IRB NUMBER: [insert LU#]

Informed Consent for Single Patient IND (Expanded Access), Including for Emergency Use Template and Instructions v3-10-2020

1. The FDA, LUC, and LUMC informed consent requirements for a single patient IND use are described here. Begin the consent process as soon as possible by discussing the situation with the patient and/or patient's legal representative, even if you don't yet have a consent form ready.

2. The informed consent must be obtained from the patient or Legally Authorized Representative before initiating treatment, including in the case of emergency use. The consent form is not the same as a standard clinical research consent form, however consent requirements in 21 CFR part 50 apply to treatment provided to patients under expanded access INDs. The consent template meets these requirements.

3. The consent document must be written for one individual and must clearly explain the individual is not otherwise eligible for other active and approved trials.

4. Refer to the manufacturer's legal agreement, for example, managed access agreement for specific consent requirements.

5. Refer to the Sponsor's Investigational Brochure for treatment plan and risks.

6. For Emergent Use INDs, submit the redacted copy of the patient's consent to the IRB after the emergency use, within 5 days and file a copy in the patient's medical record.

7. For Non- Emergent Use INDs, submit to the IRB for approval prior to utilizing the consent.

LOYOLA UNIVERSITY CHICAGO
HEALTH SCIENCES CAMPUS
MAYWOOD, ILLINOIS
DEPARTMENT OF [insert department name]

INFORMED CONSENT FOR INDIVIDUAL PATIENT EXPANDED ACCESS OF [insert investigational agent]

Participant's Name: _____

Medical Record Number: _____

INVESTIGATIONAL DRUG NAME: [insert investigational drug name]

THE APPROVAL FOR THIS INDIVIDUAL PATIENT EXPANDED ACCESS EXPIRES ON xx/xx/xxxx. *(Remove expiration line if the FDA has authorized **emergency** expanded access use and the IRB is notified within 5 days afterwards)*

(*OPTIONAL LAR LANGUAGE – REMOVE IF NOT APPLICABLE*):
You are being asked to consider that the patient receive [insert investigational agent] for the treatment of their illness. The patient is too ill to given consent right now. When the word "you" appears in this consent form, it refers to the ill person.

You can only consent for the patient if you are the patient's guardian, spouse, parent or you hold the power of attorney for healthcare.

If the patient regains his or her ability to make decisions, he or she will be informed about the treatment and asked for a decision about continued participation.

If you are a parent or guardian of a patient younger than 18 years old and have been asked to read and sign this form, the "you" in this document refers to the patient. (*This applies only when children are involved. If this text is selected for your ICD, please delete these instructions in italics; otherwise, delete this entire paragraph.)*

Patient Information

You are being offered the opportunity to decide to receive [insert investigational agent], which is a drug that {insert either current approval status by the FDA for another condition or provide a patient appropriate explanation of what the investigational drug is intended to do}.

This drug is not approved for {indicate what condition the patient has}, as such, this drug may or may not be effective in the treatment of your disease.

Taking part in this treatment is voluntary
You may choose to not receive {insert investigational agent} or may choose to stop taking the drug at any time. Deciding not to receive the drug, or deciding to stop taking the drug at any time, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with [Insert name of participating sites].

This consent form will give you information about {insert investigational agent} to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to receive the drug.

Overview and Key Information

This information gives you an overview about the treatment. More information about these topics may be found in the pages that follow.

1. **Why am I being offered {Insert name of investigational agent}?**
   It is the opinion of your treating physician that {investigational agent} is the best option for your clinical care, as {insert language that describes why this investigational agent is the best option}.

2. **What will happen to me during the treatment?**
   [Insert a short summary of the procedures] For more information, please see the Description and Explanation of Procedures section below.

3. **How long will I participate?**
   Your participation will depend on the clinical response of your disease. You will be asked to complete *[Insert total number of visits]* follow-up visits *[If applicable - state whether the visits will occur over a month, year, etc.]*. Each visit will last approximately *[Insert the approximate length of time each visit will last in minutes, hours, etc.]*.

4. **Will I benefit from this treatment?**
   [Insert one of the following:]
   We do not know if you will benefit from receiving this treatment. For more information, please see Benefit section below.

