	IRCM-2021-276	Oct. 27, 2021

Title: **The effects of low dose Naltrexone (LDN) on diseases of aging**
A retrospective cross-sectional study into off-label use of LDN

Protocol Number: ALRx002

Study population: Long, intermediate, and short-term off-label LDN users (age 18-120)

Study Design: Single-Center, retrospective, cross-sectional study

Sponsor Name, Address, and Telephone Number:

AgelessRx
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Tel :650-503-9990
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Clinical Trial Director (or coordinator)

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Compliance: The study will be conducted in accordance with the standards of Good Clinical Practice, as defined by the International Conference on Harmonisation and all applicable federal and local regulations.

Confidential Information

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1. Signature Page

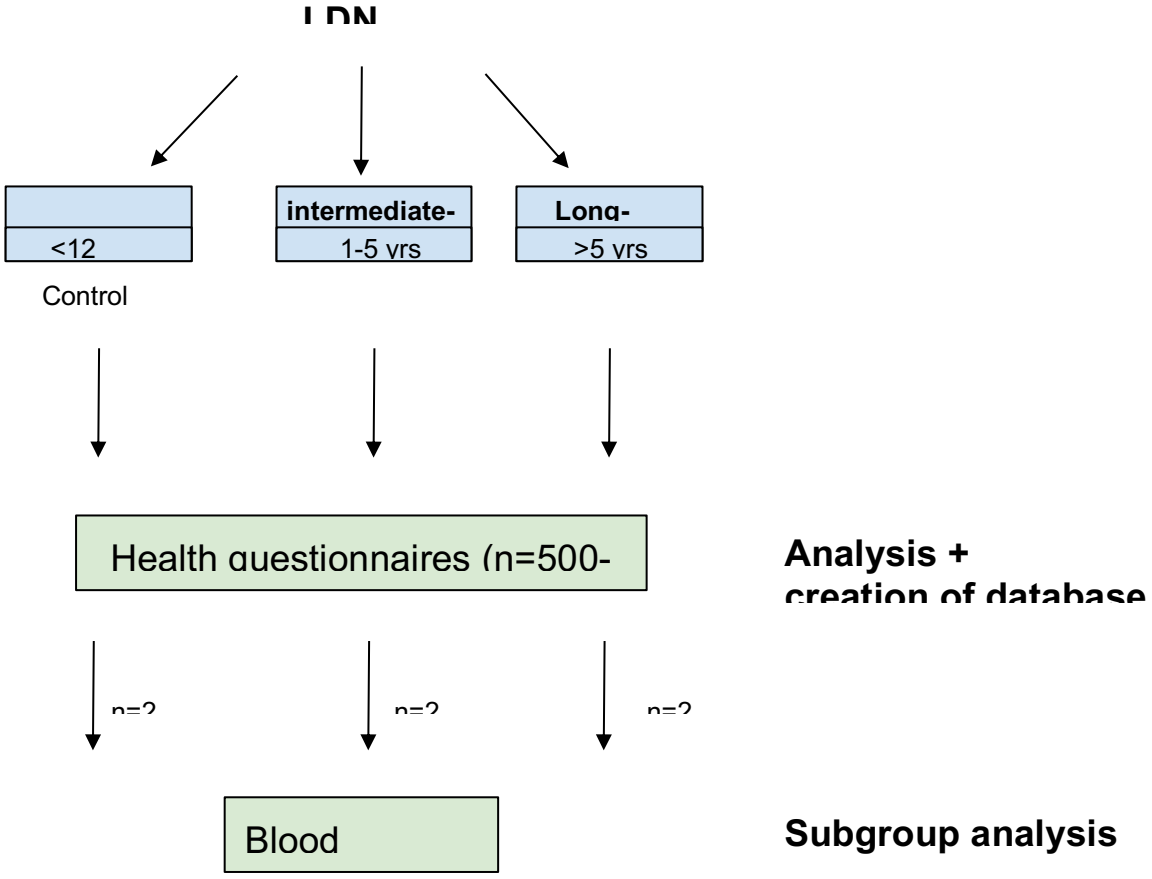
I have read this clinical protocol and confirm that to the best of my knowledge it accurately describes the design and conduct of the study titled '**The effects of low dose Naltrexone (LDN) on diseases of aging:** A retrospective cross-sectional study into off-label use of LDN'

