AlphaNet Canada Patient Reported Outcomes Grant in Alpha-1 Antitrypsin Deficiency

2022-2023 In-Cycle Grants

VERSION 2
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I. INTRODUCTION

MISSION

AlphaNet Canada and AlphaNet, Inc. (jointly, "AlphaNet") are not-for-profit organizations committed to innovative health management and customized care to individuals with alpha-1 antitrypsin deficiency (Alpha-1, AATD), while funding research for a cure.

The specific aim of the **AlphaNet Canada Patient Reported Outcomes Grant in Alpha-1 Antitrypsin Deficiency** (Program) is to promote the development of validated patient reported outcome (PRO) tools to improve clinical trial design in AATD. The Program supports development of PROs that will improve understanding of the pathogenesis of the clinical manifestations of AAT Deficiency on lung and/or liver disease. This research should improve the development and testing of treatments for the disease.

To achieve these aims, AlphaNet is offering a total of $300,000 CAD (approximately $225,000 USD at exchange rates as of this writing) for this request for applications (RFA). The number of successful applications and the scope of each individual award depends on the specific aims of the submitted applications and their priority scores. In general, AlphaNet would envision no more than four awards for $75,000 CAD ($56,000 USD) each. A maximum award size of $150,000 CAD ($112,000 USD) is allowed. Awards that can be completed in 1 year are preferred over longer-term proposals.

The timing of this award is aligned with efforts to improve the clinical trial readiness of the Alpha-1 community worldwide since the pipeline of therapies being applied to AATD is robust. Access to AlphaNet and Alpha-1 Foundation infrastructure is available to help the successful applicant, although letters of support from these programs should be part of the submission package. Current programs in the North American Alpha-1 community include the Alpha-1 Foundation Research Registry, the Alpha-1 Canada Registry, Databases of AlphaNet Canada and AlphaNet, Inc., and the NIH Alpha-1 Biomarkers Consortium (A1BC) program that is linked to the Alpha-1 Foundation Registry. The A1BC program is designed to support a wide range of meritorious biomarker research related to AATD including basic laboratory investigations, epidemiology, clinical genetics and imaging research.

Successful applicants will be required to use the A1BC cohort to validate successful PRO tools that are developed outside of this population.

GOALS OF THE ALPHANET CANADA PATIENT REPORTED OUTCOME (PRO) GRANTS AWARD PROGRAM

Patient reported outcome (PRO) measures are standardized validated survey tools that study how individuals feel or function in domains of health. PRO measures collect information from patients that inform the utility of therapies on quality of life.

Development of a PRO is often specific to the disease being studied. While validated PRO tools are available for chronic obstructive pulmonary disease (COPD) and for cirrhosis, none has been developed for AATD. AATD is a clinically heterogeneous disease with some severely deficient individuals developing lung disease, some developing liver disease, and some developing both. Among lung disease affected individuals, further heterogeneity is encountered because variable degrees of emphysema, airways hyperreactivity, and anatomic bronchiectasis are present between patients across the spectrum of age. This heterogeneity has led to difficulty in clinical trial development since traditional lung function tests do not correlate with emphysema, the predominant lung disease in the Alpha-1 community.

PROs have been collected in the Alpha-1 community on health-related quality of life (e.g., short form 36, SF-36) and lung disease specific quality of life (e.g., St. George's Respiratory Questionnaire, SGRQ). These tools are useful in reporting the burden of disease when comparing AATD to the general population.

However, what is missing in the Alpha-1 community is a targeted PRO that will allow investigators to demonstrate responsiveness to treatment(s) in a clinical trial. The development of an Alpha-1 specific PRO should provide additional complementary information about a patient's health related quality of life (HRQL). This RFA recognizes that more than one Alpha-1 PRO tool may be required to capture the heterogeneity in AATD. It is generally believed that a carefully developed, patient-tailored, and disease-specific instrument(s) is likely to be more sensitive to underlying change than generic instruments.

There are many types of PRO tools that measure functional status (physical and cognitive), symptoms and symptom burden (e.g., fatigue and dyspnea), impact on health behaviors, and the patient experience of care. The vision for this RFA is focused on development and validity analyses for a disease specific tool that is freely available and supported

by Alpha-1 community resources. Because monies are coming from the AlphaNet community, it is a requirement that the PRO tools that are developed are the intellectual property of AlphaNet, which will have rights to share these with the Alpha-1 community without cost, apply copyright to this work product, and encourage the PRO tool use in other Alpha-1 community projects. The development of a PRO tool to be used by the alpha-1 community still allows for successful grant applicants to publish the PRO tool in open-source medical journals although copyright may not be assigned.