5. **What are the risks?**
   [For greater than minimal risk treatments:] Taking part in this treatment may expose you to significant risks. We may not know or understand all the risks at this time. Some people may experience side effects or discomfort, some of which may be serious. It is very important that you understand the known risks in this treatment before you decide whether to participate. For details and a list of risks you should know about, please see the Risks/Discomforts section below.

6. **Do I have other options besides taking part in this treatment?**
   It is the opinion of your treating physician that there are no other satisfactory treatments available to you. Participation in this treatment is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

7. **Will I be paid to participate?**
   [Insert one of the following:]
   You will not receive any payment for taking part in this treatment.
   OR
   Payment for your time or travel is available if you decide to take part in this treatment. For more information, please see the Financial Information section below.

8. **Will it cost me anything to participate?**
   You will not be responsible for the cost of the drug ; however, receiving this treatment may lead to additional costs to you or your insurance. For more information, please see the Financial Information section below.

End of Overview and Key Information

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research.

PURPOSE OF THIS INVESTIGATIONAL TREATMENT: You are being told about this treatment because [specify the patient's condition and available treatments, if any]. [Name of investigational agent] has not received approval for use in treating [indication] from the Food and Drug Administration (FDA). Research studies may be happening to see how safe and how well this [drug or device] treats diseases, but you are getting this to treat your condition. The use of [Name of investigational agent] is for clinical purposes, not research.

The responsible physician for this investigational treatment is [insert PI's name and University/Departmental affiliation].

DESCRIPTION AND EXPLANATION OF PROCEDURES: If you agree to participate in this treatment, you will be asked to do the following things: [Explain in detail what procedures will be done. This includes all drugs/devices used, hospitalizations, hospital/clinic visits, telephone calls, and any follow-up visits. Include the specific amount of blood to be drawn in teaspoons and the number of times this will occur. Specify where the research related activities are being conducted, which procedures are standard of care and which are research related.]

{The following are leading sentences that may or may not be applicable. Delete them if they are not needed.}

If during your participation in this treatment, new information becomes available which would affect your being in this treatment (such as better treatments or the side effects of the treatments),

your doctor will discuss this new information with you and will help you make a decision about your continuing with this treatment.

RISKS/DISCOMFORTS: The treatment you have the opportunity to receive may not help your condition.

While participating in this treatment, you may experience the following risks, side effect and/or discomforts: *(List risks associated with participation.)*

There may be other side effects that we cannot predict or are currently unknown.

(*check here if not applicable*: ☐ *It will be removed upon IRB approval.*)
If you disclose actual or suspected abuse, neglect, or exploitation of a child, or disabled or elderly adult, the physician or any member of the staff must, and will, report this to Child Protective Services (i.e. Department of Family and Human Services), Adult Protective Services, and/or the nearest law enforcement agency.

(*check here if not applicable*: ☐ *It will be removed upon IRB approval.*)
If the research shows that you have a reportable communicable disease (for example, tuberculosis [TB] or HIV/AIDS), the researchers may report this to the appropriate authorities.
(*check here if not applicable*: ☐ *It will be removed upon IRB approval.*)
A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009.

Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

(*check here if not applicable*: ☐ *It will be removed upon IRB approval.*)
(If this treatment needs to be GDPR compliant, you need to identify what data or information that you are collecting may be identifiable, why you are collecting it and for how long you will keep it. Additional information regarding GDPR and its requirements can be found here https://www.luc.edu/gdpr/)

*(NOTE: If you need to delete the Reproductive Section **entirely**, check here*: ☐ *It will be removed upon IRB approval.)*

REPRODUCTIVE AND SEXUAL ACTIVITY INFORMATION: The {insert investigational agent} Therefore, you cannot receive this drug if you are pregnant or breast feeding.

If you are a woman of childbearing potential, a pregnancy test will be done to make certain that you are not pregnant before beginning the treatment.

Both men and women who are able to have children must use an effective method of preventing pregnancy while participating in this treatment.

In addition, as {insert investigational agent} may remain in the body for a period beyond their administration, you will be asked to continue to employ an effective method of preventing pregnancy for [insert text] [*insert period of time*] after you have finished taking the investigational drug. *{Optional sentence to be inserted based on investigator's judgment. If this text is selected for your ICD, please remove these instructions; otherwise, delete this entire paragraph.}*

You are encouraged to discuss your preferred method with Dr. [insert text].
(*Chose one*) He / She will answer any questions you have regarding effective methods of preventing pregnancy. It is important that you consult with your physician because this drug may affect the effectiveness of various methods of preventing pregnancy.

