This is a medical research study. Ththestudy doctor, Rick Hecht MD, or his UCSF research staff will explain this study to you. Medical research studies include only people who choose to take part. Take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you may ask the study doctor. This study is being supported by the Osher Center for Integrative Medicine at UCSF. You are being asked to take part because you are age 50 or older and have HIV.

Why is this study being done? The purpose of this study is to test how well an exercise program works for people with HIV and find out what effects it has on their health, compared to people who don’t do the exercise program. Study participants will all have a 66% chance of being assigned to the “exercise group”, and a 33% chance of being assigned to the “information now, exercise later group”. The assignment will be made by computer, so neither study participants nor the study doctor can make the assignments. For the people who get assigned to the exercise group, they will exercise partly in small groups and partly alone, for at least twelve weeks. They will be asked to do some aerobic exercise (walking and running, or biking) and some strength training exercise (weights) every week, and to gradually build up to spending at least three hours per week exercising. They will receive a three-month paid membership to the Embarcadero YMCA. The “information now, exercise later” group will receive a manual of health and wellness information at the start of the study, and will receive the three-month paid membership to the Embarcadero YMCA at the end of the 12 week study period.

The study is based on research which shows that aerobic and strength training in people without HIV leads to improvements in strength, body weight, lean body mass, physical fitness and quality of life. We want to test how much exercise benefits people with HIV who are over 50. It is designed to improve strength of major upper and lower body muscles, abdominal muscles and also to improve general physical fitness and function. The hope is that this type of intervention may reduce inflammation (help the immune system function) and may reduce the risk of cardiovascular disease.

How many people will take part in this study? About 30 people will take part in this study.

What will happen if I take part in this research study?

Before you begin the main part of the study: We will do the following “screening” tests, exams and procedures to find out if you can be in the main part of the study.

- **Medical history and exercise surveys, computerized health profile:** we will ask you about your medical history and your current physical activity using standardized forms, and about your mood and health using a computerized survey (the “NIH PROMIS-29 Adult Profile” which measures depression, anxiety, physical functioning, fatigue, sleep, pain, and ability to participate in activities), to find out if there are any problems with your health that we should know about before you start the study.

- **Blood sample (venipuncture):** about 9 tablespoons (138mL) of blood will be drawn by inserting a needle into a vein in your arm. This will be used to check your kidney and liver
function, glucose (sugar) level, cholesterol level, and blood counts (test for anemia). We may also do tests for inflammation (e.g., high sensitivity C-reactive protein, IL-6, D-dimer). If you do not have recent CD4 and HIV viral load tests, these may be done as well. We will give you copies of all of your lab results from this study if you want them, so you can discuss them with your health care provider.

- **Maximal oxygen consumption** ("VO2max"): we will measure your body’s ability to use the oxygen that you breathe during exercise, using a standard test called VO2max. During the test, you will wear an oxygen mask while exercising on a treadmill or stationary bike, and a computer will measure the oxygen you breathe in and how much of it your body uses. The test will be done at the UCSF Human Performance Center at UCSF Mission Bay, and will take about an hour. You will do the test once at the start of the study and again at the end.

- **Fitbit instruction** (two visits): you will come to the clinic on a different day, and meet a small group of study participants. You will all be given a “fitbit” device, which is like a computerized pedometer. The device will measure how many steps you walk per day, if you go up any stairs or hills, and how fast you walk or run. We will teach you how to download the data from the device to the internet. You will come to the clinic again, about 7-14 days later, so that we can make sure your data download is working.

**During the main part of the study:** If the screening procedures show that you can be in the main part of the study, and you choose to take part, then you will do the following.

- **Randomization**: a computer will determine which group you get assigned to. Twenty participants will be assigned to the “exercise group” and ten will be assigned to the “information now, exercise later group”. The group assignment cannot be changed, and it cannot be determined by study participants or the doctor (to prevent bias in the study results). Once all participants are enrolled and assigned to groups, we will call or email you to tell you which group you have been assigned to. If you are assigned to the “information now, exercise later group” you will receive a manual with health information in mid-March, and you will complete the Interim and Exit visits and other activities described below, but you won’t receive the paid gym membership until after you’ve completed the 12-week observation period. If you are assigned to the “exercise group”, you will complete the exercise program as described on page 4, starting in March, in addition to the other visits and procedures described below.

