Section 2 - Study Population Characteristics (Study 1)

2.1. Conditions or Focus of Study

- Gender minority (GM) identity development after gender-affirming surgery and the long-term healthcare needs of GM individuals.

2.2. Eligibility Criteria

Key informants. To inform the development of data collection instruments, we will conduct a total of 18 key informant interviews with former GAP patients (6 trans-feminine, 6 trans-masculine) and 6 VNSNY GAP clinicians. Former patients will be identified through random selection among individuals discharged from GAP services 12-18 months prior to recruitment. GAP clinicians will be make a random selection from clinicians actively providing GAP services.

Eligibility criteria for study participation. The population of interest are TGNB individuals who (1) have been admitted to VNSNY's Gender Affirmation Program; (ii) reside in one of VNSNY's four main regions (Brooklyn, Bronx, Manhattan, and Queens); (iii) are at least 18 years old; and (iv) speak either English or Spanish as their preferred language.

2.3. Age Limits	Min Age: 18 Years	Max Age:	N/A (No limit)
2.3.a. Inclusion of Individuals Across the Lifespan	InclusionLifespan_FINAL.pdf		
2.4. Inclusion of Women and Minorities	InclusionWomenMinorities_FINAL.pdf		
2.5. Recruitment and Retention Plan	RecruitmentRetention_FINAL.pdf		
2.6. Recruitment Status	Not yet recruiting		
2.7. Study Timeline	Timeline_FINAL.pdf		
2.8. Enrollment of First Participant	11/08/2021	Anticipated	

Inclusion of Individuals Across the Lifespan

The proposed study will include adults of all ages admitted to VNSNY's GAP (ages 18 and over). Children will not be included in this study. By and large, the individuals receiving post-surgical home care from VNSNY's GAP are adults; however, there have been a few rare instances where 17-year-olds were referred to GAP. TGNB children are a uniquely vulnerable population. Given that this is a very small portion of the GAP population, there is not sufficient justification for including minors in this study. A unique set of questions would be needed to examine the needs of TGNB minors during the transition period after gender-affirming surgery. There would not be a large enough sample size of this age group to fully examine these questions and their implications.

The investigative team has expertise working with and conducting research that includes individuals of all ages across the lifespan, including but not limited to Dr. Bockting's research and clinical work with TGNB individuals and Dr. Ryvicker's prior research on the older adult population. Collectively, the investigative team brings a life-course perspective to the study.

We anticipate that the age distribution of participants will reflect the age distribution of the GAP population; we will conduct descriptive analysis on an ongoing basis to assess for any selection bias by age among those who participate in the study. If we find a significant selection bias by age, we may choose to adjust our recruitment and retention methods to ensure that the study is fully inclusive across all age groups represented in the adult GAP population.

Inclusion of Women and Minorities

This study will recruit a sample of transgender and gender non-binary (TGNB) individuals who have received post-surgical home health care from VNSNY's GAP program. The study sample will reflect the overall patient population of this program. Given our previous analysis of the demographic characteristics of this population (N=346), we anticipate that our study sample will include roughly 80% transgender women and 20% transgender men. A yet unknown proportion may identify as gender non-binary; comprehensive data on gender identity, gender expression, and sex assigned at birth will be collected upon enrollment in the study.

We anticipate that over half of the study population will be a member of a racial/ethnic minority group. The racial/ethnic composition of the GAP population thus far has been 32% Black, 28% Hispanic, 36% Non-Hispanic White, 3% Asian, and less than 1% either American Indian, Alaska Native, Native Hawaiian or Pacific Islander. We expect that our study sample will be roughly in proportion of the historical GAP population.

For the qualitative component of the study, we will select a purposive sample stratified by gender identity and race/ethnicity to enhance the depth and breadth of our understanding of participants' experiences. Given the ratio of transfeminine vs transmasculine GAP patients (Table 2), we propose to select n=45 transfeminine and n=15 transmasculine interview participants. These n=60 interviewees will include n=15 participants in each of the following four racial/ethnic subgroups: (1) Black (non-Hispanic), (2) Hispanic, (3) Non-Hispanic White, and (4) Asian, American Indian, Alaska Native, Native Hawaiian, and Pacific Islander participants. The rationale for this purposive sampling strategy is based on potential gender differences in psychosocial development, quality of life, and utilization of care,[139] and on documented racial/ethnic disparities in minority stress, health and access to care within TGNB populations.[84-91,140]

Recruitment and Retention Plan

TGNB participant recruitment and retention

Eligibility criteria. The population of interest are TGNB individuals who (i) have been admitted to VNSNY's GAP; (ii) reside in one of VNSNY's four main regions (Brooklyn, Bronx, Manhattan, and Queens); (iii) are at least 18 years old; and (iv) speak either English or Spanish as their preferred language. Based on our retrospective profile of GAP patients and recent trends in referrals, we expect that 80% of potential study participants will be transfeminine and 20% transmasculine; each of these two groups will include individuals with binary and nonbinary gender identities. The proportion in each group that may self-identify as gender nonbinary is as of yet unknown; we will be able to determine this from data to be collected at T0. Given the diversity in the TGNB population with reference to gender identity, gender expression, and the use of gender-affirming healthcare options, we have chosen an inclusive approach to the overall study sample. Individuals receiving GAP services who meet the aforementioned criteria will be considered eligible, regardless of the type of surgery they had and regardless of their gender identity and expression. This will enable us to gain a deeper understanding of the diverse needs of TGNB individuals after gender-affirming surgery.

Recruitment, enrollment, and T0 structured interview. Eligible individuals will be telephoned by a member of the research team and asked to participate in the study 10 days after initial GAP admission. An in-person appointment will be scheduled within two weeks to obtain informed consent (see **Protection of Human Subjects**) and complete the Time 0 structured interview (T0); we will offer the option of the in-person appointment to be held in the participant's home or at a nearby, appropriate location (i.e., conducive for a confidential interview) of the person's choice (which may be a VNSNY or CUSON office location if convenient for the participant), for those who may have privacy concerns at their home. If an in-person visit is to be avoided because of COVID-19, we will offer the option of remote data collection using video-conference (e.g., a HIPAA compliant version of Zoom) or phone.

Tracking and scheduling of T1, T2, T3 structured interviews. All activities related to patient recruitment, enrollment, interview scheduling and completion will be recorded in a tracking database to monitor participation and retention rates and to ensure that all interviews are completed within their designated timeframes (i.e., within a 2 week window of the target date). For T1, T2, and T3 interviews, the participant will be invited to schedule an in-person meeting to be held in the participant's home or at a nearby, appropriate location conducive to a confidential interview, as done at T0; if needed, video-conference (e.g. Zoom) or phone will be offered as an alternative.

Recruitment and scheduling for Qual 1 and Qual 2 interviews. The semi-structured, qualitative interviews will be administered to a subset of 60 participants shortly after discharge from GAP (Qual 1) and at 12 months from GAP admission (Qual 2). We will select a purposive sample stratified by gender identity and race/ethnicity to enhance the depth and breadth of our understanding of their experiences. By purposively selecting subgroups based on gender and racial/ethnic identity, we will also be able to explore any intersecting inequalities related to having multiple marginalized identities (e.g., transfeminine and Black). Given the ratio of transfeminine vs transmasculine GAP patients (see Table 2 in the Research Strategy), we propose to recruit n = 45 transfeminine and n = 15 transmasculine qualitative interview participants, and n = 15 participants in each of the following four racial/ethnic subgroups: (1) Black (non-Hispanic), (2) Hispanic, (3) Non-Hispanic White, and (4) Asian, American Indian, Alaska Native, Native Hawaiian, and Pacific Islander participants (see **Table 5** below). The rationale for this purposive sampling strategy is based on potential gender differences in minority stress, psychosocial development, quality of life, and utilization of care,[139] and on documented racial/ethnic disparities in minority stress, health, and access to care within TGNB populations.[84-91,140] We anticipate that *n* = 15 will be sufficient to reach data saturation[141] within each subgroup (but will add additional participants if necessary to reach saturation). Participants will be contacted using their preferred method (e.g., email, phone) to schedule an interview appointment within two weeks of discharge from GAP (Qual 1) and again within two weeks of the 12-month mark after GAP admission (Qual 2). Interviews will take 60-90 minutes, with compensation reflecting the incremental compensation schedule to facilitate retention, conducted by investigators and staff trained in qualitative interviewing techniques and TGNB cultural competence and humility. Qualitative interviews will be scheduled for an in-person meeting to be held in the participant's home or at a nearby, appropriate location conducive to a confidential interview; video-conference (e.g. Zoom) will be

offered as an alternative if needed. Interviews will be audio-recorded and transcribed; interviewer field notes will supplement the recording with observations.

