MAGI WE CAN AGREE TO SAVE LIVES

Site Selection Questions

Site

1. Site and department name
2. Type of practice or institution: University Hospital, Community Hospital, Group Practice, Private Practice, Stand-alone Research Center, Other: _____
3. How many active patients does your [site/department] have (visits within past 12 months)?
4. How many physicians at your site treat patients with the willies?
5. How many clinical research studies are currently active at your [site/department]?
6. How many physicians at your [site/department] are currently principal investigators on clinical research studies?

Investigator

7. Investigator name
8. Credentials (MD, PhD, CPI, FACC, etc.)
9. Contact information: Address, phone (back line), fax, email, website
10. Do you have the time and resources to conduct this study?
11. Do you want to conduct this study?
    1. Why?
12. What are your primary areas of practice with %s? Area A __, Area B __, Area C __, Other: _____
13. What % of your work time do you devote to clinical research?
14. What human subjects protection (HSP) and good clinical practice (GCP) training and certifications do you have?
15. Are you affiliated with a site network or SMO?
    1. Name?
16. How many clinical research studies have you conducted in the past three years?
17. What % of these studies has been industry-sponsored?
18. In what % of these studies have you been the principal investigator at your site?
19. How many clinical research studies are you currently conducting?
20. How many clinical research studies have you conducted in the past three years on the willies?
21. How many clinical research studies have you conducted in the past three years on related conditions?
    1. Describe

Subject Enrollment

22. How many subjects did the investigator enroll in any study in the past 12 months?
23. How many subjects did the investigator enroll in studies of the willies in the past 3 years?

24. How many studies at your [site/department] will be enrolling subjects with the willies during [time period]?
25. How many active patients does the investigator have (visits in past 12 months)?
26. Of these, how many [had or have/are newly diagnosed with] the willies? (Specify eligible ICD-9 codes in the study summary.)
27. Of these, how many meet the eligibility criteria provided in the study summary?
28. Based on the study summary, how many subjects do you expect to enroll from the investigator's practice in [time period]?
29. How many additional subjects do you expect to enroll from elsewhere in your site?
30. How many additional subjects do you expect to enroll from outside your site?
31. How many patients to you expect to screen for each enrollment?
32. Will this study appeal to your patients?
    1. Why?
33. Does your site use electronic medical records (EMR)?
    1. How many active patients does it contain with the willies?
    2. How will the site monitor access EMR records?
34. Do you have a different database you can use to identify potential subjects for this study?
    1. Describe
    2. How many active patients does it contain with the willies?
35. How will you find subjects from outside your site? Advertising __%, referrals __%, other methods (with %s):
36. What is your process for contacting potential subjects and bringing them into your site?
37. Will you need the informed consent form in a language other than English?
    1. What language(s)?

Study Coordinator(s)

38. How many actively enrolling studies do your CRCs typically manage?
39. How many study nurses/coordinators (CRCs) will participate in this study?
40. Who will the primary study coordinator be?
41. How many years & months has he/she been a CRC at your site?
42. How many years & months of clinical research experience does he/she have?
43. What credentials (CCRC, RN, PA, MD, etc.) does he/she have?
44. What human subjects protection (HSP) and good clinical practice (GCP) training and certifications does he/she have?
45. What % of work time does he/she spend on clinical research?
46. How many studies has he/she managed of the willies?
47. Does the CRC have time for this study?
48. Does the CRC want to manage this study?
49. Contact information: Phone, fax, email

Capabilities & Resources

50. Does the [investigator/team member] have adequate experience with [assessment/procedure/assessment/test]?
51. Who will perform [assessment/procedure/assessment/test]?

52. Do you have access to [equipment, pharmacy, lab, dry ice, secure storage, etc.] with adequate capacity (during the required hours)?
53. Do you actively use clinical research standard operating procedures (SOPs)?
    1. Describe
54. How many subinvestigators will enroll subjects?
    1. Describe

Site Initiation

55. How long does it typically take your site to start a study of this type (from receipt of final protocol to site initiation visit)?
56. Does your site pursue IRB/IEC approval at the same time as contract & budget completion?
57. Will you use [the study's IRB/IEC] for this study?
58. If not, what is the name of the IRB/IEC you will use?
    1. How often does it meet?
    2. How long does it typically take from submission to receipt of approval letter?
59. Are there additional approvals or review committees?
    1. Names & approval times?

