|  |  |
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| **Protocol Assistant** |  |
| This form serves as a tool for investigators to verify that the research protocol contains the necessary basic elements required for IRB review. Please note that the IRB may still require additional information. |  |
|  |  |
| ***[Delete these Instructions and unused sample text prior to submission. Complete each section below. Control+click on a section heading to be taken to sample text which may help guide the completion of the protocol or an individual section.]*** :  |  |
| Title |
| Title |
| Sponsor |
| Name of the Sponsor |
| Funding Source |
| Funding Source |
| Version – Date |
| Version Date |
|  |
| **List of Abbreviations** |
| Click or tap here to enter text. |
|  |
| **[SUMMARY](#SUMMARY" \o "The summary section of a research protocol should provide a concise overview of the study, starting with an introduction to the condition or disease, its prevalence, and its impact on patients and healthcare systems. It should then highlight the limitations of existing treatments and discuss recent research findings that identify a novel mechanism or pathway critical to the disease's development. The summary should clearly state the primary objective of the study and describe the new therapy or approach being investigated, including its mechanism of action. Additionally, it should outline the study design and methodology, including participant criteria and interventions. Lastly, the summary should address the expected outcomes, emphasizing potential benefits for patients, the potential to reduce healthcare burden, and the study's overall goal of improving patient outcomes and enhancing lives, ensuring ethical considerations are briefly mentioned. )\*** |
| [Background](#SummBackground)\* |  |
| Summary Background |  |
| [Objectives](#SummObjectives)\* |  |
| Summary Objectives |  |
| [Inclusion/Exclusion](#SummIE)\* |  |
| Summary Inclusion/Exclusion criteria |  |
| Research activities and interventions |  |
| Summary of Research Activities |  |
| Duration  |  |
| Duration of the Study Participation |  |