Table 5. Purposive sampling strategy for qualitative interviews with TGNB participants shortly after GAP discharge and at 12-months after GAP admission)

Subgroups	Black (non-Hispanic)	Hispanic	Non-Hispanic White	Asian, American Indian, Alaska Native, Native Hawaiian, Pacific Islander	Total
Transfeminine	11	11	11	12	48
Transmasculine	4	4	4	3	15
Total	15	15	15	15	60

Retention plan. To retain at least 80% of T0 participants throughout the 18-month study period, we will use the retention strategies proven successful in retaining 84.5% of baseline participants at 2-year follow up in a prior study of TGNB individuals led by Dr. Bockting (Project AFFIRM).[6,42-45,120] The retention strategies are as follows:

a. Incremental compensation schedule. Participants will be compensated for their time for each completed interview, with $50 for the T0 interview, followed by $55, $60, and $65 for T1, T2, and T3 respectively. Compensation for the semi-structured, qualitative interviews will be $50 for Qual 1 and $60 for Qual 2.
b. Benefit to the community. We will appeal to participants by explaining the benefits for the community: by participating, they contribute to greater understanding of: the health and wellbeing of TGNB individuals during the transitional period after gender-affirming surgery; how identity development and social support can mitigate the impact of minority stress on HRQoL; and how healthcare providers can provide better care to TGNB individuals to support their physical and mental health.
c. Rapport and relationship with study staff. Investigators and study staff will be trained and supervised by Drs. Bockting and Jackman to ensure cultural competence in establishing rapport and effectively communicating with TGNB participants. This will include using up-to-date terminology and preferred pronouns as expressed by the participant, and demonstrating sensitivity to the particular privacy concerns that may affect a TGNB person during the transition period after gender-affirming surgery. Participants' experience with GAP and the in-person nature (or face-to-face via Zoom) of the interviews is expected to foster a trusting relationship with our project staff, facilitating retention.
d. Bilingual interview staff. To maximize study participation and retention of Spanish speakers, who comprise a substantial portion of the GAP population, we will utilize bilingual interview staff and conduct all interview types in both English and Spanish.
e. Accommodating logistical concerns. For T1, T2, and T3 interviews, for participants who have difficulty scheduling in-person interview appointments, we will offer alternatives such as a video- or phone-interview, with a mail survey as a last resort. For qualitative interviews, we will offer a video appointment if an in-person appointment is not feasible for the participant.
f. Verifying contact information. We will collect and update contact information, including: participants' name, phone, email, online handle (e.g., Facebook, Instagram), and regular mailing address (the latter with an "opt out" option to ensure privacy and prevent potential harm). This contact information will be verified at each study visit, and participants will be asked to indicate their preferred mode of communication (email, text or phone).
g. Regular contact. Participants will receive monthly communications from our study team. This will include establishing a study website, and sending participants notices of monthly updates posted on this site, as well as reminders to update or verify their contact information.
h. Reminders. Non-respondents will be sent reminder emails or texts on days 7, 10, and 14, followed by phone calls on days 18, 22, and 26, and a letter in regular mail on day 24 (unless opted out).
i. Alternative contact information (friends). At T0, participants will be asked to provide name, phone, and e-mail of two friends not living with them. This information can be updated at any time and is verified by participants' response to the monthly e-mails or texts. In case of non-response to reminders, staff will contact friends on day 20 by e-mail or text and day 24 by phone. No information about the study will be revealed; staff will state they are from the Visiting Nurse Service of New York or Columbia University School of Nursing, that their friend provided the e-mail address/phone number, and ask how the person may be reached.

Key informant recruitment

To refine our conceptual model and to inform the development of data collection instruments, we will conduct a

total of 18 key informant interviews with former GAP patients (6 transfeminine, 6 transmasculine; both groups will include participants with binary and nonbinary gender identities) and 6 VNSNY GAP clinicians.

Former GAP patients will be identified by the research team through a random selection from the EHR among individuals discharged from GAP services 12-18 months prior to recruitment. The Director of GAP (Whittington, Clinical Advisor) will make the initial contact via phone or mail to inform the individual of the opportunity to participate in this part of the study. The participant will be given information to contact the research team to complete the informed consent and schedule a time for an interview at their convenience, with $50 in compensation for completing the interview.

To identify GAP clinicians for recruitment, the research team will obtain a list of all clinicians actively providing GAP services; invitations to participate will be sent to a random selection of clinicians via email. The participant will be given information to contact the research team to complete the informed consent and to schedule an appointment at a time that is convenient during non-work hours, with compensation of $50 for completing the interview.

All key informants will be invited to schedule an in-person meeting at a location convenient to them, with the option of meeting at a VNSNY or CUSON office location. If needed, video-conference (e.g., HIPAA compliant version of Zoom) or phone will be offered as an alternative. Each interview will take 60-90 minutes and will be conducted by investigators and study staff trained in qualitative interviewing techniques.

Project Design & Timeline

Project Year	Year 1		Year 2		Year 3		Year 4		Year 5	
Project Month	1-6	7-12	13-18	19-24	25-30	31-36	37-42	43-48	49-54	55-60
Start-up activities (contracts, IRB)	X									
Convene expert advisory group meeting	X	X	X	X	X	X	X	X	X	X
Phase I Data Collection										
Key informant interviews to inform instrument development	X									
Adapt and pilot-test quantitative data collection instruments	X	X								
Phase II Data Collection										
Recruitment & baseline structured interviews		X	X	X	X	X				
Follow-up structured interviews at 3, 12 and 18 months		X	X	X	X	X	X	X	X	
Qualitative interviews with purposive sample at discharge and follow-up		X	X	X	X	X	X	X		
Database development & quality control	X	X	X	X	X	X	X	X	X	
Quantitative data analysis (baseline & follow-up)			X	X	X	X	X	X	X	
Qualitative data analysis			X	X	X	X	X	X	X	
Progress report preparation		X		X		X		X		X
Prepare & submit conference abstracts					X				X	X
Prepare & submit manuscripts			X	X	X	X	X	X	X	X

2.9. Inclusion Enrollment Reports

IER ID#	Enrollment Location Type	Enrollment Location
Study 1, IER 1	Domestic	Eligible home care clients in New York City: Bronx, Brooklyn, Manhattan, Queens

Inclusion Enrollment Report 1

1. Inclusion Enrollment Report Title* : Inclusion Enrollment Report #1

2. Using an Existing Dataset or Resource* : ❍ Yes ● No

3. Enrollment Location Type* : ● Domestic ❍ Foreign

4. Enrollment Country(ies): USA: UNITED STATES

5. Enrollment Location(s): Eligible home care clients in New York City: Bronx, Brooklyn, Manhattan, Queens

6. Comments: Projected enrollment is based on estimates from retrospective analysis of EHR data from the GAP population, supplemented by enrollment data from prior VNSNY studies. Based on the binary gender item in the existing EHR data, we assume that 80% of participants will be transfeminine and 20% transmasculine, within each racial and ethnic category. We will collect self-reported sex assigned at birth, gender identity, and race/ethnicity to capture the diversity within the study population.

Planned

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/ Alaska Native	2	0	0	0	2
Asian	10	5	0	0	15
Native Hawaiian or Other Pacific Islander	3	0	0	0	3
Black or African American	72	18	26	7	123
White	86	22	10	2	120
More than One Race	0	0	36	9	45
Total	173	45	72	18	308

Cumulative (Actual)

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

Section 3 - Protection and Monitoring Plans (Study 1)

3.1. Protection of Human Subjects	ProtectionHumanSubjects_FINAL.pdf
3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?	● Yes ○ No ○ N/A
If yes, describe the single IRB plan	Single_IRB_Plan_FINAL.pdf
3.3. Data and Safety Monitoring Plan	
3.4. Will a Data and Safety Monitoring Board be appointed for this study?	○ Yes ● No
3.5. Overall structure of the study team	

Protection of Human Subjects

1. Risks to human subjects

a. Human subjects involvement, characteristics, and design

The study cohort will be drawn from the population served by the Gender Affirmation Program (GAP) of the Visiting Nurse Service of New York (VNSNY), which provides home-based care to transgender and gender non-binary (TGNB) individuals immediately following gender-affirming surgery. We will conduct structured interviews with individuals who received GAP services (N = 300) at four points in time: shortly after admission to GAP (T0), and at 3, 12, and 18 months after admission (T1, T2, and T3, respectively). We will also conduct semi-structured, qualitative interviews with a purposively selected subsample of 60 participants shortly after discharge from GAP (Qual 1) and again at 12 months after GAP admission (Qual 2). Additionally, during months 4-6 of the project period, we will recruit a total of 18 individuals to complete key informant interviews to inform instrument development. Key informants will include 12 individuals who previously received GAP services (6 transfeminine, 6 transmasculine) and 6 GAP clinicians. We will use a single IRB for the proposed study, the VNSNY IRB.