Applicants are invited to utilize the AlphaNet research resources that include a database of symptom scores and clinical outcomes that span more than a decade. A group of approximately 70 coordinators in the US and Canada (who have Alpha-1 themselves) have monthly contact with approximately 8,000 individuals with Alpha-1 who can be invited to participate in development of PRO research. Further access is provided to a carefully phenotyped group of PiZZ individuals that are being currently enrolled in the Alpha-1 Biomarkers Consortium (A1BC), an NHLBI research study currently enrolling 270 PiZZ participants for longitudinal data collection. It is envisioned that participants in the A1BC will be followed for many years and will have provided their consent to share data with the Alpha-1 Research Registry.

The final PRO(s) developed will be validated via the A1BC program that has just begun to enroll participants with a baseline visit to one of 10 United States clinical centers. The A1BC is a 3-visit study that will enroll participants at baseline, with subsequent visits at 18 and 36 months with collection of plasma and serum, DNA, peripheral blood mononuclear cells (PBMCs), quality controlled thin slice CT scans at inspiration and exhalation, DNA, and questionnaires. Monthly contact will accurately collect exacerbation frequency and characteristics. Because development and validation cohorts for PROs are necessarily separate, successful applicants to this RFA will not use the A1BC cohort to develop a PRO.

The A1BC executive staff will work with successful applicants to integrate one or more PROs into the existing infrastructure of the A1BC program and assist in grant applications for external funding. PRO teams chosen under this award are expected to collaborate to find commonality between tasks and tools under development. As such, workshops to initiate the PRO program are planned for grantees under this award to assure that work is not being duplicated among research teams. To the extent that these workshops may change research trial design, the outcomes of these meetings in which all successful applicants will be

invited are expected to produce one or more completed products over the 2 years of the program.

If you have any questions or require additional information about these resources, please contact Mark Delvaux, President and CEO of AlphaNet, via email at mdelvaux@alphanet.org.

OVERVIEW OF APPLICATION PROCESS:

The process of receiving grant applications and awarding grants begins with this announcement of the forthcoming grant opportunity. AlphaNet and AlphaNet Canada will post this announcement of upcoming funding opportunities on its websites (www.alphanet.org and www.alphanetcanada.ca), and through other means relevant to the announced opportunities. These announcements are also emailed to those people who have made inquiries throughout the year. In addition, the announcements are emailed to those investigators who are part of the Alpha-1 Foundation's research network.

Importantly, the source of the funding for this award requires that applicant organizations are limited to institutions of higher learning in the US and Canada that qualify as donees as defined under the Canadian *Income Tax Act*. For clarity, AlphaNet Canada may provide grants to qualified donees that are conducting projects organized by AlphaNet Canada and/or fund research projects conducted through organizations that have entered into appropriate arrangements with AlphaNet Canada that meet applicable requirements under the *Income Tax Act.* Determination of whether the grant applicant's institution qualifies for funding under this Canadian law is required before grant submission.

To check donee qualification status, open List of charities and certain other qualified donees - basic search (cra-arc.gc.ca) for donees located in Canada and List of universities outside Canada registered as qualified donees - Canada.ca for donees outside of Canada.

This AlphaNet RFA is different from Alpha-1 Foundation (A1F) submissions and is in addition to the A1F grants program. Applications are **limited to 6 pages** with a submission deadline of **January 15, 2023 at 11:59PM ET**.

Proposals are reviewed and scored by a subcommittee of the AlphaNet leadership. If needed, input will be requested from ad hoc reviewers. The evaluation of the proposal is based on the following criteria: scientific merit, innovation and relevance to AlphaNet's mission. Final funding

decisions are made based on the merit scores of the proposals, the recommendation regarding funding, and the dollar amount allocated to AlphaNet for grant funding.

Once the funding decisions are made, each investigator who submitted a grant application receives a letter indicating whether the grant that he or she submitted will be funded. In addition, the investigator receives a summary statement reflecting reviewers' comments and critiques.

Those grant applications that have been funded will receive a Notice of Award packet that contains several regulatory documents. Once executed, the regulatory documents are returned to AlphaNet. Subsequently, the first payment on the grant is issued. A grant may not begin until all regulatory documents including, but not limited to, the Notice of Award, Release of Information Form, and Directory Form are executed and returned.