|  |
| --- |
| **MAIN PROTOCOL** |
|  |  |
| **[Introduction](#Introduction" \o " This section should offer a brief overview of the research, including literature evidence. It should also discuss important literature and data that provide background for the trial. Additionally, it should cover relevant clinical, epidemiological, or public health context related to the trial, and emphasize the trial's significance, including any relevant treatment issues or controversies.A discussion of the risks and benefits should be provided, including the exposure to known risks or potential risks.)\*** |
|  |  |
| [Background of the problem: epidemiology, prevalence/incidence.](#Background)\* |  |
| Background of the problem: Epidemiology, Prevalence/Incidence, Rationale of this Research’s Proposal. |  |
|  |  |
| [Proposed hypothesis (justification including the benefits)](#Hypothesis)\* |  |
| Hypothesis. |  |
|  |  |
| **Objectives** |
|  |  |
| [Main Objectives in relation to the hypothesis](#MainObjectivesText)\* |  |
| Main Objectives: Is there a Medical Condition or Disease? |  |
|  |  |
| [Secondary Objectives in relation to the Study](#SecondaryObjectives)\* |  |
| Click or tap here to enter text. |  |
|  |  |
| **[Study Design](#StudyDesign" \o " This plan outlines the study's goals, how effectiveness will be measured (endpoints), and the stage of research. It also details the type of trial (randomized, case-control, etc.), how participants are selected, and the breakdown of groups with intervention and follow-up durations. The plan clarifies the interventions or control groups used, along with the reasons for these choices and any limitations. Finally, the plan might include checks on progress throughout the trial (interim analyses), analyses of specific participant groups, and any other special considerations for subgroup analyses.)\*** |
|  |  |
| [Description of the study design](#StudyDesignText" \o " OverviewSome research studies may need to include a more complex design to effectively address the research objectives. The following are some common examples of special study designs:Crossover DesignIn a crossover design, participants receive different treatments in sequential order with a washout period between treatments. This design is often used to evaluate the efficacy of multiple interventions in the same group of participants.Cluster Randomized TrialA cluster randomized trial involves randomizing groups of individuals (clusters) rather than individual participants. This design is useful when individuals within a cluster are likely to influence each other.Case-Control StudyA case-control study compares cases (individuals with the disease or outcome) with controls (individuals without the disease or outcome) to identify potential risk factors or exposures.Cohort StudyA cohort study follows a group of individuals over time to assess the development of outcomes. This design is used to investigate the incidence and risk factors for diseases.Nested Case-Control StudyA nested case-control study is a case-control study conducted within a cohort study. It allows for efficient use of data and reduces costs.Cross-Sectional StudyA cross-sectional study examines the prevalence of a disease or condition in a population at a specific point in time.Combination of designsRandomized controlled trial with a built-in phase of dose escalation or expansionAdaptive design with an interim analysis and potential adaptation of the study protocolPlatform trial with multiple interventions or armsMaster protocol with embedded studiesUmbrella trial with multiple sub-studiesBasket trial with a single intervention and multiple disease conditionsNote: These are just a few examples of special study designs. The choice of study design depends on the research question, available resources, and ethical considerations.)\*  |  |
| Randomized, Case-Control, Observational (no interventions), Data Review. |  |
|  |  |
| * [Interactions with participants (or no interaction)](#Interactions)\*
 |  |
| Describe the type of interactions with participants, or the type of activities for data collection without interacting with participants |  |
|  |  |
| * [Medical Diagnosis/Medical Interventions](#MedicalDiagnosis)\*
 |  |
| <enter text> |  |
|  |  |
| Define the Study whether is evaluating, testing or using: |  |
| [Device](#DeviceDescription" \o "• Device manual is required for device studies (also called 'Instructions for Use') and ONE of the following:• Unredacted FDA letter granting the Investigational Device Exemption (IDE); OR• Letter from sponsor stating that the study is a non-significant risk device study and the basis for that determination; (unredacted) OR• Documentation of why the investigation is exempt from the IDE requirements under 21 CFR § 812.2(c) (such as the PMA approval letter/number or 510(k) clearance letter/number) or otherwise exempt.• Physicians seeking approval to use a Humanitarian Use Device (HUD) for treatment, not part of a research study, may use the form titled Clinical Use of a Humanitarian Use Device (HUD) (HRP-284) designed for such review requests.)\* |  |
| <enter text> |  |
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| * [Drug/Biologics](#DrugsFoodCosmeticTobacco" \o " For drugs, biologics and food supplements• Investigator’s Drug Brochure• Background information for food supplements• Documentation from sponsor or FDA verifying the IND (Investigational New Drug) number, if one is required for the research. If an IND is not required, provide the reason why in writing.• For gene transfer studies, please submit the Institutional Biosafety Committee (IBC) approval and minutes (if available). If the IBC review has yet to occur, please provide a date for the intended review and contact information for your NIH-OBA registered IBC. WCG can provide IBC oversight; see the IBC Administration & Review page at https://wcgclinical.com/.)\*
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| Food |  |
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| * Cosmetics
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| <enter text> |  |
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| * Tobacco
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| <enter text> |  |
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| * [Others: Behavioral Research](#BehavioralResearch" \o " Special Considerations for Behavioral ResearchWCG IRB reviews behavioral research. Behavioral research is non-clinical research and is oftentimes qualitative rather than quantitative. When submitting behavioral research, provide a detailed protocol, a description of the protections of confidentiality that will be used, and a description of the consent process. Also, if deception is involved, the submission must also include a description of the information to be withheld, a justification for the non-disclosure, a description of potential psychological or other risks to participant resulting from the deception, and the process for post-study disclosure of the deception and debriefing of the participants, including provisions for psychological counseling or other follow-up which may be needed.)\*
 |  |
| <enter text> |  |
|  |  |
| **[Study Population](#StudyPopulation" \o " Considering demographics and health characteristics (vulnerable population) during the planning stage is critical. This ensures the trial's effectiveness in achieving its goals and generating generalizable knowledge applicable to the broader population who might use the intervention in the future, including children, elderly and vulnerable groups.)\*** |
|  |  |
| [Inclusion Criteria](#InclusionCriteria)\* |  |
|  <enter text> |  |
|  |  |
| [Exclusion Criteria](#ExclusionCriteria)\* |  |
| <enter text> |  |
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| **[Study Interventions/Activities](#Interventions" \o " This section should outline the intervention(s) being tested in the research, along with any comparison groups receiving different intervention(s). It is essential to distinguish between [experimental] interventions, which participants receive solely because of their participation in the research, and [standard of care] procedures, which participants would receive regardless of their involvement in the study and are not influenced by the research protocol.)\*** |
|  |  |
| [Description of Research Activities and Procedures](#ResearchActivities)\* |  |
| <enter text> |  |
|  |  |
| [Research Arms or Groups of Interventions](#ResearchArms)\* |  |
| <enter text> |  |
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| Administration of Drug/Devices/Food/Cosmetics |  |
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| [End of Study activities](#EOS)\* |  |
| <enter text>  |  |
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| **[Safety Management](#SafetyManagement" \o "Describe all procedures aimed to monitor participant’s safety. This section should consider the following evaluations (not limited to): physical, psychosocial, laboratory, imaging, environmental. When applicable, describe Adverse Events, Unanticipated Problems and Events of Special Interest.)\*** |
| [Safety Plan](#SafetyPlan)\*  |  |
| <enter text> |  |
|  |  |
| [**Statistical Analysis**](#StatisticalAnalysis)**\*** |
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| **[Consent Process](#Consent" \o " The Informed Consent ProcessThe informed consent process is central to the ethical conduct of research. It is an ongoing conversation between the human research participant and the researchers that begins before consent is given and continues until the end of the participant’s involvement in the research (see consent process diagram, below). There are various tools for the investigator to use to optimize this conversation, but the most important feature of informed consent is the investigator commitment to the process. More information about informed consent is available in the FDA guidance document titled [Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors].Goals for the Informed Consent Process• Give the participant information about the research• Make sure the participant has time to consider all options• Answer all the participant’s questions before the decision is made• Make sure that all information is understood by the participant• Obtain the participant’s voluntary informed consent to participate• Continue to inform the participant throughout the research study• Continue to re-affirm participant consent to participate throughout the research study)\*** |
|  |  |
| [Traditional consent process (paper & wet ink)](#TraditionalConsent)\*  |  |
| <enter text> |  |
|  |  |
| [Alternate consent process](#AlternateConsent" \o " This section describes alternative methods for obtaining informed consent that depart from the traditional approach involving physical signatures witnessed in person. These alternatives utilize communication technologies to facilitate non-face-to-face contact and consent processes)\* |  |
| <enter text> |  |
|  |  |
| [Electronic consent process (compliant with part 11 for FDA regulated studies)](#ElectronicConsent" \o "WCG reviews the electronic (e-consent) platform onto which the study and site IRB approved consent forms are uploaded as a participant material template at the study level. Each site that intends to utilize the platform is not required to submit the platform with their site-specific consent form, instead, they will be reviewed for the study level version only, with the expectation that their site-level consent form will be uploaded.Exact representation of the IRB-approved document on an electronic device does not require IRB review of screen shots of the consent form on the device. The IRB need only approve the static version. (This is also true of other participant-facing forms that require IRB review, such as patient diaries and eCOAs.)For all FDA-regulated electronic consents, including exact representation of an IRB approved document on an electronic device, the IRB requires the signatures be confirmed to be 21 CFR part 11 compliant and requires a certificate of authenticity.e-Consent Submission TimingSponsors and investigators considering e-consent may wish to obtain IRB approval of the consent document text prior to developing the electronic consent tool. Revisions based on IRB feedback are easier to implement before e-consent programming and animation has begun.e-Consent Submission ItemsFor a typical e-consent IRB submission, the sponsor and e-consent vendor will jointly prepare the IRB submission of materials. Typical submissions include:a. scripts for any video or audio filesb. storyboards for any planned video creationc. content for any screens on the e-consent tool that will be viewed by the patientFDA has issued guidance titled Use of Electronic Informed Consent. (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-electronic-informed-consent-clinical-investigations-questions-and-answers?source=govdelivery&utm_medium=email&utm_source=govdelivery))\* |  |
| <enter text> |  |
|  |  |
| [Waivers (Documentation waivers, Consent Waivers, HIPAA Waivers)](#WiaversOfConsent" \o "Waiver of Documentation of ConsentA waiver of documentation of consent is a waiver of the requirement for a signature on a consent form. The Board will need to review the information that is provided to participants to obtain consent to ensure that the required elements of consent are included in the consent discussion. If you are requesting a waiver of documentation of consent, please submit a written statement or script of this information for the Board’s review, a 'participant information sheet.'Waivers of Consent for Non-FDA Studies If you are requesting a waiver of consent and the research is not an FDA regulated study, then criteria from 45 CFR 46.116(e) must be met: 1. The research involves no more than minimal risk to the participants. 2. The research could not practicably be carried out without the waiver or alteration 3. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format; 4. The waiver or alteration will not adversely affect the rights and welfare of the participants. 5. Whenever appropriate, the participants will be provided with additional pertinent information after participation. WCG IRB applies this standard to all requests for waiver of consent for non-FDA regulated research Waivers of Consent for FDA Studies If you are requesting a waiver of consent and the research is an FDA regulated study, then criteria from 21 CFR 50.22 must be met: 1. The clinical investigation involves no more than minimal risk to the subjects; 2. The clinical investigation could not practicably be carried out without the requested waiver or alteration; 3. If the clinical investigation involves using identifiable private information or identifiable biospecimens, the clinical investigation could not practicably be carried out without using such information or biospecimens in an identifiable format; 4. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and 5. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation. For individual emergency waivers of consent, prospective IRB approval is not always necessary if a patient's life can be saved. For more information refer to 21 CFR 50.23 (a)-(c).Waiver of Authorization for Use and Disclosure of Protected Health Information If you are a covered entity or your organization must otherwise comply with the HIPAA, and the research requires you to use or share identifiable health information, you must obtain an authorization for the use and disclosure of protected health information. If this is not practical, you need to request a waiver of authorization. If you are requesting a waiver of consent or written documentation of consent, you also need to request a waiver of authorization.)\*  |  |
| <enter text> |  |
|  |  |
| **[Privacy and Confidentiality](#Privacy" \o "For NIH funded research, please remind that a Certificate of Confidentiality has been issued.)\*** |  |
|  |  |
| <enter text> |  |
|  |  |
| **References** |
|  |  |
| <enter text> |  |

