

EXHIBIT A

Southcentral Foundation Research Terms & Conditions

Section 1. Purpose. These terms and conditions (“Terms & Conditions”) set forth the rights and obligations of Southcentral Foundation (“SCF”) and _____ (“Researcher”) (collectively referred to as the “Parties”) as they pertain to a research proposal entitled: _____ submitted to SCF by _____ and approved pursuant to the Southcentral Foundation Research Policy and Procedures (“SCF Policy” and “SCF Procedures”), which were provided to Researcher and are incorporated by this reference as if fully set forth herein. The approved research proposal shall be referred to as a “Research Project” or “Project”.

Section 2. Term. These Terms & Conditions shall become effective upon commencement of the Research Project or signing of the FDP Research Agreement, whichever is sooner, and will continue in effect until SCF issues its written approval of Researcher's final report and all SCF Property (as defined further herein) is returned to SCF, unless sooner terminated as provided herein.

Section 3. General Conditions. Researcher and SCF agree to the following:

3.1 Ethics and Code of Conduct. Researcher shall abide by the SCF Code of Conduct, which was provided to Researcher and is incorporated herein by reference.

3.2 Changes to Proposal. If Researcher makes any significant or material changes to the research proposal approved by SCF, Researcher shall advise SCF of those changes and obtain SCF’s prior written approval of such changes.

3.3 HIPAA. Researcher shall comply with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) standards for Privacy, Security and Breach Notification with regard to any protected health information (PHI), and the Privacy Act of 1974, to the extent applicable. De-identified information is not protected under HIPAA, so long as the de-identification meets HIPAA standards for same. Any information reviewed in preparation for research shall only be used as necessary to prepare, shall be necessary for research purposes, and shall not be removed from SCF’s possession until such time as the Research Project begins. The information shall at all times be protected in accordance with HIPAA Security standards and SCF policies and procedures regarding PHI, including but not limited to the use of an encrypted device. Upon request by SCF, Researcher agrees to complete a business associate agreement.

3.4 Confidentiality.

3.4.1 Researcher shall maintain confidentiality of data consistent with applicable federal law. Researcher shall comply with all applicable federal laws regarding the protection of personally identifiable information.

3.4.2 Researcher shall maintain confidentiality of data as appropriately applied to individuals and, where necessary, to families, communities, and SCF itself.

3.4.3 Researcher shall maintain confidentiality for the life of the Research Project, and after the Research Project, unless Researcher has disclosed circumstances in which confidentiality may be breached by legal or contractual obligations of the

Researcher, and confidentiality may be breached only in those specifically disclosed circumstances.

3.4.4 The Researcher will maintain confidential information, including business confidential information and information that, if released, would cause a unwarranted invasion of privacy, in accordance with applicable federal law for the life of the Research Project or until returned to SCF, whichever occurs last, unless otherwise agreed to by the parties in writing.

3.5 Reports, Presentations and Manuscripts.

3.5.1 Researcher shall present written findings to the participants and to SCF upon completion of the analyses. Researcher shall communicate findings to the study participants and to SCF in a manner mutually acceptable to SCF.

3.5.2 SCF shall review the report of research results and will confer with Researcher who will make such modifications as are suggested or required by SCF, before the report is finalized.

3.5.3 Researcher shall present and explain the final results of the Research Project to SCF within 60 days of completion of the Research Project.

3.5.4 Researcher shall submit a yearly written progress report if the duration of the project is for more than one (1) year.

3.5.5 Researcher shall submit any manuscript describing results of the Research Project to SCF for final approval before Researcher submits it for publication. SCF shall provide a timely review of this report and identify to the researcher any changes that are desired. SCF and the researcher shall work to make mutually satisfactory changes to this draft prior to issuance of a final report for SCF review and approval.

3.5.6 Researcher shall submit a copy of any final reports to SCF for its review and approval before they are finalized. Researcher shall work with SCF to make modifications requested or required by SCF.

