**Proposal for Post-Study Research on Stored Biosamples and data out of APPROACH study**

**1. Research Proposal** *(to be completed by Research Proponent)*

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| **Research title:** |
| **The party proposing research (Research Proponent):**[**Instructions:** provide function, name, title, phone] |
| **The party involved in research (APPROACH member, if applicable):**[**Instructions:** provide function, name, title, phone] |
| **Research laboratory:** [**Instructions:** laboratory where the research shall be performed] |
| **Abstract of research:**[**Instructions:** research framework, detailed objectives of the research, type of biomarkers to be tested, assay status, testing lab qualification, purpose or use of generated data] |
| **Biosample and data requirements:**[**Instructions:** specify which biosamples will be used (e.g. sample types, clinical study ID, time points) and which information and other data are required for research] |
| **Proposed research is covered in the protocol and informed consent form (ICF) (including country/site-level ICF)?**[**Instructions:** Study specific Master ICF to be consulted by Request Recipient. As there can be differences in local requirements & practices that impact use of biosamples, the country or site level ICF must be checked as well. Decision on which country or site level ICFs should be checked will depend on the footprint of the biosamples to be used.  | **Master ICF(s) covers proposed research:**[ ]  **Yes** [ ]  **No** [ ]  **Not checked yet**Please attach a copy to this proposal.**Country/Site ICF(s) covers proposed research:**[ ]  **Yes** [ ]  **No** [ ]  **Not checked yet**Please attach a list of documents that have been checked.If proposed research is not covered by ICF or other applicable legal basis for biosample use, please attach the EC/IRB approval for the proposed research or commitment to provide proof of approval. |
| **Background and significance of the selected biomarker/analyte/data analysis:**[**Instructions:** provide overview of suggested biomarkers/analytes/data analysis and describe their relevance, cite references of relevance] |
| **Methods:**[**Instructions:** describe technical performance and characteristics of proposed methods (e.g. assay format/type, specificity, quantification range, intra and inter assay CV%, volume requirements, specify biosample type to be used and provide justification for selecting the method; describe programs/software to be used] |
| **Data analysis:**[**Instructions:** describe statistical design, analysis and power calculation, specify who will perform data analysis and for which purpose the results will be used] |
| **Funding:**[**Instructions:** describe how the research will be funded. **Please note that data retrieval, sample retrieval and shipment costs need to be covered by Research proponent**] |
| **Participating Researchers:**[**Instructions:** list all researchers that will participate in the research including their role in proposed research (with clear designation of the lead researcher), affiliation, research focus area, short CV and key publications. Before receiving any personal data, make sure that each researcher was informed about use of his/her personal data for the purpose of research proposal review and approval process]☐ I confirm, that all participating researchers were informed in text form (e.g. email) in advance that the personal data they provide for purposes of this proposed research will only be processed for the purpose of research review and approval. |
| **Results sharing plan:** [**Instructions:** describe with whom the results will be shared, under which circumstances and where will the results be stored; a publication and posting plan and potential use for patent or other applications] |
| **Biosamples and data/results protection:****[Instructions:** describe how biosamples and data/results will be protected from unauthorized use and access. State whether the sample remnants will be returned to the biorepository after analysis and who will cover the associated costs, will the samples be used to exhaustion, will the samples need to be aliquoted and one or more child samples returned] |
| **Projected timelines:**[**Instructions:** describe projected timelines for research] |
| **Conflict of interest statement:**[**Instructions:** describe any potential conflicts of interest if applicable, i.e., any relationships that participating researchers believe could be interpreted as resulting in an actual, potential, or perceived conflict of interest in regard to the proposed research. The relationship in scope here may involve the same or similar subject matter; the same, similar or competing drug or device, product or service, intellectual property or asset; or has the potential to result in financial, professional or other personal gain or loss for the participating researcher] |

**2. Research Proposal Evaluation** *(to be completed by Research Proponent)*

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| 1. **Scientific criteria**
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| **Significance:** [**Instructions:** Explain how this study address an important problem and will advance scientific knowledge or clinical practice.] |
| **Approach:** [**Instructions:** Explain how the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well-reasoned, and appropriate to the aims of the project. Explain how Does the applicant acknowledge potential problem areas and consider alternative tactics?] |
| **Innovation:** [**Instructions:** Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?] |
| **Researchers:** [**Instructions:** Are the researchers appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the lead researcher and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)?] |
| **Environment:** (applicable for external research only)[**Instructions:** Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?] |
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| **Research Proponent’s signature & date:** |  |

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| 1. **Alignment with APPROACH strategy criteria** *(to be completed by Steering commitee)*
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| Potential for contributing to the advancement of the pre-clinical research | ☐ Yes☐ No |
| Potential for contributing to the advancement of the clinical program | ☐ Yes☐ No☐ N/A |
| Potential for contributing to the advancement of Click here to enter text. [**Instructions:** Use this line if you see potential for contributing to the advancement of other research type e.g. translational research, bedside-to-bench research] | ☐ Yes☐ No☐ N/A |
| Complements the current portfolio of analysis | ☐ Yes☐ No☐ N/A |
| 1. **Operational criteria** *(to be completed by Steering commitee)*
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| Is there an appropriate plan and timeline for submission/distribution/retention of research results (e.g., publication, use in marketing authorization application, etc.)? | ☐ Yes☐ No☐ N/A |
| Is notification of research results to any party required? If so, is there an appropriate notification plan? | ☐ Yes☐ No☐ N/A |
| Is there an appropriate plan for disposition of unused samples? | ☐ Yes☐ No☐ N/A |

**3. Research Proposal Review Outcome** *(to be completed by Biosample Owner)*

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| **Outcome of the research proposal review by steering commitee:** | ☐ Research proposal is approved☐ Research proposal is not approved |
| **If research proposal has been rejected, reason for rejection** | [ ]  Lack of scientific merit[ ]  Not aligned with therapeutic strategy [ ]  Lack of funding [ ]  IP concern [ ]  Other reason If other reason, please explain:Click here to enter text. |
| **Biosample Owner:**[**Instructions:** provide Biosample Owner name and role] |  |
| **Biosample Owner’s signature & date:** |  |