**Notes:**

*All documents submitted for review must be in ENGLISH.*

WCG Guide for Researchers

([*https://www.wcgclinical.com/wp-content/uploads/2020/08/Guide\_for\_Researchers-1.pdf*](https://www.wcgclinical.com/wp-content/uploads/2020/08/Guide_for_Researchers-1.pdf))

**SAMPLE TEXTS**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

< Summary Background text >

[Condition/Disease Name] is a disorder that significantly impacts patients, their families, and healthcare systems globally. Affecting an estimated [prevalence rate] of the population, it is a major cause of [specific outcome]. Despite available treatments, managing [condition/disease name] remains challenging, with patients enduring [persistent symptoms]. Current therapies, including [existing treatments], often fall short in providing effective relief and may lead to [adverse effects]. Recent research has unveiled [novel mechanism/pathway] as a key factor in the development of [condition/disease name]. Notably, [research finding] underscores the potential of targeting this pathway for therapeutic intervention. This study aims to evaluate the [primary study objective] of [new approach/therapy], a novel [therapy type] designed to [mechanism of action]. By addressing the underlying biology of [condition/disease name], we seek to develop treatments that improve patient outcomes, reduce healthcare burden, and enhance the lives of those affected.

[**[Back]**](#SUMMARY)

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< Summary Objectives text >

Primary Objectives:
 To evaluate the efficacy of [intervention] in [improving/reducing] [primary outcome measure] compared to [control group] in participants with [disease/condition].

Secondary Objectives:
 To assess the safety and tolerability of [intervention] in patients with [disease/condition].
 To determine the [pharmacokinetics/pharmacodynamics] of [intervention] in [target population].
 To explore the relationship between [baseline characteristic] and [outcome measure].
 To evaluate the cost-effectiveness of [intervention] compared to [standard treatment].
 To assess the long-term [efficacy/safety] of [intervention].

Exploratory Objectives:
 To investigate the [exploratory endpoint, e.g. 'association between [biomarker/pathway activity] and clinical response to [new approach/therapy] in patients with [condition/disease name]'].
 To assess the [exploratory endpoint, e.g. 'effect of [new approach/therapy] on patient-reported outcomes, such as patient global impression of change'] in patients with [condition/disease name].