- **Data Collection**: You will be asked to record your exercise habits every day, using various tools (the program at the gym, the fitbit, a paper diary, a mobile app). You can use multiple tools, as long as you don’t duplicate entries – that is, if you record your exercise with the computer program at the gym, don’t also enter in your mobile app. If you are a patient at SFGH, we may collect your recent HIV-related lab results from your chart, rather than re-run these tests ourselves. Before we do this, we will ask your permission. You may decline this, and if you do we will draw blood and run these tests.

- **Weekly Check In**: If you are in the “exercise group”, your Instructor will “check in” with you each week to check on your progress, to find out if you are having any problems with the exercise or the study, and to talk with you about your plan for the following week. If you can’t do the check-in (either you are not able to attend the Instructor session or you don’t have time at the session), we will contact you by phone later in the week at a time that you
choose. If we aren’t able to contact you for more than two weeks, you may not be able to continue on the study.

- **Interim Study Visit**: At about mid-April, you will return to the clinic for interim assessments (blood tests, questionnaires) and to discuss your progress with study staff. If you are in the “exercise group”, we will review your exercise diary and personalize your goals for the final six weeks of the intervention. If you have questions before the interim study visit about your progress or any problems you may be having, please call the study staff using the contact details we will give you, and you can ask your Instructor. A total of about 9 tablespoons (138mL) of blood will be drawn at this visit.

- **Exit Study Visit**: After the 12 weeks of exercise or observation are over, you will return to the clinic and we will do the same exams that you had at the start of the study: health questionnaire, assessment of physical functioning, blood tests (about 9 tablespoons, or 138mL), and VO2max.

- **Blood Collection and Storage**: At each of the three clinic visits you will have about 9 tablespoons (138mL) of blood drawn for the study, for a total of about 28 tablespoons (414mL) over the entire study. This includes 60mL of blood that will be collected for storage at the UCSF AIDS Specimen Bank. Some of the stored blood will be kept for future research. Researchers may use stored blood for new tests of immune responses to HIV, or aging-related tests, or new tests of the HIV virus. If any test results seem to have important meaning for your health care, study staff will inform your doctor or you. If you decide to leave the study in the future, you can have stored samples destroyed by requesting this via phone call to the researcher. The blood collection for storage (the 60mL in addition to the blood required to complete the study assays) is optional – you can decline to provide this extra blood. You will be asked to co-enroll in the SCOPE study because they will manage this stored blood. Please alert your counselor if you would like to decline this extra blood storage. The first 78mL of blood is not optional.
Exercise Intervention Group Only: We will ask you to slowly begin to introduce exercise into your life. We will work with you to do two types of exercise: a walk/run program (aerobic exercise) and strength training. To start, you will attend an “Initial Training Workshop”, for four hours one day, with about 15 other people. At the Initial Workshop we will teach you how to do our walk/run program, including proper preparation, form and posture to limit injuries during walking and running. There will be 3 follow-up booster sessions of about 2 hours duration over the next 12 weeks. These will be done on weekend days (Saturdays). In between sessions, additional advice on the aerobic program will be available by email with study staff and an experienced aerobic exercise instructor.

The aerobic exercise will be a walk/run program. This will start with mostly walking and gradually increase to running. If running is difficult due to injuries or personal preferences, we will work with you to do alternative forms of aerobic exercise such as using an elliptical trainer, biking (including stationary biking), or swimming. The strength training will use weights in a gym, starting for 30 minutes twice a week. You will meet in a small group (typically 3-6 people) with an instructor at the study gym twice a week, to learn how to safely use the weights. After the first month, the instruction group will meet only once per week at the study gym, and you will do the second session of 30 minutes of strength training on your own.

Over the course of the 12 weeks, we want you to slowly increase the frequency of exercise, so that by Week 12 you will be doing 40 minutes of aerobic exercise three times per week and 30 minutes of strength training two times per week. That is, by Week 12, you will be exercising a total of three hours per week. We will provide you with a detailed guide of how to achieve these milestones, including types of exercise and strength training that are recommended, and how to incorporate a new exercise routine into your life. We will teach you how to monitor your heart rate, and if funding permits we may provide you with a small heart rate monitor.

We will provide you with a membership to a local gym. If it is available we will ask you to use the computer system there to track your exercise habits. If you have a “smart phone” (e.g. iPhone or Android), we will ask you to track your exercise and share it with study staff using a free app (e.g. iSmoothRun, Runkeeper). We will teach you how to track your exercise at the Initial Training Workshop. You can also exercise at places other than the gym, such as outdoors or at home, and if you do we ask that you record that exercise in your own exercise diary as “outside exercise.” If you leave the study before the 12 weeks are over, or are asked to leave, the study-sponsored gym membership may be ended by the study investigator, if he feels this is in your best interest.