Sajad Zalzala, MD Date

2 Synopsis

Name of Sponsor/Company: AgelessRx
Title of study: The effects of low dose Naltrexone (LDN) on diseases of aging
Objectives: Primary: Assess the health benefits of long-term LDN use Secondary: ● Assess the effects of LDN on altering the clinical signs of aging as well as the physiological endpoints associated with declining health and aging. ● Create a database with LDN users and controls for future health-related correlative studies. ● Help determine dosing schedules for LDN ● Assess potential cost savings of LDN.
Methodology: Long-term (>5 years), intermediate-term (1-5 years), and short-term LDN users (<12 months) will be contacted for a retrospective, observational assessment of their health status. Participants will be asked to complete a series of questionnaires assessing their quality of life, general physical and mental health, family history, the occurrence of age-related diseases, and immune status. The short term LDN users will serve as the control group. Additionally, blood tests for immune and longevity markers will be optional for a subset of participants (n=75, 25 in each group)
Number of subjects planned: 500-2,500 (75 for blood work)
Diagnosis and main criteria for inclusion: Adult off-label users of LDN for all indications willing to share medical information and to complete questionnaires.
Criteria for evaluation: Inclusion criteria: ● Adults (aged 18-120) ● Any sex ● Any ethnicity ● Taking LDN ● Willing to complete health questionnaires ● Subgroup: willing to undergo blood testing Exclusion criteria: ● LDN doses over 20 mg/day
Statistical analysis: Obtained scores from questionnaires will be compared between study groups (long term and short term users)

3 Study Design



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5 List of Abbreviations

CMV	Cytomegalovirus
FDA	US Food and Drug Administration
GCP	Good Clinical Practice
GHQ-28	General Health Questionnaire-28
hsCRP	Human serum C-Reactive Protein
IFN	Interferon
IgG	Immunoglobulin
IL	Interleukin
IRB	Institutional Review Board
ISQ	Immune Status Questionnaire
LDN	Low dose Naltrexone
MS	Multiple Sclerosis
MyD88	Myeloid differentiation primary response 88
OGF	Opioid Growth Factor
SF-36	Short Form-36
TLR	Toll-Like Receptor
TNF	Tumor Necrosis Factor
TRIF	TIR-domain-containing adapter-inducing interferon-β

6 Background and Rationale

6.1 Naltrexone

Naltrexone, or 17-(cyclopropylmethyl)-4,5-epoxy-3,14-dihydroxymorphinan-6-one, is a non-selective opioid antagonist, with a high affinity for μ-opioid receptors. It is FDA-approved for medication-assisted treatment of opioid and alcohol dependence. Standard doses for these conditions are 50-150 mg/day, which also prevents the inhibition of the gamma-aminobutyric acid receptor and inhibits dopamine release.

Naltrexone is or has been marketed under a variety of brand names, including Adepend, Antaxone, Celupan, Depade, Nalorex, Narcoral, Nemexin, Nodict, Revia/ReVia, Trexan, and Vivitrol.

6.2 Off-label use of low dose Naltrexone

The dosing for FDA-approved use of LDN is generally above 50 mg orally per day. However, low doses have been widely used off-label for a variety of conditions.

Naltrexone is a drug that exerts different pharmacodynamic effects in lower quantities than it does at higher doses. In doses below 5 mg, it has been shown to act as a glial modulator. Its low dose effects were first used for the treatment of AIDS, for which doses of 1.5-3 mg resulted in immune-modulating effects in the 1980s and 1990s. Meanwhile, it has been used off-label for the treatment of inflammation and pain in autoimmune diseases, such as multiple sclerosis (MS), Crohn's disease, and fibromyalgia. Anecdotal reports indicate possible benefit up to 20mg per day

Immune effects
Naltrexone binds to toll-like receptor 4 (TLR4) and acts as an antagonist for this receptor. Downstream signaling of TLR4 results in the activation of the Myeloid differentiation primary response 88 (MyD88) and TIR-domain-containing adapter-inducing interferon-β (TRIF) pathways, resulting in the production of various inflammatory molecules, such as IL-1, TNF-α, IFN-β, and nitric oxide. LDN antagonizes TRIF signaling, resulting in a reduction of TNF-α and IFN-β production.

