PROs) in Canadian Patients with moderate-to-severe Ulcerative Colitis (UCanASA): A prospective observational cohort study
Principal Investigator: Dr. Mark MacMillan
File #: 2015-2182

This will acknowledge receipt of the response to the REB's conditional approval letter submitted for the above mentioned study.

This information has been reviewed, **Final Approval** is now granted by the Research Ethics Board effective September 17, 2015. Re-approval should be initiated prior to the due date of September 17, 2016.

REVIEWED:

- **Research Study Application:** version dated August 5, 2015
- **Protocol:** version 2.0 dated April 8, 2015
- **Informed Consent form and Information letter:** version dated March 18, 2015
- **Instruction for patients - Visit 1 (Baseline):** version dated May 5, 2015
- **Instruction for patients – Additional Visit 1 (Optional):** version dated May 5, 2015
- **Instruction for patients - Visit 2 (Week 8):** version dated May 5, 2015
- **Instruction for patients – Additional Visit 2 (Optional):** version dated May 5, 2015

Research Ethics Board (REB)
(Address correspondence
c/o Ethics Services)

Membership

Jeff Jennings
Chairperson/Methodological Expert
Eileen Malone
Vice Chair
Dr. Sohrab Lutchmedial
Interventional Cardiologist
Dr. Sanjay Siddhartha
Psychiatrist
Dr. Keith Wilson
Medical/ Family Medicine
Dr. Peter Martenyi
Medical/ Family Medicine
Dr. Glendon Sullivan
Medical
Dr. Hala Makary
Medical / Neonatologist
Dr. Araber Swan
Medical / Oncology
Gisia Pisegna
Pharmacist/Content Expert
Mary Reeves
Content Expert
Jonathon Chase, Q.C.
Law
Mario DiCarlo
Law
Dr. Timothy Christie, MHSc, PhD
Ethics Expert
Dr. Marc Smith, PhD
Ethics Expert
Michael Coster
Non-Scientific
Marie-Nicole LeGresley
Non-Scientific
Dr. James Croll
Methodological Expert
Marlene Mercer
Nursing/Scientific
Gordon Friars
Community
David Hanson
Community
Al Kavanaugh
Community
Audrey Lampert
Community
J. Maurice Legere
Community
Lloyd Sutherland
Community

- **Instruction for patients – Week 52 or Premature Discontinuation:** version dated May 5, 2015
- **Enrollment Form for PROGRESS Program members taking HUMIRA for Crohn's disease or adult Ulcerative Colitis:** version dated May 2014
- **Product Monograph – Humira:** version dated July 3, 2015
- **Case Report Form:** V.2Final dated June 25, 2015

Also received and on file:

- **Linked Insitution:** version undated
- **Certificate of completion – Diving into Clinical Trials-Sink or Swim – Monica Bottos:** version dated April 16-17, 2015
- **Collaborative Institutional Training Initiative (CITI Program) - Monica Bottos-Hatheway:** version dated March 24, 2015
- **CV. Monica Bottos-Hatheway**: version undated
- **CV. Dr. Mark MacMillan:** version signed and dated November 6, 2014

The Research Ethics Board for the Horizon Health Network is organized and operates according to the principles of the ICH Harmonized Tripartite Guidelines: Good Clinical Practice, Tri-Council Policy Statement and Division 5 of the Food and Drug Regulations. The Horizon Health Network REB carries out its functions in a manner consistent with Good Clinical Practices; and has reviewed and approved the clinical trial protocol and informed consent form for the trial which is to be conducted by the qualified investigator named above at the specified clinical trial site. This approval and the views of this Research Ethics Board have been documented in writing.

With kind regards,

Jeff Jennings MSc
Chair - Research Ethics Board
Horizon Health Network

JJ/jr

Centre universitaire de santé McGill
McGill University Health Centre

June 18, 2015

Dr. Talat Bessissow
687Avenue Des Pins Ouest
RoomR2.28
Montreal, Quebec

Re: MUHC Authorization to Conduct Human Subjects Research MP-CUSM-14-478-BMA

Dear Dr. Bessissow:

We are writing to confirm that the study titled " **Impact of adalimumab on patient-reported outcomes (PROs) in Canadian patients suffering from moderate-to-severe ulcerative colitis (UCanADA)** " was submitted for all institutional reviews required by the Ministry of Health and Social Services and the McGill University Health Centre policy.

The BMA Research Ethics Board (REB) has notified us that ethical approval to conduct your study has been provided.

Please refer to the MUHC Study Code **MP-CUSM-14-478-BMA** in all future correspondence relating to this study.

Enclosed you will find a fully executed original contract for your files (OCC# 2015-035).

Important Note:

You are required to advise the MUHC once the study has been initiated. Please complete the Study Status Report through the eReviews system to indicate the date the study became active.

In accordance with RI MUHC Policies (SOP-CR022), it is the investigator's responsibility to ensure that staff involved in the study has been certified to conduct clinical research. Research staff can register on the RI MUHC portal under the Clinical Research section. Should you have any questions, please do not hesitate to contact us at qaclinicalresearch@muhc.mcgill.ca.

On behalf of the MUHC, we wish you every success with the conduct of the research.

Sincerely,

Eugene Bereza MD, CM, CCFP
Director, Centre for Applied Ethics
McGill University Health Centre

Enclosures

cc: RI MUHC Study File

Centre universitaire de santé McGill
McGill University Health Centre

REB Study File
Contract Study File

Centre universitaire de santé McGill McGill University Health Centre

Centre d'éthique appliquée
Centre for Applied Ethics

May 15, 2015

Dr. Talat Bessissow
Montreal General Hospital
1650 Cedar Avenue
Room D16.137
Montreal, Quebec
H3G 1A4

Objet : Approbation des comités d'éthique et scientifique de votre projet de recherche

Re: Approval by the research ethics and science review committees of your research study

Dr. Bessissow,

Le comité d'éthique de la recherche (CER) du Centre Universitaire de Santé McGill (CUSM) qui agit comme CER évaluateur pour le projet de recherche multicentrique suivant, et aux conditions suivantes, confirme que le résultat de l'examen éthique et scientifique est positif.

The McGill University Health Centre (MUHC) Research Ethics Committee (REB) acting as the reviewing REB for the following multi-centered research and with the following conditions confirms the science and ethics reviews received positive results.

# et Titre de la recherche/ # and Research Title:	MP-CUSM-14-478 Impact of Adalimumab on Patient-reported outcomes (PROs) in Canadian Patients Suffering from Moderate-to-severe Ulcerative Colitis (UCanADA)
Nom du promoteur/ Name of sponsor:	AbbVie Corporation
Date CER / REB meeting date:	**March 12, 2015** Plénier/Full Board
Évaluation scientifique positive / Favourable science review	par le comité compétent du CUSM/by the competent MUHC Research Ethics Board
Version des documents approuvés / Version of approved documents	Research Protocol including Questionnaires(Version 1.2 January 5, 2015) in English; Revised Information and Consent Form (April 30, 2015) in French and English; Questionnaire Instructions (February 12, 2015) in French and English; Product Monograph (January 17, 2014).
Date expiration de la présente approbation éthique/ Expiry date of ethics approval	**May 14, 2016**
Renouvellement annuel / Annual renewal Suivi éthique continu / Continuing ethics review	Rapport d'étape annuel doit être déposé un mois avant la date d'expiration (ci-haut) / Annual progress report to be submitted one month prior to expiry date (above) N/A
Attestation du CER / REBA	N/A
FWA	FWA00000840

A) Renouvellement annuel de l'approbation éthique
Si la réalisation de cette recherche se poursuit pendant plus d'un

A) Annual renewal of the ethics approval
If your project lasts more than one year, it is important that

an, notre CER en confirmera à chaque année l'acceptabilité éthique, à condition que vous déposiez auprès du CER, un mois avant la date anniversaire de la présente lettre (tel qu'indiqué plus haut) un rapport d'étape annuel décrivant, dans son ensemble, la réalisation de la recherche.

B) Auprès d'un chercheur dans chaque établissement

Le *Cadre de référence des établissements publics du réseau de la santé et des services sociaux (RSSS) pour l'autorisation d'une recherche menée dans plus d'un établissement* établit, à l'article 11.2, que vous pouvez fournir une copie de la présente lettre à un autre chercheur qui veut demander à son établissement l'autorisation d'y mener la même recherche.

Lorsque vous fournirez ainsi une copie de cette lettre, veuillez également inclure:

- Les versions finales des documents du projet;
- Les lettres émanant de notre CER qui permettent de constater la teneur de l'examen éthique;
- Toute directive de notre CER quant aux modifications purement administratives qui peuvent être apportées à la version finale des documents approuvés.

Veuillez rappeler au chercheur qu'il doit, si ce n'est déjà fait :

- s'identifier et identifier son établissement auprès de notre CER;
- fournir à notre CER les documents démontrant sa compétence pour la réalisation du projet (confirmation de son privilège de recherche);
- fournir à notre CER l'information utile au sujet des populations et des conditions locales qui serait susceptible d'avoir une incidence sur l'évaluation de l'acceptabilité éthique du projet de recherche;
- déposer à chaque année, à la date indiquée ci-haut, un rapport d'étape sur le déroulement de la recherche dans son établissement. L'omission par le chercheur d'un établissement de déposer ce rapport ne compromettra pas le renouvellement annuel de l'approbation éthique couvrant l'ensemble de ce projet de recherche. Notre CER évaluateur pourra cependant demander à la personne mandatée dans cet établissement de suspendre l'autorisation donnée à un chercheur qui n'a pas déposé le rapport d'étape demandé.

