Information and Informed Consent Form

STUDY TITLE:	Examining intersections of biographies & biologies: diversity & outcomes of people with multiple sclerosis in Canada (iBio^{2}Div-MS)
PRINCIPAL INVESTIGATOR:	Dr. Ruth Ann Marrie, Department of Medicine, Centre for Clinical Research Room 222, 5790 University Avenue, Halifax, Nova Scotia. Phone: **902-473-5734**
CO-INVESTIGATORS:	Dr. Kaarina Kowalec, University of Manitoba Dr. Marcia Finlayson, Queen's University Dr. Afolasade Fakolade, Queen's University Dr. Colleen Maxwell, University of Waterloo
FUNDER	This study is being funded by the Canadian Institutes of Health Research.

1. Introduction

You have been invited to take part in a research study coordinated through Nova Scotia Health after responding to a study advertisement or invitation by letter or email. A research study is a way to answer a question about something that is not well understood. Taking part in this study is voluntary. It is up to you to decide whether to be in the study or not. Before you decide, you need to understand what the study is for, what risks you might take and what benefits you might receive. This consent form explains the study.

You may take as much time as you wish to decide whether to participate. Feel free to discuss it with your friends and family, or your health care providers.

Please ask the research team to clarify anything you do not understand or would like to know more about. Make sure all your questions are answered to your satisfaction before deciding whether to participate in this research study.

The researchers will:

- Discuss the study with you
- Answer your questions
- Keep confidential any information which could identify you personally
- Be available during the study to deal with problems and answer questions

You are being asked to consider participating in this study because:

- You are aged 18 years or older
- Live in Canada
- Have multiple sclerosis (MS) or are a volunteer without MS

- You identify as a member of one or more groups that have been under-represented in research:
    - A man
    - A racialized group other than Indigenous (previously referred to as a visible minority)
    - Two spirit, lesbian, gay, bisexual, transgender, queer, intersex or another term related to gender or sexual diversity (2SLGBTQI+)
    - Immigrated to Canada within the last ten (10) years
    - Live in a rural community of less than 10,000 people
    - Live with a disability that makes it hard to do the things you want and need to do everyday, at home and in your community

If you decide not to take part or if you leave the study early, your usual health care will not be affected.

2. Why is there a need for this study?

Over 90,000 people living in Canada have MS. Each person's experience with MS is different. These differences are likely due to a mix of factors. Examples of some of these factors are a person's sex, gender, age, ethnicity, and if they live in a city or not. Together, these factors contribute to a person's diversity. Past MS research has not included people who are diverse. Yet some diversity factors can affect the health of a person with MS. Currently, researchers are unsure which diversity factors affect health the most. This in turn limits access to the right types of support and care. The study's long-term goal is to improve health in people with MS who have not been included in past research.

3. How Long Will I Be In The Study?

The length of this study for participants is three years. The entire study is expected to take about five years to complete, and the results should be known in seven years.

4. How Many People Will Take Part In This Study?

It is anticipated that about 600 people will participate in this study throughout Canada.

5. What Will Happen If I Take Part In This Study?

This study will enroll 500 diverse people with MS and 100 diverse people without MS. The goal is to look at how a person's biology, past experiences, and surroundings affect their health. The study will involve four telephone interviews over three years, provision of a saliva sample and your postal code.

	Baseline (Interview 1)	**Year 1 (Interview 2)**	**Year 2 (Interview 3)**	**Year 3 (Interview 4)**
Interview	**X**	**X**	**X**	**X**
Saliva sample	**X**	**X**	**X**	**X**

You will be asked to:

- Be interviewed by telephone. The interview will ask questions about your diversity traits and your physical, emotional, and social health and function. The interviewer will also assess your physical and mental function. This interview will be repeated once a year for three years (60-90 minutes). The interviewer will be at the University of Waterloo Statistical Consulting and Survey Research Unit (SCSRU) in Waterloo, Ontario. If telephone access is difficult, it may be possible to complete some interview questions online.
- Measure your hip and waist sizes using a tape measure that we will send you.
- Provide a saliva sample by mail after you finish your interview. We can get saliva samples from spitting into a container (2 ml or ½ teaspoon) (5 minutes). Because genes play a key role in our health, the saliva sample will be used for genetic testing. Every person has their own unique set of genes, or "genome". Genes are responsible for making proteins that determine your traits, such as height. Genes may also determine why people get certain diseases. Genes, which you inherit from your parents, are made up of DNA. Between people, the DNA sequence of a gene can vary slightly. These differences in DNA sequence are called variants. This study uses a type of genetic test called "genomic sequencing." Genomic sequencing looks at every letter of a person's DNA. It shows us many variants. The saliva will be sent to our study laboratory at the University of Manitoba in Winnipeg, Manitoba for storage. Genetic analysis may be done at the University of Manitoba or the BC Genome Sciences Centre. If you do not consent to contribute a saliva sample, you may not enroll.

We will link your postal code to information about neighborhood and environmental factors like air pollution.

You can choose to withdraw from the study at any time. If you choose to withdraw from the study, we will not contact you in the future.

6. Are There Risks To The Study?

There are no major health risks involved in this project.

Interviews:
Some of the questions we will ask you as part of this study may be upsetting. You may refuse to answer any of the questions. You may take a break at any time during this study.

Saliva samples:

Saliva sampling should be painless.

Breach of confidentiality:
With all research, risk of privacy and confidentiality breach of your information cannot be completely removed. For example, this could happen due to unapproved and/or accidental access or use of your personal information because of human, system, technological, security or administrative error. To help prevent a privacy breach (including cyber security breach), we are taking steps to protect your information as it is approved and consented to by you for collection and use for this study, and for purposes explained in this consent form.

When you donate your saliva for genetic testing or research, you are sharing genetic information about yourself, and about blood relatives who share your genes or DNA. The information we will

look for in the genetic analysis is not likely to tell you anything specific about your health. Even so, if someone lets your genetic facts become public knowledge, it could affect your ability to get or keep a job. It could also affect your ability to get or keep some types of insurance, like life insurance. We think the chance of this ever happening to you is very small. We will do our utmost to protect the privacy of any genetic results. We do not plan to use any genetic results for clinical reasons, so no genetic results will be reported to your physician(s). This will also help protect the privacy of the results.

To protect your information, we will not keep your name or other information that may identify you with the sample or the interview data. The sample will be identified using only a code number. Files that link your name to the code number will be securely stored. Although no one can absolutely guarantee confidentiality, using a code number makes the chance much smaller that someone other than the research staff or other authorized groups or persons (discussed later in the consent form) will ever be able to link your name to your sample or to any test results.

Although your name will not be kept with the sample, information provided with your sample may have other facts about you such as your race, ethnicity, and sex. These facts are important because they will help us learn if the factors that cause MS to get worse are the same or different in male and females, and in people of different racial or ethnic backgrounds. Thus, it is possible that research findings could one day help people of the same race, ethnicity, or sex as you. However, it is also possible through these kinds of studies that genetic traits might come to be associated with such a group. We do not know the effects that this knowledge could have on you, or people like you.

7. Are There Benefits Of Participating In This Study?

There are no direct benefits to you from participating in this study. We will not give you your genetic test results because we are studying the health of groups, not individuals. Your participation may help people with MS in the future. Research using your data and samples might someday lead to the development of a medical or genetic test or treatment. You will not derive any personal financial advantage if this happens.

8. What Happens at the End of the Study?

The results of this study will be published or presented in a variety of forums. You will not be identified in any publication or presentation. You may ask for a copy of the publication(s).