Opioid rebound effect
Low dose use of Naltrexone does not result in a full blockade of opioid receptor signaling. Its blockade lasts 4-6 hours, during which there is an increased endogenous opioid production and an increased production of opioid receptors. The increased production of endogenous opioids also modulates the immune system by inhibiting the proliferation of B and T cells.

LDN also blocks the opioid growth factor (OGF) receptor, which leads to a feedback loop resulting in increased production of endogenous OGF and the OGF receptor, increasing signaling. LDN may also bind directly to the OGF receptor on immune cells, thereby functioning as an immune modulator.

Binding of OGF to the OGF receptor and increased endogenous opioid signaling can play a role in supporting the growth and development of tissues and organs. Therefore, LDN may promote cell proliferation, wound healing, and reduce inflammation.

Clinical evidence of efficacy LDN
Clinical studies into the effects of LDN on various immune-related diseases have been limited in the number of patients included and the time studied and had contradictory results. However, promising results have established the need for further studies assessing the exact effects of LDN in these conditions. Overall, trials assessing LDN have found that the drug is well tolerated and no serious adverse events were found for all conditions described below.

Crohn's disease
In a small randomized, double-blind, placebo-controlled trial LDN (4.5 mg) was tested for 12 weeks. Forty subjects with active Crohn's disease were enrolled, and in 88% of LDN users, a 70-point decline in the Crohn's Disease Activity Index score was found, compared to 40% of placebo users. Furthermore, 78% of LDN users had improved mucosal healing as assessed with colonoscopy, compared to only 28% in the placebo group.[1]

Fibromyalgia
A randomized, double-blind, placebo-controlled, crossover trial in 31 women showed a reduction in baseline pain when patients were treated with 4.5 mg LDN. Furthermore, there were significant improvements in mood and general satisfaction with life, while no effects on fatigue and sleep were noted.[2]

Multiple sclerosis (MS)
A double-blind, placebo-controlled, crossover trial of 4.5 mg LDN in 60 MS patients revealed significant improvements in mental health quality of life measures (SF-36, mental health inventory, Perceived Deficits and Pain effects scale surveys).[3] Another randomized, double-blind, placebo-controlled, crossover trial among 96 patients with relapse-remitting or secondary progressive MS with disease duration of >6 months, on the other hand, showed no measurable differences in all assessed outcome measures, including pain, quality of life, and mental and physical health.[4]

Psoriasis
A case report on psoriasis vulgaris showed the use of 4.5 mg LDN resulted in a significant reduction in psoriatic lesions after 3 months of use.[5]

Norway studies
In Norway, a documentary in 2013 about LDN led to a sudden and substantial rise in prescriptions for LDN. Researchers have used this to study the effects of LDN in this population. In the whole

study population, the average opioid consumption reduced by up to 46%. In one study, the researchers looked at inflammatory bowel disease and found that users of LDN decreased their use of several medications.[6] Similarly, in rheumatic disease, persistent LDN users had a 13% relative reduction in cumulative defined daily doses of all medicines.[7] In MS patients, there was no difference in drug consumption.[8] Overall these results indicate that the use of LDN may result in cost savings for the healthcare system.

6.3 Rationale and hypothesis

Even though a variety of clinical trials have been performed, no large-scale studies have looked into the long-term use of LDN. Its wide off-label use suggests patients benefit from this treatment, and the limited evidence from previous studies supports that.

Based on the mechanisms of action and previous research, we hypothesize that long term use of LDN may benefit patients for suppression or prevention of various chronic conditions and may prevent the development of aging-associated health issues. Therefore, we hypothesize that LDN use is a cost-saving therapy, as patients would be predicted to discontinue or avoid the use of other, costly, medications.

Given that LDN may promote immune cell proliferation, wound healing, and reduce inflammation, it might serve as a potential longevity therapy.

In this study, we aim to assess the long-term effects of LDN use on diseases of aging, such as the development of cancer, heart disease, diabetes, hypertension, and respiratory infections (e.g. pneumonia). Additionally, we will explore whether the use of LDN could be a cost-saving procedure by asking patients whether they were able to discontinue or avoid the use of medications or other medical interventions for their conditions.