C) Responsabilités du chercheur

L'approbation éthique du projet de recherche pourrait être suspendue si les conditions suivantes ne sont pas respectées :

- obtenir l'autorisation écrite de notre CER de toute modification substantielle à la recherche, incluant tout changement dans le déroulement de l'étude, les arrangements financiers et/ou l'utilisation de ressources avant d'effectuer les changements; à moins qu'une action immédiate et urgente est nécessaire pour éliminer tout danger pouvant compromettant le bien-

you submit an annual progress report for review by the evaluating REB one month prior to the anniversary date of this letter (see above) for continuation of the project.

B) To the Principle Investigator at each site

In accordance with article 11.2 of the *Cadre de référence des établissements publics du réseau de la santé et des services sociaux (RSSS) pour l'autorisation d'une recherche menée dans plus d'un établissement*, you can provide another researcher with a copy of the REB approval letter to conduct the same research at another institution.

When you provide a copy of this letter please also include the following documents:

- The final versions of all study documents;
- The REB letters indicating the changes required thus reflecting the scope of ethics review;
- Any of our directives pertaining to the administrative modifications brought to the final version of the approved documents.

Please remind the researcher(s) that he or she must provide us as soon as possible with the following:

- His or her name, title and the name of the institution where the research will be conducted;
- Documents to show that the researcher has the appropriate qualifications to conduct the research (confirmation of his or her research privileges);
- All relevant information about the local populations and circumstances that may have a bearing on the ethics review;
- An annual progress report from his or her institution to be filed with us every year by the date indicated above. Failure of the researcher(s) to submit an annual progress report from that institution will not compromise the annual ethics approval of the research. Our reviewing REB may, however, ask the Personne Mandatée in that institution to suspend the authorization of the researcher to conduct research who has not submitted the required annual report.

C) Duties of researchers

Ethics approval may be withdrawn if the following stipulations are not met:

- to obtain prior written approval from the REB for any substantive modification to the research, including changes to the study procedures, financial arrangements and/or resource utilization, before initiating the change; except where urgent action is required to eliminate an immediate hazard to a study subject;

être d'un participant;

- maintenir confidentiellement à jour le registres des participants pendant tout le temps requis par les lois et règlements et les politiques institutionnelles;
- vous conformer à toutes les lois, politiques et règlements qui gouvernent la recherches impliquant des êtres humains ainsi que les exigences du CER;
- vous conformer à toutes les demandes du CER notamment la nécessité de notifier le CER de toute réaction indésirable graves (RIG) inattendues ou pattern alarmant dans les RIG envisageables selon les politiques et procédures de chaque institution où la recherche s'est déroulée;
- aviser le CER ainsi que tous les participants à la recherche de nouvelles données émergentes significatives;
- vous conformer aux exigences de l'assurance de la qualité comme défini dans chaque institution;
- maintenir les dossiers et les données de la recherche selon les lois et règlements applicables.

Le CER du CUSM est structuré et fonctionne selon les directives publiées de *L'Énoncé de politique des trois Conseils : Éthique de la recherche avec des êtres humains2-2014*, du *Plan d'action ministériel en éthique de la recherche et en intégrité scientifique*, et en conformité avec la *Loi sur les aliments et drogues* incluant les réglements sur les aliments et drogues, sur les instruments médicaux et sur les produits de santé naturelle ainsi que les lois applicables au Québec et au Canada, les standards énoncés par le *Code of Federal Regulations* Américain qui régit la recherche sur les êtres humains, et selon les principes des bonnes pratiques cliniques (BPC) reconnues mondialement. Nous souhaitons vous aviser que les modes opératoires du CER du CUSM satisfait aux exigences de l'Attestation du comité d'éthique pour la recherche comme stipulé par Santé Canada.

En espérant le tout à votre entière satisfaction.

Bien à vous

Bertrand Lebouché M.D.
Lic 1-11755

Bertrand Lebouché, PhD, MD
Co-Président
CER du CUSM
MP-CUSM-14-478

Cc: Personne Mandatée CUSM / Mandated Person MUHC

- to maintain confidentially the updated Research Subjects Registry to be retained for the length of time required by regulations, and in accord with institutional policy;
- to comply with all relevant regulations and guidelines governing the conduct of research involving human subjects and the requirements of the REB;
- to comply with all REB requests to report study information including prompt reporting of unexpected or serious adverse events (SAEs) or alarming trends in expected SAEs, according to the policies and procedures of each institution where the study is conducted;
- to advise the REB and all study subjects of new significant findings emerging during the course of the study;
- to comply with quality assurance assessment as defined by each institution's policy,
- to maintain study records according to regulatory requirements.

The REB of the MUHC is organized and works under the published guidelines of the *Tri-Council Policy Statement 2 - 2014*, and *Plan d'action ministériel en éthique de la recherche et en intégrité scientifique*; and in compliance with the *Food and Drugs Act*, including the *Food and Drug Regulations*, *Medical Devices Regulations*, and *Natural Health Products Regulations*, and the applicable provisions of Quebec and Canadian law; and act in conformity with standards set forth in the (US) *Code of Federal Regulations* governing human subjects research, and functioning in a manner consistent with internationally accepted principles of good clinical practice (GCP). We wish to advise you that the MUHC REB working procedures completely satisfies the requirements for Research Ethics Board Attestation (REBA) as stipulated by Health Canada.

We trust this meets with your complete satisfaction.
Sincerely

MOUNT SINAI HOSPITAL

Research Ethics Board

700 University Avenue, 8th fl., Suite 8-600
Toronto, Ontario, Canada, M5G 1Z5
t: (416) 586-4875 f: (416) 586-4715
www.mtsinai.on.ca

Notification of REB Initial Approval (Delegated)

Date: April 13, 2016

To: Dr. Geoffrey Nguyen
Department of Medicine
Division of Gastroenterology
Mount Sinai Hospital
600 University Avenue, Room 437
Toronto, Ontario M5G 1X5

Re: **16-0005-E**
Impact on Adalimumab on Patient-reported Outcomes (PROs) in Canadian Patients with Moderate-to-Severe Ulcerative Colitis (UCanADA): A Prospective Observational Cohort Study

Sponsor:	AbbVie Corporation
REB Review Type:	Delegated
REB Initial Approval Date:	13 April, 2016
REB Expiry Date:	13 April, 2017
Documents Approved:	Protocol (dated 08-Apr-2015)
	Consent Form (dated 16-Feb-2016)
	Study Information for Patients (English and French) (rec. 06-Jan-2016)
	Study Newsletter (English and French) (dated 03-Jul-2015)

Documents Acknowledged:
JourneyBox Material (rec. 06-Jan-2016)
Study Visit Cards (English and French)(dated 01-Jun-2015)
Patient Questionnaire Package, Visit 1 (dated 05-May-2015)
Patient Questionnaire Package, Visit 2 (dated 05-May-2015)
Patient Questionnaire Package, Final Visit (dated 05-May-2016)
Patient Questionnaire Package, Additional Visit 1 (optional)(dated 05-May-2015)
Patient Questionnaire Package, Additional Visit 2 (optional)(dated 05-May-2015)

Health Records Access: Yes

The above named study has been reviewed and approved by the Mount Sinai Hospital Research Ethics Board. If, during the course of the research, there are any serious adverse events, confidentiality concerns, changes in the approved project, or any new information that must be considered with respect to the project, these should be brought to the immediate attention of the REB. In the event of a privacy breach, you are responsible for reporting the breach to the MSH REB and the MSH Corporate Privacy Office (in accordance with Ontario health privacy legislation – Personal Health Information Protection Act, 2004). Additionally, the MSH REB requires reports of inappropriate/unauthorized use of the information.

If the study is expected to continue beyond the expiry date, you are responsible for ensuring the study receives re-approval. The REB must be notified of the completion or termination of this study and a final report provided. As the Principal Investigator, you are responsible for the ethical conduct of this study.

The MSH Research Ethics Board operates in compliance with the Tri-Council Policy Statement 2, ICH/GCP Guidelines and Part C, Division 5 of the Food and Drug Regulations of Health Canada.

Sincerely,

Ronald Heslegrave, Ph.D.
Chair, Mount Sinai Hospital Research Ethics Board

UNIVERSITY OF CALGARY

Conjoint Health Research Ethics Board
Research Services Office
3rd Floor MacKimmie Library Tower (MLT 300)
2500 University Drive, NW
Calgary AB T2N 1N4
Telephone: (403) 220-7990
chreb@ucalgary.ca

May 26, 2016

Ethics ID: REB16-0706

Remo Panaccione

Dear Remo Panaccione :

RE: Impact of adalimumab on patient-reported outcomes (PROs) in Canadian patients suffering from moderate-to-severe ulcerative colitis

The above-named research, including:

- UCanADA Informed Consent Form, version 1, April 6, 2016
- UCanADA Patient Reported Outcomes questionnaires, version 1; May 5, 2015
- UCanADA Protocol, version 2, April 8, 2015
- HUMIRA Product Monograph, February 26, 2016

has been granted ethical approval by the Conjoint Health Research Ethics Board of the University of Calgary. The Board conforms to the Tri-Council Guidelines, ICH Guidelines and amendments to regulations of the Food and Drugs Act re clinical trials, including membership and requirements for a quorum.

You and your co-investigators are not members of the CHREB and did not participate in review or voting on this study.

This study has been reviewed by the full Conjoint Health Research Ethics Board of the University of Calgary on May 19, 2016.