The grant is administered according to the guidelines contained in this document. A final progress report is due at the end of the grant's period of performance. Each final report is reviewed and approved by the AlphaNet Medical Directors. The results of the progress reports are incorporated into the Medical Directors' reports to the AlphaNet and AlphaNet Canada Board of Directors.

Grant Format

Attached to this announcement is a MS Word document that will serve as the complete application for these awards. Note that these awards will be generated in MS Word, and submitted by email to mdelvaux@alphanet.org

The following information is required to submit a complete application.

1. **Title Page**
    - Please provide the project's title **(do not exceed 56 characters, including spaces)**, start and end dates **(dates must be in mm/dd/yyyy format),** total amount requested **(amount must be in $USD)**, and the grant category as the AlphaNet PRO Grant Opportunity.
    - **Note:** Please make sure the total dollar amount requested is not more than $150,000 CAD ($112,000 USD at exchange rates as of this writing) and the total duration of award is $\leq$ 2 years. Awards of 1 year are preferred.
2. **Applicant Information**

- This section is used to provide the contact information of the Principal Investigator, including his/her name, position title, mailing address, telephone number and applicant organization.

3. **Institutional & Signing Official Information**
   - This section is used to provide the contact information of the Institutional & Signing Official. Please make sure to fill out all of the information requested in this section.
4. **Key Personnel Information**
   - This section should be used to provide information on any Key Personnel involved in the proposed project.
   - **Note:** Postdoctoral Research Fellowship applicants must provide contact information for their Mentor.
5. **Research Plan**
   - This section should be used to provide a description of the proposed research. **The research plan may not exceed 6 pages that includes:**
     - Scientific Question and Aims
     - Hypothesis and Significance
     - Description of Approach
     - References
6. **Abstract & Keywords**
   - This section should be used to provide a lay abstract **(do not exceed 3,000 characters, including spaces)** and list of keywords associated with the proposed project. Please make sure to select all terms (general and specific research areas) that are applicable. This information will be used to assign the appropriate reviewers to your application.
7. **Application Attachments**
   - This section should be used to attach any documents pertaining to your application, including all **Biographical Sketches (mandatory for Key Personnel)**, Diagrams/Figures, etc.
   - This section should be used to validate that all required information is submitted. Sections of the application in which the applicant is required to provide information are denoted by a red asterisk.

Note: If you have any questions or require additional information, please contact Mark Delvaux at AlphaNet, mdelvaux@alphanet.org

IV. GENERAL INSTRUCTIONS FOR SUBMITTING A FULL APPLICATION

Read all the instructions thoroughly prior to preparing your full application.

Note: All documents submitted to AlphaNet, including the research plan, data sharing plan, biographical sketches, letters of support, agreements, contracts, IRB/REB approval letters, etc. must be translated to English if written in another language.

Inquiries and Interactions:
All inquiries regarding the AlphaNet's pre and post award grants processes should be directed to:

Mark Delvaux
AlphaNet
3300 Ponce de Leon Blvd.
Coral Gables, FL 33134
Email: mdelvaux@alphanet.org

Non-Personnel Costs:

- **Consultant:** An individual who provides professional advice or services for a fee, but typically not as an employee of the engaging party.

- **Consultant Costs:** Whether or not costs are involved, provide the names and organizational affiliations of all consultants, other than those involved in consortium/contractual arrangements, named in the grant application. Include information regarding consultant physicians who are involved with patient care or individuals who serve on external monitoring boards or advisory committees to the project. Describe the services to be performed in the "Budget Summary & Justification" section of the application. Include the number of days of anticipated consultation, the expected rate of compensation, travel, per diem, and other related costs. In addition, the application should include a Biographical Sketch for each consultant named in the application.

- **Equipment.** If equipment or software purchase or rental is included, list each item separately and justify each purchase in

the "Budget Summary & Justification" section of the application. Major equipment may not be requested as part of a grant application, in accordance with AlphaNet policies. Major equipment is defined as equipment that costs more than US $500.

- **Supplies.** Itemize supplies in separate categories. Categories in amounts less than US $1,000 do not have to be itemized. Any requests for supplies greater than US $1,000 must be adequately justified in the "Budget Summary & Justification" section of the application.

- **Travel.** Itemize travel requests and provide explanations in the "Budget Summary & Justification" section of the application. Discuss the purpose and destination of each trip and the number of individuals for whom funds are requested.