[**[Back]**](#SUMMARY)

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< Summary Inclusion/Exclusion text >

Inclusion Criteria
 Adults aged [XX-XX] years
 Children aged [XX-XX]
 Diagnosed with [disease] for at least [time period]
 Histologically confirmed [disease]
 Ability to understand and provide written informed consent, or provide written consent by a [Parent/Legal Guardian/Legally authorized representative]
 Laboratory tests: Blood, urine, saliva [parameters for their inclusion]
 Contraception requirements
Exclusion Criteria
 History of allergy to [drug or study-related substance]
 Current participation in another clinical trial
 Severe or uncontrolled intercurrent illness
 Inability to comply with study visits or procedures
 Pregnancy [or positive pregnancy test]

[**[Back]**](#SUMMARY)

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< Background text >

[Condition/Disease Name] is a disorder that poses a substantial burden on individuals, their families, and healthcare systems worldwide. Affecting an estimated [prevalence rate] of the population, it is a major contributor to [specific outcomes, e.g., morbidity, mortality, disability]. Characterized by [key clinical manifestations], the condition often manifests with [specific symptoms] and can significantly impair [affected functions or domains of life]. [Citation to literature evidence with epidemiologic information supporting this section]

Despite advancements in medical science, the management of [condition/disease name] remains a significant challenge. Current therapeutic options, including [existing treatments], frequently exhibit [limitations, such as lack of efficacy, adverse effects, or limited patient tolerability]. These limitations reveal the need for alternative approaches to address the unmet medical needs of patients living with this condition.

Cumulative evidence has suggested the pivotal role of [novel mechanism/pathway] in the pathophysiology of [condition/disease name]. Notably, [specific research findings] have implicated [key molecular or cellular processes] in the development and progression of the disease. These insights provide a compelling rationale for targeting this pathway as a potential therapeutic strategy.

This study aims to evaluate the [primary study objective] of [new approach/therapy], a novel [therapy type] designed to [mechanism of action]. By [modulating/inhibiting/interacting with] [specific target], this intervention seeks to [expected therapeutic benefits, e.g., improve clinical outcomes, enhance quality of life, or slow disease progression]. Ultimately, the development of effective [therapies/interventions/activities] that target the underlying [mechanisms/pathophysiology] of [condition/disease name] is essential for improving patient outcomes, reducing healthcare costs, and enhancing the overall well-being of affected individuals.

[**[Back]**](#Introduction)
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< Hypothesis text >

This study aims to investigate the relationship between [new approach/therapy] and [Condition/Disease Name], where the main hypothesis is that the [new approach/therapy] will result in a significant [improvement/reduction] of/in [outcomes] compared to [Control Group].

[**[Back]**](#Introduction)
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< Main Objectives text >

Primary Objective: To evaluate the efficacy of [intervention] in [improving/reducing] [primary outcome measure] compared to [control group] in participants with [disease/condition].

The primary endpoint for this study is [Measured endpoint: Survival/Response/Quality of Life/ Safety/Efficacy]. This endpoint has been selected as it directly addresses the primary objective of the study and is considered to be a critical indicator of treatment efficacy.

[**[Back]**](#Introduction)
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< Secondary Objectives text >

Secondary Objectives.
The study will assess the safety and tolerability profile of [intervention] in patients with [disease/condition]. Additionally, the pharmacokinetics and pharmacodynamics of [intervention] will be characterized in the target population. To further understand potential predictors of treatment response, the relationship between [baseline characteristic] and [outcome measure] will be explored. Furthermore, a cost-effectiveness analysis will be conducted to compare [intervention] with the standard treatment. Finally, the long-term [efficacy/safety] of [intervention] will be evaluated.

Secondary objectives:
 To assess the safety and tolerability of [intervention] in patients with [disease/condition].
 To determine the [pharmacokinetics/pharmacodynamics] of [intervention] in [target population].
 To explore the relationship between [baseline characteristic] and [outcome measure].
 To evaluate the cost-effectiveness of [intervention] compared to [standard treatment].
 To assess the long-term [efficacy/safety] of [intervention].

Exploratory Objectives:
 To investigate the [exploratory endpoint, e.g. 'association between [biomarker/pathway activity] and clinical response to [new approach/therapy] in patients with [condition/disease name]'].
 To assess the [exploratory endpoint, e.g. 'effect of [new approach/therapy] on patient-reported outcomes, such as patient global impression of change'] in patients with [condition/disease name].

[**[Back]**](#Introduction)

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< Study Design text >

[Describe in this section any special study design to address secondary or exploratory outcomes]

This study will employ a [briefly describe the special/combination study design] design to address the [secondary/exploratory] objectives. The use of this design is justified because [explain why this specific design is necessary to address the hypothesis].
The study will utilize [describe any specific features of the design. Use the design examples below] to [explain how these features will help to address the secondary/exploratory objectives].By combining [multiple design elements, e.g., randomization, blinding, and stratification], this study will provide a comprehensive understanding of the treatment effects and address potential confounding variables, thereby increasing the validity and reliability of the results.

This study is a [study design, e.g., retrospective chart review, randomized controlled trial, prospective cohort study, case-control study] designed to [clearly state the study's primary objective]. The study will employ a [specific design features, e.g., parallel group, crossover, factorial] design to evaluate the [intervention or exposure] in relation to [outcome]. The study will be conducted at [study location(s)] and is expected to enroll approximately [number] participants over a period of [timeframe].

[**[Back]**](#StudyDesign)
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<Interaction with Participants text>

Consenting
Prior to any study-related procedures, potential participants will be provided with comprehensive information about the study, including its objectives, procedures, potential risks and benefits, and their right to withdraw at any time. Written informed consent will be obtained from all eligible participants who voluntarily agree to participate.

Screening and Enrollment
Potential participants will undergo a screening process to determine eligibility based on predefined inclusion and exclusion criteria. Eligible participants will be invited to enroll in the study and will be provided with a unique study identification number.

Study Visits
Participants will be scheduled for a series of study visits at specified intervals to facilitate data collection and intervention administration. The frequency and duration of study visits will depend on the study design and specific research questions.

Interventions
Participants will be randomized or assigned to study groups according to the study protocol. The intervention group will receive the specified [intervention, e.g., medication, therapy, device] as outlined in the study protocol. The control group will receive [control condition, e.g., standard care, placebo].

Data Collection
Data will be collected through various methods, including but not limited to:
 Self-reported questionnaires and surveys
 Clinical assessments And examinations
 Biological sample collection
 Electronic data capture systems
 Medical record review
 Data collection will occur at baseline, during follow-up visits, and at study completion.

