GOLDEN GIFT

The Golden Gift is a 501(c)(3) Public Charity

1.0 PURPOSE

This study will employ Epigenetic Methylation and Genomic testing and blood laboratory parameters to identify biologic age shifts and genome changes that might be attributable to of the methods and frequency of administering at two dosage levels, approximately either 2 or 3 liters of yFFP into study subjects within 30 days, for therapeutic uses across a wide spectrum of conditions.

- **Age Related Conditions** In 2019, the most recent year of available data, people 55 and over accounted for 56% of total health spending, despite making up only 30% of the population. By 2030, every Baby Boomer will be age 65 or older, which means that 1 out of every 5 Americans will be of retirement age. Within just a couple decades, older people are projected to outnumber children for the first time in U.S. history. By 2035, there will be 78.0 million people 65 years and older compared to 76.7 million under the age of 18.

  90% of the nation's $3.8 trillion in annual health care expenditures are for chronic conditions. Total national health expenditures are expected to reach $5 trillion by 2025, according to the U.S. Census Bureau and the Centers for Medicare and Medicaid Services. By 2025, estimates are that US providers will face a collective shortage of about 500,000 home health aides, 100,000 nursing assistants, and 29,000 nurse practitioners. National health expenditures as a percentage of GDP will climb to 19.4% of GDP (approximately $6 trillion) in 2027, according to annual estimates from the Center for Medicare and Medicaid Services. And a major factor in that growth will be the population aging into Medicare.

  The use of yFFP as a youth factor replacement and regenerative therapy has been studied in four documented human trials, Stanford's AD & PD studies and the PD & MS studies conducted at the Texas Medical Center. Each of these studies intravenously administered approximately 2 liters of yFFP over a series of sessions that varied from two infusions over two days, to one infusion a week over eight weeks.

Since those studies, plasma exchanges that first remove old plasma and then replace the volume removed with yFFP have been proven to be safe and effective. Total plasma exchanges of 1 liter saline/albumin and 2 liters of yFFP have been successfully performed, as have two 1-liter exchanges of yFFP.

This study will compare epigenetic and blood lab results taken from just before the initial infusion or exchange, to results taken four months after the last treatment. The comparative results from each study participant that has received 70% or more of a total of 2 liters of yFFP over a period not to exceed one month through intravenous or exchange methodologies, will be analyzed and reported.

TruDiagnostic blood testing is objective. Results from all individuals will be correlated and compared with the entire study group, which is expected to allow the categorization of distinctive disease states to identify improvements derived from yFFP therapy that could apply to broad demographic and sex identified populations.

2.0 SCOPE

Sample Size: 2000 patients.

Test results will be analyzed one-month and 4 months after the final administration of young plasma, with results continuously added to the study outcomes report.

All patients will be designated to approximately receive between 2 - 3 liters of yFFP, depending upon their dosage level I or II.

3.0 DEFINITIONS

FFP: fresh frozen plasma, not necessarily from a young donor

SAE: serious adverse event

SOP: standard operating procedure

yFFP: fresh frozen plasma from a young (18 – 25 year old), sex-identified donor

4.0 RESPONSIBILITIES

Responsible Parties:

Principal Investigator: Dr. Dian Ginsberg
The Ginstitute of Functional Medicine
6750 W Loop South, Suite 425
Bellaire, TX 77401
281-569-4289 office

5.0 TRIAL STATUS

Current Status: Enrollment

Closure Date: To be determined

6.0 MATERIALS/EQUIPMENT

- Blood group-specific yFFP
- IV Starter Kit
- IV Catheter
- Apheresis device
- Plasma Warmer

7.0 STUDY DESIGN & METHOD

The study is a blood value and epigenetic outcomes investigation designed to evaluate the safety and efficacy of intravenous and exchange administered young Fresh Frozen Plasma at 25 ml/kg within dosage level I or up to 37.5 ml/kg at dosage level II, within no more than thirty days.

Each participant's starting condition will be identified by a TruDiagnostic and blood laboratory parameter test just prior to the commencement of their initial yFFP treatment. Each participants concluding condition will be identified by the same test panel taken 4 months after the conclusion of their yFFP treatment(s).

Advanced Laboratory Parameters blood tests are included, highly recommended and approved in this protocol for those Co-investigators that elect to participate, or study participants that desire to participate. Because this is a patient-funded study, the more expensive advanced tests have not been made mandatory.

