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| |  |  | | --- | --- | | **PSC PACE program:**  **P**rim**A**ry Sclerosing **C**holangitis **E**pidemiology Program |  | | |
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| Please answer all sections below and submit the completed form as a Word file to [PACE@gilead.com](mailto:PACE@gilead.com) with the email subject heading “**PSC PACE LOI – [Principal Investigator Name, Organization Name]**.” Submitted Letters of Intent (LOIs) will be reviewed on a rolling basis and either approved for full application submission or declined. Full applications will be reviewed similarly and projects will be accepted until program funds are exhausted. Note that program funds will not be allocated per month of the submission window. If you have any questions about the application form, please ask your local Gilead Medical Scientist or email [PACE@gilead.com](mailto:PACE@gilead.com). | |
| **Investigator/Sponsor Information** | |
| Principal Investigator |  |
| Telephone |  |
| Email address |  |
| Curriculum vitae attached | Yes No |
| Legal Sponsor / Primary Site |  |
| Address |  |
| City, State, Zip/Province, Postal code |  |
| Country |  |
| Description of Organization/Institution | Hospital  Academic Research  Government Entity  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Name of Subsite (if applicable) |  |
| Address |  |
| City, State, Zip/Province, Postal code |  |
| Country |  |
| Sponsor IRB/REB (check one) | Local IRB/REB Central IRB/REB |
| Name of ethics committee |  |
| Does IRB/REB require a fully executed   contract prior to review? | Yes No |
| Average time from submission to   approval | \_\_\_\_\_ weeks |
| Sponsor Contact for Submission and Negotiation of Investigator-Sponsored Research Contract |  |
| Telephone |  |
| Email Address |  |
| Has your institution applied for or received funding from Gilead in the past? | Yes No |
| Gilead Contact (if applicable) |  |
| How did you hear about STAT? (check  all that apply) | Colleague  Gilead Contact (e.g. Medical Scientist, Medical Manager)  Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  World Hepatitis Alliance  NOhep  NATAP  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Proposal** | |
| Study Title |  |
| Estimated Budget Requested from Gilead  *Any proposal greater than* ***$150,000*** *should be*  *discussed with your Gilead Medical Scientist*  *prior to submission.. Must include overhead*  *costs and all taxes if applicable. Overhead in*  *excess of 30% will* ***not*** *be approved.* |  |
| Budget Considerations (check  all that apply) |  |
| Subject-related costs | Yes No |
| Study-related personnel | Yes No |
| Diagnostic fees and services | Yes No |
| Data management expenses | Yes No |
| Publication costs (e.g., preparation of  manuscript, travel, etc.) | Yes No |
| IRB/REB review fees | Yes No |
| Overhead | Yes No |
| Overhead Cap Letter Signed and Attached  *Must be signed by Sponsor institution’s budget   officer or other designee. Signed letter must be   attached before LOI is reviewed.* | Yes No |
| Funding Requested From Other Sources?  *If yes, include name of source and amount in   USD.* | Yes: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  No |
| Study Design (check all that apply) | Prospective  Retrospective  Observational  Interventional  Modelling |
| Plan to Collect Protected Health Information | Yes No |
| Publication Plan (check all that   apply) | Conference  Manuscript |
| Do you plan to present findings to  policymakers (local, regional, national)? | Yes No |
| **Research Plan** | |
| Type your responses to Questions 1 through 5 in this document. Please limit your response in this entire  section to 1,000 words.   1. Scientific rationale 2. Primary objective 3. Research methods 4. Describe which, if any, policymakers you to plan to engage and how. 5. Study Duration (in months) | |
| **By entering my name below, I hereby certify that the above statements are true and correct to the best of my knowledge.** | |  |
| Name & Title Date | |  |