If you become pregnant, suspect that you have become pregnant, or you have fathered a child during the treatment, notify Dr. [insert text] immediately.

BENEFITS: *(Chose one sentence and delete the other)* You will not benefit from participating in this treatment. **OR** We do not know if you will benefit from participating in this treatment.

(List any known benefits -- do not overstate benefits.)

ALTERNATIVE TREATMENTS: You do not have to participate in this treatment to receive care at Loyola University Medical Center.

Your doctor has discussed other options with you along with their risks and benefits.

FINANCIAL INFORMATION: Treatment with {insert investigational agent} may or may not cost your insurance company more than the cost of getting treatment without this {insert investigational agent}. Check with your health plan insurer to find out what they will pay for. Depending on your health insurance coverage, there may be out-of-pocket costs for you like co-payment of the standard visits, co-insurance, or deductibles. You will be responsible for these expenses.

(OPTIONAL PARAGRAPH – Delete if there are no research-related billable events.)

You or your insurance company [will/will not] be billed for the [investigational agent]. You or your insurance company [will/will not] be billed for the cost of the supplies and the personnel to give you the [drug].

TREATMENT RELATED INJURY: In the event that you are injured or have side effects as a result of participating in this treatment, your doctor will take the necessary steps to treat the problem. There are no funds available from Loyola University Medical Center, Gottlieb Memorial Hospital, Loyola University Health System or Loyola University of Chicago to pay for the cost of care of the problem. You will be financially responsible for the cost of care of any problems. By signing this form, you are not giving up any legal rights to seek to obtain compensation of injury.

INFORMATION COLLECTED AND WHAT WILL HAPPEN TO IT: We may collect information on you, your test results, and how you do from you and your Loyola University Medical Center or Gottlieb Memorial Hospital medical records. The information will be collected by [insert text], the treatment physician(s), research nurses, data administrators and secretaries.

Information about you will be provided to Loyola University of Chicago; [insert text], the manufacturer of the {insert investigational drug}; data collection and investigational drug verification agencies; and/or government regulatory agencies such as the Food and Drug Administration.

[*Insert text*]. (*If data or specimens will be retained after the treatment for future research, explain where the data or specimens will be stored, who will have access to the data or specimens, and how long the data or specimens will be retained. Note that any research conducted on specimens stored for future use must obtain IRB Approval prior to initiating the treatment.)*

In this way, we will learn about [insert text]. [*INSERT-THE SAFETY AND EFFECTIVENESS OR BRIEFLY RESTATE THE MAJOR GOAL OF THE TREATMENT*].

The information we will collect and send includes:
(*Select what information, IF ANY, will be sent to the sponsor or the sponsor's designee. Place an "X" beside the sentence if it is applicable; if not, delete the line. When finished, delete these instructions.)*

____ DEMOGRAPHIC INFORMATION (e.g., name, address, phone number)

____ BILLING AND PAYMENT INFORMATION

____ MEDICAL RECORD (including, but not limited to, history and physical exam notes, progress notes, consultation reports, laboratory test results, AND/OR operative reports)

____ INFORMATION RELATING TO ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS) OR HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION

____ INFORMATION RELATING TO TREATMENT FOR DRUG OR ALCOHOL ABUSE

____ INFORMATION RELATING TO MENTAL OR BEHAVIORAL HEALTH OR PSYCHIATRIC CARE EXCLUDING PSYCHOTHERAPY NOTES

____ PHOTOGRAPHS, VIDEOTAPES, OR DIGITAL OR OTHER RADIOGRAPHIC IMAGES

____ TISSUE SAMPLES

____ BLOOD SAMPLES

____ GENETIC INFORMATION

We will collect and provide this information about you [insert text]. *INDICATE HOW LONG THE INFORMATION WILL BE COLLECTED AND SENT. FOR EXAMPLE, "*for as long as you are receiving the treatment, *", "*for your lifetime*" or "*until the manufacturer terminates the use of the drug. *".*

Once the information is disclosed outside of Loyola University Medical Center or Gottlieb Memorial Hospital, it may no longer be protected by federal privacy laws.