- Include information regarding projected patient accrual for the project/budget periods and relate this information to the budget request for patient care costs. If patient accrual is anticipated to be lower at the start or during the course of the project, plan budget(s) accordingly.

- Provide specific information regarding anticipated sources of other support for patient care costs, e.g., third party recovery or pharmaceutical companies.

- **Other Expenses.** Itemize any other expenses by category and unit cost. These might include patient travel, donor fees, publication costs, computer charges, rentals and leases, equipment maintenance, service contracts, and tuition remission in lieu of salary. Provide an explanation and justification of the costs in the "Budget Summary & Justification" section of the application. Publication expenses should be associated with the dissemination of grant results or data produced as a result of grantee's AlphaNet sponsored grant. These publication expenses include the costs of producing publications, abstracts, manuscripts and/or presentations at scientific conferences or meetings based on or resulting from any study or research performed during the grant's period of performance.

- **Consortium/Contractual Costs.** List each participating consortium/contractual organization and the costs associated

with the consortium/contractual organization. Consortium arrangements may involve personnel costs, supplies, and other allowable costs, but may not include facilities and administrative (indirect) costs. Contractual costs for support services, such as clinical services, or data processing, are occasionally sufficiently high to warrant a similar categorical breakdown of costs.

Note: AlphaNet limits indirect costs to 10% of the total grant award that is inclusive of facilities and administrative costs or overhead costs. Fringe benefits, if applicable, must be included in the direct salary costs.

Note: All budgetary information supplied as part of the application must be in US dollars and reflect the currency exchange rate at the time of the grant application submission.

1. **Budget Summary & Justification**
   - Provide a justification and explanation of the expenses listed for each period in the "Budget Period Detail" section of the application.

     Note: Each expense item listed in the budget must be clearly justified in this section. List only the direct costs requested in this application.

2. **Organization Assurances**
   - **Assurances/Certifications:** Each application to AlphaNet requires that the following assurances and certifications be accounted for by the official signing the application on behalf of the applicant organization.

     Human Subjects
     Research on Transplantation of Human Fetal Tissue
     Women and Minority Inclusion Policy
     Inclusion of Children Policy
     Research Using Human Embryonic Stem Cells
     Vertebrate Animals
     Debarment and Suspension
     Drug-Free Workplace
     Lobbying
     Non-Delinquency on Federal Debt
     Research Misconduct
     Civil Rights

Handicapped Individuals
Sex Discrimination
Age Discrimination
Recombinant DNA and Human Gene Transfer Research
Financial Conflict of Interest (except Phase I SBIR/STTR)
Certification of Research Institution Participation (STTR only)

Notice of Proprietary Information: When the application contains information that constitutes trade secrets; or information that is commercial or financial; or information that is confidential or privileged, the information must be identified by asterisks (*) in the Research Plan and Data Sharing Plan. The information is furnished to AlphaNet in confidence with the understanding that it shall be used or disclosed only for evaluation of this application; provided that, if a grant is awarded as a result of, or in connection with, the submission of this application, AlphaNet shall have the right to use or disclose the information to the extent authorized by law. This restriction does not limit AlphaNet's right to use the information if it is obtained without restriction from another source.

As part of the peer review process, the peer review group carefully considers protections from research risk. The peer review group will assess the adequacy of safeguards of the rights and welfare of research participants based on the information in the grant application. If you are uncertain whether or not your research proposal requires Institutional Review Board (IRB) / Research Ethics Board (REB) approval, please consult the National Institutes of Health (NIH) website and your IRB / REB. AlphaNet mirrors the NIH's policy on human subjects' research and Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2018).

Most if not all proposals submitted to this RFA will require the use of an IRB/REB. IRB/REB approval is not required at the time of the grant application submission.

Human Subjects:

- **No Human Subjects:** Check "No" if activities involving human subjects are not planned at any time during the proposed project period. If the answer is "No", then the remaining parts of this section are not applicable to your grant application.

- **Human Subjects Involved:** Check "'Yes" if activities involving human subjects are planned at any time during the proposed project period, either at the applicant organization, any other performance site or collaborating institution. "Yes" should be checked even if the research is exempt from the NIH's regulations for the protection of human subjects, or if the research will be conducted at an institution, or in a country, that does not require certification or review of human subject research. AlphaNet will only fund grants that provide assurance of protection for human subjects according to the standards set forth by the NIH and TCPS 2.

  Exemptions from Human Subjects Regulations: Check "Exempt" if the activities proposed are designated to be exempt from the regulations. Insert the exemption number corresponding to one of the six exemption categories described in the "Exemption Categories" section of this document.