Please note that this approval is subject to the following conditions:

1. A renewal must be submitted by **May 26, 2017** , containing the following information:
   i. The number of participants recruited;
   ii. A description of any protocol modification;
   iii. Any unusual and/or severe complications, adverse events or unanticipated problems involving risks to participants or others, withdrawal of participants from the research, or complaints about the research;
   iv. A summary of any recent literature, finding, or other relevant information, especially information about risks associated with the research;
   v. A copy of the current informed consent form;

vi. The expected date of termination of this project.

2. A Final Report must be submitted at the termination of the project.

Please accept the Board's best wishes for success in your research.

Sincerely,

Kathleen Oberle, PhD, Vice-Chair , CHREB

UNIVERSITY OF CALGARY

Conjoint Health Research Ethics Board
Research Services Office
3rd Floor MacKimmie Library Tower (MLT 300)
2500 University Drive, NW
Calgary AB T2N 1N4
Telephone: (403) 220-7990
chreb@ucalgary.ca

CERTIFICATION OF INSTITUTIONAL ETHICS REVIEW

This is to certify that the Conjoint Health Research Ethics Board at the University of Calgary has examined the following research proposal and found the proposed research involving human participants to be in accordance with University of Calgary Guidelines and the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* 2010 (TCPS 2). This form and accompanying letter constitute the Certification of Institutional Ethics Review.

Ethics ID:	REB16-0706
Principal Investigator:	Remo Panaccione
Co-Investigator(s):	There are no items to display
Student Co-Investigator(s):	There are no items to display
Study Title:	Impact of adalimumab on patient-reported outcomes (PROs) in Canadian patients suffering from moderate-to-severe ulcerative colitis
Sponsor (if applicable):	Contract Funded.

Effective: May 26, 2016 **Expires:** May 26, 2017

Restrictions:

This Certification is subject to the following conditions:

1. Approval is granted only for the project and purposes described in the application.
2. Any modification to the authorized study must be submitted to the Chair, Conjoint Health Research Ethics Board for approval.
3. An annual report must be submitted within 30 days prior to expiry date of this Certification, and should provide the expected completion date for the study.
4. A final report must be sent to the Board when the project is complete or terminated.

Approved By: **Date:**

Kathleen Oberle, PhD, Vice-Chair, CHREB May 26, 2016

IRB APPROVAL/REB ATTESTATION

DATE:	2015-SEP-29
TO:	Dr. Denis Petrunia Discovery Clinical Services Ltd. 601A Discovery Street Victoria, BC, V8T 5G4
PROTOCOL:	AbbVie Corporation - P15-325 Impact of adalimumab on patient-reported outcomes (PROs) in Canadian patients with moderate-to-severe ulcerative colitis (UCanADA): a prospective observational cohort study (Pro00011211)
SITE APPROVAL:	2015-SEP-29
EXPIRY DATE:	2016-FEB-09

IRB APPROVED DOCUMENTATION

Protocol Version(s):

- P15-325 Version 2.0 dated April 8, 2015

Consent Form(s):

- Informed Consent Form Version Date: 2015-FEB-08

Other Material(s):

- Patient Instructions for Questionnaires (undated)
- Patient Module Version Draft 2 dated 2015-JAN-30
- Product Monograph for Pr HUMIRA® adalimumab 40 mg in 0.8 mL sterile solution (50 mg/mL) subcutaneous injection Version dated 2014-JAN-17
- Patient Module Version 2 dated 5 May 2015 (English)
- Patient Module Version 2 dated 5 May 2015 (French)

The above referenced research was reviewed by the Ontario Institutional Review Board (ON IRB) of Institutional Review Board Services. The IRB approved the research, as described above.

You have been unconditionally approved as the Investigator at your site for the above study.

Membership List

You can access a copy of the most recent IRB membership list by going to your CIRBI homepage ("My Home") and selecting "Chesapeake IRB Homepage", then selecting the "IRB Services Reference Materials".

Investigator Responsibilities

Your responsibilities are defined in pertinent regulations, ICH GCP Guidelines as well as the General Guidance: Investigator Responsibilities. You can access a copy of the General Guidance: Investigator

IRB Services, 372 Hollandview Trail, Suite 300, Aurora, Ontario, Canada L4G 0A5
tel. (905) 727-7989 *fax* (905) 727-7990 *e-mail* info@irbservices.com *web* www.irbservices.com

Responsibilities by going to your CIRBI homepage ("My Home") and selecting "Chesapeake IRB Homepage", then selecting the "IRB Services Reference Materials".

Your responsibilities to the IRB include, but are not limited to, informing the IRB of the following using CIRBI:

- Modifications to research (e.g., protocol amendments, revised consent forms, new or revised subject recruitment materials, change of site information, change of investigator)
- Prompt Reporting Events (e.g., protocol deviations, serious unexpected adverse reactions, unanticipated problems)
- Continuing review/termination reports (i.e., progress reports)

Compliance Statement/Attestation

IRB Services attests that the protocol and consent document(s) have been approved, as described above, and the membership of the IRB complies with the requirements defined in Health Canada regulations, 21 CFR parts 56 and 312.3 and 45 CFR 46. The IRB carries out its functions in accordance with good clinical practices (e.g., ICH GCP Guidelines) and Health Canada regulations and in compliance with FDA 21 CFR parts 50 and 56, DHHS 45 CFR part 46, and the Tri-Council Policy Statement for Ethical Conduct of Research Involving Humans, as appropriate to the research.

The IRBs of IRB Services are registered with OHRP and FDA as follows:
- ON IRB registration #IRB00000776
- QC IRB registration #IRB00005290

If you have any questions please do not hesitate to contact us at 905-727-7989 or via Contact IRB in CIRBI.

Sincerely,
Institutional Review Board Services

Anna Carnevale
Coordinator
Client Services

IRB Services, 372 Hollandview Trail, Suite 300, Aurora, Ontario, Canada L4G 0A5
tel. (905) 727-7989 *fax* (905) 727-7990 *e-mail* info@irbservices.com *web* www.irbservices.com

Patient Authorization (Consent) for Use/Disclosure of Data

Study Title: Impact of adalimumab on patient-reported outcomes (PROs) in Canadian patients suffering from moderate-to-severe ulcerative colitis (UCanADA)

Study Number: P15-325

Study Sponsor: AbbVie Corporation

Doctor: **Dr. Denis Petrunia**

Address: **Discovery Clinical Services Ltd.**
601A Discovery Street
Victoria, BC, V8T 5G4
250-386-0023

Dear Patient,

You are being treated for ulcerative colitis with the approved medication HUMIRA® (adalimumab). The manufacturer of this drug and sponsor of this research, AbbVie Canada, is interested in collecting information to assess the real-life effect of HUMIRA® on psychological distress/depression symptoms, disability, fatigue, pain, or sleep quality in moderate-to-severe patients with ulcerative colitis. The research project presented below deals with the collection and storage of data only and is not designed for drug testing.

Your treating doctor is participating in this project to collect data about the standard treatment of your disease with the approved medication.

For a period of 52 weeks, information about your demographics data, medical history, disease history, your medications, your disease progression and your quality of life will be documented by your doctor and by yourself via questionnaires during your routine doctor visits. The study consists of 4 to 5 visits (inclusion, week 8, follow-up (1 and/or 2) and week 52 visits). Each visit will last about 1 hour. The questionnaires will take about 35 minutes to complete. As part of this research, the company is hoping to obtain information from approximately 200 patients with ulcerative colitis.

PATIENT REIMBURSEMENT OF PARKING EXPENSES

You will not be paid for your participation in this study. There will be no cost to you for participating in this study. You may be reimbursed for parking expenses incurred due to a longer routine doctor visit in order to complete the study questionnaires. You will be reimbursed to a maximum of twenty ($20.00) dollars for each visit. If you do not complete the study, you will receive reimbursement only for the visits you have completed up to a maximum of twenty dollars ($20.00) per visit. Reimbursement will be paid periodically.

PATIENTS AT HEART EDUCATIONAL WEBSITE (*OPTIONAL*)

The Patients at Heart (PaH) program has been in place in Canada since 2009 and reflects AbbVie's desire to put patients at the heart of clinical research. The Web site (www.patientsatheart.com) is designed to support and educate patients who are participating or considering taking part in a clinical trial. This program will be made optional and complementary to the UCanADA study.

The Web site includes a public section that contains information about all essential aspects of clinical trials and the best ways to prepare for them, patient's testimonials as well as detailed information on some conditions. The Web site also has a study-specific section for patients participating in the UCanADA study, which will include a personal account giving patients access to a journal and trial timeline as well as additional information regarding the trial.

Patient Authorization (Consent) for Use/Disclosure of Data

Patients interested in participating in this optional part of the study will receive a code and password from the principal investigator, in order to register on the Web site, and will have the opportunity to create a personal account to get access to the journal, trial timeline, and other trial details.

All data registered to the Web site will remain confidential as per AbbVie's Privacy Policy and to the extent of the limitations imposed by a Web site.

CONFIDENTIALITY:
Your privacy rights are protected by federal and provincial law. The federal Personal Information Protection and Electronic Documents Act (PIPEDA) and applicable provincial legislation pertaining to personal information and personal health information are designed to protect the privacy of your personal information. This Consent Form explains how your personal information will be collected, stored, used and disclosed for study P15-325 and describes your rights, including the right to see your personal information.

DATA WE COLLECT FROM YOU:
Your health information from your original medical records and data resulting from your participation in this research will be collected. Your health information could include physical examination details, as well as the results of questions you are asked by the study doctor or by filling out questionnaires.

