**Feasibility and Study Planning Guide**

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| **Trial Title:**  |   |
| **Sponsor:** |   | **CRO:** |   |
| **Protocol #:** |  | **Sponsor's Protocol #:** |   |
| **Principal Investigator (PI):** |  | **Department:** |   |
| **Completed by:**  |  | **Date completed:**  |  |
| **Email:** |  | **Phone:** |  |
| **Mail Slot:** |  | **Fax:** |  |

This Feasibility and Study Planning Guide is to be used by any University of Arkansas for Medical Sciences (UAMS) investigator who is considering participation in an industry-sponsored clinical trial. Its goal is to guide the investigator and their designee through a comprehensive review of the clinical and business aspects of the trial to add clinical value in an efficient manner.

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| **GENERAL TRIAL INFORMATION** |
| **Questions for Sponsor**  |
| 1 | Is the trial currently open? If not, when do you expect it to be? |   |
| 2  | Is there an NCT number? If not, when will it be registered on ClinicalTrials.gov? |   |
| 3 | What is the accrual goal of the trial? How many subjects have been enrolled to date? | Accrual goal: \_\_\_\_\_ Current enrollment: \_\_\_\_\_ |
| 4 | What is the target date of completion of enrollment? |   |
| 5 | How many sites have activated the trial to date? |   |
| 6 | What is the sponsor's goal or limit for enrollment at UAMS? |   |
| 7  | How many IND Safety Reports have been issued in the past 12 months? | # INDSRs: \_\_\_\_\_ |
| **Questions for UAMS** |
| 8 | Has this investigator served as a principal investigator (PI) previously? If so, how many studies overall & how many are current? If not, does the PI have a mentor? | Yes No # of overall studies: # of current studies: Mentor: |
| 9 | How many studies is the PI actively recruiting for at this time? What is the overall accrual goal for all active studies the PI is conducting? | # studies actively recruiting:# overall accrual goal: |
| 10a | Does PI have a study team? (i.e., Research Coordinator/Nurse/Assistant)  | Yes No  |
| 10b |  If yes, does study team have specific experience to conduct the trial and are there adequate resources given other ongoing studies? If no, justify.  | Yes No Justify:  |
| 11 | Does PI have any known conflict of interest issues involving this trial? (i.e., PI has received compensation from sponsor or has a patent on item to be tested).  | Yes No  |
| 11a | If yes, has the PI contacted the UAMS Conflict of Interest Administrator to determine if a management plan is required?  | Yes No |
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| **PROTOCOL** |
| **Questions for UAMS** |
| 12 | Does the study (i.e., objectives, procedures, and safety considerations) agree with PIs clinical and ethical judgement for patient treatment? | Yes No  |
| 13 | Can the protocol be adequately integrated with routine standards of care?  | Yes No  |
| 14 | Given PIs current workload, does PI have adequate time to supervise this study? | Yes No  |
| 15 | Are there any competing trials ongoing at UAMS? | Yes No  |
| 15a |  If so, will there be a sufficient number of eligible patients for this trial? | Yes No  |
| 16 | Is this study similar to previous studies conducted at UAMS?  | Yes No  |
| 16a |  If so, were the previous studies successfully completed?  | Yes No  |
| 17 | Will special procedures require evaluations or testing outside of regular clinic hours?  | Yes No  |
| 18 | Which alternate treatments are available for this patient population? |   |
|  |  |  |  |  |  |  |  |  |
| **RECRUITMENT AND ENROLLMENT** |
| **Questions for UAMS** |
| 19 | What is the source of potential subjects? (Ex. Clinic, community, inpatient) |   |
| 20 | Does PI have direct access to potential subjects? | Yes No  |