The primary outcome is the change, if any, in the epigenetic age or genome pattern and improvement of blood parameters representing body organ function of the yFFP treated patients.

There will be multiple study sites participating throughout the State of Texas.

Definition of end of study

The end of the study will be four months after the last participant's final yFFP treatment.

The study duration will be open ended until it is determined to be closed.

Study outcomes will be continuously reported as results become available.

Interim reports of cumulative outcomes will be periodically produced.

Serious Adverse Events (SAE) will be monitored for 14-days after final dose of yFFP or until resolution.

8.0 SECONDARY OBJECTIVES

Secondary objectives: are to achieve a better understanding of this technology including the following:

- Factors predicting a beneficial response
- Effects on additional outcome parameters quality of life, and short-term risk profile

Secondary outcomes will be:

- Adverse events
- Patient biologic and psychologic parameters associated with a beneficial response

All other outcomes are exploratory.

9.0 SUBJECT POPULATION

Inclusion criteria

A. Age 34 years and above.

Exclusion criteria

Any individuals meeting any of the following will be excluded from the study:

A. Other significant disease, which in the view of the study doctor may make assessment of the efficacy of yFFP difficult.
B. Unstable medical conditions.
C. Must weigh at least 45.5 kg. Cannot weigh more than 130 kg.
D. A severe disease state diagnosis.
E. Litigation. Patients in litigation will be excluded only if conclusion of that litigation is imminent during the course of the study.
F. Complete IgA deficiency.
G. Rare contraindications to yFFP therapy as per summary of product characteristics.
H. Receiving yFFP for other reasons.
I. Ongoing drug or alcohol abuse.
J. Psychiatric disorder that could, in the judgement of the site investigator, interfere with successful study participation.
K. Unwillingness or inability to complete the study or an inability to understand the questionnaires being used.
L. Cancer other than basal cell carcinoma within the last 5 years. However, those patients who have received definitive treatment, such as curative

surgery more than 6 months ago, with no known recurrence can be included.

M. A history of hypercoagulable or thrombophilic clotting abnormalities.
N. A history of thromboembolic events: ischemic stroke, confirmed myocardial infarction, pulmonary embolism; deep venous thrombosis except where immobility related (for example, after injury or operation).
O. Unstable angina pectoris.
P. Medications that might react with yFFP such as blood thinners
Q. Renal failure or serum creatinine greater than 1.5 times the upper limit of normal at screening.
R. Any medical condition that, in the opinion of the investigator, would make it unsafe for the patient to participate or which would interfere with assessment of the outcome measures.
S. Participation in another interventional trial within 3 months of randomization. Participation in non-interventional studies is not a reason for exclusion.

10.0 SCREENING, RECRUITMENT AND CONSENT

Patients will be identified by the Golden Gift and participating co-investigators.

Strategies will be implemented to maximize awareness of the trial in the patient population and increase referrals to the recruiting centers (informative materials will be included as part of the study documents).

Patients will be given the "Patient Information Sheet" to read at least 24-hours before the screening visit, where they will be given the "Informed consent."

At the screening visit, there will be an opportunity for the participants to ask questions of a member of staff trained in all trial procedures, as delegated by the PI. The Principal Investigator will ensure that the participants meet the inclusion and exclusion criteria at the point of screening.

Patients will be telephoned within 2 days, and maximally, 4 days after baseline testing to confirm eligibility to participate.

Screen failures may be rescreened ONLY where there is a short-term reason for ineligibility, such as non-availability for study visits due to planned holidays or an ongoing acute illness.

A screening log will be kept at site to document details of patients invited to be screened for participation in the study. For patients who decline or are ineligible, this will document any reasons available for nonparticipation (where provided). The log will ensure potential participants are only approached once.

The original signed consent form will be retained in the investigator site file, with a copy in the participant's medical notes, and a copy provided to the participant.

The participant will specifically consent to their GP being informed of their participation in the study.

The right to refuse to participate without giving reasons will be respected.

11.0 STUDY MEDICATION

yFFP

The experimental intervention is 25 to 37.5 ml/kg (total) within 30 days, in any combination with ongoing normal standard treatment.

The plasma used must be ABO compatible with the recipient. Plasma does not need to be Rh compatible.