9. What Are My Responsibilities?

As a study participant you will be expected to:

- Follow the directions of the research team;
- Complete interviews and provide a saliva sample

10. Can My Participation in this Study End Early?

Yes. If you choose to participate and later change your mind, you can say no and stop the research at any time. If you wish to withdraw your consent, please inform the research team. If you choose to withdraw your consent, your decision will have no effect on your current or future healthcare. There are two types of withdrawal:

No further contact: We will no longer contact you or ask you to participate in ongoing study activities. We will continue to have your permission to keep and use information and samples you have already provided.

No further use: We will no longer contact you or ask to participate in ongoing study activities or collect additional information about you. Any information you have provided will be removed from our databases, and all biological samples will be destroyed. It may not be possible to withdraw de-identified information shared with other researchers or study results already published. Your signed consent and withdrawal would be kept as a record of your wishes.

Can I withdraw my sample?

If you agree to have your saliva/DNA sample stored, you may later decide that you want to withdraw it from storage. If you decide that you want to withdraw it from storage, you should contact one of the research team contacts listed in this consent form and tell him or her to have your sample discarded. Your sample will be discarded, but any data collected from testing your sample up until that point will remain part of the research.

Also, the Nova Scotia Health Research Ethics Board, the Canadian Institutes of Health Research and the principal investigator have the right to stop participant recruitment or cancel the study at any time.

11. What Will Happen To My Sample After The Study Is Over?

After our study is over, we would like to keep any unused DNA from your saliva sample that is left over from the genetic analysis and allow it to be used for future health-related research. The samples will be stored for 20 years in total, during which time they will be made available for research.

If you agree to have your sample stored for future research, we will store the sample under a code number. We will keep the file that links the code number to your name private. We may share the samples with other researchers. These researchers may be from NS Health, Dalhousie University, other universities, other non-profit organizations, or for-profit companies doing health-related research. Your data will not be sold. We will not give other researchers any information that would allow them to identify you. We will always know which sample belongs to you, but other researchers will not. If the samples are ever sent to other countries, the same laws, and regulations we have here might not apply, and they may be used for purposes other than those we outline in this consent form. They may even be used for things that are against your values and beliefs. Please keep this in mind when choosing whether to allow us to store your sample for future research. Please be aware that after you provide us with a saliva sample, you have released your permission over how it may be used.

A Research Ethics Board, like the one that helps protect you during this research project, will review and approve all future projects before any other researchers gain access to your sample.

You can choose not to have your sample stored for future research and still be part of this study. You will have the chance to state whether you agree to have your sample stored for future research at the end of this consent form.

12. What About New Information?

It is possible (but unlikely) that new information may become available while you are in the study that might affect your health, welfare, or willingness to stay in the study. If this happens, you will be informed in a timely manner. You will be asked whether you wish to continue taking part in the study or not.

13. Will It Cost Me Anything?

Compensation
There are no costs to you for participating in this study. You will receive an e-gift card of $40 per interview for your time.

Research Related Injury If you become injured (privacy breach) as a direct result of allowing access to your information, the following will apply. Your signature on this form indicates that you have understood to your satisfaction the information regarding your participation in this research study. In no way does this waive your legal rights nor release the principal investigator, the research team, the study funder or involved institutions from their legal and professional responsibilities.

14. What About My Privacy and Confidentiality?

Your contact information will be shared with the research team at the University of Waterloo Statistical Consulting and Survey Research Unit using a password-protected and secure method. The interview data are being collected by the Statistical Consulting and Survey Research Unit at the University of Waterloo, on behalf of the researchers at NS Health. The data, with no personal identifiers, collected from this study will be maintained on a password-protected computer database in a restricted access area of the university. The data will be electronically archived after completion of the study and retained for seven years. A copy of the data will be securely shared with the NS Health Research team and securely stored on NS Health servers.

Your contact information may also be shared with the research team at the University of Manitoba, our saliva storage site, if you need support providing your saliva sample. The information will be shared using a password-protected and secure method.

