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| NASH Models of Care Program – Letter of Intent |
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| Please answer all sections below and submit the completed form as a Word file to NASHModelsofCare@gilead.comwith the email subject heading, “**NASH Models of Care LOI- [Principal Investigator Name, Organization Name]**.” The completed letter of Letter of Intent must be received by Gilead by **July 15, 2019**. Letters received after this date will not be accepted for consideration. If you have any questions about the application form, please ask your local Gilead Medical Scientist or email NASHModelsofCare@gilead.com. |
| **Investigator/Sponsor Information** |
| Organization/Institution Name |  |
| Principal Investigator |  |
|  Degree/Title |  |
|  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)*No more than 1 subsite permitted.* |  |
|  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 the NASH Models of Care program? (check all that apply) |  [ ]  Colleague [ ]  Gilead Contact (e.g. Medical Scientist, Medical Manager) Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [ ]  NATAP [ ]  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Proposal** |
| Study Title |  |
|  Estimated Budget Requested from Gilead *Must not exceed $500,000 USD. Must include  overhead costs and all applicable 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 |
| **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 how you see this research impacting local or broader systems in NASH care?
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 |  |