ABO phenotype of the recipient	**ABO phenotype of units to transfuse (in order of preference)**
O	O, A, B, AB
A	A, AB
B	B, AB
AB	AB

https://www.utmb.edu/bloodbank/components/blood-component-abo-compatibility-chart

https://www.utmb.edu/bloodbank/components/plasma

For reported side effects of Spectrum Plasma yFFP infusion, please refer to AABB Circular of Information.

Contraindications include:

Absolute contraindications to the use of yFFP are documented intolerance to plasma or its components or selective deficiency of immunoglobulin A (IgA).

Relative contraindications are Heart failure or pulmonary edema.

Additional Cautions:

Patients should avoid citrus and highly acidic fruits (example: strawberries, blueberries, loganberries, cranberries, currants, gooseberries, pineapple etc.) before and for a day after their last infusion, as patient may experience a reaction due to citrate.

Selection and timing of dose for each participant

Solutions will be available in 200 ml Spectrum Plasma yFFP infusion bags. Level I and Level II prescriptions will be rounded up to the next whole unit.

Due to transfusion associated circulatory overload (TACO) concerns, the per-session infusion volume has been established at 12.5 ml per kg and then rounded up to the next whole 200 ml unit of yFFP, taking into consideration that the upper advisable infusion volume is 15 ml per kg, per infusion treatment.

Device-driven plasma exchanges are not associated with TACO and therefore Level I and Level II dosages can be administered in one or more treatment sessions.

https://www.omnicalculator.com/health/fresh-frozen-plasma-dose

All patients who receive ≥70% of the target dose within a total of 30 days will be included in the study.

yFFP will be infused intravenously at an initial rate of not more than 2 ml/minute for 15 minutes. If well tolerated, the rate of administration may be increased to 10-15 ml/minute for the remainder of the infusion.

Infusion rate adjustments can be made if patients experience mild adverse clinical effects, reducing to 2 ml /minute in the first instance and further if required, while aiming for sufficient time to complete the entire infusion in a single day.

The dosing is based on the patient weight, clinicians should refer to this table before administering the study drug

Weight range Min (in kg)	Weight Range Max (in kg)	Volume to be Administered (in ml)	Bags (200 ml) to be dispensed	Bags – Infusion 1	Bags - Infusion 2
45.5	55.4	1,400	7	4	3
55.5	65.4	1,600	8	4	4
65.5	75.4	1,800	9	5	4
75.5	85.4	2,200	11	6	5
85.5	95.4	2,400	12	6	6
95.5	105.4	2,600	13	7	6
105.5	115.4	2,800	14	7	7
115.5	125.4	3,200	16	8	8
125.5	135.4	3,400	17	8	9

12.0 PACKAGING AND LABELING OF INVESTIGATIONAL MEDICINAL PRODUCT

Medicinal product will be supplied by Spectrum Plasma in Fresenius Kabi individual 200 ml bags, containing yFFP and 23-27 ml dextrose solution of citric acid.

Packaging and labeling will be completed in accordance with FDA regulations and Current Good Manufacturing Practice (CGMP). Spectrum Plasma is a FDA-AABB & CLIA registered, audited and accredited blood bank that will supply the investigation with FDA approved [21CFR640.30] plasma exclusively collected from healthy, 18-25 year old sex-identified volunteer donors in full compliance to AABB and State of Texas regulations. yFFP is a registered trademark of Spectrum Plasma, Inc.

13.0 PRESCRIPTION OF THE MEDICINAL PRODUCT

Medication will be prescribed by an authorized study physician according to the protocol, using a trial-specific prescription. The volume to be dispensed per patient will be calculated according to patient weight (dosing-schedule Table) and the site investigator will dispense the required number of bags.

Participants will be informed of potential adverse reactions and advised to seek medical help and contact the research team, if required.

Patients will carry cards with an emergency 24-hour emergency phone number.

Documentation of prescribing and dispensing study medication shall be maintained for study records in the patient file and a copy of all documents will be sent to the Investigator.

A specific prescription must be submitted to the Spectrum Plasma Blood Bank no later than two days prior to the patient's infusion.

14.0 DISPENSING AND DISTRIBUTION OF THE MEDICINAL PRODUCT

The study drug will be stored in a secure area with limited access within each site in the original shipping container until just prior to the infusion to ensure product temperature is maintained at -18°C or colder.

15.0 ADMINISTRATION OF THE MEDICINAL PRODUCT

If site prefers to run a slower infusion than described above, this will not be considered a protocol violation.

It is recommended that patients be offered diphenhydramine orally prior to starting the infusion or exchange.