Study cohort criteria

The population of interest are TGNB individuals who (i) have received VNSNY's GAP services; (ii) reside in one of VNSNY's four main regions (Brooklyn, Bronx, Manhattan, and Queens); (iii) are at least 18 years old; and (iv) speak either English or Spanish as their preferred language. Based on our preliminary data collected from GAP patients and trends in referrals over the last year, we expect that 80% of GAP participants during the course of our enrollment period will be transfeminine and 20% transmaculine. They will include both binary transgender women and men as well as individuals who self-identify as gender nonbinary. As of yet, the proportion of the GAP population that may self-identify as gender nonbinary is unknown; we will be able to determine that from data collected at baseline (T0). We have chosen this inclusive approach given the diversity in gender identity and expression among the TGNB population, all of whom may pursue gender-affirming surgical procedures and thus enroll in GAP. Individuals receiving GAP services who meet the aforementioned criteria will be considered eligible, regardless of the type of surgery they had and regardless of their gender identity and expression. This will enable us to gain a deeper understanding of the diverse needs of TGNB individuals after gender-affirming surgery.

Within the study cohort, we will select a subsample of 60 participants for qualitative interviews shortly after discharge from GAP (Qual 1) and at 12 months from GAP admission. We propose to recruit n = 45 transfeminine and n = 15 transmasculine qualitative interview participants, and n = 15 participants in each of the following four racial/ethnic subgroups: (1) Black (non-Hispanic), (2) Hispanic, (3) Non-Hispanic White, and (4) Asian, American Indian, Alaska Native, Native Hawaiian, and Pacific Islander participants (see also **Recruitment and Retention**).

Key informant criteria

Former GAP patients will be identified by the research team through a stratified random selection from the EHR among individuals discharged from GAP services 12-18 months prior to recruitment. We will use retrospective EHR data to identify a potential pool of key informants for two subgroups: transfeminine and transmasculine previous GAP patients. To identify GAP clinicians for recruitment, the research team will obtain a list of all clinicians actively providing GAP services; invitations to participate will be sent to a random selection of clinicians via email.

b. Study procedures, materials, and potential risks

We will collect, extract and/or acquire data from several sources. Quantitative data sources will include: data extracted from the EHR after the informed consent process has been completed, including administrative and clinical assessment data routinely collected by the HHC clinician upon admission; structured patient interviews conducted shortly after GAP admission (T0) and at 3, 12, and 18 months (T1, T2, T3); and publicly available geographic data sources on NYC neighborhood characteristics. Qualitative data will include: key informant

interviews conducted in the first 6 months of the project period to refine our conceptual model and inform instrument development; and semi-structured interviews conducted with a purposively selected subsample (see above under "Study cohort criteria" and in **Recruitment and Retention**) of participants shortly after GAP discharge (Qual 1) and at 12 months from GAP admission (Qual 2). A tracking database will be developed using Microsoft Access to record all patient recruitment, enrollment, and data collection activities, monitoring participation and retention rates, and ensuring consistent implementation of data collection protocols and interview scheduling. Quantitative interview data will be submitted into the web-based platform REDCap. All quantitative data will be cleaned and merged using SAS, then analyzed using statistical software (e.g., SAS, Stata, or R). Qualitative interview transcripts will be stored and analyzed in DeDoose, a web-based qualitative analysis software.

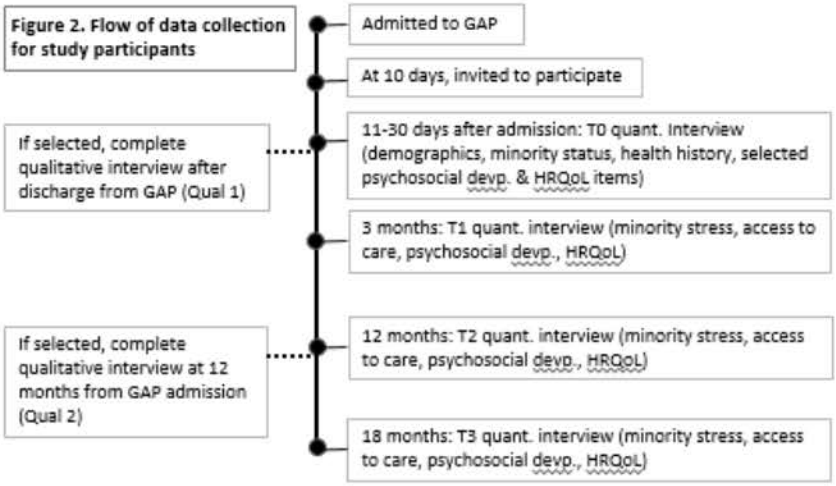
Recruitment, enrollment and data collection procedures for study cohort

A HIPAA Waiver of Authorization will be submitted to the IRB for review and approval along with the full human subjects protocol. This waiver will request approval for accessing the EHR data elements needed to identify eligible GAP patients and their contact information. This waiver will also include a request for permission to access a limited set of EHR elements of eligible individuals who do not enroll in the study, in order to assess for selection bias. The flow of data collection for participants in the study cohort is shown below in Figure 2, which is also available in the Research Strategy.

Eligible individuals will be telephoned by a trained member of the research team and asked to participate in the study 10 days after initial GAP admission. This approach to recruitment is consistent with that of several prior studies conducted by the VNSNY Research Center in which VNSNY patients were recruited for study participation and primary data collection.[80,123-125,128,129,132] An in-person appointment will be scheduled within two weeks to complete the informed consent process as well as the Time 0 structured interview (T0). We will offer the option of the in-person appointment to be held in the participant's home or at a nearby, appropriate location (i.e., conducive for a confidential interview) of the person's choice (which may be a VNSNY or CUSON office location if convenient for the participant), for those who may have privacy concerns at their home. If an in-person visit is to be avoided because of COVID-19 or for any other reason, we will offer the option of remote data collection using video-conference (e.g., a HIPAA compliant version of Zoom) or phone. The same procedures will be followed for the T1, T2, and T3 structured interviews, and for the Qual 1 and Qual 2 qualitative interviews with purposively selected participants.

Each interview will take 60-90 minutes to complete, and will be conducted by trained study staff, supervised by investigators to ensure sensitivity in communicating effectively with TGNB participants diverse in race/ethnicity, and to optimize the reliability and validity of the collected information. As done in our prior work, we will translate all interview instruments into Spanish and deploy bilingual interviewers, given the substantial proportion of GAP patients whose preferred language is Spanish. With permission from participants, qualitative interviews will be audio-recorded and transcribed by a HIPAA-compliant transcription company. The interviewers will also take written field notes to supplement the recording with observations during each interview.

To maximize retention, we will use several strategies (see **Recruitment and Retention** for more detail). Participants will be asked to provide their phone number(s), email and regular mailing address, as well as social media handle (e.g., Facebook, Instagram), and indicate their preferred method of contact. Monthly brief messages with project updates from the study team will include reminders to update their contact information. We will also ask participants to provide contact information for up to 2 friends who we may discretely contact in case we have not



been successful at follow-up to reach the participant directly. Participants will be compensated for their time and effort for each completed interview: $50 for the T0 interview, followed by $55, $60, and $65 for T1, T2, and T3 respectively. Compensation for the semi-structured, qualitative interviews will be $50 after discharge from GAP and $60 at 12 months.

Recruitment, enrollment and data collection procedures for key informants

To recruit former GAP patients identified as eligible for key informant interviews, the Director of GAP (Whittington, Clinical Advisor) will make the initial contact via phone or mail to inform the individual of the opportunity to participate in this part of the study. The person will be given information to contact the research team to complete the informed consent and schedule a time for an interview at their convenience, with $50 in compensation for completing the interview.

To recruit GAP clinicians randomly selected for key informant interviews, the research team will send invitations to participate via email. The clinician will be given information to contact the research team to complete the informed consent and to schedule an appointment at a time that is convenient during non-work hours, with compensation of $50 for completing the interview.

All key informants will be invited to schedule an in-person meeting at a location convenient to them, with the option of meeting at a VNSNY or CUSON office location. If needed, video-conference (e.g., Zoom) or phone will be offered as an alternative. Each interview will take 60-90 minutes and will be conducted by study staff trained and supervised in qualitative interviewing techniques and in communicating effectively with diverse TGNB participants. Interviews will be audio-recorded and transcribed by a HIPAA-compliant transcription company. The interviewers will also take written field notes to supplement the recording with observations during each interview.

Potential risks

The following are potential risks that a participant in our study may face:

1. Breach of confidentiality of research data;
2. Being “outed” and potential associated harm;
3. Discomfort with being asked personal questions about their identity; stress, discrimination, and violence; psychosocial development; access to care; and HRQoL, including sexual functioning and satisfaction.

