**CLINICAL TRIAL FEASIBILITY REVIEW**

The purpose of the Clinical Trial Feasibility Review Process is to meet expectations in assessing research trial feasibility at Emory University. The feasibility review will involve a thorough assessment and proactive review of the protocol by representatives from applicable departmental resource areas to determine enrollment barriers and operational requirements. Individuals participating in the feasibility review will document and provide their assessment to the [Insert Research Administrator]. A feasibility review must occur prior to protocol approval and submission for pre-award approvals.

**INSTRUCTIONS:**

Please complete form for all trials (*interventional and non-interventional).*

**Protocol Title:**

**Principal Investigator:**

**Clinical Research Coordinator(s):**

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| 1. **PATIENT ACCRUAL & PI WORKLOAD**

**(Completed by *[Research Administrator or Designee]* & Investigator)** |
| **Patient Population Seen at University (TriNetX data):** |  |  |  |  |  |  |  |
| **Overall Target Accrual Goal:**  |  | **Current Overall Accrual** *(if available)***:** |  | **Primary Accrual Completion Date:** |  |
| **Total Accrual Goal:** |  | **Annual Accrual Goal:** |  | **Participating Sites Accrual Goal (Grady or VA, others):** |  |
| **Accrual Duration (months):** |  |  **Total # of Trials by PI** (actively accruing and patients in follow-up): |  | **Total # of Accruing Trials by PI:** |  |

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| 1. **CLINICAL OPERATIONS CONSIDERATIONS**

**(Completed by Research Manager)** |  |  |
|  | **YES** | **NO** | **NA** | **UNK** | **Comments** |
| Does the [PI] expect staffing to be adequate and experienced to conduct the trial once opened?If no, please review/discuss with Dept Vice-Chairman of Research and be prepared to discuss with [Dept/Div Research Administration]. | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Are personnel required to conduct special procedures or efficacy measures? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Does the [PI] anticipate any staffing challenges in operationalizing this protocol at participating sites? *(Consider response to “Participating Site Accrual Goal” question in section A above)* | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Additional Comments |  |
| **Clinical Operations Considerations Assessment** |
| **Completed by Research Manager** | **Low****(**no feasibility challenges) | **Moderate****(**some feasibility challenges) | **High****(**many feasibility challenges) | **Comments** |
| What impact do the responses above have on feasibility? | [ ]  | [ ]  | [ ]  |  |

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| 1. **REGULATORY CONSIDERATIONS**

**(Completed by Regulatory Team)** |  |  |
|  | **YES** | **NO** | **NA** | **UNK** | **Comments** |
| Is current staffing adequate and experienced to complete a timely study start-up process? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Is current staffing adequate and experienced to maintain ongoing regulatory activities once the trial is activated? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Is the Sponsor using a central IRB? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Will the Sponsor make IRB submissions on behalf of the site?  | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Does the Sponsor expect the study to be excessively monitored? If yes, please explain in comments. | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Additional Comments |  |
| **Regulatory Considerations Assessment** |
| **Completed by Regulatory Team** | **Low****(**no feasibility challenges) | **Moderate****(**some feasibility challenges) | **High****(**many feasibility challenges) | **Comments** |
| What impact do the responses above have on feasibility? | [ ]  | [ ]  | [ ]  |  |

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| 1. **FINANCIAL CONSIDERATIONS**

**(Completed by [Departmental Research Administrator])** |  |  |
|  | **YES** | **NO** | **NA** | **UNK** | **Comments** |
| Will the Sponsor reimburse trial participants? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Does [Investigator] have financial resources to support the trial if it is unfunded or underfunded? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| If sponsor study budget is available, will the Sponsor pay for pre-study activities if the study is not activated at Emory University due to contractual issues? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| If sponsor study budget is available, does the sponsor expect the study to be audited by a regulatory body and are audit preparation costs factored into the study budget? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Are special equipment or supplies required and provided by the Sponsor? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Additional Comments |  |
| **Financial Considerations Assessment** |
| **Completed by Research Manager** | **Low****(**no feasibility challenges) | **Moderate****(**some feasibility challenges) | **High****(**many feasibility challenges) | **Comments** |
| What impact do the responses above have on feasibility? | [ ]  | [ ]  | [ ]  |  |

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| 1. **QUALITY AND TRAINING CONSIDERATIONS**

**(Completed by [Departmental Research Administrator])** |  |  |
|  | **YES** | **NO** | **NA** | **UNK** | **Comments** |
| Is current staffing adequate and experienced to support the quality and education necessary for trial conduct? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| If monitoring off-site, are there appropriate resources in place?  | [ ]  | [ ]  | [ ]  | [ ]  |  |
| If this is a multi-site trial with an Emory PI serving as the main study PI, are appropriate monitoring resources in place?  | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Additional Comments |  |
| **Quality and Training Considerations Assessment** |
| **Completed by Quality Management Team** | **Low****(**no feasibility challenges) | **Moderate****(**some feasibility challenges) | **High****(**many feasibility challenges) | **Comments** |
| What impact do the responses above have on feasibility? | [ ]  | [ ]  | [ ]  |  |