Patients must be under continuous nurse observation during the infusion; in cases where no reduction of the infusion rate is required, the average infusion duration for a participant of 75 kg to 90 kg body weight is about 1.5 to 2 hours. Exchange durations will vary between 1 to 1 hours, based upon the exchange volume.

In the event that patients do not receive their entire first infusion, either due to having to stop early because of time constraints arising from long infusion duration with a low rate, or because side effects are intolerable even with the lowest infusion rate, they should still be offered the second infusion. Details of the amount infused should be recorded in the notes section of the infusion form.

Where the infusion cannot be tolerated, and the patient wishes to not receive additional infusion, the patient is withdrawn from further infusion. Any patient that does not complete the second TruAge test will not be included in the study.

16.0 SAFETY MONITORING

Blood monitoring is only required for the protocol in response to adverse events.

17.0 HEMATOLOGY, BIOCHEMISTRY, ADVANCED LABORATORY, AND FUNCTIONAL TESTING

Hematology

- White blood cell and differential count (eosinophils, basophils, neutrophils, lymphocytes and monocytes)
- Red blood cell and indices (PCV, MCV, MCH, MCHC)
- Hemoglobin
- Platelets
- Serum IgA
- Serum IgM
- Serum IgG.
- C-reactive Protein

Biochemistry

- Sodium

- Potassium
- Urea
- Serum creatinine
- ALT, AST, GGT, Bilirubin.

Elective Advanced Laboratory Parameters

Leptin-_____ ng/ml

HbA1c-_____%

Adiponectin-_____ ug/ml

Troponin-_____ng/ml NT-

ProBNP-_____

TNF alpha-_____

Cystatin C-_____

IL6-_____

18.0 ALLOCATION

Identification and allocation of patients

A patient identification number will be assigned after consent has been signed.

19.0 STUDY DATA

Database

Source data will be entered by authorized staff onto a password protected Excel spreadsheet. All data entered will be QA-verified against the source documents.

Database passwords, data handling and confidentiality/format of records

Database access will be strictly restricted through passwords to the authorized research team.

All participant contact/screening and recruitment data will be stored on spreadsheets on DropBox, which will have restricted access from password

protected computers. Accrual data will be anonymized and collated by the Investigator. No identifiable data will be transferred.

At the end of the study, essential documentation will be archived in accordance with sponsor and local requirements. The retention of study data will be the responsibility of the Principal Investigator.

20.0 ON-SITE/CENTRAL MONITORING

The Principal Investigator and study physicians will conduct on-site/central monitoring.

The Investigator may identify data fields that should be checked against the source data during site monitoring visits, where there are data queries, the research nurses will be responsible for resolving the queries.

The QA will review responses before closing the query.

21.0 STATISTICAL CONSIDERATIONS

Data analysis will be performed using a password-protected computer independent of study sponsor or clinical sites.

22.0 STATISTICAL ANALYSIS

A comprehensive statistical analysis plan will be developed and agreed upon with the trial's oversight committees. Section 26 contains a tentative outline for the statistical analysis of the UPDRS scores.

23.0 EFFICACY

Primary analysis:

The differences between the baseline TruDiagnostic, blood laboratory parameter draw and functional test values at baseline and values at 4 months provide objective summaries of disease severity change over the course of the study. The accumulated data will be categorized by and identified with the methods of administration. In view of the categorical nature of the data, other analyses will be explored. Those additional analyses may include a permutation test or other bootstrap methodology.

***Secondary analysis*:**

Changes in the epigenetic ages, laboratory values, and other findings attributable to the volume and frequency of administering yFFP, such as comparing outcomes from a single large volume exchange vs a one-month series of weekly infusions, and 2 liter treatments to 3 liter treatments.

24.0 SAMPLE SIZE CALCULATION

The sample size was calculated based on available participant populations.

FFP has long been an approved medication in the US. This study addresses the potential benefits of FDA approved [21CFR640.30] Plasma exclusively collected from medically qualified18 – 25 year old volunteer donors. yFFP is a registered trademark of Spectrum Plasma, Inc.

25.0 COMPLIANCE AND WITHDRAWAL

Subject compliance

Compliance will be measured by attendance at infusion or exchange visits and tolerance of entire prescribed volume.

Treatment cessation

Patients who develop an unexpected new condition precluding further participation will be withdrawn from receiving further infusions.