2. Adequacy of protection against risks

a. Informed consent

Consent for study cohort participants

The informed consent process will be completed at the beginning of the T0 appointment. The consent will include: permission for the study team to access the patient’s VNSNY EHR records beyond what was available for recruitment (e.g., OASIS assessment data); permission to contact the participant for subsequent structured (quantitative) interviews (T1, T2, T3); and permission to contact the participant for qualitative interviews shortly after discharge from GAP and at 12 months from GAP admission (Qual 1 and Qual 2), should the person be selected to be part of the purposive qualitative subsample. All participants will be informed that their participation is completely voluntary, and that they can decline to answer any interview questions, stop an interview at any time, or withdraw from the study if they so wish, without in any way affecting their eligibility or receipt of HHC services or jeopardizing their relationship with VNSNY or CUSON. All participants will be informed about the confidentiality safeguards of the data collected in the interviews and of their personal information. For the qualitative interviews, participants will be informed that the interview will be audiotaped and transcribed by a HIPAA-compliant transcription company.

All quantitative interview staff involved in completing the informed consent process will be employed, trained, and supervised directly by the VNSNY Research Center, which has extensive experience in recruiting, training, and supervising interviewers.[80,123-125,128,129,132] All qualitative interview staff will be employed, trained, and

supervised by CUSON investigators Bockting and George. Training will include an overview of study objectives and consent procedures, review of general interviewing techniques and methods for achieving respondent cooperation, review of each interview question, and practice interviews. Training for this study will also include cultural competence and humility in communicating effectively with particpants diverse in gender identity and expression and in race/ethnicity. All project staff responsible for recruiting participants and conducting interviews will be fully trained in appropriate approaches for recruitment to ensure voluntary participation.

Consent for key informants

Upon invitation to complete a key informant interview, prospective informants will be told about the overall purpose of the study, the goal of the key informant interviews, and how their responses will be used to assist in refinement of the study's conceptual model and in preparation of the research tools and instruments. If the person agrees, they will be invited to schedule an appointment. The informed consent process will be completed during this appointment prior to completing the interview. The person will be informed that their participation is completely voluntary, and they can decline to answer any interview questions or stop an interview at any time. The person will also be informed that their responses or their decision whether or not to participate in the interview will not in any way affect their eligibility or receipt of HHC services or jeopardize their relationship with VNSNY or Columbia University. GAP clinicians will also be informed that their responses or decisions to complete the interview will not in any way affect their employment or be individually shared with their employer such that their responses would be identifiable. All key informants will be informed about the confidentiality safeguards of the data collected in the interviews and of their personal information. They will also be informed that the interviews will be audio-recorded and transcribed by a HIPAA-compliant transcription company.

b. Protections against risk

All investigators and study staff have or will have completed training on the protection of human subjects in research as recommended by the Office of Human Research Protection by the time of their involvement in the study. Key personnel also have been trained in the human subject research implications of the Health Insurance Portability and Accountability Act (HIPAA); other staff also has been trained or will receive HIPAA training. Other members of the study team will work with analytic data sets that will be de-identified. The proposed participant and key informant identification and interview procedures have been successfully used in several other studies at the study sites.

We will have the following procedures in place to protect against the risks of a breach of confidentiality, being outed, and discomfort participants may experience during data collection.

1. Breach of confidentiality of research data

All participants will be informed about the potential for loss of confidentiality and the procedures we have in place to minimize this risk. All data used for recruitment and scheduling, quantitative data collection and extraction, and analysis will be stored on a secure server maintained by VNSNY in a password-protected, designated folder accessible only to project staff involved in data collection, database development and analysis. This secure server is maintained by VNSNY's Information Technology department for use by the VNSNY Research Center. The server is password protected, HIPAA compliant and continually backed up. Project-specific files are stored in a restricted folder only accessible to project staff who need to access the files for data collection, dataset preparation and analysis. Within that restricted, project-specific folder, we will designate a subfolder that contains identifiable files with contact information used for recruitment, tracking and scheduling of interviews to be stored separately from the interview response data and EHR data not needed for contacting patients (e.g., health history and clinical assessment data upon GAP admission). Only project staff who need access to the contact information for recruitment and scheduling will be granted access to that subfolder. Within that subfolder, the identifiable information will be stored in an Access database, which has been used successfully for tracking efforts related to recruitment and scheduling of interviews in several prior studies conducted by the VNSNY Research Center. A crosswalk file with a study-specific ID number will be created to allow for de-identified merging.

Quantitative interview data will be entered by trained interviewers into REDCap, encrypted and stored securely

on this web-based platform, protected by firewalls and backed up continuously. All quantitative data will be cleaned and merged using SAS, then analyzed using statistical software (e.g. SAS, Stata, or R), within the project-specific, password protected folder on the VNSNY secure server. This designated folder will be accessible only to project staff involved in data analysis. Investigators and study staff will then be able to access a de-identified database via a secure web-based portal / ftp site. Qualitative interview transcripts will be de-identified and stored on a secure server maintained by CUSON, which will be protected by firewalls and backed up continuously, before being entered into DeDoose, which is a web-based qualitative analysis software solution that is encrypted and secure. Data will remain archived upon completion of the study for at least 7 years.

The research study will also be covered by a Certificate of Confidentiality issued by the Department of Health and Human Services (DHHS), providing protections to the researchers from having to release the names or other identifying characteristics of participants.

2. Being “outed” and potential associated harm

The focus of the study is on transgender and gender nonbinary (TGNB) individuals who have a stigmatized identity. We expect their gender minority status to be known to some but not to others. The confidentiality around their status is of utmost importance, particularly given the potential harm of disclosure (i.e., exposure to prejudice events and experiences of discrimination which may include rejection, abuse, and violence). This risk will be discussed with potential participants during the informed consent process. As outlined above, all identifying information will be separated from the data and stored in secure databases at VNSNY or CUSON, encrypted, and accessible only via username and password to the investigators or their designees (i.e., study staff). During retention efforts, communications will not mention the nature of the study or the association with Columbia’s Program for the Study of LGBT Health; rather, study staff will indicate that they are with VNSNY or CUSON. Finally, a Certificate of Confidentiality will be obtained from DHHS. With this Certificate, the researchers are protected from releasing research data in which participants are identified without their written consent. This is especially important as participants may report having been involved in illegal activity, (e.g., sex work). However, the Certificate does not prevent the researchers from reporting suspected or known neglect or sexual or physical abuse of a child, or threatened violence to self or others. Such information will be reported to the appropriate authorities in accordance with state or federal law.

3. Discomfort with being asked personal questions

Participants may experience discomfort with being asked personal questions about their identity; stress, discrimination, and violence; psychosocial development; access to care; and HRQoL, including sexual functioning and satisfaction. In case participants have concerns about discomfort they experience during the study, they can contact the study staff or investigators, which include licensed mental health professionals (e.g., Drs. Bockting, who is a New York State Licensed Psychologist, Director of the Columbia Gender Identity Program, and expert in the mental health needs of TGNB individuals). Our extensive experience conducting research with TGNB people and other vulnerable populations, however, indicates that the risk of such discomfort is minimal, especially since the interviews will be conducted in-person in mutually agreed upon, safe locations, or alternatively, via Zoom. Participants can monitor their level of self-disclosure and may choose not to answer questions or discontinue participation at any time. Nevertheless, study staff will pay close attention to any signs of distress that may emerge during the interviews (fidgety behavior, distractibility, signs of discomfort) or any mention of distress; even if no signs are present. Before the end of the study visits, study staff will ask participants how they felt throughout the study visit. If a participant acknowledges being distressed, a referral will be offered to appropriate support and health services. In case of risk for suicide or self-harm, standard mental health service procedures will be followed to ensure participants are safe and protected. Study staff will consult with Dr. Bockting, Licensed Psychologist, if any distress occurs that rises to this level.

Training and supervision of interview staff will also help to ensure that discomfort is minimal for participants. Interviewers will be trained in cultural competence and humility in communicating effectively with participants diverse in gender identity, gender expression, and race/ethnicity. This will include competence in understanding and responding appropriately to the particular concerns that may affect TGNB particpants of

diverse racial and ethnic backgrounds. With guidance from the GAP Director (Whittington, Clinical Advisor) and Dr. Bockting, experienced staff will go out on initial study visits with new interviewers. They will continuously monitor the performance of each interviewer, which will include ensuring that staff use TGNB-friendly terminology, name and pronouns as expressed by the participant, and being responsive to other considerations related to the specific vulnerabilities of TGNB individuals and TGNB individuals of color during the transition period after gender-affirming surgery.

3. Potential benefits of the proposed research to participants and others

As this study is not a clinical trial, there are no intended, direct benefits to individual participants. However, it is possible that some TGNB individuals who participate either as part of the study cohort or as key informants will experience psychological benefit from sharing their perspectives on their health, healthcare relationships, their needs during the transitional period after surgery, psychosocial development and quality of life. Given that the TGNB community faces persistent stigma, discrimination, and barriers to services, participants may find it affirming to have a research team dedicating time to inquire about their experiences in a safe and non-judgmental context.