HOW YOUR DATA WILL APPEAR:
Your identity and contact details will not be disclosed. Rather, your identity and contact details will be replaced by a code, such as a number.

WHY WE COLLECT THIS DATA:
Your health information will be used in study reports or for scientific presentations, but in a way that will not identify you by name. Your health information will be kept confidential and, unless required by law, will not be made publicly available. After the research has been completed, it is possible that your coded health information will be used for future studies on the drug/condition covered by the current project.

WHO WILL SEE YOUR DATA:
The only people with access to your health information in identifiable form will be your doctor and personnel helping your doctor conduct the research, sponsor representatives who are checking that the research is conducted properly, and ethics committee(s) and local and foreign regulatory authorities where required by law.

By signing this document you are allowing your doctor and personnel at the facility to permit AbbVie and/or AbbVie's representatives to have access to your health information for the purpose of collecting data, verifying the data is correct, and checking that the research is conducted properly.

Some of these organizations may be located outside of the country or region in which you live, including in countries where data protection requirements may be different or less restrictive than in your home country or region. However, AbbVie will take reasonable measures to keep your health information confidential. By signing this document, you agree to the transfer of your health information to such countries, including the United States of America.

HOW LONG WILL YOUR INFORMATION BE KEPT:
Your personal health information will be kept for a minimum of 5 years.

Patient Authorization (Consent) for Use/Disclosure of Data

TAKING BACK YOUR PERMISSION TO USE OR DISCLOSE YOUR PERSONAL HEALTH INFORMATION:
To take back your permission to use or disclose your health information you must notify your study doctor. Any information that has already been collected at the time you take back your permission will be kept and, where the law allows, your health information, will continue to be used by your doctor or AbbVie or other parties involved with the research. No new data will be collected about you after you withdraw your permission.

RIGHTS TO YOUR DATA:
You may have the right to access, correct and make a copy of your medical records as allowed by applicable privacy laws. You may ask to see your records by requesting such records from your doctor. However, to ensure the valid results of the research, you agree that you may not be able to review or make a copy of some of your records related to the research until after the research has been completed.

When you sign this document, you agree to the access, collection, processing and transfer of your health information as described in this Patient Authorization document.

The research project has no influence on the nature of the treatment for your disease. You will neither be subject to additional check-ups nor will you receive any other therapy than the therapy your doctor intended for you. Participation is of course voluntary. In case you decide against participating or if you withdraw your agreement later on, this will not have any detrimental effect on you.

I agree that my health information may be used for this research as described in this document.

_____
Patient Name (printed)

_____ _____
Signature **Date**

_____
Name of Person Obtaining Consent

_____ _____
Signature **Date**

IRB MEMBERSHIP LIST

IRB Member's Name	Profession	Role	Gender	ON IRB[1]	QC IRB[2]	Affiliated?
Diego Astein, MD	Physician - Radiologist	Physician Scientist	M	Member	Alternate	No
Morris A. Blajchman, MD, FRCPC	Physician – Hematology/Internal Medicine	Physician Scientist	M	Chair	Alternate	No
Elaine Cadotte, MA	Translation	Community Representative, Non-scientist	F	Alternate	Member	No
Michelle Charest, BSc, MAP, MEd, DESS, MA, PhD	Nursing	Scientist, Member knowledgeable in ethics relevant to biomedical research	F	Alternate	Member	No
Gordon DuVal, MA, SJD	Legal, Ethicist	Member knowledgeable in laws/ethics relevant to biomedical research, Non-scientist	M	Alternate	Member	No
Melvin H. Freedman, MD, FRCPC, FAAP	Physician – Pediatric Hematology/Oncology	Physician Scientist, Member knowledgeable in ethics relevant to biomedical research	M	Member	Alternate	No
Herschel Gold, BA, LL.B	Lawyer	Member knowledgeable in laws relevant to biomedical research, Non-scientist	M	Member	Alternate	No
Frank Guttman, BSc, CFEM, MD, MA, FRCSC, CSPQ, FAAP, FACS	Physician – Pediatric Surgery	Physician Scientist	M	Alternate	Member	No
Brian Hardy, PharmD, FCSHP, FCCP	Pharmacy	Scientist	M	Member	Alternate	No
William Harvey, MSc., PhD, BA	Regulatory Affairs	Scientist, Member knowledgeable in laws/ethics relevant to biomedical research	M	Vice-Chair	Alternate	No
Albert Jordan, MA	Professional Translator/French	Community Representative, Non-scientist	M	Alternate	Member	No
Fernand Laurendeau, BA, MD, FRCSC, FACS	Physician – Surgery	Physician Scientist	M	Alternate	Chair	No
Ramesh Mehra	Engineer	Community Representative, Non-scientist	M	Alternate	Alternate	No
Cameron Mitchell, BA, CIP	Research Ethics	Community Representative, Non-scientist	M	Alternate	Alternate	Yes
Dan Popovici-Toma, MD	Medical Advisor	Physician Scientist	M	Alternate	Alternate	No
Jean Poupart, BComm, LLL, DDN	Notary, Research Ethics	Member knowledgeable in laws/ethics relevant to biomedical research	M	Alternate	Alternate	No
Carol Sadorra, PhD	Research Consultant	Non-Scientist	F	Alternate	Alternate	No
Suzette Salama, BPharm, MSc, PhD	Ethicist, Pharmacy	Member knowledgeable in ethics relevant to biomedical research, Scientist	F	Alternate	Alternate	No
Robert Sarrazin, BPharm	Regulatory Affairs	Scientist, Member knowledgeable in laws relevant to biomedical research	M	Alternate	Vice-Chair	No
Marc Servant, BSc, MSc, PhD	Pharmacology	Scientist	M	Alternate	Alternate	No
Philip Shaposnick, BA, BCL	Legal	Community Representative, Non-scientist	M	Alternate	Alternate	No
H. Mitchell Shulman, MDCM, FRCPC, CSPQ	Physician – Emergency Medicine	Physician Scientist	M	Alternate	Alternate	No
Marianne Vanderwel, MEng, MSc	Quality Assurance, Research Ethics	Scientist, Member knowledgeable in laws/ethics relevant to biomedical research	F	Alternate	Member	No
Leslie Wood, BA	Communications	Community Representative, Member knowledgeable in ethics relevant to biomedical research, Non-scientist	F	Member	Alternate	No

[1]FDA/OHRP Registration IRB00000776 Institutional Review Board Services IRB #1
[2]FDA/OHRP Registration IRB00005290 Institutional Review Board Services IRB #3

IRB Services, 372 Hollandview Trail, Suite 300, Aurora, Ontario, Canada L4G 0A5
tel. (905) 727-7989 *fax* (905) 727-7990 *e-mail* info@irbservices.com *web* www.irbservices.com

Western Research

Research Ethics

Western University Health Science Research Ethics Board
HSREB Delegated Initial Approval Notice

Principal Investigator: Dr. Terry Ponich
Department & Institution: Schulich School of Medicine and Dentistry\Medicine-Dept of,London Health Sciences Centre

Review Type: Delegated
HSREB File Number: 107483
Study Title: Impact of adalimumab on patient-reported outcomes (PROs) in Canadian patients suffering from moderate-to-severe ulcerative colitis (UCanADA): a prospective observational cohort study
Sponsor: Abbvie Corporation

HSREB Initial Approval Date: March 31, 2016
HSREB Expiry Date: March 31, 2017

Documents Approved and/or Received for Information:

Document Name	Comments	Version Date
Western University Protocol		2016/02/04
Revised Letter of Information & Consent		2016/02/25
Other	Table 1 Schedule of Assessments	2015/04/08
Data Collection Form/Case Report Form	CRFs	2015/05/05
Sponsor Protocol	AbbVie P15-325 Study Protocol Amendment 8-V2.0 - Received for Information	2015/04/08

The Western University Health Science Research Ethics Board (HSREB) has reviewed and approved the above named study, as of the HSREB Initial Approval Date noted above.

HSREB approval for this study remains valid until the HSREB Expiry Date noted above, conditional to timely submission and acceptance of HSREB Continuing Ethics Review.

The Western University HSREB operates in compliance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans (TCPS2), the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Guideline for Good Clinical Practice Practices (ICH E6 R1), the Ontario Personal Health Information Protection Act (PHIPA, 2004), Part 4 of the Natural Health Product Regulations, Health Canada Medical Device Regulations and Part C, Division 5, of the Food and Drug Regulations of Health Canada.

Members of the HSREB who are named as Investigators in research studies do not participate in discussions related to, nor vote on such studies when they are presented to the REB.

The HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940.

Ethics Officer, on behalf of Dr. Joseph Gilbert, HSREB Chair

Ethics Officer to Contact for Further Information Erika Basile __ Nicole Kosiki __ Grace Kelly __ Katelyn Harris __ Vikki Tran __

This is an official document. Please retain a copy for your files.

CENTRE DE RECHERCHE | CHUS

Le 04 septembre 2015

Dre Joannie Ruel
Gastroentérologie
CHUS - Hôtel-Dieu

OBJET: Autorisation de réaliser la recherche suivante:
2016-1195
Effets de l'adalimumab sur les résultats signalés par le patient, chez des patients canadiens atteints d'une forme modérée à grave de colite ulcéreuse

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Dre Ruel,

Il nous fait plaisir de vous autoriser à réaliser la recherche identifiée en titre au Centre intégré universitaire de santé et de services sociaux de l'Estrie - Centre hospitalier universitaire de Sherbrooke.