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| 1. **ENROLLMENT CONSIDERATIONS**

**(Completed by Departmental Research Administrator & PI)** |  |  |
|  | **YES** | **NO** | **NA** | **UNK** | **Comments** |
| Are the inclusion & exclusion criteria reasonable to meet the accrual goal?  | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Does the washout period impact enrollment? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Does age impact enrollment? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Will duration of participation impact enrollment? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Will the frequency of visits impede participation or scheduling? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Will the frequency of dosing impact enrollment or scheduling? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Could procedural discomfort to the study participant impact participation or participant compliance? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Do we have access to the right patient population? *(See section A for accrual considerations.)* | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Additional Comments |  |
| **Enrollment Considerations Assessment** |
| **Completed by Research Manager** | **Low****(**no feasibility challenges) | **Moderate****(**some feasibility challenges) | **High****(**many feasibility challenges) | **Comments** |
| What impact do the responses above have on feasibility? | [ ]  | [ ]  | [ ]  |  |

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| 1. **PROTOCOL CONSIDERATIONS**

**(Completed by Departmental Research Administrator & PI)** |  |  |
|  | **YES** | **NO** | **NA** | **UNK** | **Comments** |
| Are there competing trials? If so, are there enough eligible patients to support this trial? Provide justification for competing trials. *(See section A for accrual considerations.)* | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Is the protocol similar to previously conducted studies? If so, were the previous studies successfully completed? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Does the study require research specific EKGs? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Is specialized equipment required? Is there appropriate training and space for the equipment. If yes, please comment.  | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Will special procedures require evaluations or testing outside of regular clinic hours? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Are frequent and/or severe Adverse Events expected? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Does the staff/study team require special training on the protocol? (i.e., procedural, biosafety concerns) | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Have you successfully worked with this Sponsor in the past? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Additional Comments |  |
| **Additional Protocol Considerations Assessment** |
| **Completed by Research Manager** | **Low****(**no feasibility challenges) | **Moderate****(**some feasibility challenges) | **High****(**many feasibility challenges) | **Comments** |
| What impact do the responses above have on feasibility? | [ ]  | [ ]  | [ ]  |  |

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| 1. **ANCILLARY SERVICES CONSIDERATIONS**

**(Completed by Departmental Research Administrator. If yes, verify resources are available with applicable ancillary committees/representatives.)** |
| **Imaging Resources**  | **YES** | **NO** | **NA** | **UNK** |  |  |
| **Comments** |
| Are there special imaging requirements? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Additional Comments |  |
| **In-Patient Unit Resources** | **YES** | **NO** | **NA** | **UNK** |  |  |
| **Comments** |
| Will in-patient resources be required? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Additional Comments |  |
| **Discoveries and Developmental Therapeutics Resources** | **YES** | **NO** | **NA** | **UNK** |  **Comments** |
| Will Discoveries and Developmental Therapeutics resources be required for any length of time? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Additional Comments |  |
| **Laboratory Resources** | **YES** | **NO** | **NA** | **UNK** |  |  |
| **Comments** |
| Will special laboratory equipment and personnel be adequate to conduct the protocol? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Are extended hours required? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Additional Comments |  |
| **Ophthalmology Resources** | **YES** | **NO** | **NA** | **UNK** |  |  |
| **Comments** |
| Are there special ophthalmology requirements? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Additional Comments |  |
| **Outpatient Resources** | **YES** | **NO** | **NA** | **UNK** |  |  |
| **Comments** |
| Are there special outpatient requirements? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Additional Comments |  |
| **Research Pharmacy Resources** | **YES** | **NO** | **NA** | **UNK** |  |  |
| **Comments** |
| Are there special research pharmacy requirements? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Additional Comments |  |
| **Pathology Resources** | **YES** | **NO** | **NA** | **UNK** |  |  |
| **Comments** |
| Are there special pathology requirements? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Additional Comments |  |
| **Cardiology**  | **YES** | **NO** | **NA** | **UNK** |  |  |
| **Comments** |
| Are there special cardiology requirements? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Additional Comments |  |
| **Dermatology**  | **YES** | **NO** | **NA** | **UNK** |  |  |
| **Comments** |
| Are there dermatology requirements? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Additional Comments |  |
| **Audiology**  | **YES** | **NO** | **NA** | **UNK** |  |  |
| **Comments** |
| Are there audiology requirements? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Additional Comments |  |
| **Other Ancillary Department: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **YES** | **NO** | **NA** | **UNK** |  |  |
| **Comments** |
| Are there special protocol requirements that need consideration? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Additional Comments |  |
| **Ancillary Services Considerations Assessment** |
| **Completed by Research Manager** | **Low****(**no feasibility challenges) | **Moderate****(**some feasibility challenges) | **High****(**many feasibility challenges) | **Comments** |
| What impact do the responses above have on feasibility? | [ ]  | [ ]  | [ ]  |  |

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| **SIGNATURES** |
|  |  |  |
| Research Administrator Signature |  | Date |
|  |  |  |
| Principal Investigator Signature |  | Date |