Protecting your privacy is an important part of this study. Every effort to protect your privacy will be made. If the results of this study are presented to the public, nobody will be able to tell that you were in the study.

However, complete privacy cannot be guaranteed. For example, the principal investigator may be required by law to allow access to research records.

If you decide to participate in this study, the research team will not access your health records during this study. However, personal health information will be collected from you directly. Study

personnel will collect only the information needed for this study. “Personal health information” is health information about you that could identify you because it includes information such as your name, telephone number, date of birth, information from the study interviews, and results of genetic testing.

Once we take your saliva sample, we will assign it a code number. We will separate your name and any other information that points to you from your sample. We will keep files that link your name to the code number in a secure place away from your sample.

Access to Research Records

Other people may need to look at the personal health information you shared to make sure the study followed the required laws and guidelines. These people might include:

- The Canadian Institutes of Health Research
- The Nova Scotia Health Research Ethics Board (NS Health REB) and people working for or with the NS Health REB because they oversee the ethical conduct of research studies within Nova Scotia Health
- The Committee for Harmonized Health Impact, Privacy, and Ethics Review (CHIPER) and people working for CHIPER because they oversee the ethical conduct of health research studies in Manitoba

Use of Your Study Information

More and more, researchers like us see that sharing study data with other researchers is important. Sharing study data can let other researchers answer new questions without making study participants go through the process again. It also lowers research costs. We want to use the data and samples from this study for future research projects, not just the one you are part of now. Those future projects can focus on any topic. Those projects might be unrelated to the goals of this study. We would also like to make the study data and samples available to other researchers who may do unique analyses that we do not do at our study sites. These other researchers may be at Nova Scotia Health or at other research centres around the world. Researchers will need to be approved to access the data by a Research Ethics Board and the principal investigators of this study. Data access will be time-limited.

Any study data sent outside of Nova Scotia Health will have a code and will not contain your name, email, or address, or any information that directly identifies you.

The research team and the other people listed above will keep the information they see or receive about you confidential, to the extent permitted by applicable laws. Even though the risk of identifying you from the study data is very small, it can never be eliminated. The research team will keep any personal health information about you in a secure and confidential location for 20 years. Your study data may be destroyed after this time based on the advice of an ethics board. Your personal health information will not be shared with others without your permission.

You have the right to be informed of the results of this study once the entire study is complete.

The REB and people working for or with the REB may also contact you personally for quality assurance purposes.

Please be aware that once your de-identified data is sent outside of Canada it may be accessed by regulatory authorities in other countries who may not have the same privacy laws as we do.

All information sent outside of Canada will be transferred in compliance with all relevant Canadian privacy laws.

Your access to records
You have the right to access, review, and request changes to your study data.

Use of Your Personal Email
If you prefer not to use your personal email for study-related communication, the research team can help you set up a separate email account (e.g., a generic Gmail address) to be used exclusively for the study. This helps reduce the amount of personal information shared with third-party platforms or study partners.

15. Declaration of Financial Interest

The funder is reimbursing the principal investigator's institution to conduct this study. The amount of payment is sufficient to cover the costs of conducting the study.

16. What About Questions or Problems?

For more information about the study, you may call the principal investigator in charge of this study and/or any other research team member listed below.

The principal investigator is Dr. Ruth Ann Marrie.
Email: msepidemiology@nshealth.ca

Your research coordinator at NS Health is Chiara Gottheil
Telephone: 902-221-7284
Email:msepidemiology@nsheath.ca

Your research coordinator at University of Manitoba is Hayley Riel
Email: Hayley.Riel@umanitoba.ca
Telephone: 204-296-0354

If you are experiencing technical issues related to completing the interview online, you can contact either the Statistical Consulting and Survey Research Unit (SCSRU).
Email: scrsruccinb@uwaterloo.ca
Telephone: 1-866-303-2822

Or Dr. Colleen Maxwell
Colleen.maxwell@uwaterloo.ca
Telephone: 226-972-7200

17. What Are My Rights?

You have the right to all information to help you decide whether to participate in this study. You also have the right to ask questions about this study and to have them answered to your satisfaction before you make any decision. You also have the right to ask questions and to receive answers throughout this study. You have the right to withdraw your consent at any time.