  Note: Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research will be grounds for AlphaNet to reject the grant application without peer review. AlphaNet will make a final determination whether the proposed research is covered by the regulations or is in an exempt category, based on the information provided in the Research Plan. In doubtful cases, the Principal Investigator/Program Director should contact the AlphaNet leadership team to discuss the specifics of your institution's policies and exemptions. Applicants may also consult the NIH's Office for Human Research Protections (OHRP) by accessing their website for guidance and further information.

  Human Subjects Activities Not Exempt from Regulations: Check either "Approved" or "Pending" if the planned research activities involving human subjects are not exempt and provide the approved or estimated pending date of IRB/REB approval.

  Human Subjects Assurance Number: If the applicant organization has an approved Federal Wide Assurance (FWA), Multiple Project Assurance (MPA), Single Project Assurance (SPA) or Cooperative Project Assurance Number on file with the OHRP, this assurance number cannot be entered on this screen – it will appear only if properly entered in the institution profile (for the institution you selected in the institution section of the proposal). If no assurance number appears here, please contact

your institution's grants and contacts office to have them add the assurance numbers to the institution profile.

Check "Not applicable" if the applicant organization does not have an approved assurance on file with OHRP. Do not provide the human subjects assurance number of any collaborating institution. In this case, the applicant organization, by the signing off on the application, is declaring that it will comply with 45 CFR Part 46 and proceed to obtain a human subjects' assurance.

Note: If your proposed Research Plan requires IRB/REB approval, the approval must be obtained and submitted to AlphaNet prior to starting the grant. The A1BC executive staff will work with the successful applicant(s) to assure this is completed in a timely way. A grant may not begin until all regulatory documents including, but not limited to, the Notice of Award, Release of Information Form, and Directory Form are executed and returned to AlphaNet, Inc. Also, a copy of the IRB/REB or IACUC approval letter needs to be sent to AlphaNet before the first payment is issued (if applicable). IRB/REB approval is not required at the time of the grant application submission.

Note: If a grant involves human subjects, each key personnel named in the grant application is required to have successfully obtained his or her Human Subjects Research Training to the standards set by their IRB.

Special Populations:

- Investigators who conduct research involving fetuses, pregnant women, human in vitro fertilization, prisoners, or children must follow the provisions of the regulations in subparts B, C, and D of 45 CFR Part 46, respectively, which describe the additional protections required for these populations. Relevant information may be obtained at the OHRP website. Exemptions 1-6 listed in this document do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization. Also, Exemption 2 below, for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

- **Inclusion of Women and Minorities:** If you are conducting clinical research, use the "Inclusion of Women" and "Inclusion of Minorities" sections of the application form to address each of the items identified below with respect to your plans for the "Inclusion of Women" and/or the "Inclusion of Minorities" as they relate to the proposed research. AlphaNet policy requires that women and members of minority groups and their subpopulations be included in all AlphaNet supported biomedical and behavioral clinical research projects involving human subjects. The inclusion must be addressed in developing a research design appropriate to the scientific objectives of the study. Inclusion is required unless a clear and compelling rationale shows that inclusion is inappropriate with respect to the health of the subjects or that inclusion is inappropriate for the purpose of the study. Exclusion under other circumstances may be made based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be excluded routinely from participation in clinical research. This policy applies to research subjects of all ages.

- **Inclusion of Children:** AlphaNet policy requires that children (i.e., individuals under the age of 21) must be included in all human subjects' research, conducted or supported by the AlphaNet unless there are clear and compelling reasons not to include them. Therefore, proposals for research involving human subjects must include a description of plans for including children. If children will be excluded from the research, the application or proposal must present an acceptable justification for the exclusion.

  In the section entitled, "Inclusion of Children", the applicant should provide either a description of the plans to include children or if children will be excluded from the research. The grant application must provide an acceptable justification (see below) for the exclusion.

  If children are included, the description of the plan should include a rationale for selecting or excluding a specific age range of children. When children are included, the plan

also must include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.

AlphaNet will assess each application as being "acceptable" or "unacceptable" with regard to the age-appropriate inclusion or exclusion of children in the research project.

Justifications for Exclusion of Children
It is expected that children will be included in all research involving human subjects unless one or more of the following exclusionary circumstances can be fully justified:

1. The research topic to be studied is not relevant to children.

2. There are laws or regulations barring the inclusion of children in the research.

3. The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be redundant. Documentation of other studies justifying the exclusions should be provided.

