Thank you for contacting the Recruitment Innovation Center to assist with your SIP content. Before adding your content below, please ensure that you have completed the 15 minute SIP Training Module (00129901) in the Duke Learning Management System (LMS).

In addition to providing the content below, we also ask that you have an appropriate “short title” so visitors to the Clinical Trials Directory know whether the study may be relevant to them.

Add 2-5 lay-friendly and easy to understand words to describe your study. For example, if your study is called “STAR Xm29” add in the condition being studied so it reads “STAR Xm29 (Breast Cancer).” Follow the [Short Title Guidelines i](https://duke.app.box.com/s/859xdu899ptaaqz9cj06j1y35nlorqw4)f necessary. You do not need to submit an amendment in iRIS to make this change; however, we strongly recommend doing so for efficiency.

You may now include the URL for an IRB-approved website, e-consent or other location in the treatment section.

Finally, make sure there is a “Study site contact” listed under in OnCore. The person assigned to this will have their name, email, and/or telephone number listed as the contact person for that study so the public knows whom to contact for more information or to sign-up.

Example of the SIP Console:

|  |  |
| --- | --- |
| **Protocol Number**  | Pro0012345 |
| **Short Title** |  |
| **Objective** *What is the condition being studied?*  | People at risk for developing Alzheimer's disease (people with the APOE4 gene)  |
| **Treatment** *What is involved?*  | The study is divided into two periods, a Screening Period and a Study Dosing Period. If you choose to join the study, you will:- Go through a Screening Period which lasts about 12 weeks and includes 5-7 visits for:-- Genetic testing for the APOE genotype -- Interviews with a study doctor for memory testing -- A brain MRI and PET scan, -- A lumbar puncture (spinal tap) -- Blood and urine tests, EKG, neurological and physical exams, and skin exams Study Dosing Period: During this period of the study, you will:- Be randomized (like flipping a coin) to get: -- A study drug (CNP520) by mouth once a day for 5-8 years -- A placebo (sugar pill) by mouth once a day for 5-8 years - Have visits every 3 months for the first year, then every 6 months until the end of the study -- At various visits you will complete questionnaires, have skin checks, EKGs, physical exams, an MRI and/or a PET scan, and lab***If you would like to include a link to an IRB-approved website or pre-screening survey, please add the URL to this box.***  |
| **Description** *What is the purpose of the study?*  | We are doing this study to learn more about the effects of exercise and medication on symptoms of worry and stress in adults with heart disease.  This study is important because symptoms of worry and stress are risk factors for worsening heart health.  |
| **Key** **Eligibility** *Who can participate in the study?*  | Adults age 40 and older who:- Have a history of heart disease (e.g., stent, heart attack, bypass graft, or angina). - Have feelings of worry, stress, tension, nervousness, panic, or anxiety. - Are not currently taking medicine to enhance mood. - Are not currently in a formal exercise program.  For more information about who can be in this study, please contact the study team.  |

# **SIP Content Worksheet**

Please provide your study information below. If you have any questions please contact the RIC at studyrecruitment@dm.duke.edu

**Study Demographics**

|  |  |
| --- | --- |
| **PI** |  |
| **Regulatory CRC** |  |
| **Primary CRC** |  |
| **Current OnCore Protocol Status:** | [ ] Abandoned\* | [ ] On Hold | [ ] Suspended | [ ] Institutional Approval Sign-Off | [ ] Open to Accrual | [ ] Any other status  |
| **Comments** | *If you want a study with any of the above OnCore statuses posted to the Directory, please delete this text and explain why. The RIC will consider these requests on a case-by-case basis.* |
| As part of Duke’s commitment increasing diversity and reducing disparities, we can now include Spanish language translations of SIP content on the Clinical Trials Directory. However, we ask that you try to identify someone to provide the translation whenever possible. If you are unable to identify someone who can translate your SIP content, please let us know. | **Do you wish to have a Spanish Translation included?**[ ]  [ ] Yes No |

**Coming in September 2020: \*For “Abandoned” Studies Only:**

|  |  |
| --- | --- |
| Because “Abandoned” studies are no longer required to update their OnCore entry, the RIC will need to know when to pull the study off the Clinical Trials Directory (e.g., the study has completed enrollment or is permanently closed).Please provide the estimated date you expect this to occur. We will follow-up with you at that time. | Anticipated date to remove the study from the Directory: |
| Click or tap to enter a date. |

**SIP Content**

|  |  |
| --- | --- |
| **Protocol Number** |  |
| **Short Title** |  |
| *What is the condition being studied?*  |   |
| *What is involved?*  | ***If you would like to include a link to an IRB-approved website or pre-screening survey, please add the URL to this box.*** |
| *What is the purpose of the study?*  |  |
| *Who can participate in the study?*  |  |

|  |  |
| --- | --- |
| **Version:** | **Spanish Translation** |
| **Short Title** | Title on the Directory will not be translated |
| *¿Cuál es la condición que se estudia?* |  |
| *¿Qué se pedirá hacer??* |  |
| *¿Cuál es el propósito del estudio?* |  |
| *¿Quién puede participar en el estudio?* |  |
| **Detalles del estudio de investigación** |
| **Título completo** |  Will pull full title from OnCore without a translation |
| **Investigador/Investigadora principal** | Pulls from OnCore but adds PI profile link/photo from different database |
| **Número de protocolo** | Pulls from OnCore |

Once you have entered your SIP Content, please save the file using the following naming convention:

**SIP\_PROxxxxxx\_date.docx** (where date is the date you completed the form and sent it to the RIC)

Send your file to studyrecruitment@Duke.edu with **SIP Content\_PROxxxxxx in the subject line**.

A member of the RIC will review your SIP content and return it to you with any edits in track changes. We will continue to negotiate edits with you until you are satisfied, then the RIC will take the necessary steps to put the content into the SIP Console for your study.