| 21 | Estimate total potential subject pool; Data Warehouse or EPIC may be available for such data. Contact triservices@uams.edu |   |
| 22 | Based on current / past knowledge, how many subjects can be enrolled based on estimates and review? | Total # \_\_\_\_\_\_\_\_\_\_\_ # Subjects per Month \_\_\_\_\_\_ Ratio of screen to failure: \_\_\_\_\_\_\_ |
| 23 | Will a recruitment plan be required? | Yes No NA |
| 24 | Will sponsor provide resources and/or plan for recruitment? (If yes, comment) | Yes No NA |
| 25 | Will advertisements be required for the trial? | Yes No NA |
| 26 | Are inclusion/exclusion criteria reasonable to meet enrollment? | Yes No NA |
| 27 | Will any of the following factors impede enrollment? If yes, comment. | Yes No NA |
|  27a | Age? | Yes No NA |
|  27b | Duration of participation? | Yes No NA |
|  27c | Geographic location of patient? | Yes No NA |
|  27d | Frequency of visits? | Yes No NA |
|  27e | Frequency of dosing? | Yes No NA |
|  27f | Medication restrictions? | Yes No NA |
|  27g | Other medical conditions? | Yes No NA |
|  27h | Procedural discomforts? | Yes No NA |
|  27i | Washout period? | Yes No NA |
|  27j | Other? | Yes No NA |
|   |  |  |  |  |  |  |  |  |
| **BUDGET** |
| **Questions for Sponsor** |
|  28 | Who is the contact for budget negotiations? | Name: E-mail: Phone:  |
|  29 | Is a budget template available for review? | Yes No If no, when would it be available? |
|  30 | Will sponsor provide CPT codes for non-standard and standard of care procedures? | Yes No NA |
|  31 | Is there reimbursement available for subjects' travel, lodging, mileage, parking, gas, cars or time? | Yes No NA |
|   31a |  If yes, how is this being paid? |   |
|  32 | What is the reimbursement schedule? (i.e., quarterly, milestones, CRF completion)  |   |
| **Questions for UAMS** |
|  33 | Who will build study budget? | Name: E-mail: Phone: |
|  34 | What is the sponsor's expected timeline for completion of budget negotiation? |   |
|  35 | Will sponsor provide reimbursement for screen failures?  | Yes No If yes, how many?  |
|  36 | What is the sponsor's expectation for data submission? |   |
|  37 | Who will manage the trial account? | Staff Position: |
|   |   |   |   |   |   |   |   |   |
| **CONTRACTING** |
| **Questions for Sponsor** |
| 38 | Who is the contact for contract negotiations? | Name: E-mail: Phone: |
| 39 | Who is the contact for consent negotiations? | Name: E-mail: Phone: |
| 40 | Are startup fees non-refundable? | Yes No |
| 41 | Is sponsor willing to pay for subject injury?  | Yes No |
| 42 | Will UAMS need to have a subsite to perform part of the study? | Yes No |
| **Question for UAMS** |
| 43 | Is there a master agreement between the sponsor and the institution? | Yes No |
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| **DATA MANAGEMENT** |
| 44 | Are copies of the CRFs available for the site to review? | Yes No |
| 45 | How will research data be captured? | Paper CRFs eCRFs Name of application  |
| 46 | Who will be recording data in CRFs? (i.e., department, staff) | Staff Position:  |
| 47 | Will offsite training be provided to the staff for completion of the sponsor's CRFs/e/CRFs? | Yes NoWhere: \_\_\_\_\_ # hours: \_\_\_\_\_ # days \_\_\_\_\_ |
|  48 | Will onsite training be provided to the staff for completion of the sponsor's CRFs/e/CRFs? | Yes NoWhere: \_\_\_\_\_ # hours: \_\_\_\_\_ # days \_\_\_\_\_ |
|  49 | What is the anticipated number of CRF pages/entry screens per patient? | # Baseline: \_\_\_\_\_ # Per cycle of treatment: \_\_\_\_\_ # Off-treatment: \_\_\_\_\_ # Follow-up period: \_\_\_\_\_ # Off-study: \_\_\_\_\_ # Other: \_\_\_\_ |
|  50 | If the site has previously utilized the sponsor's/CRO's eCRF application, will retraining of site's data management staff be required?  | Yes No NA |
|  51 | Will the site be required to complete documentation logs? | Yes No If yes, what logs will be required for the site to complete? |