Cette autorisation vous est accordée sur la foi des documents que vous avez déposés auprès de notre établissement, notamment la lettre du CÉR Comité d'éthique de la recherche du Centre Universitaire de santé McGill portant la date du 15 mai 2015 qui établit que votre projet de recherche a fait l'objet d'un examen scientifique et d'un examen éthique dont le résultat est positif. Si ce CER vous informe pendant le déroulement de cette recherche d'une décision négative portant sur l'acceptabilité éthique de cette recherche, vous devrez considérer que la présente autorisation de réaliser la recherche dans notre établissement est, de ce fait, révoquée à la date que porte l'avis du CER évaluateur.

Cette autorisation de réaliser la recherche suppose également que vous vous engagez :

1. à vous conformer aux demandes du CÉR évaluateur, notamment pour le suivi éthique continu de la recherche;
2. à rendre compte au CÉR évaluateur et au signataire de la présente autorisation du déroulement du projet, des actes de votre équipe de recherche, s'il en est une, ainsi que du respect des règles de l'éthique de la recherche;
3. à respecter les moyens relatifs au suivi continu qui ont été fixés par le CÉR évaluateur;
4. à conserver les dossiers de recherche pendant la période fixée par le CÉR évaluateur, après la fin du projet, afin de permettre leur éventuelle vérification;
5. à respecter les normes administratives en vigueur dans l'établissement

La présente autorisation peut être suspendue ou révoquée par notre établissement en cas de non-respect des conditions établies. Le CÉR évaluateur en sera alors informé.

Vous consentez également à ce que notre établissement communique aux autorités compétentes des renseignements personnels qui sont nominatifs au sens de la loi en présence d'un cas avéré de manquement à la conduite responsable en recherche de votre part lors de la réalisation de cette recherche.

Nous vous invitons à entrer en communication avec nous pendant le déroulement de cette recherche dans notre établissement, si besoin est. Vous pouvez aussi solliciter l'appui de notre CÉR en vous adressant à Mme Caroline Francoeur, poste 13473, pour obtenir les conseils et le soutien voulu.

Nous désirons également vous faire part qu'à titre de partie contractante, nous conserverons un original du contrat (ou entente financière) et de ses annexes, signé par toutes le parties. Pour faire ouvrir une unité administrative en lien avec ce projet, bien vouloir contacter Mme Lysanne Lebrun, au poste 23531, ou par courriel à l'adresse suivante: llebrun.chus@ssss.gouv.qc.ca

Vous souhaitant tout le succès escompté dans le déroulement de cette étude, nous vous prions d'agréer l'expression de nos sentiments les meilleurs.

Sylvain Bernier, M.A.P., Ph.D.
Directeur administratif de la recherche
Centre intégré universitaire de santé et de services sociaux
de l'Estrie - Centre hospitalier universitaire de Sherbrooke

Centre universitaire de santé McGill | McGill University Health Centre

Centre d'éthique appliquée
Centre for Applied Ethics

May 15, 2015

Dr. Talat Bessissow
Montreal General Hospital
1650 Cedar Avenue
Room D16.137
Montreal, Quebec
H3G 1A4

Objet : Approbation des comités d'éthique et scientifique de votre projet de recherche

Re: Approval by the research ethics and science review committees of your research study

Dr. Bessissow,

Le comité d'éthique de la recherche (CER) du Centre Universitaire de Santé McGill (CUSM) qui agit comme CER évaluateur pour le projet de recherche multicentrique suivant, et aux conditions suivantes, confirme que le résultat de l'examen éthique et scientifique est positif.

The McGill University Health Centre (MUHC) Research Ethics Committee (REB) acting as the reviewing REB for the following multi-centered research and with the following conditions confirms the science and ethics reviews received positive results.

# et Titre de la recherche/ # and Research Title:	MP-CUSM-14-478 Impact of Adalimumab on Patient-reported outcomes (PROs) in Canadian Patients Suffering from Moderate-to-severe Ulcerative Colitis (UCanADA)
Nom du promoteur/ Name of sponsor:	AbbVie Corporation
Date CER / REB meeting date:	March 12, 2015 Plénier/Full Board
Évaluation scientifique positive / Favourable science review	par le comité compétent du CUSM/by the competent MUHC Research Ethics Board
Version des documents approuvés / Version of approved documents	Research Protocol including Questionnaires(Version 1.2 January 5, 2015) in English; Revised Information and Consent Form (April 30, 2015) in French and English; Questionnaire Instructions (February 12, 2015) in French and English; Product Monograph (January 17, 2014).
Date expiration de la présente approbation éthique/ Expiry date of ethics approval	May 14, 2016
Renouvellement annuel / Annual renewal Suivi éthique continu / Continuing ethics review	Rapport d'étape annuel doit être déposé un mois avant la date d'expiration (ci-haut) / Annual progress report to be submitted one month prior to expiry date (above) N/A
Attestation du CER / REBA	N/A
FWA	FWA00000840

A) Renouvellement annuel de l'approbation éthique
Si la réalisation de cette recherche se poursuit pendant plus d'un

A) Annual renewal of the ethics approval
If your project lasts more than one year, it is important that

an, notre CER en confirmera à chaque année l'acceptabilité éthique, à condition que vous déposiez auprès du CER, un mois avant la date anniversaire de la présente lettre (tel qu'indiqué plus haut) un rapport d'étape annuel décrivant, dans son ensemble, la réalisation de la recherche.

B) Auprès d'un chercheur dans chaque établissement

Le *Cadre de référence des établissements publics du réseau de la santé et des services sociaux (RSSS) pour l'autorisation d'une recherche menée dans plus d'un établissement* établit, à l'article 11.2, que vous pouvez fournir une copie de la présente lettre à un autre chercheur qui veut demander à son établissement l'autorisation d'y mener la même recherche.

Lorsque vous fournirez ainsi une copie de cette lettre, veuillez également inclure:

- Les versions finales des documents du projet;
- Les lettres émanant de notre CER qui permettent de constater la teneur de l'examen éthique;
- Toute directive de notre CER quant aux modifications purement administratives qui peuvent être apportées à la version finale des documents approuvés.

Veuillez rappeler au chercheur qu'il doit, si ce n'est déjà fait :

- s'identifier et identifier son établissement auprès de notre CER;
- fournir à notre CER les documents démontrant sa compétence pour la réalisation du projet (confirmation de son privilège de recherche);
- fournir à notre CER l'information utile au sujet des populations et des conditions locales qui serait susceptible d'avoir une incidence sur l'évaluation de l'acceptabilité éthique du projet de recherche;
- déposer à chaque année, à la date indiquée ci-haut, un rapport d'étape sur le déroulement de la recherche dans son établissement. L'omission par le chercheur d'un établissement de déposer ce rapport ne compromettra pas le renouvellement annuel de l'approbation éthique couvrant l'ensemble de ce projet de recherche. Notre CER évaluateur pourra cependant demander à la personne mandatée dans cet établissement de suspendre l'autorisation donnée à un chercheur qui n'a pas déposé le rapport d'étape demandé.

C) Responsabilités du chercheur

L'approbation éthique du projet de recherche pourrait être suspendue si les conditions suivantes ne sont pas respectées :

- obtenir l'autorisation écrite de notre CER de toute modification substantielle à la recherche, incluant tout changement dans le déroulement de l'étude, les arrangements financiers et/ou l'utilisation de ressources avant d'effectuer les changements; à moins qu'une action immédiate et urgente est nécessaire pour éliminer tout danger pouvant compromettant le bien-

you submit an annual progress report for review by the evaluating REB one month prior to the anniversary date of this letter (see above) for continuation of the project.

B) To the Principle Investigator at each site

In accordance with article 11.2 of the *Cadre de référence des établissements publics du réseau de la santé et des services sociaux (RSSS) pour l'autorisation d'une recherche menée dans plus d'un établissement*, you can provide another researcher with a copy of the REB approval letter to conduct the same research at another institution.

When you provide a copy of this letter please also include the following documents:

- The final versions of all study documents;
- The REB letters indicating the changes required thus reflecting the scope of ethics review;
- Any of our directives pertaining to the administrative modifications brought to the final version of the approved documents.

Please remind the researcher(s) that he or she must provide us as soon as possible with the following:

- His or her name, title and the name of the institution where the research will be conducted;
- Documents to show that the researcher has the appropriate qualifications to conduct the research (confirmation of his or her research privileges);
- All relevant information about the local populations and circumstances that may have a bearing on the ethics review;
- An annual progress report from his or her institution to be filed with us every year by the date indicated above. Failure of the researcher(s) to submit an annual progress report from that institution will not compromise the annual ethics approval of the research. Our reviewing REB may, however, ask the Personne Mandatée in that institution to suspend the authorization of the researcher to conduct research who has not submitted the required annual report.

C) Duties of researchers

Ethics approval may be withdrawn if the following stipulations are not met:

- to obtain prior written approval from the REB for any substantive modification to the research, including changes to the study procedures, financial arrangements and/or resource utilization, before initiating the change; except where urgent action is required to eliminate an immediate hazard to a study subject;

être d'un participant;

- maintenir confidentiellement à jour le registres des participants pendant tout le temps requis par les lois et règlements et les politiques institutionnelles;
- vous conformer à toutes les lois, politiques et règlements qui gouvernent la recherches impliquant des êtres humains ainsi que les exigences du CER;
- vous conformer à toutes les demandes du CER notamment la nécessité de notifier le CER de toute réaction indésirable graves (RIG) inattendues ou pattern alarmant dans les RIG envisageables selon les politiques et procédures de chaque institution où la recherche s'est déroulée;
- aviser le CER ainsi que tous les participants à la recherche de nouvelles données émergentes significatives;
- vous conformer aux exigences de l'assurance de la qualité comme défini dans chaque institution;
- maintenir les dossiers et les données de la recherche selon les lois et règlements applicables.

