Guide to the Submission of an Initial Application

1. Login to iRIS.
2. Click "**Create a New Study**" under "Featured Study Operations."
3. Select "**Study Application**". Click "**Start selected Application**."
4. Enter the title of your study. Please do not use all caps. This will be the official title in all documents. All associated documents must include this title.
5. Enter a study number or alias and whether you will be using subject management in the appropriate fields. For studies that involve a contract, please select "**Yes**" for subject management.
6. Click "**Save and Continue to the Next Section**."
7. The department of the person filling out the application will be automatically displayed.
8. To add an additional department, click "**Add Department**" on the right; otherwise, skip to 11.
9. Enter the department name in the box and click "**Search**."
10. Select the check mark box next to the department you wish to select and click "**Save**" at the bottom.
11. Click "**Save and Continue to the Next Section**."
12. Click "**Setup Study Personnel**."
13. Input the search criteria and click "**Find User/Search Directory.**"
14. Once the correct person's name comes up, click the envelope icon under "**Select.**" Designate the role (note PIs must meet the requirements of HSCEP OP 73.08).
15. Select if you'd like this person to also be include as a Study Contact and then click "**Save**."
16. Please verify completion of educational requirements for each person selected by clicking on the graduate icon located to the left of the person's name. All of the required training must be listed and current.
17. If you are unable to locate the person, they do not have an account and they must request one. They cannot be added to a study until they set up an account.
18. Repeat steps 13 through 16 until all study personnel have been listed.
19. Department approver is required (i.e. signatory authority/department chair/dean) and cannot be the same as the Principal Investigator. If the PI is the department chair, the alternate will need to be designated as the department approver.
20. Once you are done selecting personnel, click "**Close Setup of Study Personnel**."
21. Click "**Save and Continue to the Next Section**."
22. Select "IRB" for the Study Type. Click "**Save and Continue to the Next Section**."
23. Respond to the questions in the "Direction" section, as appropriate. For studies that require additional committee approval, please upload the approval documents under "Other Study Documents" and attach them to the Initial Review Form.
24. Click "**Save and Continue to the Next Section**."
25. For the scientific abstract, please do not copy and paste the entire protocol or research procedures in this section.
26. Click "**Save and Continue to the Next Section**."
27. For the research procedures, please only include the procedures. Please make sure to clarify those that are standard of care versus those that are for research purposes only. These should match the consent form as well.
28. If surveys are being used, please upload the documents under "Other Study Documents" and attach them to the Initial Review Form. Click "**Save and Continue to the Next Section**."
29. If there is no sponsor, please select "Internal" and list the department of the PI. Check off "funding" and indicate "no funds" in the next question.
30. For all TTUHSC El Paso personnel, always check off "TTUHSC El Paso" as the location where the research will take place. If there are additional sites, select those as well. If other, upload supporting documentation under "Other Study Documents" and attach them to the Initial Review Form. Click "**Save and Continue to the Next Section**."
31. For Study Materials, complete the fields and click "**Save and Continue to the Next Section**."
32. For Subject Population, complete the fields. When enrolling from the special populations, please include justification and precautions. Click "**Save and Continue to the Next Section**."