De-identified data from this treatment may be shared with others to learn about your treatment results. We will remove or code any personal information that could identify you before data are shared to ensure that no one will be able to identify you from the information we share, however this cannot be guaranteed. Once identifying information is removed, the information and samples cannot be withdrawn from further use. You will not be asked to sign an additional consent for this use.

It is possible that the manufacturer of {insert investigational agent}, [insert text], research nurses, data collection and/or manufacturer verification agencies, data administrators or staff, [insert text], or the Food and Drug Administration will come to Loyola University Medical Center or Gottlieb Memorial Hospital and view the medical record (see above for description of content) and your treatment records. They may take notes or copy pages of the medical record. This is done to verify the accuracy of the information Loyola University of Chicago is sending to them.

The results of your treatment may be published in a journal for the purpose of advancing medical knowledge. You will not be identified by name or by any other identifying information in any publication or report.

Consent for LUMC to use and disclose your medical information is required in order for you to participate in this treatment.

This authorization does not expire.

WITHDRAWAL OF CONSENT: Your consent to use and disclose your medical information for the purpose of receiving {insert investigational agent} is completely voluntary. You can withdraw your consent to use and disclose your information and your consent to participate in this treatment at any time without affecting your ability to receive care and treatment at Loyola University Medical Center or Gottlieb Memorial Hospital, as applicable, unrelated to the {insert

investigational agent. Withdrawal means that all treatment procedures and follow-up will stop and we will not send any more information about you to the manufacturer of this drug or its designees. However, information already used and disclosed to the manufacturer prior to the time of your withdrawal from this treatment may continue to be used and disclosed by Loyola University of Chicago and the sponsor.

[CUSTOMIZE THIS PARAGRAPH IF IT IS NECESSARY FOR PARTICIPANT TO CONTINUE SEEING DOCTOR].
For your safety, we may ask that you return to clinic one more time for [insert text]. We will also ask that you return any unused {insert investigational agent}. If you withdraw from treatment, you will need to contact your physician(s) to discuss what other options may be available.

If you withdraw from the treatment, we will ask that you sign the form attached to this consent and send it to [insert text] or give it to the treatment staff. Your withdrawal from the treatment will not have any effect on any actions by Loyola University Medical Center, Gottlieb Memorial Hospital, or Loyola University of Chicago taken before the attached form is received by Loyola University of Chicago.

Your physician, the Institutional Review Board, the regulatory authorities, or the manufacturer of {insert investigational agent}, [insert text], may terminate the treatment at any time with or without your consent.

[*MODIFY THIS PARAGRAPH AS NEEDED OR DELETE ENTIRELY]* Your physician may choose to stop your treatment because of unexpected or serious side effects, treatment non-compliance, or because you are not taking the medication as you were instructed. You may also be removed from the treatment if your physician feels that you are not benefiting from the treatment.

CONSENT

I have fully explained to _____ the nature and purpose of the above-described procedure and the risks that are involved in its performance. I have answered and will answer all questions to the best of my ability. I may be reached at [insert text].

_____Date:____/_____/____
Signature

[insert PI Name], the Physician for this treatment, , or (*Choose one*) his her associates will be available to answer any questions you may have. [insert PI Name] can be reached at: [insert 24 hour phone number].

If you ever feel that you have been injured by receiving {insert investigational agent} or if you have any questions concerning your rights as a recipient of this investigational agent, you may contact either Kenneth Micetich, MD, Chair of the Institutional Review Board for the Protection of Human Subjects-Loyola University Chicago Health Sciences Campus, at 708-216-2633 or

Cynthia Tom-Klebba, MA, CIP, Director of the Human Research Subjects Protection Program at 708-216-4608.

Although you have the right to revoke this authorization, you accept that such revocation will not apply to any uses and disclosures of your information that are described in the Loyola University Health System Notice of Privacy Practices or otherwise allowable under any Federal or State laws.

You will receive a signed copy of this informed consent document.

You have been fully informed of the above-described treatment with its possible benefits and risks. Your signature below indicates that you are willing to participate in this treatment and agree to the use and disclosure of information about you as described above. You do not give up any of your legal rights by signing this consent document.

_____Date:____/_____/____
Signature: Participant

_____Date:____/_____/____
(Signature: Witness)

[A witness signature line is to be included if the participant lacks the capacity to consent. This may include but is not limited to: individuals requiring a Legally Authorized Representative, Minors or other individuals who lose or may lose the capacity to consent during their participation in the treatment]

(Optional Signature Lines for ICD's with Child's Assents attached. Delete if not needed.)

