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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 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.  |
| **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? (checkall 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)
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| **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 |  |