If you have questions about your rights as a research participant and/or concerns or complaints about this research study, you can contact

The Nova Scotia Health Research Ethics Board Manager (cell: 902-222-9263; email: ResearchEthics@nshealth.ca)

The Committee for Harmonized Health Impact, Privacy and Ethics review (204-775-1096/ 1-866-248-4375, toll-free; email: CHIPER@researchmb.ca

In the next part you will be asked if you agree (consent) to join this study. If the answer is "yes", please sign the form

18. Consent Form Signature Page

- I have reviewed the information in this consent form related to the study called:

  Examining intersections of biographies & biologies: diversity & outcomes of people with multiple sclerosis in Canada (iBio^{2}Div-MS)
- I was given the opportunity to discuss this study. All my questions were answered to my satisfaction.
- I authorize access to my personal *health* information and research study data as explained in this form.
- I confirm that I have read and understand the information contained in this consent form about the Genetic Testing.
- I understand that by agreeing to participate in this study, I agree to participate in the Genetic Testing.
- I agree to allow the collection and storage of a saliva sample as described in this consent form.
- I understand that my saliva sample will be used in the Genetic Testing.
- This signature on this consent form means that I agree to take part in this study. I understand that I am free to withdraw at any time without affecting my future health care.

I agree to be contacted for future follow-up for additional studies directly related to this study. YES ☐ NO ☐

I agree to be contacted for future follow-up, related to other studies. YES ☐ NO ☐

I agree to have my saliva and genetic data, collected during the present study, stored and used for future research purposes. YES ☐ NO ☐

I agree to share my data with other researchers. YES ☐ NO ☐

E-messaging (email and texting) can be used by a member or members of the research team to communicate with you while you are in this study in addition to telephone calls. All communication from members of the NS Health site done with you will be done through an NS Health email account or phone call or text by phone issued to a research member through NS Health. All efforts are made to keep information sent or received private, but it is possible other people may be able to see, read, and change messages sent to or from NS Health.

Interviews by the University of Waterloo Statistical Consulting and Survey Research Unit (interview) site will be done by telephone (Call display: UWaterloo 519-888-4567). You could be contacted by text message if they cannot reach you by telephone.

Communication from the University of Manitoba (saliva sample) site will be done through a University of Manitoba email account or from the cell phone number of the University of Manitoba research coordinator.

I give my permission to be contacted by a member or members of the research team from an NS Health email account or an NS Health cell phone by research staff to communicate during this study.

YES ☐
NO ☐ (required for participation for reminders, e-gift card distribution)

I give my permission to be contacted by a member or members of the research team from the University of Manitoba using a University of Manitoba email account or by a cell phone to communicate during this study.
(initials and date).

YES ☐
NO ☐

I give my permission to be contacted by a member or members of the research team from the University of Waterloo Statistical Consulting and Survey Research Unit using a University of Waterloo telephone number.

YES ☐
NO ☐ (required for participation, because interview is by telephone)

_____ _____ ____ / _____ / ____
Signature of Participant Name (Printed) Year Month Day*

_____ _____ _____
Email address of participant Phone of participant Alternate phone number

Preferred contact time (mark all that apply)

☐ Morning ☐ Afternoon ☐ Evening ☐ Sunday

Indicate your time zone

☐ Pacific ☐ Mountain ☐ Central ☐ Eastern ☐ Atlantic ☐ Newfoundland

_____ _____ ____ / _____ / ____
Signature of Person Conducting Consent Discussion Name (Printed) Year/ Month / Day*

_____ _____ ____ / _____ / ____
Signature of Principal Investigator Name (Printed) Year Month Day*

I will be given a signed copy of this form.