- to maintain confidentially the updated Research Subjects Registry to be retained for the length of time required by regulations, and in accord with institutional policy;
- to comply with all relevant regulations and guidelines governing the conduct of research involving human subjects and the requirements of the REB;
- to comply with all REB requests to report study information including prompt reporting of unexpected or serious adverse events (SAEs) or alarming trends in expected SAEs, according to the policies and procedures of each institution where the study is conducted;
- to advise the REB and all study subjects of new significant findings emerging during the course of the study;
- to comply with quality assurance assessment as defined by each institution's policy,
- to maintain study records according to regulatory requirements.

Le CER du CUSM est structuré et fonctionne selon les directives publiées de *L'Énoncé de politique des trois Conseils : Éthique de la recherche avec des êtres humains2-2014*, du *Plan d'action ministériel en éthique de la recherche et en intégrité scientifique*, et en conformité avec la *Loi sur les aliments et drogues* incluant les règlements sur les aliments et drogues, sur les instruments médicaux et sur les produits de santé naturelle ainsi que les lois applicables au Québec et au Canada, les standards énoncés par le *Code of Federal Regulations* Américain qui régit la recherche sur les êtres humains, et selon les principes des bonnes pratiques cliniques (BPC) reconnues mondialement. Nous souhaitons vous aviser que les modes opératoires du CER du CUSM satisfait aux exigences de l'Attestation du comité d'éthique pour la recherche comme stipulé par Santé Canada.

The REB of the MUHC is organized and works under the published guidelines of the *Tri-Council Policy Statement 2 – 2014*, and *Plan d'action ministériel en éthique de la recherche et en intégrité scientifique*; and in compliance with the *Food and Drugs Act*, including the *Food and Drug Regulations*, *Medical Devices Regulations*, and *Natural Health Products Regulations*, and the applicable provisions of Quebec and Canadian law; and act in conformity with standards set forth in the (US) *Code of Federal Regulations* governing human subjects research, and functioning in a manner consistent with internationally accepted principles of good clinical practice (GCP). We wish to advise you that the MUHC REB working procedures completely satisfies the requirements for Research Ethics Board Attestation (REBA) as stipulated by Health Canada.

En espérant le tout à votre entière satisfaction.

Bien à vous

Bertrand Lebouché M.D.
Lic 1-11755

Bertrand Lebouché, PhD, MD
Co-Président
CER du CUSM
MP-CUSM-14-478

We trust this meets with your complete satisfaction.
Sincerely

Cc: Personne Mandatée CUSM / Mandated Person MUHC

The University of British Columbia
Office of Research Ethics
Clinical Research Ethics Board – Room 210, 828 West 10th Avenue, Vancouver, BC V5Z 1L8

ETHICS CERTIFICATE OF EXPEDITED APPROVAL

PRINCIPAL INVESTIGATOR:	INSTITUTION / DEPARTMENT:	UBC CREB NUMBER:
Baljinder S. Salh	UBC/Medicine, Faculty of/Medicine, Department of	H15-02092

INSTITUTION(S) WHERE RESEARCH WILL BE CARRIED OUT:

Institution	Site
Vancouver Coastal Health (VCHRI/VCHA)	Vancouver General Hospital
Vancouver Coastal Health (VCHRI/VCHA)	Diamond Health Care Centre

Other locations where the research will be conducted:
N/A

CO-INVESTIGATOR(S):
Peter W.C. Kwan
Fergal Donnellan
Eric M. Yoshida
Michael Byrne
James Gray
Nazira Chatur

SPONSORING AGENCIES:
- AbbVie Inc.

PROJECT TITLE:
Impact of adalimumab on patient-reported outcomes (PROs) in Canadian patients with moderate-to-severe ulcerative colitis (UCanADA): a prospective observational cohort study

THE CURRENT UBC CREB APPROVAL FOR THIS STUDY EXPIRES: February 4, 2017

The UBC Clinical Research Ethics Board Chair or Associate Chair, has reviewed the above described research project, including associated documentation noted below, and finds the research project acceptable on ethical grounds for research involving human subjects and hereby grants approval.

This approval applies to research ethics issues only. The approval does not obligate an institution or any of its departments to proceed with activation of the study. The Principal Investigator for the study is responsible for identifying and ensuring that resource impacts from this study on any institution are properly negotiated, and that other institutional policies are followed. The REB assumes that investigators and the coordinating office of all trials continuously review new information for findings that indicate a change should be made to the protocol, consent documents or conduct of the trial and that such changes will be brought to the attention of the REB in a timely manner.

DOCUMENTS INCLUDED IN THIS APPROVAL:

Document Name	Version	Date
Protocol:		
AbbVie UCanADA P15-325 Protocol V2 08-Apr-2015	2	April 8, 2015
Consent Forms:		

APPROVAL DATE:

AbbVie UCanADA Main ICF V4_11Jan2016	4	January 11, 2016	
Investigator Brochures:			
HUMIRA Product Monograph 18Mar2015	N/A	March 18, 2015	
Questionnaire, Questionnaire Cover Letter, Tests:			
VOLP_FOLLOWUP_V2_5MAY2015	2	May 5, 2015	
VOLP_BASELINE _V2_5MAY2015	2	May 5, 2015	
eq-5d-5l_v2_5may2015	2	May 5, 2015	
SIBDQ_V2_5MAY2015	2	May 5, 2015	
PHQ9_V2_5MAY2015	2	May 5, 2015	
MOS 12 STEP_V2_5MAY2015	2	May 5, 2015	
FACIT F_V2_5MAY2015	2	May 5, 2015	
WPAI_V2_5MAY2015	2	May 5, 2015	
COVERPAGE_pro_V2_5MAY2015	2	May 5, 2015	**February 4, 2016**
Other Documents:			
SOC Progress Enrollment Form_Sep 2015	N/A	September 1, 2015	
IBD Disability Index	1	October 27, 2015	
Patient Brochure UC V3	3	August 24, 2015	
AbbVie UCanADA Thank-you Card Visit 1	N/A	August 24, 2015	
Patient Brochur UCanADA V3	3	August 24, 2015	
REB Letter re: Patients at Heart Program 24Aug2015	N/A	August 24, 2015	
AbbVie UCanADA Thank-you Card Visit 3	N/A	August 24, 2015	
AbbVie UCanADA Thank-you Card Visit 5	N/A	August 24, 2015	
AbbVie UCanADA Thank-you Card Visit 4	N/A	August 24, 2015	
Patients at Heart Website Patient Info	2	June 2, 2015	
AbbVie UCanADA Thank-you Card Visit 2	N/A	August 24, 2015	

CERTIFICATION:

In respect of clinical trials:

1. The membership of this Research Ethics Board complies with the membership requirements for Research Ethics Boards defined in Division 5 of the Food and Drug Regulations.

2. The Research Ethics Board carries out its functions in a manner consistent with Good Clinical Practices.

3. This Research Ethics Board has reviewed and approved the clinical trial protocol and informed consent form for the trial which is to be conducted by the qualified investigator named above at the specified clinical trial site. This approval and the views of this Research Ethics Board have been documented in writing.

The documentation included for the above-named project has been reviewed by the UBC CREB, and the research study, as presented in the documentation, was found to be acceptable on ethical grounds for research involving human subjects and was approved by the UBC CREB.

Approval of the Clinical Research Ethics Board by :

Dr. Christopher Nguan, Co-Chair

IRB APPROVAL/REB ATTESTATION

DATE:	Friday, March 6, 2015
TO:	Dr. Ranjit Singh Percuro Clinical Research Ltd. 1105 Pandora Avenue, Suite 200 Victoria, BC, V8V 3P9
PROTOCOL:	AbbVie Corporation - P15-325 Impact of adalimumab on patient-reported outcomes (PROs) in Canadian patients with moderate-to-severe ulcerative colitis (UCanADA): a prospective observational cohort study (Pro00011211)
SITE APPROVAL:	2015-MAR-06
EXPIRY DATE:	9 Feb 2016

IRB APPROVED DOCUMENTATION

Protocol Version(s):

- P15-325 Version 1.2 dated 2015-JAN-05

Consent Form(s):

- Informed Consent Form Version Date: 2015-FEB-08

Other Material(s):

- Patient Instructions for Questionnaires (undated)
- Patient Module Version Draft 2 dated 2015-JAN-30
- Product Monograph for Pr HUMIRA® adalimumab 40 mg in 0.8 mL sterile solution (50 mg/mL) subcutaneous injection Version dated 2014-JAN-17

The above referenced research was reviewed by the Ontario Institutional Review Board (ON IRB) of Institutional Review Board Services. The IRB approved the research, as described above.

You have been unconditionally approved as the Investigator at your site for the above study.

The consent document(s) referenced are valid for use at your site.

Membership List

You can access a copy of the most recent IRB membership list by going to your CIRBI homepage ("My Home") and selecting "Chesapeake IRB Homepage", then selecting the "IRB Services Reference Materials".

