



ORIEN RESEARCH INTEREST GROUP PROPOSAL FOR USE OF EXISTING AVATAR DATA

Project ID

This project proposal does not require an executed Statement of Work and qualifies for a notice of opt-in for participation based on satisfying the following 3 criteria: 1) only existing, deidentified AVATAR data will be shared, 2) no prospective specimen or data collection is required, and 3) no monetary transfer or compensation to participating sites is required. A Member's notice of opt-in to participate via the ORIEN Intermember Project Dashboard will be confirmed by Aster Insights and all eligible AVATAR cases must be approved prior to transfer to the Lead Institution.

Project Title:

Lead Investigator(s): [First, Last, credentials]

Lead Institution:

Title:

Department:

Email Address:

Study Objective:

Background and Rationale (*include references*):

Hypothesis:

Specific Aims:

Criteria for Inclusion in Patient Cohort:

INSERT SPECIFIC INCLUSION CRITERIA; add as much detail as possible including ICD/histology codes if requesting anything more specific than an entire disease group

Exclusion Criteria:

Indicate if there is a minimal molecular data availability requirement

Examples: patients without germline WES available should be excluded from the dataset OR patients without gWES, tWES, and RNAseq available should be excluded from the dataset)

Molecular Data Requested: Check all that apply

☐ Germline WES ☐ Tumor WES ☐ Tumor RNA-seq ☐ Other (please thoroughly describe)

File types Requested: Check all that apply

☐ VCF ☐ CRAM

Research Plan/Study Design:

Data Analysis & Methods:

Study Timeline: Provide a timeline and/or expected duration of the study. Indicate if there are any associated deadlines.

Expected publications and/or grant submissions: Provide any guidance on publications and/or grant submissions expected to result from the Project.

References:

Compensation:

No compensation to participating sites is planned for this Project; however, the Lead Investigator acknowledges that Project data transfers to the Lead Institution for incremental participating ORIEN site data beyond three (3) transfers provided at no cost, should they be needed, will be invoiced to the Lead Investigator at \$1,380 each by Aster Insights.

Data Sharing Terms:

This project involves only existing, deidentified, coded AVATAR Data, does not require prospective specimen or data collection, and does not require monetary transfer or compensation to participating sites, thus the Tier 3 requirement for a fully-executed research agreement between the Disclosing Member and the applicable Receiving Member(s) is hereby waived and shall be expressly permitted by this Proposal ("Proposal") and notice of opt-in. Prior to sharing data with the Lead Investigator, Aster Insights will obtain written approval, via electronic mail or other means, confirming the ORIEN member's opt-in status, and the list of eligible patients to be included in the dataset from each applicable participating site.

Data Sharing and Authorship Acknowledgement by Lead Investigator:

☐ By checking this box, the Lead Investigator(s) acknowledges and Institution agrees, as follows: (i) the terms and conditions of the ORIEN Master Collaboration Agreement dated May 21, 2014, as amended, extended and/or joined (the "ORIEN Agreement") are incorporated herein by reference. Further the terms and conditions of the Addendum #1 to ORIEN Master Collaboration Agreement for ORIEN Avatar Participation between Aster Insights and the Lead Institution, as may be amended from time to time in writing by Aster Insights and the Lead Institution ("ORIEN Avatar Agreement") and the Data Sharing Addendum to ORIEN Master Collaboration Agreement between Aster Insights and the Lead Institution, as may be amended from time to time in writing, are each hereby incorporated herein by this reference; (ii) to use the Data solely in connection with the Project described within this Proposal and any substantive modifications to the research plan will require submission of a revised Proposal; (iii) to abide by the recommendations of the ORIEN Authorship and Acknowledgement Guidelines on Scholarly and Research Publications; (iv) to comply with all applicable laws, rules and regulations, and the requirements of all regulatory authorities with jurisdiction, in the performance of the Project; and (v) hereby expressly consents to the use of the Data accessed through Tiers 1 or 2, and as further described herein, in grant applications and/or publications.

The Lead Investigator shall provide all data and information generated under or related to the Project and all related research to the extent such data and information falls within the scope of the ORIEN Agreement and/or the ORIEN Avatar Agreement, to Aster Insights promptly and on a continuing basis



in compliance with the ORIEN Agreement and/or the ORIEN Avatar Agreement, and its amendments, as applicable.

NOTICE OF OPT IN AND APPROVAL OF ELIGIBLE CASES (for participating site use only)

Confirming “opt-in” status and co-investigators:

☐ Our institution has reviewed the ORIEN Project Proposal, agrees to participate, and grants Aster Insights permission to transfer existing de-identified AVATAR data for our approved list of eligible patients, on our behalf, and hereby expressly consents to the use of the Data accessed through Tiers 1 or 2, and as further described herein and in the Proposal, in grant applications and/or publications. We further acknowledge and agree that the terms and conditions of the ORIEN Master Collaboration Agreement dated May 21, 2014, as amended, extended and/or joined (the “ORIEN Agreement”) are incorporated herein by reference. Further the terms and conditions of the Addendum #1 to ORIEN Master Collaboration Agreement for ORIEN Avatar Participation between Aster Insights and our institution, as may be amended from time to time in writing by Aster Insights and our institution (“ORIEN Avatar Agreement”) and the Data Sharing Addendum to ORIEN Master Collaboration Agreement between Aster Insights and our institution, as may be amended from time to time in writing, are each hereby incorporated herein by this reference.

This project involves only existing, deidentified, coded AVATAR Data, does not require prospective specimen or data collection, and does not require monetary transfer or compensation to participating sites, thus the Tier 3 requirement for a fully-executed research agreement between the Disclosing Member and the applicable Receiving Member(s) is hereby waived and shall be expressly permitted by this Notice of Opt-in.

☐ Our institution does not wish to opt-in or has changed its determination for participation and will NOT be participating

The list of eligible patients provided by Aster Insights is:

- ☐ Approved, no amendments
- ☐ Approved as attached, with our amendments to the list

OPTIONAL SIGNATURES OF PARTICIPANTS BASED ON INSTITUTIONAL POLICY

Signed by: _____
Printed Name: _____
Institution: _____
Title: _____
Date: _____

Signed by: _____
Printed Name: _____
Title: _____