Study completion
Upon completion of the study, participants will be informed of the study results and provided with a summary of their individual data, as appropriate. Participants will be thanked for their contributions to the research.

<No interactions with Participants text>

Data Collection
For studies without interaction with participants (e.g., observational studies, registry studies), data collection is the primary participant-related activity. Data will be obtained through a variety of methods, including:
 Medical record review: Extraction of relevant clinical information from electronic or paper-based medical records.
 Database queries: Accessing existing databases or registries for relevant data.
 Biospecimen collection: Obtaining biological samples (e.g., blood, tissue) for analysis, if applicable.
 Surveys or questionnaires: Administering surveys or questionnaires to gather participant-reported outcomes, if feasible.

Data privacy And Confidentiality
Robust data privacy and confidentiality measures will be implemented to protect participant information. This includes:
 De-identification of data/Anonymous data collection
 Secure data storage
 Compliance with relevant data protection regulations

[**[Back]**](#DescriptionStudyDesign)
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<Medical Diagnosis/Medical Intervention>

Intervention Arms
Participants will be [randomly assigned/or stratified by relevant factors] to one of the following study groups:
Intervention Group: Participants in this group will receive [detailed description of the intervention, including dosage, frequency, duration, and route of administration]. The intervention will be administered according to a standardized protocol to ensure consistency in delivery. [Repeat the Intervention Group as needed: e.g., Intervention 1, Intervention 2, etc.]

Control Group: Participants in this group will receive [describe the control condition, e.g., standard of care, placebo, or no active treatment]. The control group will serve as a comparator to assess the effectiveness of the intervention.

Intervention Delivery And Adherence
The intervention will be delivered by [specify who will administer the intervention, e.g., healthcare providers, trained research staff] who have undergone rigorous training on the study protocol and intervention procedures. To ensure adherence to the study protocol, [describe adherence monitoring strategies, e.g., pill counts, electronic monitoring, patient diaries].

Intervention Modification
Any modifications to the intervention regimen, including dose adjustments, treatment interruptions, or early discontinuation, will be documented in accordance with the study protocol. A protocol deviation form will be completed for each modification, detailing the reason for the change and the actions taken.

[**[Back]**](#DescriptionStudyDesign)
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< Device Description text >

Device/Equipment Description
[Clearly describe the specific device or equipment to be used in the study, including its purpose, technical specifications, and relevant regulatory approvals -FDA approved (with indications for use)/Not FDA approved].

Data Acquisition And Management
[Explain how data will be collected from the device or equipment, including data transfer methods, storage, and security measures. Describe any data processing or analysis that will be performed.]

Device/Equipment Safety
[Address any potential safety concerns associated with the device or equipment, including risk mitigation strategies and emergency procedures.]

Training of the Research Team/Operators
[Describe the training requirements for personnel using the device or equipment. Outline the assessment of proficiency and competency.]

Note: The specific details of this section will vary depending on the type of device or equipment used in the study.

<For FDA non-approved Devices that are considered Non-Significant Risk, use the following rationale>

The [Sponsor] has determined that the [Device] studied in this research is a Non-Significant Risk device, [Justify by explaining how the intended use aligns with the indications for use, and how it fulfills the specified criteria as applied in this protocol]

 The device is NOT intended as an implant that presents a potential for serious risk to the health, safety, or welfare of a subject.
 The device is NOT purported or represented to be for a use in supporting or sustaining human life that presents a potential for serious risk to the health, safety, or welfare of a subject.
 The device is NOT for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health that presents a potential for serious risk to the health, safety, or welfare of a subject.
 The device does NOT otherwise present a potential for serious risk to the health, safety, or welfare of a subject.

[**[Back]**](#Device)
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< Drugs/Biologics, Food, Cosmetics, Tobacco Description text >

Drug Description
[Clearly describe the drug, including its generic and trade name, chemical composition, intended use, dosage form, and regulatory status.]

Drug Sourcing And Storage
[Specify the source of the drug, including manufacturer, supplier. Outline the storage conditions and requirements for the drug, such as temperature, light exposure, duration of storage.]

Drug Preparation And Administration
[Describe the procedures for preparing the drug for administration, including reconstitution, dilution, or other necessary steps. Specify the route of administration, dosage, and frequency.]

Drug Management And Disposal
[Outline the procedures for drug management, including inventory control, expiration date tracking, procedures for returning non-used drugs and proper disposal of unused or expired drugs.]

Note: The specific details of this section will vary depending on the drug being used in the study.

[**[Back]**](#DrugBiologics)
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Behavioral Research Procedures Description

Intervention
The study intervention is a carefully designed program aimed at promoting [describe the intended behavior change or outcome]. This program is based on [briefly describe the theoretical framework underpinning the intervention, e.g., cognitive-behavioral theory, social learning theory]. By understanding the theoretical basis of the intervention, we can better design and deliver a program that is effective in achieving our goals.

Components
The intervention program consists of several key components, including [detail the specific components or modules of the intervention]. These components are designed to work together to promote behavior change and improve outcomes. The program will be delivered by [specify the qualifications and training of interventionists], who have received specialized training in the intervention protocol. The program will be delivered in a [describe the intervention setting, e.g., individual, group, or online] format, and will consist of [number] sessions, each lasting approximately [duration] minutes.

Implementation
To ensure that the intervention is delivered consistently and effectively, we have developed a detailed intervention manual that outlines the structure, content, and therapeutic techniques used in each session. Interventionists will undergo rigorous training to master the intervention protocol, and we will monitor adherence to the manual through [specify methods for monitoring adherence, e.g., session recordings, therapist checklists, patient-reported outcomes]. This will help us to ensure that the intervention is delivered as intended and that any variations in delivery are minimized.