33. For Subject Characteristics, complete the fields and click "**Save and Continue to the Next Section**."
34. For Subject Recruitment, please clearly identify how subjects will be recruited using appropriate methods. Click "**Save and Continue to the Next Section**."
35. Inclusion/Exclusion criteria should match all other study documents. Please review for accuracy. Click "**Save and Continue to the Next Section**."
36. For Potential Risks and Benefits, complete the fields and click "**Save and Continue to the Next Section**."
37. For Data and Safety Monitoring, complete the fields and click "**Save and Continue to the Next Section**."
38. Clearly indicate whether there are any costs associated and if they are standard of care or research related. This should match in all documents. Click "**Save and Continue to the Next Section**."
39. If using TTUHSC El Paso funds, compensation must be in the form of Swift Cards (Visa gift cards). Amounts should match in all documents and should state whether they are prorated. Click "**Save and Continue to the Next Section**."
40. For Protection of Confidential Information, if PHI is being accessed but not collected, such as a chart review where the MRN is present in the data, please select "Yes." Complete the remaining fields and click "**Save and Continue to the Next Section**."
41. For Select Your Consent Process, if you did not skip the Exempt questions and made a selection as to what exempt category your study qualifies as, this section will not populate. If your study does involve consent, go back and select to skip the exempt questions. If you are not obtaining consent such as for a chart review, you can select "Waiver or alteration of consent process." If you are obtaining consent, such as verbal consent, but are not documenting it, you may select "Waiver of documentation of consent". Click "**Save and Continue to the Next Section**."
42. Depending on your selection, different sections will populate in order for you to justify and/or elaborate on your selection. Complete the fields and click "**Save and Continue to the Next Section**."
43. For the HIPAA section, please review the list of the 18 HIPAA identifiers which you can access by clicking the circled question mark at the right. Click "**Save and Continue to the Next Section**." Depending on your selection, additional questions may populate.
44. Proceed through the application and answer all questions, as applicable, by clicking "**Save and Continue to the Next Section**" until you get to the end of the application.
45. When you reach the end, click "**Save and Continue to Next Section**" to transfer to the Initial Review Submission Form.
46. Enter the lay summary into the text editor and click "**OK**" when finished.
47. Under "Comments" add any information that you think would be helpful for review, e.g., IBC application submitted and pending, etc.
48. The application will automatically be attached under "Application."
49. Click "**Save and Continue to Next Section**."
50. Under "Study Documents" click "**Add a New Document**" if you have not yet uploaded any documents. If documents have been uploaded under "Other Study Documents," skip to 57.
51. Click the outlined box to select your file or drag it into the box.
52. Enter "version 1" in the appropriate field.
53. Enter the version date in the appropriate field.
54. Select a category from the drop-down menu.
55. Click "**Save Document**."
56. Repeat steps 50 through 55 for any other additional documents that need uploading, e.g., protocol, data collection sheet, surveys/questionnaires, brochures/flyers, etc.
57. Click "**Select or Revise Existing**" to attach documents previously uploaded under "Other Study Documents." The available documents will be displayed with a green circle with a plus sign inside. Once attached, the document(s) will display under the "Study Documents" section of this form.
58. Click "**Save and Continue to Next Section**."
59. Under "Informed Consent," click "**Add a New Consent**" if you have not yet uploaded a consent form. If a consent has already been uploaded under the "Informed Consent" section, skip to 74.
60. Click "**Add an Informed Consent from the List of Informed Consent Template Documents**." Click "**Next Screen**."
61. Select the appropriate template from the drop-down list and click "**Download Template**."

62. A box will pop open that indicates “Open, Save, Cancel.”
63. Click “**Open**” and the document will open up for editing in Word.
64. Click “**Enable Editing**.”
65. Change the version date in the footer of the consent form to the date you revised the document or the current date.
66. When editing is complete, save the document to your desktop and close it.
67. In the iRIS window, enter the title of the consent.
68. Click the outlined box to select your file or drag it into the box.
69. Enter version 1.
70. Enter a version date that corresponds with the consent form footer.
71. Enter a category.
72. Select the language.
73. Click “**Save Consent**” and the form will be attached to the initial review submission form.
74. For previously uploaded consent forms, click “**Select or Revise Existing**” to attach. The available documents will be displayed with a green circle with a plus sign inside. Once attached, the document(s) will display under the “Informed Consent” section of this form.
75. Click “**Save and Continue to Next Section**.”
76. Exit form.
77. Review the initial review submission form and make sure that all documents needed are attached. If they are not attached, please review the steps indicated above.
78. At this point you can exit the form and return at a later time, notify the PI to sign off if you are not the PI, or sign off and submit if you are the PI.
79. Click to “**Notify PI to Sign Off**” or “**Sign Off and Submit**.”
80. Only the PI and signatory authority/chair/dean are required to sign off. Everyone listed on the study is selected by default so you will need to uncheck all of the other names before continuing.
81. Click “**Save – Signoff Routing List**.” Verify the list represents the finalized personnel for review and signoff. Select “Yes.” Click “**Save – Start Signoff Routing**.”
82. The entire submission, including all attached documents, should be displayed above the approval section. This includes the initial review form, application, protocol, consent form, etc. Please make sure that all required documents are attached before signing off. If any documents are missing, please do not sign off. If you do not see the documents needed for review listed here, please go back to attach.
83. Read the investigator agreement and click on “**Approve**.”
84. Enter your iRIS credentials.
85. Click “**Save Sign Off**.”
86. The submission will then be routed to the signatory authority/chair/dean for approval.
87. Once the chair/dean approves, it will be routed to the IRB office.
88. On the main study page, under “Studies Submission Status,” you are able to track the submission by clicking to expand the + under “Task Status” for details on the submission history and to track its location/status.
89. Please allow enough time for this approval process and to meet IRB submission deadlines.
90. IRB administrative staff will prescreen all IRB submissions. If the submission is incomplete or otherwise not fully prepared for review, it will be retracted so that the items can be addressed. At this time, all edits should occur to the original documents. Revisions should not be made. When the submission is received by the IRB it should be the first version of all documents.
91. When the item has been placed on an agenda for review, an iRIS notice is sent to the PI and study contact. If a notice is not received, please log into iRIS to check on the status of the submission by clicking on tracking or contact the IRB directly.