Table: Study Activities by Week and Time Commitment (in hours), Blue = Exercise Group Only

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<th>Activity</th>
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<th>Wk 1</th>
<th>Wk 2</th>
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<td>Clinic Visits, Blood Draws</td>
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<td>On Your Own</td>
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<td>TOTAL TIME (46-54 hrs)</td>
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<td>5-6</td>
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*The Enrollment Visit can be completed any time before the Initial Training Workshop.
Study location: All study procedures will be done at our research clinic at Ward 84 at San Francisco General Hospital. The Workshops will be at a UCSF facility to be determined, and the Instruction sessions will be at the study gym.

How long will I be in the study? In general, participation in the study assessments will take a total of about five hours over a period of 12-14 weeks. In addition, if you are assigned to the “exercise group” you will have ten hours of Workshops and the time you will be exercising on your own, which will be about three hours per week.

There is a table on page 4 of this form that shows specifically which activities you’ll be asked to participate in, and at what “weeks” they occur. That is, there are three clinic visits ("Enrollment" at week 0, "Interim" at week 6, and "Exit" at week 13), for everyone. For participants in the exercise group only, there will also be four training workshops ("Initial" at week 0, and 3 "boosters" at weeks 2, 4, and 8), weekly training instruction for 12 weeks (one hour per week for weeks 1-4, 30 minutes per week for weeks 5-12), and about 2.5 hours of exercise “on your own” each week. Total time commitment, including all time spent exercising, will be 46 – 54 hours over the life of the study for those in the exercise group.

If funding permits this, you will also be asked to do another follow up visit about 6 months after the start of the study (approximately week 36), for us to conduct the same assessments that you had at the start of the study: health questionnaire, assessment of physical functioning, and blood tests. Study staff will let you know if this visit is planned near the end of the main exercise period (around 12 weeks).

What side effects or risks can I expect? You may have side effects while on the study. You should talk to your study doctor about any side effects you experience while taking part in the study. For more information about risks and side effects, ask one of the researchers.

- Blood drawing (venipuncture) risks: Drawing blood may cause temporary discomfort from the needle stick, bruising, and infection.

- Group assignment risks: you will be assigned to either the “exercise group” or the “information now, exercise later” group by chance. The exercise intervention may prove to be less effective or to have more risks than the information intervention, or than other available interventions. This will not be known until after the study has been completed and the data have been analyzed.

- Exercise risks: Risks and side effects related to increasing exercise include sore muscles, minor discomfort during exertion, and a muscle strain or pull. Rarely, exercise may lead to a muscle tear, serious joint injury, or heart attack. Exercise will reduce the risk of heart attack in general but can increase your chance of a heart attack during heavy exercise. The exercise program is planned to gradually increase exercise to limit this risk.

Are there benefits to taking part in the study? Taking part in this study may make your health better. While doctors hope that increasing exercise will improve health for people living with HIV, there is no proof of this yet. The intervention you receive may prove to be more effective than the other intervention, although this cannot be guaranteed.

Can I stop being in the study? Yes, you can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He will help you to stop your participation.
safely. The study doctor may stop you from taking part in this study at any time if he believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What other choices do I have if I do not take part in this study? The alternative is to not participate in the study.

Will my medical information be kept private? We will do our best to make sure that the personal information in your medical record is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The UCSF Committee on Human Research may look at and/or copy your medical records for quality assurance.

What are the costs of taking part in this study? You will not be charged for any study activities. The study will pay for the cost of a membership to the local gym for you for 12 weeks, either starting in mid-March if you are assigned to the “exercise group”, or starting in early June if you are assigned to the “information now, exercise later” group.

Will I be paid for taking part in this study? In return for your time, effort and travel expenses, you will be paid $100 for taking part in this study. You will be paid in cash when you complete the final study visit. If you do not complete the study, you will receive $20 by check for any of the three study visits you completed; we will need to mail the check to you several weeks after the final study visit, and you will need to provide your social security number for the check. If funding allows us to add a follow-up visit at week 36, you will receive $20 in cash at that visit.

What happens if I am injured because I took part in this study? It is important that you tell your study doctor, Rick Hecht MD, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her at 476-4082 x 431. If you cannot reach him directly, you can contact study staff and ask them to contact him for you.