Findings from the study will benefit the broader TGNB population by strengthening the evidence on the psychosocial and healthcare needs of TGNB individuals during the transitional period after gender-affirming surgery. In turn, study findings and their implications for future interventions will have the potential to improve TGNB individuals' engagement in their care and mitigate the pervasive disparities in healthcare access, outcomes, and quality of life affecting this population.

4. Importance of the knowledge to be gained

TGNB people have gained greater visibility in US society in recent years. However, the physical and mental health of TGNB individuals remains a critical public health issue.[3,5] TGNB people face persistent stigma, discrimination, and barriers to services that affect their health and wellbeing over the life course.[6,7] Since the 1990s, a growing body of research has focused on TGNB health, largely focused on care for individuals early in their gender transition as well as HIV risk.[8-13] There is a dearth of evidence on the healthcare needs of TGNB individuals after surgery, their psychosocial adjustment during this phase of their identity development, their quality of life and long-term physical and emotional wellbeing. The goal of this prospective, mixed methods, longitudinal cohort study is to build a rich evidence base on TGNB identity development after surgery and the long-term healthcare needs of TGNB individuals, examining changes in multiple domains of quality of life and their relationships with healthcare providers. Our study will be the first to examine the psychosocial development of a diverse cohort of TGNB individuals at multiple points in time following gender-affirming surgery and assess health-related quality of life after surgery comprehensively. The study will address a significant gap in the current evidence on best practices to support TGNB individuals during a pivotal life course transition, with the potential to improve their engagement in care and mitigate the pervasive disparities in healthcare access, outcomes, and quality of life affecting this population.

Since the main risks of the study are an unlikely breach of confidentiality, the remote possibility of inadvertently being "outed" (given the measures we are taking to prevent such a breach and disclosure), and some discomfort in answering personal questions during interviews (from which participants can withdraw at any time); and the major benefit is the advancement of scientific knowledge to inform the future development of services and interventions to facilitate psychosocial development and improve access to care and HRQoL for this health disparity population, the risks appear very minor in comparison to the substantial expected benefit.

Single IRB Plan

We will use a single IRB for the proposed study, the VNSNY IRB. Written agreement of the proposed single IRB plan was obtained from the Trustees of Columbia University in the City of NY and the University of Pennsylvania sub-awardees and will be renewed if awarded.

Section 4 - Protocol Synopsis (Study 1)

4.1. Study Design

4.1.a. Detailed Description

4.1.b. Primary Purpose

4.1.c. Interventions

Type	Name	Description

4.1.d. Study Phase

Is this an NIH-defined Phase III Clinical Trial? ❍ Yes ❍ No

4.1.e. Intervention Model

4.1.f. Masking ❍ Yes ❍ No

❑ Participant ❑ Care Provider ❑ Investigator ❑ Outcomes Assessor

4.1.g. Allocation

4.2. Outcome Measures

Type	Name	Time Frame	Brief Description

4.3. Statistical Design and Power

4.4. Subject Participation Duration

4.5. Will the study use an FDA-regulated intervention? ❍ Yes ❍ No

4.5.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/ Investigational Device Exemption (IDE) status

4.6. Is this an applicable clinical trial under FDAAA? ❍ Yes ❍ No

4.7. Dissemination Plan

Delayed Onset Studies

Delayed Onset Study#	Study Title	Anticipated Clinical Trial?	Justification
The form does not have any delayed onset studies			

Vertebrate Animals

Not Applicable.

Select Agents

No select agents will be involved in this study.

Multiple PI Leadership Plan

Rationale. The proposed study is a multiple PI project. The justification for the multiple PI leadership plan is that this study will require the joint expertise of these two PIs to achieve the study aims. The multidisciplinary nature of the study's aims and the mixed methods design call for a joint leadership structure. Dr. Ryvicker (MPI/Contact PI) brings extensive experience conducting research on disparities in healthcare access and outcomes, home- and community-based services for underserved populations, and social determinants of health, including data science projects that link neighborhood environmental data with patient electronic health record and service utilization data. Dr. Ryvicker's expertise will be needed for oversight of participant recruitment and coordination with VNSNY GAP clinical leadership, quantitative data collection, preparation of the analytic dataset involving extraction and merging of EHR files with structured interview data, quantitative analysis, and situating study findings within the context of health disparities research. Dr. Bockting has a track record of NIH-funded research in transgender health and is an internationally known expert in gender-affirming healthcare and TGNB identity development across the lifespan. His expertise is needed for oversight in selecting and adapting measures specific to TGNB psychosocial development and HRQoL, instrument and protocol preparation, qualitative data collection and analysis, and situating all study activities and interpretation of findings within the latest evidence on TGNB health.

Governance and organizational structure. All scientific decisions will be made jointly by the two PIs. Ryvicker will serve as Contact PI. She has experience in obtaining NIH funding and grants administration. She will be responsible for project administration and budget, as well as communication between the PIs and NIH. Drs. Bockting and Ryvicker have worked collaboratively on this project since its inception. To communicate effectively the project staff (PIs, project management and coordination staff, the statistician, programming and analytic support staff) will meet on a weekly basis. All senior personnel (PIs and Co-Investigators) will meet at least monthly throughout the study and more frequently as needed. The Project Manager (VNSNY) will provide documentation and administrative support to set up routine meetings. Meetings will alternate between CUSON and VNSNY; both institutions will provide meeting space as an in-kind contribution to the project.

Administrative, technical, and scientific responsibilities. The project staff will be selected, trained, and supervised jointly by the PIs; standard operating procedures and quality monitoring protocols will be developed jointly. Both PIs will be responsible for maintaining all IRB approvals and project-specific oversight. Both PIs will be involved in all aspects of the study while each taking primary lead in different activities.

Dr. Ryvicker will lead the VNSNY team which includes Co-I Dr. Kathryn Bowles, Co-I Dr. Kasey Jackman, biostatistician Yolanda Barrón-Vayá, a project coordinator, data analyst/programmer, a research analyst and quantitative interview staff. Dr. Ryvicker will be the primary lead in: overseeing activities related to participant recruitment, retention, and tracking; quantitative data collection and extraction; database development and preparation of the quantitative analytic dataset; quantitative analysis; and facilitating communication with program leadership of VNSNY's GAP. Dr. Ryvicker will oversee the subaward contract to CUSON for Dr. Bockting's team, UPenn for Dr. Bowles' role as Co-I and the consultant contract for Dr. Kasey Jackman as Co-I.

Dr. Bockting will lead the CUSON team which includes Co-I Dr. Maureen George, a project coordinator and research assistant. Across the CUSON and VNSNY partnership, Dr. Bockting will be the primary lead in: Training and supervision of investigators and study staff in TGNB health and cultural competency; selection and adaptation of existing measures related to gender identity and expression, psychosocial development, access to care for TGNB people, gender affirmation, and TGNB-specific aspects of HRQoL; overseeing the development of the qualitative interview guide, qualitative data collection, analysis, and interpretation; and coordinating collaboration with the expert advisors. Dr. Bockting will also take the lead in the dissemination of findings to the TGNB community and the field of transgender health.

Drs. Ryvicker and Bockting will be equal partners and share responsibilities in decision-making, administration, implementation, reporting, and dissemination of findings.

Communication plan

Scientific progress will be reviewed at least monthly, and Drs. Ryvicker and Bockting will meet in person to review progress and address issues that arise. In order to ensure smooth communication across the study, standardized electronic communication using the project management suite of Microsoft tools (e.g. Microsoft Teams, Planner, etc) will be used.

Key roles and responsibilities. A detailed work plan will be created outlining administrative, technical and scientific responsibilities for each task and the staff person leading the effort. A high-level responsibility matrix at the organizational level is provided below.

	VNSNY	CUSON
Serve as the contact PI	✓	
Complete subcontracts	✓	
Secure approval from Institutional Review Board	✓	✓
Prepare data collection protocols and instruments	✓	✓
Facilitate communication about study activities with VNSNY GAP clinical leadership	✓	
Oversee coordination and facilitate communication with expert advisory group		✓
Participant cohort recruitment, retention and tracking	✓	
Data collection of structured interviews (quantitative)	✓	
Preparation of quantitative analytic dataset	✓	
Quantitative data analysis (Aims 1 & 2)	✓	
Oversee qualitative interviewee recruitment (key informant interviews; Qual 1 & Qual 2 interviews)		✓
Qualitative data collection	✓	✓
Qualitative data analysis (Aim 3)		✓
Manage reporting requirements to NIH	✓	
Prepare conference abstracts for submission	✓	✓
Present findings at scientific conferences	✓	✓
Prepare and submit manuscripts for scholarly publications	✓	✓

Conflict resolution. If a conflict develops, the PIs will meet and attempt to resolve the dispute. If they fail to resolve the dispute, they will seek the assistance of Dr. Elizabeth Corwin (Vice Dean of Research, CUSON) and Margaret McDonald (Associate Director of the VNSNY Research Center). If the PIs continue to have difficulty resolving a dispute which jeopardizes their ability to complete the proposed project, they will ask Dr. Larson and Ms. McDonald to appoint a committee to oversee the process for resolving the dispute. The overarching goal throughout this process will be to protect the integrity of the project.

