參加研究同意書
Consent To Be A Research Subject

Consent To Be A Research Subject	同意成爲研究對象
PURPOSE AND BACKGROUND Drs. John W. Park, Laura J. Esserman, Michael Campbell, Michael McGrath, Joe Gray and associates at the University of California, San Francisco (UCSF) Medical Center are conducting a research study to develop blood tests to detect the presence of cancer and determine cancer type. We hope the results of this study will help us develop better ways to prevent and screen for breast cancer. We also hope that information from this study will help improve our ability to direct therapy and determine how well a treatment is working. In order to accomplish this, we aim to study and describe (profile) tumors and the environment in which they develop. We will also study immune function, specific genes and small proteins in the blood, tumor and any microscopic rare tumor cells that might be found traveling around in the blood or bone marrow. You are being asked to participate in this study because you have recently been diagnosed with breast cancer or ductal carcinoma in situ (DCIS). Approximately 850 patients will take part in this study at	**目的和背景** Drs. John W. Park, Laura J. Esserman, Michael Campbell, Michael McGrath, Joe Gray 和研究人員在加州大學舊金山分校醫療中心（UCSF）正進行一項研究，用血液去測試是否有癌症和癌症的類型。我們希望這項研究的結果能幫助我們發展更好的方法來預防和檢查乳癌。我們也希望這項研究將有助於指導治療的方法和評估醫療的成效。 爲了做到這一點，我們的目標是研究和描述（描繪特色）腫瘤和其成長的環境。我們還會研究免疫功能、特異基因、在血液中的小蛋白質、腫瘤和任何可能被發現於血液裡或骨髓四周的微型罕見腫瘤細胞。 因爲你最近被診斷患有乳癌或者乳管原位癌(DCIS)，所以你被邀請參與此項研究。大約有 850 個病人會在 UCSF 醫療中心參

the UCSF Medical Center.

What are we looking for in your blood, bone marrow, and tissue?

We have tests that allow us to identify rare (one in a million) tumor cells in the blood and bone marrow that may be involved in the spread of cancer. We would like to study how these cells, called circulating tumor cells, can provide information about long-term outcomes in breast cancer patients.

In addition, we will study immune cells. In breast cancer patients, immune cells may be abnormal and can possibly contribute to the development of some cancers. We will also look for specific genes and proteins in the blood that may help determine someone's risk for getting cancer and whether or not cancer is present in the body.

Lastly, we are interested in studying any leftover tissue that is removed during surgery but is not used by doctors for diagnostic purposes. Instead of being discarded, this tissue would be stored in our tumor bank and used for research on the genetics of tumor tissues. By profiling the genes that are turned on and off in tumors, we hope to better understand the biology of different types of cancer. Any tissue, blood and bone marrow that is not used immediately for research will be stored. In the fu-

與此項研究。

我們在你的血液、骨髓和腫瘤組織中要找尋些甚麼？

我們有一些測試能夠識別在血液和骨髓中罕見（百萬分之一）的腫瘤細胞，它們可能涉及癌症的擴散。我們想研究這些被稱爲循環的腫瘤細胞去獲得有關乳癌患者長期療程效果的資料。

此外，我們會研究免疫細胞。在乳癌患者中，免疫細胞可能是不正常的，有可能會助於某些癌症的生長。我們也會在血液中尋找個別的基因和蛋白質，這可能有助 於確定一個人將來患上癌症的風險和是否患有癌症。

最後，我們有興趣研究在手術過程中被切除但沒有被醫生留用作診斷的腫瘤組織。 與其被丟棄，這些組織將被儲存在我們的腫瘤庫和將會被用於腫瘤組織的遺傳學研究。通過分析腫瘤組織里產生和停止制作腫瘤的基因，我們希望更了解不同類型癌症的生物學。

任何不立即用於研究的腫瘤組織、血液和骨髓都會被儲存起

ture, these samples may be used for continuing research on early detection, prevention and treatment of breast cancer.	來。在將來可能繼續用於如何做早期檢測、預防和治療乳癌的研究。
PROCEDURES If you agree to participate in this study, the following steps will be taken to obtain the additional samples for research: 1. A blood sample (between 60-72 milliliters (ml) or 4-5 tablespoons) will be taken from a vein in your arm or other available site. We will draw this sample at two time points: 12 ml (or I tablespoon) may be drawn prior to surgery in conjunction with standard preoperative blood tests. The remaining 60 ml (4 tablespoons) will be drawn while you are under anesthesia in the operating room. 2. If you decide to undergo chemotherapy before surgery, a blood sample (about 10-22 ml) will be taken before you receive your first treatment. If you decide to undergo chemotherapy after surgery, you will have the option of donating a blood sample (about 10 ml) at the time you complete your chemotherapy. The blood sample would be taken in conjunction with standard blood tests, or through the same needle used to administer chemotherapy.	**研究程序** 如果您同意參與這項研究，以下的措施將用以獲得額外的樣本作研究用途： 1. 從你的手臂或其他可用的靜脈採取血液樣本 [60−72 毫升（ml）之間或 4−5 湯匙]。我們會分開兩個階段抽取樣本：12 毫升（或 1 湯匙）血可以在手術前的血液測試一同抽取。其餘的 60 毫升血（4 湯匙）可在手術室被麻醉後抽取。 2. 如果你決定在手術前接受化療，那麼第一次化療前會先抽取第一份血液樣本（約 10−22 毫升）。如果你決定在手術後才接受化療，你可選擇在你完成化療後抽血（約 10 毫升）。抽取血液樣本將透過標準的抽血過程或通過用做化療的針抽血。

3. For patients diagnosed with invasive cancer ONLY: A bone marrow sample will also be obtained in the operating room. The sample will be obtained under sterile conditions using a needle that is slightly thicker then a pencil lead. This needle will be inserted into your hip, about one-half inch below the surface of the bone. A syringe will be used to draw about 2-3 teaspoons (l 0-15 ml) of bone marrow fluid from 2 to 3 separate sites within one incision in your hip. A local anesthetic will also be administered at the site. This procedure takes about 5-I 0 minutes, and will not increase any expenses associated with your operation.