7 Objectives

7.1 Primary Objective

- Assess the health benefits of long-term LDN use. Health benefits will be assessed using questionnaires in a retrospective format.

7.2 Secondary Objectives

- Assess the effects of LDN on altering the clinical signs of aging as well as the physiological endpoints associated with declining health and aging.
- Create a database with LDN users and controls for future health-related correlative studies.
- Help determine dosing schedules for LDN
- Assess potential cost savings of LDN.

8 Experimental plan

8.1 Study Design

Long-term (>5 years), intermediate-term (1-5 years), and short-term (<12 months) LDN users will be contacted for a retrospective, observational assessment of their health status. Participants will be asked to complete a series of questionnaires assessing their quality of life, general physical and mental health, family history, age-related diseases, and immune status.

The short-term LDN users will serve as the control group within this study since effects on aging-associated diseases are not expected to be seen within the first 12 months.

Additionally, blood tests for immune and longevity markers will be optional for a subset of participants. We aim to assess the blood of 25 patients in each of the three study groups, totaling 75 patients. The first patients included in the study who have finalized their questionnaires will be asked to participate, and the first 25 that consent will be included in the blood assessment study. No other inclusion criteria apply for the blood study.

We will include adult off-label users of LDN for all indications willing to share medical information and to complete questionnaires. Doses higher than 20mg/day will be considered high doses and will be excluded.

8.2 Cost of Participation

There will be no costs of participation for the included patients.

8.3 Number of Centers and Subjects

The research will be conducted by AgelessRx. All recruitment and participation will be via telemedicine using the AgelessRx website (agelessrx.com).

8.4 Study Duration

We anticipate this study will take six months to perform. All patients are asked to fill out surveys once, and a subset of them will be asked to participate in a biomarker study, for which blood is taken once. Quest Diagnostics and other participating labs will perform blood sampling and analysis.

9 Subject Selection

9.1 Number of participants

We anticipate including 500-2,500 subjects (depending on interest), of whom 75 will be asked to perform blood analysis (25 in each study group: short-term, medium-term, and long-term LDN users).

9.2 Inclusion Criteria

- Adults (aged 18-70?)
- Any sex
- Any ethnicity
- Taking LDN
- Willing to complete health questionnaires
- Technologically competent to complete web forms
- Subgroup: willing to undergo blood testing

9.3 Exclusion Criteria

- LDN doses over 20 mg/day
- Terminal cancer patients (defined as stage IV and/or with a life expectancy of 12 months or less)

9.4 Withdrawal

Participants are free to withdraw from the study at any time. They can do so by notifying the Principal Investigator per email or phone call. Participants can provide consent whether or not to allow the use of data obtained up to that moment.

10 Schedule of Assessments and Procedures

10.1 Patient recruitment

Patients will be recruited by contacting members of the LDN Research Trust (https://ldnresearchtrust.org/). This organization has over 10,000 members, of which the majority are LDN users. LDN Research Trust has agreed to message their members to recruit participants for this study. Other LDN interest groups may also be contacted to help recruit patients. Additionally, the study will be advertised on the website of AgelessRx (agelessrx.com) to recruit patients, as well as patients already taking LDN through the AgelessRx telemedicine platform

10.2 Screening

Patients interested in participating will be screened for eligibility criteria by Dr. Sajad Zalzala and his staff via the AgelessRx telemedicine platform.

10.3 Enrollment

Once patients are considered eligible, web forms will be sent to be filled out by the patient. Additionally, 25 patients in each group (short, intermediate, and long-term users) will be asked for voluntary blood tests. The first patients included will be asked to participate, and the first 25 patients who consent will be included in the blood assessment study.

10.4 Evaluations

All patients will be asked to answer questionnaires. We will be assessing the patient's disease history, family history, adverse effects of LDN, and current health status, quality of life, and immune status. Furthermore, 25 patients in each group will be asked to have blood drawn for additional assessments.