Accepted Variances
While the intervention is standardized, we also recognize that individual participants may have unique needs and preferences. To address this, we have built in opportunities for tailoring the intervention to individual participants. This may include [describe tailoring strategies, e.g., adjusting the pace of intervention, modifying intervention components]. By allowing for flexibility and adaptation, we can ensure that the intervention is optimized for each participant and that they receive the most effective support possible.

Naïve Condition
Participants in the control group will receive [describe the control condition, e.g., usual care, waitlist control, attention control]. This control condition is designed to [describe the purpose of the control group, e.g., provide a comparison group, minimize expectancy effects]. By including a control group, we can compare the outcomes of participants who receive the intervention to those who do not, and gain a better understanding of the intervention's effectiveness.

[**[Back]**](#Others)

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Inclusion Criteria
 Adults aged [XX-XX] years
 Children aged [XX-XX]
 Diagnosed with [disease] for at least [time period]
 Histologically confirmed [disease]
 Ability to understand and provide written informed consent, or provide written consent by a [Parent/Legal Guardian/Legally authorized representative]
 Laboratory tests: Blood, urine, saliva [parameters for their inclusion]
 Contraception requirements

<Inclusion of Pregnant Participants>
Pregnant participants must meet the following criteria:
o Gestational Age: between XX-XX weeks.
o Must be receiving prenatal care from a qualified healthcare provider
o Must have a [singleton/multiple] pregnancy
o Must not have any known complications or risk factors for pregnancy that could compromise their participation in the study
o Pregnant subjects are eligible for participation, but must be in their [first/second/third] trimester at the time of enrollment and meet the study's specific inclusion criteria for pregnant women.

<Excluding Pregnancies>
 Women of childbearing potential must have a negative pregnancy test result at screening and agree to use effective birth control throughout the study.

< Vulnerable Population text >

[Inclusion of Children/Adult subjects unable to consent by themselves]
 Individuals with limited capacity and unable to consent by themselves, a Parent, Legal Guardian/Legally Authorized Representative (LAR) will be required to provide informed consent on their behalf.

[Exclusion of LAR/minors]
The participant must be able to understand and comply with the research activities and sign the consent form.

< Prisoners text >

Imprisoned or Detained Individuals: Individuals who are currently incarcerated or detained [will not] be eligible for this study [due to the potential for undue influence or coercion].

< Requirement to sign the consent/assent document text >

[Examples of language used to request signatures, depending on the research requirements]
 Provide informed consent by signing the Informed Consent Form.
 If you are under 18 years old, your parent or guardian must:
 Provide informed consent by signing the Informed Consent Form and the Participant Information Sheet.
 Sign the Assent Form, indicating that you understand the study and are willing to participate.

[**[Back]**](#StudyPopulation)
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Exclusion Criteria
 History of allergy to [drug or study-related substance]
 Current participation in another clinical trial
 Severe or uncontrolled intercurrent illness
 Inability to comply with study visits or procedures
 Pregnancy [or positive pregnancy test]

[**[Back]**](#StudyPopulation)
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<Study Procedures text>

Screening and Enrollment: Potential participants will undergo a screening process to determine eligibility based on predefined inclusion and exclusion criteria. Eligible participants will provide written informed consent and be enrolled into the study. [Describe Screening process].

Baseline Assessment: A comprehensive baseline assessment will be conducted to collect demographic, medical, and clinical data. This assessment may include [list of baseline assessments, e.g., medical history, physical examination, laboratory tests, questionnaires].
Intervention Delivery: The experimental intervention will be administered according to a standardized protocol. Participants will be monitored for adherence to the intervention regimen.

Follow-up Assessments: Participants will undergo scheduled follow-up assessments to evaluate [the efficacy, safety, and tolerability of the intervention]. Assessments will include [list of follow-up assessments].

Data Collection: Data will be collected through various methods, including [list of data collection methods].

[**[Back]**](#Interventions)
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<Randomized Controlled Trials>

In order to ensure the highest level of internal validity and minimize potential biases, this randomized controlled trial will employ a rigorous participant allocation and randomization process. The following details outline the methodology used to allocate participants to either the intervention or control group:

Randomization Method: This study will utilize a [ specify randomization method] to ensure that participants are randomly assigned to either the intervention or control group. Stratification will be based on [specify factors].
To prevent biases during the allocation process, a centralized randomization system will be used. Participating sites will have access to a web-based randomization system that generates a random allocation sequence, and participants will be allocated to a group in real-time. The allocation sequence will be generated by a statistician not involved in the study, and the allocation list will be kept confidential.
The randomization process will be conducted electronically, using a validated randomization software system. The system will generate a unique randomization number for each participant, which will correspond to a specific allocation group.
To ensure balance between groups, baseline characteristics will be compared between the intervention and control groups to assess for differences. Any significant imbalances will be addressed using [analysis of covariance (ANCOVA) or other adjustment techniques].

<Non-Randomized Studies>

Participant assignment to study groups will be based on [predefined criteria]. The following details outline the methodology used to assign participants to study groups:
Eligibility Criteria: [A clear set of eligibility criteria will be established to define the population of interest]. Participants will be selected based on these criteria, which will be clearly described in the protocol.
Selection Process: The selection process [describe the selection process, including the methods used to identify and recruit participants]. Efforts will be made to minimize biases during the selection process by using systematic approaches to identify participants.

<Bias Mitigation>

To minimize potential biases, the following methodological approaches will be employed:
Matching: Participants will be matched based on relevant covariates to create comparable groups. This will be done using [ specify matching method].

[**[Back]**](#Interventions)
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< EOS (end of study) text >

Study Completion Criteria
The study will be considered complete upon the fulfillment of the following criteria:
• Enrollment of the target sample size.
• Completion of the final follow-up visit for all enrolled participants.
• Collection of all required data and documentation.
• Resolution of any outstanding protocol deviations or adverse events.