26.0 WITHDRAWAL OF PARTICIPANTS

Study drug must be discontinued for the following:

1. The participant decides he/she no longer wishes to continue.

2. Withdrawal is recommended by the Investigator or another clinician (for example, intercurrent illness during course of study or side effects from study drug).

Patients will be discontinued for the following:

Patient never receives any medicine (that is, the first infusion is never started - this is also termed 'non-compliance').

Participants have the right to withdraw from the study at any time and for any reason without providing a reason. The investigator also has the right to withdraw participants from the study if they consider that it is in the best interests of the participant. Should a participant decide to withdraw from the study, he/she will be asked to volunteer a reason for withdrawal but are at liberty not to state a reason.

27.0 DATA MONITORING, QUALITY CONTROL AND QUALITY ASSURANCE

This protocol has been developed by clinicians.

Day to day management of study will be the responsibility of the Investigator.

Dr. Dian Ginsberg: Principal Investigator

The IP will arrange telephone conferences and provide weekly recruitment and status reports.

Investigators' meetings will be periodically held to review the results. A final meeting will be held at the conclusion of the study.

Each individual practice site physician or nurse will be responsible for the day-to-day study conduct at site. This includes establishing and carrying out the trial at his/her center in accordance with national and local law, public health regulations and FDA regulations.

They will ensure that all site-specific documentation is complete and correct; and that all staff involved in the trial are compliant with regulations, and that they are appropriately trained in those aspects relevant to their role in the study while being familiar with the trial protocol.

The Investigator is also responsible for managing recruitment on target and collecting and submitting accrual and outcome data in a timely manner; providing and responding promptly to SAEs and agreeing to monitoring audit visits by Quality Assurance as required.

Provisions for managing any SAE, such as the identification of the nearest emergency room, must be in place prior to commencement of the study by the investigator.

Central and site monitoring of study conduct, and data collected will be performed by each individual site study physician or nurse. Full details will be documented in a monitoring plan. The main areas of focus will include:

- Consent
- Serious adverse events
- Essential documents
- Drug accountability and management.

All monitoring findings will be reported and followed up with appropriate persons in a timely manner.

28.0 DIRECT ACCESS TO SOURCE DATA AND DOCUMENTS

The investigators agree to provide full access to all source data, study data and materials to the sponsor for purposes of monitoring, audit or inspection.

29.0 PHARMACOVIGILENCE

Refer to AABB Circular of Information.

30.0 UNEXPECTED ADVERSE REACTIONS

Adverse event reporting will be in compliance with FDA. Most adverse drug reactions that occur in this study, whether serious or not, will be expected treatment-related side effects as FFP has a well-established side-effect profile and approximately 20% of all blood plasma transfused is from 18-25 year old donors (yFFP).

FFP can cause adverse reactions such as:

- Chills, headache, fever, vomiting, allergic reactions, nausea, arthralgia, low blood pressure and mild back pain, which may occur occasionally.
- Increase in serum creatinine level and/or acute renal failure have been observed.
- Very rarely, thromboembolic reactions, such as myocardial infarction, stroke, pulmonary embolism, and deep vein thromboses have occurred.

Details of further spontaneously reported adverse reactions include the following:

- Cardiac disorders: angina pectoris (very rare)
- General disorders and administrations site conditions: rigors (very rare)
- Immune system disorders: anaphylactoid shock (very rare), hypersensitivity (very rare)
- Blood pressure decreased (very rare)
- Musculoskeletal and connective tissue disorders: back pain (very rare)
- Respiratory, thoracic, and mediastinal disorders: Dyspnea NOS (very rare); or
- Vascular disorders: shock (very rare).

The adverse events reported above are expected in the sense that they are possible known side-effects of the study medication, but all reported instances of both serious and non-serious adverse events will be reported in this study.

During the trial, investigators will be made aware of any updates to the summary of product characteristics (SPC) but the protocol need not be amended every time there is a change unless it directly affects the study conduct. The source of accurate information regarding the active medication must always be the SPC and not the study protocol, and the above information is provided to reflect the situation at study start only.

31.0 PROVISIONS FOR MANAGING ADVERSE REACTIONS

In the rare event of a serious complication, subjects can be taken to a nearby ER such as SignatureCare Emergency Center, 3209 Montrose Blvd Houston, TX 77006 (281) 479-3293.