10.4.1 Questionnaires

We will include one or more of the following standardized questionnaires in our assessments:

- SF-36: Short form assessment including 36 questions to measure the quality of life
- GHQ-28: Provides four scores measuring somatic symptoms, anxiety and insomnia, social dysfunction, and severe depression
- ISQ: Immune Status Questionnaire, optimized to measure perceived immune status, consists of seven representative immune-associated symptoms and diseases
- Other standardized questionnaires as deemed feasible by the PI

Additionally, we will add standard questions assessing family history, and information about the dosing, duration of use, reasons for taking LDN, age, sex, weight, length, smoking and alcohol

use history, substance abuse history, physical activity, other medications, and side effects of the drug, and other questions related to health and medical history.

10.4.2 Blood tests

Blood tests will be conducted in a subset of patients in each group. Blood tests will include assessment of one or more of:

- Standard measures of risk of age-associated diseases (glucoregulatory markers, lipids), as well as markers of inflammation, which will also be used to calculate Levine's Phenotypic Age
- Immune Health Tests - this will include CD4/CD8 ratio, CMV IgG, hsCRP, and cytokines such as TNFα and IL-6 testing.
- Methylation age clock testing - The DNAm clocks that will be used to precisely measure aging may include:
    - Horvath original DNAm clock - 353 CpGs - estimates chronological age
    - Hannum original DNAm clock - 71 CpGs - estimates chronological age
    - Zhang estimator DNAm clock - 10 CpGs - estimates mortality risk
    - PhenoAge DNAm clock - 656 CpGs - estimates biological age
    - Skin Age DNAm clock - 391 CpGs - estimates skin and blood age
    - GrimAge DNA m clock - 1030 CpGs - estimates mortality risk

  All of these DNAm clocks can be done on one blood sample (0.1cc) and one DNA methylation array (Illumina EPIC chip)

11 Statistical Analysis

Demographic and baseline characteristics will be summarized using descriptive statistics. Blood tests will be analyzed using analysis of variance. The evaluation will be performed by research coordinators/MDs blinded to the patient's subgroups.

12 Ethics

12.1 Ethical Conduct of the Study

The study and any amendments will be reviewed by an Institutional Review Board (IRB). The study will be conducted following the ethical principles that have their origins in the Declaration of Helsinki. The study will be conducted under good clinical practices (GCP).

12.2 Participant Information and Consent

Informed consent will be obtained for all subjects enrolled in the study. Participants will receive a digital PDF version of the informed consent documentation associated with the study (Appendix A). Participants will have the opportunity to ask questions before consenting. Participants will be asked to sign it electronically.

A study coordinator or the principal investigator will go through the consent forms with each participant to ensure the participants truly understand the study and implications of being a participant. It will be stressed that:

1) No benefits of any kind can be expected from participation in this study
2) The subjects may withdraw from the study at any time without a penalty of any kind
3) There may be risks and costs associated with participating in the study

Consent will be documented by the signature of both the participant and the investigator (or staff), confirming that the participant completely understands the study. We will use an e-signature service for this purpose, which will be sent to participants after chart review by the clinical coordinator or designated staff members.

12.3 Study Participant Confidentiality

All study records for analysis will be de-identified so that records cannot be directly linked to the participant and are only linked to the participant via coded identifiers. Data will be stored on a password-protected HIPAA-compliant cloud service.

13 Administrative Procedures

13.1 Modifications to the Protocol

Modifications to the protocol will be added to the Clinical Study Protocol and communicated with the IRB.

13.2 Plans for Dissemination of Findings

We intend to disseminate the findings primarily in four ways:
1) Publications in peer-reviewed medical journals
2) Lectures at scientific conferences
3) Lectures at non-scientific public events
4) Announcements via the AgelessRx website
5) Outreach to various media outlets
6) LDN advocacy groups, such as the LDN RT