End of Study Visit
Upon completion of the intervention period, participants will undergo a final end-of-study visit. This visit will include:
Comprehensive assessment: A thorough evaluation of participant outcomes, including primary and secondary endpoints.
Safety evaluation: Assessment of any adverse events or treatment-related complications.
Data collection: Collection of final study data, such as questionnaires, biological samples, and clinical measurements.
Return of study materials: Collection of any study-related materials provided to participants (e.g., devices, medication).

Follow-up Procedures
Depending on the study design and research objectives, follow-up assessments may be conducted after the end of the study to evaluate long-term outcomes or safety. Follow-up visits will include [specify follow-up assessments, e.g., clinical evaluations, questionnaires, biological samples].

Data Management and Analysis
Upon study completion, a comprehensive data management and analysis plan will be executed. This includes data cleaning, coding, and verification to ensure data accuracy and integrity. Statistical analyses will be conducted according to the prespecified statistical analysis plan.
Study Findings and Dissemination

Study findings will be summarized in a comprehensive final report, including descriptive statistics, inferential analyses, and interpretation of results. The report will adhere to relevant reporting guidelines (e.g., CONSORT, STROBE). Dissemination of study results will occur through peer-reviewed publications, conference presentations, and other appropriate channels.

Participant Communication
Study participants will be informed of the study completion and provided with a summary of the study findings, as appropriate. Participants will be thanked for their contributions to the research.

Record Retention and Archiving
All study-related records, including participant data, informed consent forms, and regulatory documents, will be retained for a minimum of [specify retention period] in accordance with applicable regulations and institutional policies. Electronic data will be securely archived to allow for future reference and secondary analysis.

Study Closure
Following the completion of data analysis, reporting, and archiving, the study will be formally closed. A final study report will be submitted to the [institutional review board (IRB) or ethics committee], and regulatory authorities will be notified of the study closure.

Data sharing
Data sharing plans will be developed in accordance with relevant data sharing guidelines and participant consent. Data sharing may include depositing data in public repositories or controlled access data centers.
By adhering to these procedures, the study will ensure the integrity of the research, the protection of participant rights, and the dissemination of valuable knowledge.

[**[Back]**](#Interventions)
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< Safety Plan >

Definitions (Adverse Events, Serious Adverse Events, Severity of Events, Unanticipated Problems, Events of Special Interest, Relatedness to the investigational intervention, Expectedness of Adverse Events).
[AE and AEs Reporting, monitoring]
[Unanticipated Problems]
[Pregnancy Reporting and Follow-up]

Safety Monitoring And Reporting
Participants will be closely monitored for adverse events (AEs) throughout the study. A standardized AE reporting form will be used to document all suspected adverse reactions. Serious adverse events (SAEs) will be reported to the [regulatory authority] within [specified timeframe].

Adverse Events (AEs) Monitoring
Participants will be closely monitored for AEs throughout the study. The study team will use a standardized AE reporting form to document all suspected adverse reactions, including those related to the intervention, study procedures, or related to the underlying condition.

Reporting of Adverse Events
All AEs will be reported to the study principal investigator (PI) within 24 hours of occurrence. The study PI will review and document all AEs, and report them to the Institutional Review Board (IRB) and [regulatory authority] in accordance with applicable regulations. Serious adverse events (SAEs) will be reported to the [regulatory authority] within [24 hours] of occurrence.

Risk Mitigation
To minimize risks to participants, the following measures will be implemented:
 • Informed consent: Participants will be fully informed about the potential risks and benefits of the study, and will provide written consent before enrolling.
 • Screening procedures: Participants will undergo thorough screening to identify potential risks, such as underlying medical conditions or medication use.
 • Emergency protocols: The study team will develop and implement emergency protocols for handling medical emergencies or AEs.
 • Regular monitoring: Participants will be regularly monitored for AEs, and their vital signs and laboratory results will be reviewed.

Data Safety Monitoring Board (DSMB)
The DSMB will provide independent oversight of the study, with responsibility for reviewing study progress and safety data, advising the study team on study modifications or termination, and monitoring participant safety and well-being.

The study investigator will be responsible for reporting AEs and SAEs to the IRB and [regulatory authority], documenting AEs and SAEs in the participant's medical record, communicating with participants about potential risks and benefits, and providing emergency contact information to participants.

[**[Back]**](#SafetyManagement)
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< Statistical Analysis/Sample Size >

This study will analyze the following variables to test the proposed hypotheses: [list the specific variables to be analyzed]. Each objective of the study will have its own endpoint, and multiple hypotheses will be formulated as necessary to adequately address each objective.

The background information supporting the assumptions for the sample size calculations is based on [briefly describe the relevant literature or research that informed the estimates]. Specifically, our sample size calculations take into account [provide specific details about the assumptions made, such as expected effect sizes, variability, and dropout rates]. Based on these calculations, we believe that it is feasible to conduct the proposed research within the proposed timeframe.

In addition to the primary analyses, [list any secondary analyses, such as subgroup analyses or exploratory analyses]. [provide a rough estimate of the power for these endpoints, e.g. 'expect to have 80% power to detect a significant difference in XY outcomes between groups']. [briefly describe the assumptions and calculations used to determine power].