_____Date:____/_____/____
(Signature: Parent/Legal Guardian)

_____Date:____/_____/____
(Signature: Parent/Legal Guardian)

_____Date:____/_____/____
(Signature: Witness)

(If Assent is needed, 1) use the signature lines above, 2) cut the Child's Assent from page 9, 3) paste text here, 4) delete these instructions, and 5) delete the instructions on page 9.)

(*OPTIONAL – REMOVE IF NOT APPLICABLE and IF NOT CONSENTING LEGALLY AUTHORIZED REPRESENTATIVES*):

_____Date:____/_____/____
Signature: Legally Authorized Representative (if applicable)

_____
Legally Authorized Representative's relationship to participant

Consent for Continued Participation:

At the time that you became ill, you were not able to make a decision about receiving this treatment. The person making medical decisions on your behalf during your illness agreed for you to receive {insert investigational agent}. Now that you are again able to make decisions, you can choose whether or not to remain a participant.

If you decide to continue the treatment, , you will be asked to review and sign the full consent form for this treatment.

If you decide to end your participation, your personal and medical information gathered since the start of the treatment may still be used. .

Please check below to indicate your decision:

_____ I wish to continue with the treatment with {insert investigational agent}
_____ I wish to end my treatment with {insert investigational agent}.

_____Date:____/_____/____
Signature of Participant

_____Date:____/_____/____
Signature of Person Obtaining Informed Consent

_____Date:____/_____/____
Signature of Witness

PROJECT TITLE: [insert text]

REVOCATION OF AUTHORIZATION TO
RELEASE PROTECTED HEALTH INFORMATION (PHI)

I, _____, hereby revoke my consent to participate in the Individual Patient Expanded Access of [enter investigational agent], at Loyola University Medical Center, Gottlieb Memorial Hospital, or Loyola University of Chicago, as applicable. I also revoke my consent to release information I provided to Loyola University Medical Center, Gottlieb Memorial Hospital, or Loyola University of Chicago, as applicable, that allowed use and disclosure of my medical information to [insert text] as outlined on the consent form, which I signed on ____/_____/____ (INSERT DATE CONSENT WAS SIGNED ORIGINALLY). I understand that this revocation does not apply to any action Loyola University Medical Center, Gottlieb Memorial Hospital, or Loyola University of Chicago, as applicable, have taken in reliance on the consent I signed earlier.

_____Date:____/_____/____
Signature: Participant

Please return this form to:

[insert text]
Loyola University of Chicago
2160 South First Avenue
Maywood, Illinois 60153

INSTRUCTIONS: CHILD'S ASSENT TO CONSENT

Federal Regulations now require the assent of children for participation in research protocols. Recognizing that the rate of development of many children is different and that their ability to adequately comprehend the implications of participation in research projects varies significantly with age, the Loyola University Chicago Health Sciences Campus Institutional Review Board has drafted the following statement:

For children below the age of eight (8), parental consent is all that is required. It is still appropriate that the investigator discuss with the child the mode of therapy in a fashion that may leave the child with some idea of what the plans for his or her therapy are.

Between the ages of eight (8) and twelve (12), the investigator must discuss with the child what is involved in the investigational therapy. The types of procedures, medication, side effects and purposes of the investigational protocol should be discussed with the child. While parental consent is still required for children in this age group, formal assent of the child will not be required but it is suggested.

Children above the age of twelve (12) should be treated as adult participants in a research project. Full disclosure must be made to them concerning the risks and benefits of the project as well as procedures, drugs, and other factors that may be related to the project.

A witness assent in writing is "required" from a child greater than twelve (12) years of age; parental consent is also required. Witnesses to the children's assent should be impartial observers and neither members of the family nor the investigators team.

TEXT TO USE FOR ASSENT:

CHILD'S ASSENT TO CONSENT

I have been fully informed of the research project and what my part in the project will be. I have also been fully informed of any side effects that may occur during my participation. I give permission to be part of this treatment. I know that Dr. [insert PI Name] will be available to answer any questions I may have. I understand that I am free to withdraw this Assent to Consent and participation at any time. I have received a copy of this Child's Assent to Consent.

_____Date:____/_____/____
(Signature: Participant)

_____Date:____/_____/____
(Signature: Witness)