14 Reference List

1. Smith JP, Bingaman SI, Ruggiero F, et al. Therapy with the opioid antagonist naltrexone promotes mucosal healing in active Crohn's disease: a randomized placebo-controlled trial. *Dig Dis Sci*. 2011;56(7):2088-2097. doi:10.1007/s10620-011-1653-7
2. Younger J, Noor N, McCue R, Mackey S. Low-dose naltrexone for the treatment of fibromyalgia: findings of a small, randomized, double-blind, placebo-controlled, counterbalanced, crossover trial assessing daily pain levels. *Arthritis Rheum*. 2013;65(2):529-538. doi:10.1002/art.37734
3. Cree BAC, Kornyeyeva E, Goodin DS. Pilot trial of low-dose naltrexone and quality of life in multiple sclerosis. *Ann Neurol*. 2010;68(2):145-150. doi:10.1002/ana.22006
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5. Bridgman AC, Kirchhof MG. Treatment of psoriasis vulgaris using low-dose naltrexone. *JAAD Case Rep*. 2018;4(8):827-829. doi:10.1016/j.jdcr.2018.06.001
6. Raknes G, Simonsen P, Småbrekke L. The Effect of Low-Dose Naltrexone on Medication in Inflammatory Bowel Disease: A Quasi Experimental Before-and-After Prescription Database Study. *J Crohns Colitis*. 2018;12(6):677-686. doi:10.1093/ecco-jcc/jjy008
7. Raknes G, Småbrekke L. Low dose naltrexone: Effects on medication in rheumatoid and seropositive arthritis. A nationwide register-based controlled quasi-experimental before-after study. *PloS One*. 2019;14(2):e0212460. doi:10.1371/journal.pone.0212460
8. Raknes G, Småbrekke L. Low dose naltrexone in multiple sclerosis: Effects on medication use. A quasi-experimental study. *PloS One*. 2017;12(11):e0187423. doi:10.1371/journal.pone.0187423

Appendix A Consent Form

Study Title:	**The effects of low dose Naltrexone (LDN) on diseases of aging** A retrospective cross-sectional study into off-label use of LDN
Principal Investigator:	Dr. Sajad Zalzala
Institute:	AgelessRx Inc
Sponsor:	AgelessRx Inc Dr. Sajad Zalzala
Telephone number (24 hrs):	650-503-9990

Invitation and brief summary:
We invite you to participate in this study, which has been set up by AgelessRx. The study is funded by AgelessRx. The study has been reviewed and approved by an institutional review board (IRB): The Institute of Regenerative and Cellular Medicine.

In this study, we will investigate any effects of low dose Naltrexone (LDN) on general health and diseases related to aging. If you choose to take part in this study, you will be asked to complete a number of questionnaires that will tell the researchers something about your health, in the past and present, your medication use, as well as your medical family history. A subgroup of participants in this study will be asked to provide a blood sample for additional tests. These tests are directed to look at markers for aging, immune, and general health status.

Taking part in this study is entirely voluntary. We urge you to discuss any questions about this study with the Principal Investigator or Research Coordinator of this study. Talk to family and friends about it and take your time to make your decision. If you decide to participate, you must sign this form to show that you want to take part and understand what the study entails.

Purpose of the study
No studies have yet investigated the long-term effects of LDN use, and how it affects the general health of patients taking this medication. We aim to investigate this by assessing the health of patients using LDN for various conditions. We also aim to determine whether LDN use has prevented the use of other medications.

What would participating in this study entail?
If you decide to take part in this study, you will be asked to complete a number of questionnaires that assess your physical and mental health, daily activities, medical history, and your family history. There will also be questions about medication use in the past and present.

A subgroup of patients will be asked to provide a blood sample for additional tests. These tests are directed to look at markers for aging, immune, and general health status. The blood sample will be obtained by a regular blood draw, and will be a maximum of 5 tubes. Some tests may be done at home with a cheek swab or finger-prick. You will receive information about the specific tests if you are part of the subgroup. You do not have to participate in this part of the study if you only want to take part in the questionnaire part of the study.

Nothing will change in your regular health care if you decide to take part in this study. You will not be asked to stop or change the dosing of your medication, including LDN.

Am I eligible to take part in this study?

If you are interested in this study, the study coordinator or principal investigator will assess whether you are eligible for the study. If you are a user of LDN for any medical reason, have the legal ability to make your own decisions, and have expressed an interest in volunteering for this study, you will be considered for participation. Adults aged 18-70 are eligible, and there are no restrictions in ethnicity, gender, socioeconomic status, educational status, sexual preference, religious preference, or political views in this study. To qualify you need to be taking LDN and be willing to complete health questionnaires. Since all contact will be via telemedicine and all questionnaires are to be completed online, you need to be willing and competent to use telemedicine and web forms. You are not eligible for this study if you take a dose of LDN over 20 mg/day and if you have terminal cancer.