[**[Back]**](#Statistics)

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< Traditional consent process (paper & wet ink) >

• Give the person providing informed consent as much time as they need to decide.
• If the person providing informed consent needs more time than is allowed by the research design, not enroll the prospective subject.
• Evaluate whether the person providing informed consent is experiencing time pressure to decide, and if so, do not enroll the prospective subject, even if the person providing informed consent agrees to be in the research.
• Ensure there is no threat of harm or adverse consequences to the prospective subject for a decision to not take part in the research.
• Stop the informed consent process once the person providing consent indicates that he or she does not want to take part in the research.
• Evaluate whether the person providing informed consent is being coerced or unduly influenced by others to take part in the research, and if so, not enroll the prospective subject, even if the person providing informed consent agrees to be in the research.
• Communicate in the preferred language of the person providing informed consent.
• Adapt the presentation of the information to the subject's capacities in terms of intelligence, rationality, maturity and language.
• Invite and answer questions from the person providing informed consent.
• Evaluate whether the person providing informed consent understands the information provided, and not enroll a prospective subject who does not understand, even if that person providing informed consent agrees to be in the research.
• Ensure that no information is provided to the prospective subject or the person providing informed consent that is made to waive or appear to waive any of the prospective subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.
• Communicate to the person providing informed consent all the information in the consent document or script approved by the IRB.
• Not enroll a prospective subject when the person obtaining informed consent is unwilling to listen to or consider the information, even if the person providing informed consent agrees to be in the research.

[**[Back]**](#Consent)

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< Alternate Consent Process >

Remote Communication: Consent can be acquired by reaching out to participants via phone calls, video conferencing, or secure online platforms.
Technology-Aided Consent: Interactive electronic tools are employed to guide participants through the consent process and capture their electronic consent.
Asynchronous Consent: In certain scenarios, participants may review consent information online or over the phone with the research team and subsequently return the signed consent document by mail, through a secure online platform or in person at their next visit.

These alternative approaches are designed to offer accessible and convenient means for participants to provide informed consent, while maintaining adherence to ethical principles and regulatory requirements.

[**[Back]**](#AltConsent)
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< Electronic Consent >

The electronic consent process will be conducted as follows:

The investigator or study staff will introduce the study [include the specific method, technology, platform] and provide an overview of the eConsent document.
Participants will review the eConsent document independently and have ample time to ask questions. [Describe the method that participants will contact the research team for questions and clarifications] Participants will have the opportunity to ask questions and have them answered by the investigator or study staff.
Following review and discussion, participants will provide an electronic signature [indicate the platform/system] to indicate their consent.
The [platform/system] used is compliant with 21 CFR Part 11 requirements.

More resources at: [*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-electronic-informed-consent-clinical-investigations-questions-and-answers?source=govdelivery&utm\_medium=email&utm\_source=govdelivery*](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-electronic-informed-consent-clinical-investigations-questions-and-answers?source=govdelivery&utm_medium=email&utm_source=govdelivery)

[**[Back]**](#Consent)
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< Waiver of Consent text >

Minimal Risk: The research involves no more than minimal risk to participants, as [describe the justification for minimal risk].
Practicability: Obtaining informed consent from all participants is impracticable due to [explain reasons, e.g., retrospective chart review, emergency research, public benefit or service programs].
No Adverse Impact: Waiving or altering informed consent will not adversely affect the rights and welfare of participants.
Participant Information: Participants [will/will not] be provided with information about the research study after participation.

< Waiver of Documentation of Consent text >

Minimal Risk: The research involves no more than minimal risk to participants, as [describe the justification for minimal risk].
Privacy/Confidentiality: Research activities and methodologies can be observed outside of a research setting, and typically do not necessitate to sign a consent.

The study team will provide to the participants information about the study, including the required elements of informed consent and their rights, and obtain oral informed consent from participants, documenting the consent process in the research records.

< HIPAA Waiver text >

The proposed study involves the collection, use, and disclosure of protected health information (PHI) for the purpose of evaluating [study purpose]. In accordance with the Health Insurance Portability and Accountability Act (HIPAA) of 1996, it is required to obtain authorization from participants for the use and disclosure of their PHI. However, due to the nature of the study, it is impractical and unbearably burdensome to obtain such authorization. Therefore, we are requesting a [partial/waiver of HIPAA authorization] for the proposed study.

The following reasons justify a [partial/waiver of HIPAA authorization] for this study:
[Description for the reasons to request the HIPAA Waiver]

[**[Back]**](#Waivers)
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< Privacy and Data Protection >

Protecting participant privacy and ensuring data confidentiality are paramount to the ethical conduct of this research. A robust data protection plan will be implemented to safeguard participant information throughout the study.

Data Minimization and Pseudonymization
To minimize the amount of collected data, only information directly relevant to the study objectives will be collected. Personal identifiers will be removed from research data as soon as feasible, creating a pseudonymized dataset for analysis. [A database will be maintained to link study identifiers to source data for audit and safety monitoring purposes].

Data security
Comprehensive security measures will be implemented to protect research data from unauthorized access, use, disclosure, modification, or destruction. These measures include:
• Access Control: Implementing strict access controls to research data, limiting access to authorized personnel on a need-to-know basis.
• Data Encryption: Employing robust encryption technologies to protect data both at rest and in transit.
• Secure Data Storage: Storing research data on secure servers with firewalls and intrusion detection systems.
• Data Backup and Recovery: Implementing regular data backup and disaster recovery plans to protect against data loss.

Participant Information
Participants will be provided with clear and concise information about how their data will be collected, used, and protected. They will be informed of their rights regarding data access and control.

Data sharing
Data sharing, if applicable, will be conducted in accordance with established data sharing agreements and relevant regulations. Data sharing plans will outline the specific data elements to be shared, the recipients of the data, and the safeguards to protect participant privacy.

Breach Response
A comprehensive data breach response plan will be in place to address potential breaches of confidentiality. Procedures for identifying, containing, investigating, and mitigating the impact of a breach will be followed. Notification to affected participants and regulatory authorities will be conducted as required by applicable laws and regulations.

By implementing these comprehensive data protection measures, the study will safeguard participant privacy, maintain data integrity, and comply with relevant ethical and regulatory standards.

[**[Back]**](#CoC)
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