Other

60. Has your [site/investigator] been inspected by the FDA or similar regulatory agency in the past five years?
    1. What was the outcome?
    2. Provide copy of 483 or equivalent document.
61. What challenges and risks, if any, do you see for this study? If so, how will you address them? How can we, the sponsor, address them?
    1. Study design
    2. Subject recruiting, screening & enrollment
    3. Subject adherence & retention
    4. IRB and other approvals
    5. Contract & budget
62. Additional comments or questions
63. Which, if any, of the answers above are uncertain?
64. Who completed this questionnaire?
65. Role and contact information (if not above)

Alternate and Additional Questions

Site

[none]

Investigator

66. Do you consider yourself a key opinion leader? Explain
67. How many years of clinical research experience do you have?
68. On average, how many (industry-sponsored) clinical studies do you conduct per year?
69. What % of your studies are investigator-initiated?

70. When was your last study of the willies?
71. List 5 previous trials of the willies, with details: class of compound, indication, phase, # of subjects enrolled, year.
72. Do you have experience with this type of study? (e.g., gene therapy)
73. Are you board-certified? Board-eligible?
74. Do you have a DEA license?
75. Have you conducted a study with a Schedule 1 study drug?

Subject Enrollment

76. What is the estimated monthly/annual/current number of [potential/eligible] subjects available for this study?
77. What % of patients with the willies are likely to be interested in participating in a clinical trial?
78. Does this study offer your patients an acceptable risk/benefit ratio?
79. What types of patients would you enroll or not enroll in this study?
80. What % of patients with the willies participate in clinical trials?
81. How will you identify potential subjects for this study?
82. How do you typically recruit subjects for studies of the willies?
83. How will you recruit subjects for this study?
84. If your initial subject recruiting plan is inadequate, what is your contingency plan?
85. If your initial subject recruiting plan is inadequate, what is your back-up plan?
86. Are you willing to submit a blinded list of at least nn potential subjects (who have expressed interest in the study)?
87. Would you be willing to work with a centralized subject recruiting program?
88. Do you have access to potential subjects in a hospital/living facility? If so, is traveling to the facility a problem?
89. From what [departments/units/labs/clinics] at your site will you recruit subjects?
90. Can you enroll/screen potential subjects 24/7?
91. What geographical area do you serve and what is its population?
92. What is the [disease/severity/comorbidity/age/gender/race/geography] of potential subjects?
93. What % of new patients previously received [therapy]?
94. What is your standard of care for the willies?
95. What % of patients with the willies normally receive [therapy]?
96. Are you willing and able to use [study therapy]?
97. Do you currently use [therapy] to treat the willies?
98. Are you willing and able to conduct a placebo-controlled study of the willies?

Study Coordinator(s)

99. He/she has experience with EDC in how many studies?
100. Does he/she have a computer with high-speed Internet access for EDC?
101. Does he/she have experience with electronic subject diaries? Describe
102. Who would the other key members of the study team be, and their roles?

Capabilities & Resources

103. Can you use a central laboratory?
104. Do you have a local laboratory? What is its name?
105. What is your site's access to public transportation?
106. Is parking readily available? At what price?
107. What waiting areas are available for family members and during long visits?
108. What food and beverage services are available? During what hours?
109. Do you have a pharmacist to prepare study drug?
110. Do you have a subinvestigator who can do blinded assessments?
111. What is the brand and model of the equipment?
112. Can you administer study drug during [required hours]?
113. Do you have a dedicated, analog, direct-dial fax line?
114. Do you provide Internet access to site monitors with laptops, without special login or configuration requirements?
115. How many satellite sites will participate? Describe

Site Initiation

116. Can you use our standard clinical trial agreement template (with negotiated modifications, if any)?
117. What contracts are needed other than a clinical trial agreement with both the site and investigator?
118. Can you attend a site qualification visit in [period of time]?
119. Can the investigator and CRC attend the investigator meeting on [dates]?

Other

120. Has your [site/investigator] been audited by sponsors in the past five years? When and what was the result?
121. Do you want to participate in the PK sampling part of this study?
122. Do you have experience with PK sampling?
123. What is the primary language at your site?
124. Do the investigator and CRC speak English?
125. Do you have a 24/7 contact available for subjects?