What are the possible benefits of participating in this study?

There are no expected health benefits for participating in this study. However, your contribution to research could help patients in the future and might lead to a better understanding of the health effects of LDN. You will be provided with the results of the study and any personal test results of potential blood draws.

What are the possible disadvantages or risks of taking part in this study?

There are no expected health risks in participating in this study. It will cost you time to complete the questionnaires and you might be asked for a blood draw. The information you provide will remain confidential. There is no cost to participate in this study.

How will information about me be kept confidential?

All your information will be stored in research databases and will be coded with a unique anonymous study identification number. Your anonymous information and blood samples will be available only to researchers who have obtained approval from scientific and ethical

committees for their research. Individuals working for the sponsor AgelessRx, regulatory authorities, and the institutional review board might obtain access to your data. Insurance companies and employers will not have access to your personal information, blood samples, or test results. The data may be published in a scientific journal, at conferences, and on other platforms, but your name and identity will not be used.

Your permission for the use, retention, and sharing of your identifiable health information will expire two years after the completion of the study. At that time the research information not already in your medical record will be destroyed. Any research information in your medical record will be kept indefinitely.

What happens next if I decide to participate in this study?
If the study coordinator and/or principal investigator finds that you are eligible to participate in this study, you will be asked to sign this form to provide consent. After that, you will be sent a number of online questionnaires to complete.

If you are eligible for the subgroup blood analysis, the study coordinator or the principal investigator will contact you to offer to participate in this part of the study. You will receive information and a requisition for a blood draw and instructions on how to obtain it.

Where can I find more information about the institutional review of this study?
For more information about participation in a research study and about your institutional review board (IRB), a group of people who review the research to protect your rights, please visit The Institute of Regenerative and Cellular Medicine IRB's website at https://ircm.org. Included on this website, under the heading "IRB Regulations," you can access information about the protection of human research participants. Relevant federal regulations can be found at the following websites:
http://www.fda.gov/RegulatoryInformation/Guidances/ucm126420.html and
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

How can I withdraw from the study?
If you decide you do not want to take part anymore during the study, you can withdraw from the study at any time. This will not impact your regular health care. You do not have to give a reason for your withdrawal. You can do so by contacting the principal investigator of this study:

Dr. Sajad Zalzala
Email: doctor@agelessrx.com
Tel: (313) 355-8657

Fax: (888) 655-7536

We thank you for considering taking part in this study. For more information or if you have any questions, please contact:

Dr. Sajad Zalzala
Email: doctor@agelessrx.com
Tel: (313) 355-8657
Fax: (888) 655-7536

Signature section

A) I confirm that I have read the information above for the study entitled: "The effects of low dose Naltrexone (LDN) on diseases of aging". I have had the opportunity to consider the information, ask questions, and these have been answered satisfactorily.

Signature: _____

B) I understand that my participation is voluntary and that I am free to withdraw at any time during or after the study period without giving any reason, without my medical care or legal rights being affected.

Signature: _____

C) I understand that relevant sections of my medical notes and data collected during the study, might be looked at by individuals working for the sponsor AgelessRx, for regulatory authorities, or the IRB, where it is relevant to this research. I give permission for these individuals to have access to my records.

Signature: _____

D) I understand that the information collected about me will be used to support other research in the future, and might be shared anonymously with other researchers.

Signature: _____

Signature and consent/permission to take part in the research study

Participant: By signing this consent form, you indicate that you have read and understand this consent form, and volunteer to participate in this research study. You understand that you will receive a copy of this form. You voluntarily choose to participate, but understand that your consent does not take away any legal rights in the case of negligence or other legal faults of anyone who is involved in the study. You further understand that nothing in this consent form is intended to replace any applicable federal, state, or local laws. You will receive a copy of the signed and dated form to keep for future reference.

_____	_____	_____	_____
Signature of Participant	Date	Time	Printed Name

Explaining the Research: Your signature below means that you have explained the research to the participant or participant representative and have answered any questions about the research.

_____	_____	_____	_____
Signature of person who explained this research	Date	Time	Printed Name