Change in location. If a PI moves to a new institution, attempts will be made to transfer the relevant portion of the grant to the new institution. In the event that the PI cannot carry out his or her duties, an equally qualified PI will be recruited as a replacement.

Budget allocation. In the budget, expenses, salaries and finance and administration costs have been allocated in accordance with the resources needed by each PI to perform their responsibilities in the grant.

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The Trustees of Columbia University in the City of New York
SPONSORED PROJECTS ADMINISTRATION
SUBCONTRACT PROPOSAL FACE PAGE

PRIME INSTITUTION Legal/Corporate Name **Visiting Nurse Service of New York**	**SUBCONTRACT INSTITUTION** Legal/Corporate Name **The Trustees of Columbia University in the City of NY**
Principal Investigator: Miriam Ryvicker	Principal Investigator: Walter Bockting
Department: Center for Home Care Policy and Research	Department: School of Nursing
Address: 5 Penn Plaza, Fl 12	☒ **Medical Center:** 630 West 168th Street, Box 49
City: New York State: NY Zip: 10001	New York, NY 10032-3702
Email: miriam.ryvicker@vnsny.org Phone#: 212-609-5775	grants-office@columbia.edu Ph: (212) 305-4191 Fax: (212) 305-3697
EIN #: 133189926	EIN # 135598093 DUNS #: 621889815
DUNS #: 078881778	☐ **Morningside:** 615 West 131st Street
For Profit: ☐ Non Profit: ☒ Fiscal Year End: 12/31 FCOI Policy: Y ☒ N ☐	New York, NY 10027-7922 ms-grants-office@columbia.edu Ph: (212) 854-6851 Fax: (212) 854-2738 EIN # 135598093 DUNS #: 049179401
	For Profit: ☐ Non Profit: ☒ Fiscal Year End: 06/30 FCOI Policy: Y ☒ N ☐

Prime Sponsor: NIH

Title of Project: Gender Affirmation, Quality of Life, and Access to Care: A Mixed-Method Longitudinal Investigation

Dates of Proposed Project Period: 04/01/2021-03/31/2026
Dates of Initial Budget Period: 04/01/2021-03/31/2022

Estimated Total Costs (Direct and Indirect):

First Year Direct: $141,303	First year Indirect: $87,608	Total: $228,911
Project Total Direct: $784,809	Project Total Indirect: $486,581	Project Total: $1,271,390

Human Research Subjects:	Y ☒ N ☐	IRB Approval: ☒ Pending ☐ Approval Date:	
Laboratory Animals:	Y ☐ N ☒	IACUC Approval: ☐ Pending ☐ Approval Date:	
Fixed Price Subaward:	Y ☐ N ☒	Cost Reimbursement Subaward: Y ☒ N ☐	
Per Patient Subaward:	Y ☐ N ☒	Cost per Patient: $	

AUTHORIZED COLUMBIA UNIVERSITY OFFICIAL:

Name: Ariel Gutierrez Title: Senior Project Officer

Address: 630 West 168th Street, Box 49
New York, NY 10032-3702

Email Address: grants-office@columbia.edu Telephone Number: 212-305-4191

We agree to abide by the prime sponsor's policies and are prepared to negotiate the necessary inter-institutional agreements consistent with those policies.

SIGNATURES:

Principal Investigator: Walter Bockting PhD Date: 06.22.2020

Authorized Official: Ariel Gutierrez Date: 6/22/2020

Revision date: March 2015

SUBRECIPIENT COMMITMENT FORM

Complete and return a signed copy to VNSNY's Center for Home Care Policy & Research

Subrecipient Legal Name: Trustees of the University of Pennsylvania

Subrecipient PI Name: Kathryn Bowles

Address where research will be performed: 340 Clarie Fagin Hall, 418 Curie Blvd City: Philadelphia State: PA

Zip Code +4 (Please enter your performance site 9 digit zip code required for NIH submissions) 19104-4217

Proposal Title: Gender Affirmation, Quality of Life, and Access to Care: A Mixed-Method Longitudinal Investigation

Performance Period Begin Date: April 1, 2020 End Date: March 31, 2026

VNSNY's PI Name: Dr. Miriam Ryvicker

Prime Sponsor: NIH

SECTION A – Proposal Documents

The following documents are included in our proposal submission and covered by the certifications below (check as applicable):

- ☑ **STATEMENT OF WORK**
- ☑ **BUDGET AND BUDGET JUSTIFICATION** (required)
  Direct Cost Total $ 63,875 Indirect Cost Total $ 39,905 Total Amount Requested $ 103,780
- ☑ Biosketches of all Key Personnel, in agency-required format
- ☐ Other: _____
- ☐ Other: _____

SECTION B - Certifications

1. **Facilities and Administrative Rates** included in this proposal have been calculated based on:
   - ■ Our federally-negotiated F&A rates for this type of work, or a reduced F&A rate that we hereby agree to accept.
   - ☐ Other rates (please specify in Section C *Comments below).*

2. **Type of Organization:** University

3. **Small Business Concern:** ☐ **Yes** ☐ **No**
   Subrecipient represents that it is a small business concern as defined in 13 CFR 124.1002.
   If "Yes": Subrecipient represents that it is a: Select one

4. **Registered in System of Award Management (SAM):** ☑ **Yes** ☐ **No**

5. **Cost Sharing:** ☐ **Yes** ■ **No** **Amount:** _____
   Cost sharing amounts and justification should be included in the subrecipients budget.

6. **Human Subjects:** ■ **Yes** ☐ **No** ☐ **Not applicable** **If yes, enter U.S. Federal-Wide Approval.No.** 00004028
   ☐ **No FWA# is available**

   Please Note: ***If "Yes",*** *If funded and applicable, copies of the IRB approval form must be provided before any subaward will be issued. In accordance with VNSNY policy, VNSNY's IRB must conduct a secondary review of the subaward work and issue a companion approval before any subaward will be issued.*

7. **Conflict of Interest:**
   - ☑ Subrecipient Organization/Institution certifies that it has an active and enforced conflict of interest policy that is consistent with the provision of OMB Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards 2 CFR §200.112, "Conflict of Interest." Subrecipient also certifies that, to the best of its knowledge, (1) all financial disclosures have been made related to the activities that may be funded by or though a resulting agreement and required by its conflict of interest policy; and (2) all identified conflicts of interest have or will have been satisfactorily managed, reduced or eliminated in accordance with subrecipient's conflict of interest policy prior to the expenditure of any funds under any resultant agreement.
   - ☐ Not applicable because this project is not being funded by federal funding or any program requiring financial disclosures.
   - ☐ Subrecipient does not have an active and/or enforced conflict of interest policy and hereby agrees to abide by VNSNY's policy, available at https://www.vnsny.org/for-healthcare-professionals/vnsny-research-center/.

8. Debarment, Suspension and Other Responsibility Matters:

Subrecipient also certifies that neither it nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from receiving funds from any Federal department or agency; it is not delinquent on any Federal debt; it is in compliance with Drug Free Workplace Act of 1988; it is in compliance with 42 CFR par 50 (Objectivity in Research) regarding financial conflict of interest; no Lobbying was performed with regard to the proposal; and assurances are on file for Misconduct in Science, Civil Rights, Handicapped Individuals, Sex Discrimination and Age Discrimination.

9. Audit and Access to Records:

Subrecipient certifies by signing this subrecipient commitment form that it complies with the Uniform Guidance, will provide notice of the completion of required audits and any adverse findings which impact this subaward as required by parts 200.501-200.521, and will provide access to records as required by parts 200.336, 200.337, and 200.201 as applicable.

SECTION C- Audit Status

Does the subrecipient receive an annual audit in accordance with 2 CFR Subpart F 200.501? ☑ Yes ☐ No

- If "Yes": Fiscal year ending of most recent audit 2019.
  - Is audit available in the Federal Audit Clearing house? ☑ Yes ☐ No (If no, complete VNSNY's A133 certification on page 3 and submit required documentation with Subrecipient Commitment Form.

SECTION D - Comments

Please provide an explanation if you are unable to complete this form in full, and feel free to include any other relevant comments/notes below

APPROVED FOR SUBRECIPIENT

The information, certifications and representations above have been read, signed and made by an authorized official of the Subrecipient named herein. The appropriate programmatic and administrative personnel involved in this application are aware of agency policy in regard to subawards and are prepared to establish the necessary inter-institutional agreements consistent with those policies.