32.0 PROTOCOL SPECIFICATIONS

For purposes of this protocol

1. Any serious adverse events will be recorded throughout the duration of the trial until 14 days after cessation of study drug or until resolution.
2. Non-serious adverse events will be recorded throughout duration of trial until 14 days after cessation of study drug.
3. Serious adverse events exclude any pre-planned hospitalizations not associated with clinical deterioration.

33.0 RECORDING AND REPORTING SERIOUS ADVERSE EVENTS OR REACTIONS

All adverse events and all serious adverse events should be recorded. All serious adverse events must be reported to the IRCM IRB within 48 hours. Depending on the nature of the event, the additional reporting procedures below should be followed. Any questions concerning adverse event recording/reporting should be directed to the Principal Investigator in the first instance.

34.0 NON-SERIOUS ADVERSE EVENTS

All non-serious adverse events will be recorded on the "Patient infusion log". Severity of all AEs will be graded on a three-point scale of intensity (mild, moderate, or severe):

Mild: Discomfort is noticed, but there is no disruption of normal daily activities.

Moderate: Discomfort is sufficient to reduce or affect normal daily activities.

Severe: Discomfort is incapacitating, with inability to work or to perform normal daily activities.

Relation of an AE to treatment should be assessed by the investigator/delegate (must be a clinician) on-site. Investigators will be responsible for managing all adverse events according to local protocols, as the study blood product is already approved for use in other indications.

35.0 SERIOUS ADVERSE EVENTS

All Serious Adverse Events (SAEs) shall be recorded and reported on the serious adverse event form and sent to the Principal Investigator within 24 hours of learning of its occurrence. The initial report can be made by completing the "Report of Adverse Transfusion Form" and faxing or emailing to the Principal Investigator. A record of this notification (including date of notification) must be clearly documented to provide an audit trail. In the case of incomplete

information at the time of initial reporting, all appropriate information should be provided as follow-up as soon as this becomes available.

Relationship of the SAE to the treatment should be assessed by the investigator/delegate (must be a clinician) at that site, as should the expected or unexpected nature of any serious adverse reactions. As this is a blinded study involving a placebo and biologics product, seriousness, causality and expectedness should be evaluated as though the patient was on the blood product.

All SAEs-reporting responsibilities to FDA will be that of Principal investigator, with the support of the clinical sites.

SAEs that are fatal or life-threatening must be reported as soon as possible and no later than 12 hours after the study physician is first aware of the reaction, and the Investigator will report to FDA within 24 hours of first becoming aware. Any additional relevant information must be reported within a further 7 days.

SAEs that are not fatal or life-threatening must be reported within 3 days to the sponsor.

All investigators will be informed of all SAE's assessed as fulfilling criteria as possibly, probably or definitely related to the study intervention and unexpected per the SPC.

36.0 ETHICS AND REGULATORY ISSUES

The conduct of this study will be in accordance with the recommendations for physicians involved in research on human subjects adopted by the Texas Medical Board.

Information sheets will be provided to all eligible subjects and written informed consent obtained prior to any study procedures. Participants will be provided with a copy of the completed consent form for their records.

The participating Investigators have participated and signed off on this protocol.

37.0 FINANCE AND INSURANCE

The Golden Gift, a registered 501(c)(3) nonprofit, is the sponsor of this study and will be the largest source of funding. Spectrum Plasma will supply the medication (yFFP).

The investigators have liability for clinical negligence that harms individuals towards whom they have a duty of care. No provision has been made for potential liability for issues arising from negligence in study design. There are no arrangements for non-negligent compensation.

38.0 PUBLICATION POLICY

The data will be the property of the Principal Investigator. Publication will be the responsibility of the Principal Investigator. All manuscripts abstracts or other modes of presentation will be reviewed by the Principal Investigator prior to submission. Reference will be made to any particular study subject (whose identity is to remain confidential), as applicable. Results of the study will also be reported to the Sponsor/Funder in the required format.

39.0 AUTHORS' CONTRIBUTIONS

Dr. Dian Ginsberg is the current Principal Investigator.

Applicable References

21CFR 210, 211, 600,601, 606,607, 610, 630, 640, 660, 820.

42 CFR 493

AABB Standards for Blood Banks & Transfusion Services

https://www.nature.com/articles/s41591-019-0673-2

https://jamanetwork.com/journals/jamaneurology/fullarticle/2709116

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https://www.fda.gov/regulatory-information/search-fda-guidance-documents/label-and-investigational-use-marketed-drugs-biologics-and-medical-devices

End Document