4. A separate, age-specific study in children is warranted and preferable. Examples include:

    a. The relative rarity of the condition in children, as compared to adults (in that extraordinary effort would be needed to include children, although in rare diseases or disorders where the applicant has made a particular effort to assemble an adult population, the same effort would be expected to assemble a similar child population with the rare condition); or

    b. The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or

c. Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children (including different cognitive, developmental, or disease stages or different age-related metabolic processes). While this situation may represent a justification for excluding children in some instances, consideration should be given to taking these differences into account in the study design and expanding the hypotheses tested, or the interventions, to allow children to be included rather than excluding them; or

5. Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). While children usually should not be the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis; or

6. Study designs aimed at collecting additional data on pre-enrolled adult study subjects (e.g., longitudinal follow-up studies that did not include data on children); or

7. Other special cases justified by the investigator and found acceptable to the review group.

Definition of a Child

For the purpose of implementing these guidelines, a child is defined as an individual under the age of 21 years.

The definition of child described above will pertain to these guidelines (notwithstanding the FDA definition of a child as an individual from infancy to 16 years of age, and varying definitions employed by some states). Generally, state laws define what constitutes a "child," and such definitions dictate whether or not a person can legally consent to participate in a research study. However, state and country laws vary, and many do not address when a child can consent to participate in research. Federal regulations (45 CFR Part 46,

subpart D, Sec.401-409) address DHHS protections for children who participate in research and rely on State definitions of "child" for consent purposes. Consequently, the children included in this policy (persons under the age of 21) may differ in the age at which their own consent is required and sufficient to participate in research under state law. For example, some states consider a person age 18 to be an adult and therefore one who can provide consent without parental permission.

3. Application Attachments

- This section should be used to attach any documents pertaining to your application, **including the Research Plan, Data Sharing Plan, Introduction (for revised applications ONLY)**, all Biographical Sketches, Letters of Support, Diagrams/Figures, etc.
- **Biographical Sketch Format Page:** Provide the information requested on the Biographical Sketch Form Page, which can be downloaded in this section of the application. A Biographical Sketch must be provided for each key personnel, including mentors and consultants, named in the grant application.
    - Complete the educational block at the top of the format page. Additionally, provide the information described in A and B below.
        - A. Positions and Honors. List in chronological order previous positions, concluding with your present position. List any honors. Include present membership on any Federal Government public advisory committee and membership on any Alpha-1 community organizations.
        - B. Selected peer-reviewed publications or manuscripts in press (in chronological order). Do not include manuscripts submitted or in preparation.
    - Information provided on the Biographical Sketch Form will be used by the reviewers in the assessment of each individual's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team.

New and revised applications may include the following materials as attachments:

- Surveys, questionnaires, data collection instruments, and clinical protocols.
- Diagrams/Figures.

Note: All Biographical Sketches provided may not exceed five pages.

Note: All documents submitted as attachments to the application (research plan, data sharing plan, biographical sketches, letters of support, introduction, etc.) may be submitted as separate or combined files in either .doc or .pdf formats.

VI. Criteria for Funding, Notification & Conditions of Awards

Criteria for Funding

Topics deemed to be suitable for funding are determined by AlphaNet, Inc.

The final funding decisions are made by AlphaNet, Inc. based on the availability of funds and research priorities. AlphaNet, Inc. is a not-for-profit organization and grant funding is obtained as a result of fundraising efforts. Therefore, AlphaNet's ability to fund grants is contingent upon the availability of funds.

Notification and Disbursement of Funding

Each applicant is notified, in writing, of the status of the grant application on behalf of the AlphaNet's CEO. Each applicant organization is required to sign a Notice of Award that specifies the AlphaNet's terms and conditions of the award. The initial installment of award funds will be disbursed upon receipt of the executed regulatory documents.

Conditions of the Grant Award

In accordance with AlphaNet's mission, AlphaNet awards grants to certain researchers or research institutions based on the criteria established by the Board of Directors. In addition to the criteria contained in grant applications, and the specific limitations applicable to each grant, as set forth in the Notice of Award, there are General Terms and Conditions that apply to all of AlphaNet's grants. The Terms and Conditions document can be found on AlphaNet's website (www.alphanet.org). Compliance with such Terms and Conditions is also a condition of a grant award. Such Terms and Conditions are

incorporated herein by reference and your acceptance of any award amount from AlphaNet constitutes your acknowledgement of receipt and agreement to comply with each and every of such Terms and Conditions.