Investigator Responsibilities

Your responsibilities are defined in pertinent regulations, ICH GCP Guidelines as well as the General Guidance: Investigator Responsibilities. You can access a copy of the General Guidance: Investigator

IRB Services, 372 Hollandview Trail, Suite 300, Aurora, Ontario, Canada L4G 0A5
tel. (905) 727-7989 *fax* (905) 727-7990 *e-mail* info@irbservices.com *web* www.irbservices.com

Responsibilities by going to your CIRBI homepage ("My Home") and selecting "Chesapeake IRB Homepage", then selecting the "IRB Services Reference Materials".

Your responsibilities to the IRB include, but are not limited to, informing the IRB of the following using CIRBI:

- Modifications to research (e.g., protocol amendments, revised consent forms, new or revised subject recruitment materials, change of site information, change of investigator)
- Prompt Reporting Events (e.g., protocol deviations, serious unexpected adverse reactions, unanticipated problems)
- Continuing review/termination reports (i.e., progress reports)

Compliance Statement/Attestation

IRB Services attests that the protocol and consent document(s) have been approved, as described above, and the membership of the IRB complies with the requirements defined in Health Canada regulations, 21 CFR parts 56 and 312.3 and 45 CFR 46. The IRB carries out its functions in accordance with good clinical practices (e.g., ICH GCP Guidelines) and Health Canada regulations and in compliance with FDA 21 CFR parts 50 and 56, DHHS 45 CFR part 46, and the Tri-Council Policy Statement for Ethical Conduct of Research Involving Humans, as appropriate to the research.

The IRBs of IRB Services are registered with OHRP and FDA as follows:
- ON IRB registration #IRB00000776
- QC IRB registration #IRB00005290

If you have any questions please do not hesitate to contact us at 905-727-7989 or via Contact IRB in CIRBI.

Sincerely,
Institutional Review Board Services

Anna Carnevale
Coordinator
Client Services
(Phase I & Special Projects Team)

IRB Services, 372 Hollandview Trail, Suite 300, Aurora, Ontario, Canada L4G 0A5
tel. (905) 727-7989 *fax* (905) 727-7990 *e-mail* info@irbservices.com *web* www.irbservices.com

Research Institute
Institut de recherche

uOttawa

UNIVERSITY OF OTTAWA HEART INSTITUTE
INSTITUT DE CARDIOLOGIE DE L'UNIVERSITÉ D'OTTAWA

Ottawa Health Science Network Research Ethics Board/ Conseil d'éthique de la recherche du Réseau de science de la santé d'Ottawa
Civic Box 411 725 Parkdale Avenue, Ottawa, Ontario K1Y 4E9 613-798-5555 ext 14902 Fax 613-761-4311
http://www.ohri.ca/ohsn-reb

April 8, 2016

Dr. Richmond Sy
The Ottawa Hospital - General Campus
IBD Centre Of Excellence
Division of Gastroenterology,
501 Smyth Rd., W1213
Ottawa, ON K1H 8L6

Dear Dr. Sy:

Re: Protocol # 20150709-01H Impact of adalimumab on patient-reported outcomes (PROs) in Canadian patients with moderate-to-severe ulcerative colitis (UCanADA): a prospective observational cohort study

Thank you for the e-mail of April 8, 2016 from Melissa Tessier requesting an extension to allow more time for the sponsor to provide translation certificates.

PLEASE NOTE: THE APPROVAL OF THIS PROTOCOL IS CONDITIONAL UPON A FULLY-SIGNED STUDY CONTRACT/AGREEMENT BETWEEN THE OTTAWA HOSPITAL RESEARCH INSTITUTE, THE PRINCIPAL INVESTIGATOR AND THE SPONSOR (OR AS OTHERWISE REQUIRED). YOU CANNOT START THE STUDY, OR BEGIN TO RECRUIT RESEARCH PARTICIPANTS INTO THE STUDY UNTIL THE STUDY CONTRACT/AGREEMENT HAS BEEN SIGNED BY ALL PARTIES, AND HAS BEEN RECEIVED BY THE OTTAWA HOSPITAL RESEARCH INSTITUTE'S CONTRACTS OFFICE. FOR FURTHER DETAILS, PLEASE CONTACT CONTRACTS ADMINISTRATION AT CONTRACTS@OHRI.CA OR AT 613-798-5555 EXT. 19843.

Ethical approval has been extended to April 18, 2016.

Upon receipt, review and approval of the French Ulcerative Colitis Brochure, and missing French translation certificates/letters, in hardcopy, approval may be extended for up to one year to include the recruitment of French speaking participants.

The OHSN-REB complies with the membership requirements and operates in compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans; the International Conference on Harmonization - Good Clinical Practice: Consolidated Guideline; the provisions of the Personal Health Information Protection Act 2004; and the Food and Drug Act of Health Canada and its applicable Regulations.

The OHSN-REB has reviewed and approved the clinical trial protocol and informed consent form for the trial which is to be conducted by the qualified investigator named above at the specified clinical trial site. This approval and the views of this Research Ethics Board have been documented in writing.

Yours sincerely,

Raphael Saginur, M.D.
Chairperson
Ottawa Health Science Network Research Ethics Board

/kd

Research Institute
Institut de recherche

uOttawa

UNIVERSITY OF OTTAWA HEART INSTITUTE
INSTITUT DE CARDIOLOGIE DE L'UNIVERSITÉ D'OTTAWA

Ottawa Health Science Network Research Ethics Board/ Conseil d'éthique de la recherche du Réseau de science de la santé d'Ottawa
Civic Box 411 725 Parkdale Avenue, Ottawa, Ontario K1Y 4E9 613-798-5555 ext 14902 Fax 613-761-4311
http://www.ohri.ca/ohsn-reb

April 14, 2016

Dr. Richmond Sy
The Ottawa Hospital - General Campus
IBD Centre Of Excellence
Division of Gastroenterology,
501 Smyth Rd., W1213
Ottawa, ON K1H 8L6

Dear Dr. Sy:

Re: Protocol # 20150709-01H Impact of adalimumab on patient-reported outcomes (PROs) in Canadian patients with moderate-to-severe ulcerative colitis (UCanADA): a prospective observational cohort study

Thank you for the e-mail of April 14, 2016 from Melissa Tessier enclosing the outstanding French documentation.

The following documents are approved:
•French Postcards (visits 1-5), received March 2, 2016
•French Welcome Cards (visits 1-5), dated June 1, 2015
•French Study Brochure, received March 2, 2016
•French Ulcerative Colitis Brochure, received April 14, 2016
•French Newsletter- Theme A, dated July 8, 2015
•French Newsletter- Theme B, dated July 8, 2015
•French Newsletter- Theme D, dated July 8, 2015
•French Newsletter- Theme E, dated July 8, 2015
•French Questionnaires dated May 5, 2015
•French Participant Informed Consent Form (version 1) dated December 10, 2015

Ethical approval has been extended to February 8, 2017 to include the recruitment of French speaking participants.

The OHSN-REB complies with the membership requirements and operates in compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans; the International Conference on Harmonization - Good Clinical Practice: Consolidated Guideline; the provisions of the Personal Health Information Protection Act 2004; and the Food and Drug Act of Health Canada and its applicable Regulations.

The OHSN-REB has reviewed and approved the clinical trial protocol and informed consent form for the trial which is to be conducted by the qualified investigator named above at the specified clinical trial site. This approval and the views of this Research Ethics Board have been documented in writing.

Yours sincerely,

Raphael Saginur, M.D.
Chairperson
Ottawa Health Science Network Research Ethics Board

/kd

IRB APPROVAL/REB ATTESTATION

DATE:	2015-OCT-16
TO:	Dr. Osman Tarabain Dr. O. Tarabain Clinic 2301 Tecumseh Rd. East, Suite 140 Windsor, ON, N8W 1E6
PROTOCOL:	AbbVie Corporation - P15-325 Impact of adalimumab on patient-reported outcomes (PROs) in Canadian patients with moderate-to-severe ulcerative colitis (UCanADA): a prospective observational cohort study (Pro00011211)
SITE APPROVAL:	2015-OCT-16
EXPIRY DATE:	2016-FEB-09

IRB APPROVED DOCUMENTATION

Protocol Version(s):

- P15-325 Version 2.0 dated April 8, 2015

Consent Form(s):

- Informed Consent Form Version Date: 2015-FEB-08

Other Material(s):

- Patient Instructions for Questionnaires (undated)
- Patient Module Version Draft 2 dated 2015-JAN-30
- Product Monograph for Pr HUMIRA® adalimumab 40 mg in 0.8 mL sterile solution (50 mg/mL) subcutaneous injection Version dated 2014-JAN-17
- Patient Module Version 2 dated 5 May 2015 (English)
- Patient Module Version 2 dated 5 May 2015 (French)

The above referenced research was reviewed by the Ontario Institutional Review Board (ON IRB) of Institutional Review Board Services. The IRB approved the research, as described above.

You have been unconditionally approved as the Investigator at your site for the above study.

Membership List

You can access a copy of the most recent IRB membership list by going to your CIRBI homepage ("My Home") and selecting "Chesapeake IRB Homepage", then selecting the "IRB Services Reference Materials".

IRB Services, 372 Hollandview Trail, Suite 300, Aurora, Ontario, Canada L4G 0A5
tel. (905) 727-7989 *fax* (905) 727-7990 *e-mail* info@irbservices.com *web* www.irbservices.com

Investigator Responsibilities

Your responsibilities are defined in pertinent regulations, ICH GCP Guidelines as well as the General Guidance: Investigator Responsibilities. You can access a copy of the General Guidance: Investigator Responsibilities by going to your CIRBI homepage ("My Home") and selecting "Chesapeake IRB Homepage", then selecting the "IRB Services Reference Materials".