|  52 | When is research data required to be entered into the eCRFs upon completion of study visits/interventions? Note: NCI expectation is 2 weeks | # days: \_\_\_\_\_ # weeks: \_\_\_\_\_ |
|  53 | Will extra copies of the CRFs be required to be submitted to the sponsor at any time during the trial or at the completion of the trial? | Yes No |
|  54 | Will the sponsor allow the institutions' EMR to be used as source documents? | Yes No |
|  55 | Will a CRO manage this study? | Yes No If yes, name of CRO:  |
| 56 | Will there be scheduled telephone calls to clinical research staff? | Yes No If yes, anticipated number of calls per month? \_\_\_\_\_ During IRB approval process: \_\_\_\_ During enrollment period: \_\_\_\_\_ During follow-up and data cut-off periods:\_\_\_\_\_ Other: \_\_\_\_\_ |
|  57 | Are there any pre-planned data requests, cohort review, interim data lock or data reviews? | Yes No Describe if applicable:  |
|   |
| **REGULATORY REVIEW** |
| 58 | Will a central IRB complete the initial review & approval of this trial? If so, what is its name? | Name: E-mail: Phone:  |
| 59 | What is the contact information for the individual responsible for reviewing the initial & revised ICF prior to submission to the IRB? | Name: E-mail: Phone:  |
| 60 | Will sponsor provide a consent template? If not, who will create this? | Yes No Staff Position:  |
| 61 | Will the site be reimbursed for preparation of all protocol amendments and progress reports?  | Yes No  |
| 62 | What documents will the sponsor require to be updated and within what time frame? |   |
| 63 | Which research staff will be required to be listed on the FDA Form 1572? |   |
|   |  |   |  |  |  |  |  |  |
| **RESEARCH TRAINING** |
| 64 | How much time will be required for training of the staff? | # hours: \_\_\_\_\_ # days: \_\_\_\_\_ |
| 65 | Is there a required Investigator's meeting? | Yes No If yes, where & when? |
| 66 | Which staff is required to show evidence of research training? |   |
| 67 | Will sponsor accept the institution's research training CITI or will additional training be required?  | Accept Additional  |
| 67a |  If additional is required, what program and format (conference call, on-line, in-person, etc) is the training and in what time frame must it be completed?  | hours: \_\_\_\_\_ # days: \_\_\_\_\_ Online Conf/Live  |
| 68 | Does study team have access to Scientific Liaison or Study MD? (If yes, list contact information) | Yes No Name:Phone:Email:  |
|   |
|  | **CLINICAL MANAGEMENT** |
| 69 | Will the sponsor provide equipment and/or supplies needed to complete study procedures? | Yes No If yes, what? |
| 70 | Are frequent and severe AEs expected? *If yes, comment on clinical implications and note resource effects here.* | Yes No |
| 71 | Are EKGs submitted in real time?  | Yes No NA |
| 72 | Will the subjects be required to complete study questionnaires? If so, in what format? | Yes No NA |
| 73 | Who will order all tests and procedures? | Staff Position: |
| 74 | Are specialized equipment, imaging, laboratory services or supplies required? *If yes, comment on availability (e.g., obtain from other departments or sponsor, or must be purchased, etc.).* | Yes No  |
| 75 | Is this study being conducted in patient care areas? Will in-patient care be required?  | Clinical Care: Yes No In-Patient: Yes No  |
| 76 | Will this study utilize the TRI Clinical Research Team (CRT)? If yes, specify. Complete UCore Request for Services: https//core.uams.edu | Yes No □ Nursing □ Coordinator □ Regulatory □ Laboratory □ Data Management □ Other |
| 77 | Are other personnel required to conduct special procedures or efficacy measures? (*If yes, identify sub-specialist physicians, technicians, physical therapists, respiratory therapist, etc.).* | Yes No  |
| 78 | Are there specific facility requirements?  | Yes No  |