3.6 Specimens.

3.6.1 All specimens collected from SCF patients during the research project shall be the property of SCF and shall be returned to SCF when the research is complete or the Research Project is otherwise terminated, unless otherwise agreed to in writing by the Parties. Specimens shall include any substances created by Researcher which contain/incorporate the specimens, as well as any substances that constitute an unmodified functional subunit or product of the specimens.

3.6.2 SCF shall retain ownership of the specimens of human biological material collected from SCF patients during the Research Project. SCF shall work with the Researcher to determine the disposition of the specimens when the research is completed, unless otherwise agreed to in writing by the Parties.

3.6.3 All specimens collected during the research project shall be handled as outlined

in the consent document and according to the policies of the Alaska Area Specimen Bank, as well as all applicable state and federal statutes and regulations.

3.6.4 Specimens shall be used only as described in the research proposal and the Scope of Work. No other analysis or use of the specimens is permitted without prior written approval of SCF.

3.6.5 No specimens can be shared with other investigators without the review and approval of SCF. Researcher agrees to complete any documentation or training reasonably required by SCF prior to sharing of specimens.

3.6.6 Specimens shall be used solely for the Research Project will only be used at SCF or at the Researcher's facility, under the direction of Researcher or others working under his/her direct supervision.

3.6.7 Any requests for the specimens from anyone other than those persons working under the Researcher's direct supervision shall be referred to SCF.

3.7 Intellectual Property.

3.7.1 All ownership of and financial benefit from anything resulting from the research including, but not limited to, any product, item, report, article, publication or anything else, whether in the nature of items in trade and commerce or personal or intellectual property, developed pursuant to the Research shall be held solely by SCF no matter when developed or by whom. These shall be the sole property of SCF provided that they are developed as a result of the research or utilizing the results of the research authorized hereunder.

3.7.2 Inventions and Discoveries. Researcher shall disclose to SCF any inventions or discoveries resulting from the Research Project as soon as possible after creation and reduction to practice. SCF shall notify Researcher in writing within thirty (30) days of receipt of disclosure whether:

1. SCF desires to file a patent application on any invention and/or discovery resulting from the Research Project; or
2. SCF does not desire that a patent application be filed in which case SCF's rights to such invention or discovery shall be forfeit with no further obligation to SCF.

3.7.3 Should SCF desire to file a patent application, SCF shall select and retain patent counsel. Researcher shall cooperate fully with SCF's patent counsel and provide any information, affidavits, or other documentation or testimony as may be required. Should SCF desire to file a patent application, all patent application filing costs, including those for patentability opinions, shall be borne by SCF. Should SCF desire not to file a patent application, Researcher may retain its own patent counsel and shall bear all patent filing costs.

3.7.4 Works by a Researcher that is a federal government employee are not copyrightable. Any inventions made by a federal government employee Researcher shall be owned pursuant to applicable federal law. Ownership of and title to all other data and research materials produced solely by one party's investigators shall be

owned by that party; other jointly-developed data and research materials will be jointly owned.

3.8 Co-Investigators. An SCF staff member may be a co-investigator in the Research Project, as determined by SCF. This staff person will be responsible, among other duties, for sending all reports and protocols through the appropriate SCF Vice President for approval; provided, however, that Researcher shall not be relieved from the obligation to obtain appropriate approvals if the SCF staff member fails to do so.

3.9 Native Hiring Preference. When possible, Alaska Natives shall receive hiring preference in all phases of the Research Project.

3.10 Compliance with SCF Policies and Procedures. To the extent consistent with applicable federal law, researcher and SCF shall adhere to SCF Research Policy and Procedures. For example, researcher shall obtain approval of the research protocol by the Alaska Area IRB, abide by the Federal Policy for the Protection of Human Subjects (45 CFR Part 46), and follow the process for obtaining approval from the SCF board outlined in the Procedures.

3.11 Federal Eligibility. Researcher shall not be debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from participation in any federal department or agency. Researcher represents and warrants that it is not presently indicted for or otherwise criminally or civilly charged by a government entity, and has not within three years preceding this Research Project: (1) been convicted of or had a civil judgment rendered against them for commission of fraud or criminal offense in connection with obtaining, attempting to obtain, or performing a public contract or subcontract, violation of Federal or State antitrust statutes relating to the submission of offers, or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements or receiving stolen property; or (2) had one or more contracts terminated for default by any federal agency.