Signature of Subrecipient's Authorized Official	Trustees of the University of Pennsylva Legal Name of Subrecipient's Organization/Institution
Amy Camilleri, Associate Director Name and Title of Authorized Official	3451 Walnut Street, 5th Floor Address
pennaors@lists.upenn.edu Email	Philadelphia, PA 19104-6205 City, State, Zip
215-898-7293 Phone	23-1352685 Federal Employer Identification Number (EIN), if applicable
06/17/2020 Date	04-225-0712 Subrecipient's DUNS
	PA-003 Subrecipient's Congressional District

Penn Nursing

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Biobehavioral Health Science
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Philadelphia, PA 19104-4217
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bowles@nursing.upenn.edu
www.nursing.upenn.edu

Kathryn H. Bowles, PhD, RN, FAAN, FACMI
vanAmeringen Professor in Nursing Excellence

June 16, 2020

Dear Dr. Ryvicker,

It is with great excitement and interest that I submit this letter of intent to participate as a Co-Investigator on this innovative study, **Gender Affirmation, Quality of Life, and Access to Care: A Mixed-Method Longitudinal Investigation**. Health related quality of life among transgender and gender non-binary individuals is so important to their long term adjustment, health, and welfare. If this project is funded, I greatly look forward to participating in this important work and commit to being responsible for helping to oversee study activities, enrollment and retention, data collection, selection of HRQOL instruments, interpretation of findings, and dissemination.

Kathryn H. Bowles, PhD, RN, FAAN, FACMI
vanAmeringen Professor in Nursing Excellence
University of Pennsylvania School of Nursing
Vice President and Director of the Center for Home Care Policy and Research
Visiting Nurse Service of New York

June 11, 2020

Miriam Ryvicker, PhD
Senior Research Scientist
Center for Home Care Policy and Research
Visiting Nurse Service of New York

Walter Bockting, PhD
Co-Director, Program for the Study of LGBT Health
Professor of Medical Psychology (In Psychiatry and Nursing)
Columbia University

Re: "Gender Affirmation, Quality of Life, and Access to Care: A Mixed-Method Longitudinal Investigation"

Dear Drs. Ryvicker and Bockting,

I am writing this letter of support for the proposal to the National Institutes of Health (NIH) entitled **"**Gender Affirmation, Quality of Life, and Access to Care: A Mixed-Method Longitudinal Investigation.**"** The proposed study is a collaboration between the Visiting Nurse Service of New York (VNSNY) and the Columbia University School of Nursing.

If awarded I will support the project by bringing to the study team my expertise on the vulnerability, health and wellbeing of TGNB people, particularly in the areas of stress and mental health. I will participate in the development of the qualitative interview guides; training of the research team and study staff in cultural competency in working with TGNB individuals and their communities; analysis and triangulation of qualitative and quantitative data; and the interpretation and dissemination of study findings. I understand that I will be compensated at a rate of Institutional Base Salary for a total of EFFORT in each of the five years of the study.

I will be an active participant in all phases of this study. I look forward to working on this first of its kind research study to understand the psychosocial adjustment and health-related quality of life of TGNB individuals after gender-affirming surgery. I look forward to working with the research team on this important project.

Sincerely,

Kasey Jackman, PhD, RN, PMHNP-BC

June 16, 2020

Miriam Ryvicker, PhD
Senior Research Scientist
Center for Home Care Policy and Research
Visiting Nurse Service of New York

Walter Bockting, PhD
Co-Director, Program for the Study of LGBT Health
Research Scientist, New York State Psychiatric Institute
Professor of Medical Psychology (In Psychiatry and Nursing)
Division of Gender, Sexuality, and Health
Columbia Psychiatry / NYSPI and the Columbia University School of Nursing

Dear Drs. Ryvicker and Bockting,

As the Director of the Gender Affirmation Program (GAP) of the Visiting Nurse Service of New York (VNSNY), I enthusiastically support the study proposed in your R01 application to the National Institute of Nursing Research (NINR) entitled "Gender Affirmation, Quality of Life, and Access to Care: A Mixed-Method Longitudinal Investigation." The proposed study is a collaboration between the Visiting Nurse Service of New York (VNSNY) and Columbia University. The investigators propose to examine changes over time in psychosocial development and quality of life in a cohort of TGNB individuals who have undergone surgery and receive gender-affirming, home-based post-surgical care from VNSNY. The study will include both quantitative and qualitative data collection from a cohort of individuals receiving services from GAP clinicians, as well as key informant interviews from prior GAP patients and current GAP clinicians to assist in the development of study protocols and instruments.

In addition to providing institutional endorsement for this study in my role as GAP's Director, I look forward to serving as Clinical Advisor to the research team. In this capacity, I will assist in communication efforts with GAP clinicians to inform them of the research activities as needed during the 5-year project period. I also may be called upon to provide input on the protocol development and interpretation of findings. I understand that interpretations of the findings may lead to one or more scholarly publications, and as Clinical Advisor I may contribute to these publications as a co-author.

It is worth noting how the COVID-19 pandemic has impacted the GAP population, with gender-affirming surgeries having been postponed during the months of March through May 2020. However, surgeries at our referring hospitals have resumed as of June 2020, and we anticipate that referral volume into GAP will return to our pre-pandemic levels by the time the proposed study begins.

I look forward to contributing as Clinical Advisor to this important and innovative study that will advance the evidence base on the healthcare needs of TGNB individuals in the community.

Sincerely,

Shannon Whittington RN MSN CCM

Certified LGBTQ+ Health
Gender **A**ffirmation **P**rogram **D**irector

Pronouns: She her hers

Visiting Nurse Service of New York
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CALLEN-LORDE

June 10, 2020

Miriam Ryvicker, PhD
Senior Research Scientist
Center for Home Care Policy and Research
Visiting Nurse Service of New York

Walter Bockting, PhD
Co-Director, Program for the Study of LGBT Health
Professor of Medical Psychology (In Psychiatry and Nursing), Columbia University
Research Scientist, New York State Psychiatric Institute

Re: "**Gender Affirmation, Quality of Life, and Access to Care: A Mixed-Method Longitudinal Investigation"**

Dear Drs. Ryvicker and Bockting,
I look forward to serving as an expert advisor should you be funded for your R01 application to the National Institutes of Health (NIH) entitled **"Gender Affirmation, Quality of Life, and Access to Care: A Mixed-Method Longitudinal Investigation."** The proposed study is a collaboration between the Visiting Nurse Service of New York (VNSNY) and the Columbia University School of Nursing. The investigators propose to examine changes over time in psychosocial development and quality of life in a cohort of TGNB individuals who have undergone surgery and received gender-affirming, home-based post-surgical care from the VNSNY.

I am an internal medicine and infectious disease clinician with over 20 years of experience in gender affirming care for transgender patients and a recognized expert in transgender medicine. My current role as co-chair for the World Professional Association of Transgender Health Standards of Care guidelines revision means that I can provide the most up-to-date and evidence-based knowledge of perioperative care to this project.

As a member of the group of expert advisors, I will meet with the team of investigators approximately every 6 months for the duration of the 5-year project period, either in person or by video- or phone-conference. I will contribute my expertise to the development of the data collection protocols, selection and adaptation of measures, interpretation and dissemination of findings. I anticipate each of these meetings will take about EFFORT of my time for which you will provide an honorarium of $500 (for a total of $1,000 per year). I understand that interpretation of the findings may lead to one or more scholarly publications, and as an expert advisor, I may contribute to these publications as an author or co-author.

This is an important study, the first of its kind to understand the psychosocial adjustment and health-related quality of life of TGNB individuals after gender-affirming surgery. I look forward to participating as an expert advisor to advance the evidence base on the health and related prevention and care needs of this health disparity population.

Sincerely,

Asa Radix, MD, PhD, MPH, FACP

Chelsea
356 West 18th Street
New York, NY 10011
212.271.7200

Thea Spyer Center
230 West 17th St
New York, NY 10011
212.271.7200

Bronx
3144 3rd Ave
Bronx, NY 10451
718.215.1800

Mount Sinai *Center for Transgender Medicine and Surgery*

June 11, 2020

Miriam Ryvicker, PhD
Senior Research Scientist
Center for Home Care Policy and Research
Visiting Nurse Service of New York

Walter Bockting, PhD
Co-Director, Program for the Study of LGBT Health
Professor of Medical Psychology (In Psychiatry and Nursing), Columbia University
Research Scientist, New York State Psychiatric Institute

Re: "Gender Affirmation, Quality of Life, and Access to Care: A Mixed-Method Longitudinal Investigation"

Dear Drs. Ryvicker and Bockting,

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As the Executive Director of the Mount Sinai Center for Transgender Medicine and Surgery, I bring my expertise in the development of comprehensive health care delivery systems for transgender individuals to the proposed project.

