|  |  |  |
| --- | --- | --- |
|  | | |
| NASH Models of Care Program – Letter of Intent | | |
|  | | |
| Please answer all sections below and submit the completed form as a Word file to [NASHModelsofCare@gilead.com](mailto:NASHModelsofCare@gilead.com)  with 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](mailto: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) | | |
| **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 | | |  |