3.12 Project Compliance. If the Project is subject to compliance requirements related to human subjects, vertebrate animals or human embryonic stem cells, the parties agree to comply with such requirements and Researcher shall document such compliance in accordance with the reasonable request of SCF.

3.13 Conflicts of Interest. Researcher agrees to report to SCF all conflicts or potential conflicts of interest within a timely manner, to enable SCF to address and report, if necessary.

3.14 Audit Status. Researcher represents and warrants that it receives an annual audit in accordance with Uniform Guidance Single Audit requirements and agrees to share the findings of such audit with SCF and cooperate with any additional monitoring necessary as a result of risks identified in the audit.

Section 4. Termination

4.1 Termination for Cause. In the event a party commits a material breach of any of its obligations under these Terms and Conditions, or any other obligations under the FDP Research Agreement and related documents, the other party may terminate the Research Agreement on written notice to the defaulting party unless the defaulting party cures the

breach within ten (10) days of receipt of written notice of the breach.

4.2 Termination without Cause. Either party may terminate the FDP Research Agreement on sixty (60) days prior written Notice to the non-terminating party prior to the expiration of the Agreement. The Parties shall agree to a resolution of all outstanding matters in the event of such termination, which shall include, but not be limited to, Researcher turning over all data and research materials to SCF and agreeing not to use any of the data or information obtained through the research in the future without the express written consent of SCF.

4.3 Remedies. This section is not intended to limit the remedies available at law or equity in the event of a material breach.

Section 5. Data Sharing & Ownership.

5.1 Data Ownership and Access. SCF shall retain sole ownership of any data collected, created, or obtained by SCF during the Project. Access to data that is de-identified pursuant to HIPAA standards (“De-identified Data”) shall be subject to the terms outlined in the FDP Research Agreement. SCF will share De-identified Data with Researcher for data analysis that is necessary to complete research aims and to co-develop and publish reports or other dissemination activities of the Project. SCF grants Researcher the option to maintain a copy of De-identified Data, which is subject to the same limitations placed by Alaska Area Institutional Review Board (AAIRB) approval on SCF.

5.2 Data Protection. De-identified Data shall be protected by Researcher in a manner applicable with federal, state, tribal, and local statutes and regulations. De-identified Data shall also be protected in accordance with applicable IRB approvals. Any De-identified Data that is found to be re-identifiable, whether or not it may then be deemed to be a “Limited Data Set”, protected health information (PHI), or contain personally identifiable information as these terms are used in HIPAA and associated regulations, shall be treated as confidential and shall be protected in accordance with HIPAA and other applicable federal and state requirements. Researcher recognizes and accepts responsibility to ensure appropriate investigator training and conduct in compliance with data protection.

5.3 Data Transfer and Storage. Researcher will transfer and store De-identified Data in a manner compliant with federal, state, tribal, and local statutes and regulations. Data transfer and storage will also be subject to the same limitations placed by AAIRB approval on SCF. At a minimum, De-identified Data will be stored in locked files, cabinets, and secure, password-protected databases on secure servers in locations with restricted access. Transfer of De-identified Data will be done in a manner that maintains any confidentiality restrictions which may be placed on data. Researcher will maintain and keep De-identified Data to the limited extent necessary to complete any study aims, reports, and dissemination activities authorized by Project parameters. De-identified Data shall only be kept for a period approved by the AAIRB.

5.4 Data Use. De-identified Data shall be used solely for the purpose of and only to the extent required to meet Researcher’s obligations to the Federal Government under its Prime Award. In connection with the Project, the parties agree to utilize established SCF oversight committees (e.g., Research Oversight Committee, Executive Committee, Board of Directors, Privacy Board, etc.) to review and approve data use requests. All data use requests involving data collected, created, or obtained by SCF must be approved by the

AAIRB in IRB applications; any new uses of De-identified Data not previously approved by the AAIRB, must be approved, with the consent of SCF, by the AAIRB in new applications.