As a member of the group of expert advisors, I will meet with the team of investigators approximately every 6 months for the duration of the 5-year project period, either in person or by video- or phone-conference. I will contribute my expertise to the development of the data collection protocols, selection and adaptation of measures, interpretation and dissemination of findings. I anticipate each of these meetings will take about EFFORT of my time for which you will provide an honorarium of $500 (for a total of $1,000 per year). I expect that interpretation of the findings will lead to multiple scholarly publications. As an expert advisor, I look forward to contributing to these publications as an author or co-author.

This is an important study, the first of its kind to understand the psychosocial adjustment and health-related quality of life of TGNB individuals after gender-affirming surgery. I am eager to join you to advance the evidence base for health care needs of this health disparity population.

Sincerely,

Joshua D. Safer, MD, FACP, FACE

Executive Director
Mount Sinai Center for Transgender Medicine and Surgery
Mount Sinai Health System

Professor of Medicine
Icahn School of Medicine at Mount Sinai

UNC
CENTER FOR HEALTH EQUITY RESEARCH

THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

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CAMPUS BOX 7240
CHAPEL HILL, NC 27599-7240

June 10, 2020

Miriam Ryvicker, PhD
Senior Research Scientist
Center for Home Care Policy and Research
Visiting Nurse Service of New York

Walter Bockting, PhD
Co-Director, Program for the Study of LGBT Health
Professor of Medical Psychology (In Psychiatry and Nursing), Columbia University
Research Scientist, New York State Psychiatric Institute

Re: "**Gender Affirmation, Quality of Life, and Access to Care: A Mixed-Method Longitudinal Investigation"**

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I am an Assistant Professor of Social Medicine in the Center for Health Equity Research at the University of North Carolina. I bring to the proposed project my expertise in qualitative and mixed methods intersectionality research as well as a long history of providing care and conducting research with trans and non-binary populations. As a member of the group of expert advisors, I will meet with the team of investigators approximately every 6 months for the duration of the 5-year project period, either in person or by video- or phone-conference. I will contribute my expertise to the development of the data collection protocols, selection and adaptation of measures, interpretation and dissemination of findings. I anticipate each of these meetings will take about EFFORT of my time for which you will provide an honorarium of $500 (for a total of $1,000 per year). I understand that interpretation of the findings may lead to one or more scholarly publications, and as an expert advisor, I may contribute to these publications as an author or co-author.

This is an important study, the first of its kind to understand the psychosocial adjustment and health-related quality of life of TGNB individuals after gender-affirming surgery. I look forward to participating as an expert advisor to advance the evidence base on the health and related prevention and care needs of this health disparity population.

Sincerely,

Tonia Poteat, PhD, MPH, PA-C

June 13, 2020

Miriam Ryvicker, PhD
Senior Research Scientist
Center for Home Care Policy and Research
Visiting Nurse Service of New York

Walter Bockting, PhD
Co-Director, Program for the Study of LGBT Health
Professor of Medical Psychology (In Psychiatry and Nursing), Columbia University
Research Scientist, New York State Psychiatric Institute

Re: "Gender Affirmation, Quality of Life, and Access to Care: A Mixed-Method Longitudinal Investigation"

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I am trained as a social worker and hold an MSW from University of California, Berkeley. I bring my extensive expertise in transgender health, transgender health disparities and HIV to the proposed project.

As a member of the group of expert advisors, I will meet with the team of investigators approximately every 6 months for the duration of the 5-year project period, either in person or by video- or phone-conference. I will contribute my expertise to the development of the data collection protocols, selection and adaptation of measures, interpretation and dissemination of findings. I anticipate each of these meetings will take about EFFORT of my time for which you will provide an honorarium of $500 (for a total of $1,000 per year). I understand that interpretation of the findings may lead to one or more scholarly publications, and as an expert advisor, I may contribute to these publications as an author or co-author.

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Sincerely,

JoAnne G. Keatley, MSW, Director Emeritus

Center of Excellence for Transgender Health, UCSF

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Robert Hayes
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Affiliated with

NewYork-Presbyterian Healthcare System

Community Healthcare Network

June 24, 2020

Miriam Ryvicker, PhD
Senior Research Scientist
Center for Home Care Policy and Research
Visiting Nurse Service of New York

Walter Bockting, PhD
Co-Director, Program for the Study of LGBT Health
Professor of Medical Psychology (In Psychiatry and Nursing), Columbia University
Research Scientist, New York State Psychiatric Institute

Re: "Gender Affirmation, Quality of Life, and Access to Care: A Mixed-Method Longitudinal Investigation"

Dear Drs. Ryvicker and Bockting,
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I am the Vice President of ID/LGBT Programs at Community Healthcare Network. I bring my expertise in working with the Transgender, Non-Binary, and Gender non-conforming population, their determinants of health and barriers and access to care for the proposed project. Part of my interest is to do qualitating advice to patients who decide to go for their affirming surgeries process and post care afterward.

As a member of the group of expert advisors, I will meet with the team of investigators approximately every 6 months for the duration of the 5-year project period, either in person or by video- or phone-conference. I will contribute my expertise to the development of the data collection protocols, selection and adaptation of measures, interpretation and dissemination of findings. I anticipate each of these meetings will take about EFFORT of my time for which you will provide an honorarium of $500 (for a total of $1,000 per year). I understand that interpretation of the findings may lead to one or more scholarly publications, and as an expert advisor, I may contribute to these publications as an author or co-author.

This is an important study, the first of its kind to understand the psychosocial adjustment and health-related quality of life of TGNB individuals after gender-affirming surgery. I look forward to participating as an expert advisor to advance the evidence base on the health and related prevention and care needs of this health disparity population.

Sincerely,
Luis Freddy Molano, MD
VP ID/LGBT Programs

June 10, 2020

Miriam Ryvicker, PhD
Senior Research Scientist
Center for Home Care Policy and Research
Visiting Nurse Service of New York

Walter Bockting, PhD
Co-Director, Program for the Study of LGBT Health
Professor of Medical Psychology (In Psychiatry and Nursing), Columbia University
Research Scientist, New York State Psychiatric Institute

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I am a Assistant Professor of Surgery at the Icahn School of Medicine – Plastic Surgeon at the Mt Sinai School of Medicine. I bring my expertise in Transgender Surgery/Plastic & Reconstructive Surgery to the proposed project.

As a member of the group of expert advisors, I will meet with the team of investigators approximately every 6 months for the duration of the 5-year project period, either in person or by video- or phone-conference. I will contribute my expertise to the development of the data collection protocols, selection and adaptation of measures, interpretation and dissemination of findings. I anticipate each of these meetings will take about EFFORT of my time for which you will provide an honorarium of $500 (for a total of $1,000 per year). I understand that interpretation of the findings may lead to one or more scholarly publications, and as an expert advisor, I may contribute to these publications as an author or co-author.

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Sincerely,

John Henry Pang, MD
Department of Surgery/Division of Plastic Surgery
Icahn School of Medicine at Mount Sinai

NYU Langone Health

June 10, 2020

Miriam Ryvicker, PhD
Senior Research Scientist
Center for Home Care Policy and Research
Visiting Nurse Service of New York

Walter Bockting, PhD
Co-Director, Program for the Study of LGBT Health
Professor of Medical Psychology (In Psychiatry and Nursing), Columbia University
Research Scientist, New York State Psychiatric Institute

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I am a Plastic Surgeon at NYU Langone Health and have a practice dedicated to gender affirming surgery. I bring my expertise gender affirming surgery to the proposed project.

As a member of the group of expert advisors, I will meet with the team of investigators approximately every 6 months for the duration of the 5-year project period, either in person or by video- or phone-conference. I will contribute my expertise to the development of the data collection protocols, selection and adaptation of measures, interpretation and dissemination of findings. I anticipate each of these meetings will take about EFFO of my time for which you will provide an honorarium of $500 (for a total of $1,000 per year). I understand that interpretation of the findings may lead to one or more scholarly publications, and as an expert advisor, I may contribute to these publications as an author or co-author.

This is an important study, the first of its kind to understand the psychosocial adjustment and health-related quality of life of TGNB individuals after gender-affirming surgery. I look forward to participating as an expert advisor to advance the evidence base on the health and related prevention and care needs of this health disparity population.

Sincerely,

Rachel Bluebond-Langner MD
Laura and Isaac Associate Professor of Plastic Surgery
Hans-Jorg Wyss Department of Plastic Surgery
NYU Langone Health

RESOURCE SHARING STATEMENT

This study proposes analysis of highly sensitive information in a population that frequently faces stigma, discrimination, and gender-related abuse. Our dataset will be contextualized with individual characteristics which, even in a dataset stripped of identifier, increase the potential risk of re-identification. This prohibits us from making study data publicly available to other researchers. However, upon written request from members of the research community, we will share the following resources produced during the study:

- documentation of procedures for data collection and extraction
- programming code used to construct the analytic dataset
- the data dictionary for the master analytic dataset
- the analytic plan for each study aim
- the interview instruments used for data collection

Authentication of Key Biological and/or Chemical Resources

No biological or chemical resources will be involved in this study.