Treatment and Compensation for Injury: If you are injured as a result of being in this study, treatment will be available. The costs of the treatment may be covered by the University of California, depending on a number of factors. The University does not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Committee on Human Research at 415-476-1814.

What are my rights if I take part in this study? Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution. In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form. We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.
Who can answer my questions about the study? You can talk to your study doctor about any questions, concerns, or complaints you have about this study. Contact your study doctor Rick Hecht MD at 476-4082 x431, or the Project Director Lisa Loeb at 476-4082 x357.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Office of the Committee on Human Research at 415-476-1814.

Optional Related Studies. This item is optional, and we will only include you in other related studies if you give us your permission below.

1) We may give your specimens and certain medical information about you (for example, diagnosis, CD4 count, age if less than 85) to other scientists or companies not at UCSF, including to a government health research database, but we will not give them your name, address, phone number, or any other information that would identify you. Reports about any research will not be given to you or your doctor.

2) Sometimes specimens are used for genetic research (about diseases that are passed on in families). Genetic information taken from the specimens (also known as genotype data) and the medical record data (also known as phenotype data) may be shared broadly in coded form. Even if we use the specimen for genetic research, we will not put the results in your medical record. The research will not change the care you receive. Your specimen and any information about you will be kept until it is used up or destroyed. It may be used to develop new drugs, tests, treatments or products. In some instances these may have potential commercial value. Your personal health information cannot be used for additional research without additional approval from either you or a review committee.

3) Your specimens will be kept indefinitely. If you decide later that you do not want your specimens and information to be used for future research, you can notify the investigator in writing (Dr. Hecht at 995 Potrero Avenue, San Francisco, 94110) and we will destroy any remaining identifiable specimens and information if they are no longer needed for your care. However, if any research has already been done using portions of your specimens, the data will be kept and analyzed as part of those research studies.

If you participate in the optional “Other Studies” section above, and if those other studies involve genetic testing, there is a risk that information about taking part in a genetic study may influence insurance companies and/or employers regarding your health. To further safeguard your privacy, genetic information obtained in this study, if any, will not be placed in your medical record. Taking part in a genetic study may also have a negative impact or unintended consequences on family or other relationships. If you do not share information about taking part in this study, you will reduce this risk. Although your name will not be with the sample, it will have other facts about you such as your age or race/ethnicity. These facts are important because they will help us learn if the factors that cause HIV to occur or get worse are the same or different based on these facts. Thus it is possible that study findings could one day help people of the same race, ethnicity, or sex as you. However, it is also possible through these kinds of studies that genetic traits might come to be associated with your group. In some cases, this could reinforce harmful stereotypes.
Making Your Choice. Please read each sentence below and think about your choice. After reading each sentence, put your initials in the "Yes" or "No" box. If you have any questions, please talk to your doctor or nurse, or call our research review board at IRB's phone number. No matter what you decide to do, it will not affect your care.

1. My specimens may be kept for use in research to learn about, prevent, or treat HIV.
   
   YES  NO

2. My specimens may be kept for use in research to learn about, prevent or treat other health problems (for example: diabetes, Alzheimer's disease, or heart disease).

   YES  NO

3. Someone may contact me in the future to ask me to take part in more research.

   YES  NO

CONSENT.

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep. You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled. If you wish to participate in this study, you should sign below.

______________________________  ________________________________
Date  Participant's Signature for Consent

______________________________  ________________________________
Date  Person Obtaining Consent
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
EXPERIMENTAL SUBJECT'S
BILL OF RIGHTS

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject I have the following rights:

1) To be told what the study is trying to find out,
2) To be told what will happen to me and whether any of the procedures, drugs, or devices is different from what would be used in standard practice,
3) To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me for research purposes,
4) To be told if I can expect any benefit from participating, and, if so, what the benefit might be,
5) To be told of the other choices I have and how they may be better or worse than being in the study,
6) To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study,
7) To be told what sort of medical treatment is available if any complications arise,
8) To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my right to receive the care I would receive if I were not in the study,
9) To receive a copy of the signed and dated consent form,
10) To be free of pressure when considering whether I wish to agree to be in the study.

If I have other questions I should ask the researcher or the research assistant. In addition, I may contact the Committee on Human Research, which is concerned with protection of volunteers in research projects. I may reach the committee office by calling: (415) 476-1814 from 8:00 AM to 5:00 PM, Monday to Friday, or by writing to the Committee on Human Research, Box 0962, University of California, San Francisco, CA 94143.

Call 476-1814 for information on translations.

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