5.5 Data Return and Destruction. At the end of the Project, or upon termination, De-identified Data shall only be kept to fulfill Project-related study aims, reports, and dissemination activities for up to three years after the end of the Project Period, and then must be destroyed. At that time, De-identified Data and any copies of De-identified Data retained by Researcher must be returned to SCF, or destroyed.

Section 6. General Provisions.

6.1. Confidentiality. Except as may be required by State or Federal law, Researcher and SCF shall not divulge, communicate, use to the detriment of the other party or for the benefit of themselves or of any other person or persons, or misuse in any way confidential information discovered or disclosed to each other as a result of the delivery, execution or performance of the Research Project.

6.2. Costs and Expenses. Except as expressly provided to the contrary, each party shall pay all of its own expenses incurred with respect to the negotiation, execution and delivery of the FDP Research Agreement and the exhibits hereto. Fees, costs and expenses for the Project, if any, shall be paid in accordance with the Scope of Work.

6.3. Severability. Researcher and SCF agree that should any provision in these Terms & Conditions be found unenforceable, invalid or unlawful as determined by a court of competent jurisdiction, such unenforceable provision shall in no way affect the enforceability, validity or lawfulness of the FDP Research Agreement or any other provisions thereof.

6.4 Attorney Fees. In any action or proceeding arising out of the FDP Research Agreement, the Prevailing Party in that action or proceeding shall be entitled to recover from the non-prevailing party all reasonable attorney fees and costs. "Prevailing Party" shall include without limitation a party who dismisses an action in exchange for sums allegedly due; the party who receives performance from the other party for an alleged breach of contract or a desired remedy where the performance is substantially equal to the relief sought in an action; or the party determined to be the prevailing party by a court of law.

6.5 Waiver. Waiver by one party of the performance of any covenant, term or condition within these Terms & Conditions shall not invalidate the FDP Research Agreement or these Terms & Conditions, nor shall it be considered waiver by such party of any other covenant, term or condition. Waiver by any or all parties of the time for performing any act shall not constitute waiver of the time for performing any other act or identical act required to be performed.

6.6 Amendment & Assignment. Neither party shall have the right to amend or assign the FDP Research Agreement without the written consent of the other party.

6.7 Inurement. These Terms & Conditions shall be binding upon and inure to the benefit of the successors in interest of the respective parties.

6.8 Interpretation. These Terms & Conditions shall be construed as a whole and in accordance with its fair meaning. Captions and subtitles are for convenience and shall not have any legal effect.

6.9 Notice. Any notice required or permitted to be given shall be written, and may be given by personal delivery or by registered or certified mail, first-class postage prepaid, return receipt requested. Notice shall be deemed given upon actual receipt in the case of personal delivery, or upon mailing. Mailed notices shall be addressed as follows, but each party may change address by written notice in accordance with this paragraph:

To Researcher:

Name

Address

City, State ZIP

Phone

Fax

To SCF:

April Kyle, M.B.A.
Southcentral Foundation
4501 Diplomacy Drive
Anchorage, AK 99508

Phone: (907) 729-4955

Fax: (907) 729-5000

6.10 Liability and Indemnification. Researcher agrees to indemnify and hold harmless SCF, its officers, agents and employees from any liability, loss or damage they may suffer as a result of claims, demands, costs or judgments against them arising out of the activities to be carried out pursuant to the obligations of the FDP Research Agreement, including but not limited to the use by Researcher of the results obtained from activities performed by SCF; provided however, that the following is excluded from Researcher's obligation to indemnify and hold harmless:

1. The negligent failure of SCF to substantially comply with any applicable government requirements; or
2. The negligence or willful malfeasance of any SCF officer, agent or employee involved in the Research Project.

6.11 Governing Law. The Research Project and the related FDP Research Agreement shall be governed by and construed in accordance with the laws of the United States and the State of Alaska (notwithstanding any choice of law principles), where applicable.