|  |   |   |   |   |   |   |   |   |
| **BIOLOGICAL SAMPLES & PROCESSING**  |
| 79 | Are biopsies required as part of the trial? (If yes, provide specific CPT codes for each type)  | Yes No NA If yes, CPT Codes: |
| 80 | Will the protocol require the subjects' pathology slides to be sent for central review? | Yes No NA If yes, how many and what stain application? |
| 81 | Does the time commitment for the collection of biologic samples match with the staff effort reimbursed by the sponsor? | Yes No NA  |
| 82 | Will a central laboratory be used to analyze lab samples? | Yes No NA If yes, who? |
| 83 | Will Sponsor reimburse if local lab is used for laboratory tests? | Yes No NA If yes, who? |
| 84 | What is the turnaround time for the reporting of laboratory results by the central laboratory? | # days: \_\_\_\_\_ |
| 85 | Will the sponsor provide study supplies to collect, process, or store samples? | Yes No NA |
| 86 | If samples are to be stored at the site in a freezer &/or refrigerator, what temperature and monitoring requirements required? | Temperature: \_\_\_\_\_ Monitoring Requirement:  |
| 87 | Will a refrigerated centrifuge be required to process samples? | Yes No NA |
| 88 | Are logs to record samples required to be completed by the site? | Yes No NA |
| 89 | Are there timed samples required? | Yes No NA |
| 90 | Will after hours processing or shipping of samples be required? (if yes, enumerate # per patient and frequency) | Yes No NA # per pt \_\_\_\_ freq? \_\_\_\_ times per \_\_\_\_\_  |
|   |   |   |   |   |   |   |   |   |
| **PHARMACY** |
| 91 | Will study drug be provided? (if yes, submit request to pharmacy for review) | Yes No NA |
| 92 | Will supportive therapy be provided at no cost by the sponsor? | Yes No NA |
| 93 | Is the pharmacy manual or investigator brochure available for review? | Yes No NA |
|   |   |   |   |   |   |   |   |   |
| **RADIOLOGY REVIEW** |
| 94 | Does the study involve the use of imaging? (If yes, specify.) Any pre-review requirements for radiology other than Radiological safety committee? | Yes No □ MR □ CT □ PET □ PET/CT |
| 95 | Will the site be required to submit copies of imaging studies for a central review? | Yes No NA If yes, who is the Central Reviewer and method of transfer preferred? |
| 96 | Is a radiology manual available for review? | Yes No NA |
| 97 | Does the sponsor require equipment and site qualification? | Yes No NA |
|  98 | Does the sponsor require phantom study for central reading lab? | Yes No NA |
|   |   |   |   |   |   |   |   |   |
| **MONITORING VISITS**  |
| 99 | How many days after the first subject is enrolled will the first monitoring visit be performed? | # days: \_\_\_\_\_ |
| 100 | What is the frequency of monitoring visits? | Every # weeks: \_\_\_\_\_ |
| 101 | Who will be performing the monitoring visits? |   |
| 102 | How many monitors will be visiting the site to complete monitoring visits? |   |
| 103 | Will sponsor require conference calls during trial conduct? | Yes No If yes, who all is expected to participate? |
| 104 | Will there be QA audits completed by the sponsor at any time during the trial? | Yes No NA |
| 105 | What is the time expectation for the site to resolve queries? | # hours: \_\_\_\_\_ # days: \_\_\_\_\_  |
|   |   |   |   |   |   |   |   |   |
| **LONG TERM STORAGE & DISPOSITION OF RESEARCH RECORDS, SAMPLES, & RESEARCH SUPPLIES** |
| 106 | How long will research data be required to be retained by the institution? | # years: \_\_\_\_\_ |
| 107 | How should the institution handle unused samples, CRFs, & study supplies? |   |
| 108 | Are there anticipated requirements for long-term storage of samples? (If yes, how long and where stored?) | Yes No NA# years: \_\_\_\_\_ |

**PRINCIPAL INVESTIGATOR'S SIGNATURE:**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**