Your responsibilities to the IRB include, but are not limited to, informing the IRB of the following using CIRBI:

- Modifications to research (e.g., protocol amendments, revised consent forms, new or revised subject recruitment materials, change of site information, change of investigator)
- Prompt Reporting Events (e.g., protocol deviations, serious unexpected adverse reactions, unanticipated problems)
- Continuing review/termination reports (i.e., progress reports)

Compliance Statement/Attestation

IRB Services attests that the protocol and consent document(s) have been approved, as described above, and the membership of the IRB complies with the requirements defined in Health Canada regulations, 21 CFR parts 56 and 312.3 and 45 CFR 46. The IRB carries out its functions in accordance with good clinical practices (e.g., ICH GCP Guidelines) and Health Canada regulations and in compliance with FDA 21 CFR parts 50 and 56, DHHS 45 CFR part 46, and the Tri-Council Policy Statement for Ethical Conduct of Research Involving Humans, as appropriate to the research.

The IRBs of IRB Services are registered with OHRP and FDA as follows:
- ON IRB registration #IRB00000776
- QC IRB registration #IRB00005290

If you have any questions please do not hesitate to contact us at 905-727-7989 or via Contact IRB in CIRBI.

Sincerely,
Institutional Review Board Services

Anna Carnevale
Coordinator
Client Services

IRB Services, 372 Hollandview Trail, Suite 300, Aurora, Ontario, Canada L4G 0A5
tel. (905) 727-7989 *fax* (905) 727-7990 *e-mail* info@irbservices.com *web* www.irbservices.com

Centre intégré
de santé et de services
sociaux de Chaudière-
Appalaches
Québec

Le 7 juillet 2015

Docteur Raymond Bourdages
Service de gastroentérologie
CISSS de Chaudière-Appalaches
Hôtel-Dieu de Lévis

Objet : Autorisation de réaliser la recherche suivante :

« Effets de l'adalimumab sur les résultats signalés par le patient, chez des patients canadiens atteints d'une forme modérée à grave de colite ulcéreuse (étude UCanADA) »

MP-CUSM-14478 (CUSM)

2016-906 (CISSS de Chaudière-Appalaches)

Docteur,

Vous trouverez ci-joint trois exemplaires du contrat, pour le projet mentionné en titre, dûment signés par les représentants autorisés du CISSS de Chaudière-Appalaches. Bien vouloir transmettre les trois exemplaires du document à la compagnie AbbVie pour signature. Vous serez autorisée à débuter le projet de recherche susmentionné au CHAU Hôtel-Dieu de Lévis à la réception d'un exemplaire du contrat signé par les représentants de la compagnie.

En référence aux ententes conclues dans le cadre de l'étude de la convenance institutionnelle, les départements/services suivants recouvreront des coûts directs pour ce projet de recherche :

- Service des archives;

Cette autorisation vous est accordée sur la foi des documents que vous avez déposés auprès de notre établissement, notamment la lettre du CER, datée du 15 mai 2015 qui établit que votre projet de recherche a fait l'objet d'un examen scientifique et d'un examen éthique dont le résultat est positif. Si ce CER vous informe pendant le déroulement de cette recherche d'une décision négative portant sur l'acceptabilité éthique de cette recherche, vous devrez considérer que la présente autorisation de réaliser la recherche dans notre établissement est, de ce fait, révoquée à la date que porte l'avis du CER évaluateur.

Cette autorisation suppose également que vous respecterez les modalités énoncées ci-après.

Notre établissement a reçu une copie de la version finale des documents se rapportant à la recherche, approuvée par le CER évaluateur. Les modifications administratives ont été apportées au formulaire de consentement, conformément aux directives du CER évaluateur.

Cette autorisation de réaliser la recherche suppose également que vous vous engagez :

Siège social
363, route Cameron
Sainte-Marie (Québec) G6E 3E2
Téléphone : 418 386-3363
Télécopieur : 418 386-3361
www.cisss-ca.gouv.qc.ca

975, rue de la Concorde
Lévis (Québec) G6W 8A7
Téléphone : 418 380-8996

1) à vous conformer aux demandes du CER évaluateur, notamment pour le suivi éthique continu de la recherche;

2) à rendre compte au CER évaluateur et au *Guichet unique de la recherche* de la présente autorisation du déroulement du projet, des actes de votre équipe de recherche, s'il en est une, ainsi que du respect des règles de l'éthique de la recherche;

3) à respecter les moyens relatifs au suivi continu qui ont été fixés par le CER évaluateur;

4) à conserver les dossiers de recherche pendant la période fixée par le CER évaluateur, après la fin du projet, afin de permettre leur éventuelle vérification;

5) à respecter les modalités arrêtées au regard du mécanisme d'identification des sujets de recherche dans notre établissement, à savoir la tenue à jour et la conservation de la liste à jour des sujets de recherche recrutés dans notre établissement. Cette liste devra nous être fournie sur demande.

La présente autorisation peut être suspendue ou révoquée par notre établissement en cas de non-respect des conditions établies. Le CER évaluateur en sera alors informé.

Vous consentez également à ce que notre établissement communique aux autorités compétentes des renseignements personnels qui sont nominatifs au sens de la loi en présence d'un cas avéré de manquement à la conduite responsable en recherche de votre part lors de la réalisation de cette recherche.

Je vous invite à entrer en communication avec le *Guichet unique de la recherche* pendant le déroulement de cette recherche dans notre établissement pour obtenir les conseils et le soutien voulu.

En terminant, je vous demanderais de toujours mentionner dans votre correspondance au sujet de cette recherche le numéro attribué à votre demande par notre établissement ainsi que le numéro attribué au projet de recherche par le CER évaluateur.

Veuillez agréer, Docteur, l'expression de nos sentiments distingués.

Le Président-directeur général
du CISSS de Chaudière-Appalaches

Daniel Paré

DP/jd

p. j.

c. c. Dr Bertrand Lebouché, Vice-président du CER du CUSM
Guichet unique de la recherche du CISSS de Chaudière-Appalaches
Dr Talat Bessissow, Hôpital Général de Montréal

IRB APPROVAL/REB ATTESTATION

DATE: 2015-SEP-29

TO: Dr. Chadwick Williams
Dr. Chadwick Ian Williams Professional Corporation
600 Main Street, Building C, Suite 205
Saint John, NB, E2K 1J5

PROTOCOL: AbbVie Corporation - P15-325
Impact of adalimumab on patient-reported outcomes (PROs) in Canadian patients with moderate-to-severe ulcerative colitis (UCanADA): a prospective observational cohort study (Pro00011211)

SITE APPROVAL: 2015-SEP-29

EXPIRY DATE: 2016-FEB-09

IRB APPROVED DOCUMENTATION

Protocol Version(s):

- P15-325 Version 2.0 dated April 8, 2015

Consent Form(s):

- Informed Consent Form Version Date: 2015-FEB-08

Other Material(s):

- Patient Instructions for Questionnaires (undated)
- Patient Module Version Draft 2 dated 2015-JAN-30
- Product Monograph for Pr HUMIRA® adalimumab 40 mg in 0.8 mL sterile solution (50 mg/mL) subcutaneous injection Version dated 2014-JAN-17
- Patient Module Version 2 dated 5 May 2015 (English)
- Patient Module Version 2 dated 5 May 2015 (French)

The above referenced research was reviewed by the Ontario Institutional Review Board (ON IRB) of Institutional Review Board Services. The IRB approved the research, as described above.

You have been unconditionally approved as the Investigator at your site for the above study.

Membership List

You can access a copy of the most recent IRB membership list by going to your CIRBI homepage ("My Home") and selecting "Chesapeake IRB Homepage", then selecting the "IRB Services Reference Materials".

Investigator Responsibilities

Your responsibilities are defined in pertinent regulations, ICH GCP Guidelines as well as the General Guidance: Investigator Responsibilities. You can access a copy of the General Guidance: Investigator

IRB Services, 372 Hollandview Trail, Suite 300, Aurora, Ontario, Canada L4G 0A5
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Responsibilities by going to your CIRBI homepage ("My Home") and selecting "Chesapeake IRB Homepage", then selecting the "IRB Services Reference Materials".

Your responsibilities to the IRB include, but are not limited to, informing the IRB of the following using CIRBI:

- Modifications to research (e.g., protocol amendments, revised consent forms, new or revised subject recruitment materials, change of site information, change of investigator)
- Prompt Reporting Events (e.g., protocol deviations, serious unexpected adverse reactions, unanticipated problems)
- Continuing review/termination reports (i.e., progress reports)

Compliance Statement/Attestation

IRB Services attests that the protocol and consent document(s) have been approved, as described above, and the membership of the IRB complies with the requirements defined in Health Canada regulations, 21 CFR parts 56 and 312.3 and 45 CFR 46. The IRB carries out its functions in accordance with good clinical practices (e.g., ICH GCP Guidelines) and Health Canada regulations and in compliance with FDA 21 CFR parts 50 and 56, DHHS 45 CFR part 46, and the Tri-Council Policy Statement for Ethical Conduct of Research Involving Humans, as appropriate to the research.

The IRBs of IRB Services are registered with OHRP and FDA as follows:
- ON IRB registration #IRB00000776
- QC IRB registration #IRB00005290

If you have any questions please do not hesitate to contact us at 905-727-7989 or via Contact IRB in CIRBI.

Sincerely,
Institutional Review Board Services

Anna Carnevale
Coordinator
Client Services

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