4. Tissue that is initially removed from the body will be sent to the UCSF Pathology Department for examination, as is normally done with any tissue removed during an operation. This tissue, thought to contain the cancer, would be removed regardless of your participation in this study. After the pathologist has evaluated all tissue, a portion of the specimens will be sent to the tissue bank where they will be used for laboratory investigations. The tissue bank will only receive the portion of the specimen that remains after all testing related to diagnosis and treatment has been completed.

3. 只涉及確診有入侵性癌症的患者：骨髓樣本也在手術室里抽取。樣本將在無菌環境中用比鉛筆芯粗一點的針而取得。這支針會從臀部插入約二分之一英寸至骨的表面。注射器會從同一切口中到兩至三個不同的臀部位抽取 2–3 茶匙骨髓液（10–15 毫升）。過程期間局部切口會被麻醉。此過程需時約 5 – 10 分鐘，任何手術費用不會因此而增加。

4. 如正常程序一樣，被切除的腫瘤組織，最初從身體里取出後被送到加州大學舊金山分校的病理科檢查。 無論你參與這項研究與否 ， 這懷疑有癌的組織都會被切除。在病理學家評估了所有的腫瘤組織後，其中一部分樣本被送到組織庫，用於實驗性測試。組織庫只能接收到在完成所有相關診斷和治療後所餘下的樣本。

Upon giving your consent to participate in the study, you will also be asked to fill out a questionnaire covering parts of your social and medical history; this should take 10-15 minutes. After your breast surgery and after the tests in this study are performed, your doctor(s) will follow you in the usual manner. Information about what happens to your cancer will be collected for this study from your medical record for 5 to 10 years. You should let your doctor's office know if you change doctors or move away so that you may continue to be followed by the study. It is important that we are able to obtain information about your treatment and track your progress after surgery.	在你同意參與這項研究時，你會同時被要求填寫一份問卷，它涵蓋了你的社交和病歷，填寫需時約 10−15 分鐘。在做了乳房手術和各種測試後，你的醫生會將按照常規跟進你。 你患癌症爲期約 5 至 10 年的所有相關醫療的紀錄會被收集作研究用途。你應該讓你的醫務所知道，如果你換了醫生或搬走，你還可以繼續參與研究計劃。重要的是，我們能夠獲取有關治療訊息，並追蹤你手術後的情況。
Portions of your bone marrow, blood and tissue that are removed during your participation in this study will be saved and may be used again in the future for other research purposes. You may contact the researchers at any time and request that your samples be withdrawn from research use and any identifiable samples still in their possession be destroyed.	你部分獲得因作研究的骨髓，血液和組織將被保存，並可能再次在未來用於其他研究。你可以在任何時間聯繫研究人員，並要求你的樣本從研究中撤回，並將研究中有你的名字的樣本銷毀。
In addition, if you provide consent, you may be asked to participate in future studies based on the results of this initial research. Participation in these future studies is completely voluntary, and if you	此外，如果你同意，根據初步的研究結果，你可能會被要求參加進一步的研究。參加這些未來的研究完全是自願的，如果選擇不參加，它絕不會影響你的醫療照

choose not to participate, it will in no way affect your care. You do not have to participate in this research study. Whether you participate in this study or not, your breast cancer will be treated with standard medical care.	顧。 你沒有必要參與這項研究。無論你參與這項研究與否，你接受的乳癌治療待遇是不會變的。
RISKS AND DISCOMFORTS • There will probably be some soreness and a small line for one or two days at the site in your upper hip where the bone marrow needle was introduced. There may be a small bruise within the tissue at the needle site, which will go away after a few days. There is a very small risk, which happens to fewer than I in 100 patients, of prolonged bleeding or infection at the needle site. • There may be some discomfort associated with the blood draw. There may be associated bruising. In very rare cases, taking blood from your vein can cause complications such as bleeding or infection. Oftentimes, the blood needed for our research can be drawn at the same time as standard blood tests or placement of the intravenous line prior to surgery; this allows the blood to be taken through the same needle stick as these standard clinical procedures.	**風險和不適** ● 在一至兩天內，你可能有一些酸痛和在髖上部插入骨髓針的位置有一個小線口。抽取組織的位置可能會有青腫 ，但幾天後它就會消失。另外有一個非常小的風險， 發生比例約 1:100 個患者在針口延長出血或受到感染。 ● 抽血時可能讓你感到有少許不適，甚至可能有瘀傷。在極少數情況下，從靜脈抽血可引起併發症，如出血或感染。通常，我們需要用作研究的血液可以在如常的抽血程序中或在手術前插入的靜脈鹽水管抽血。這可以如常的臨床過程中，用同一個的針口抽血。

FINANCIAL RISKS / REIMBURSEMENT	**金融風險/費用報銷**
You will not be asked to pay for the study procedures nor will you be paid for participating in this study. If any new products, tests or discoveries that result from this research have potential commercial value, you will not share in any financial benefits.	你不會被要求支付相關研究程序的費用，也不用爲參與這項研究支付費用。但如果研究發現任何新產品、測試或發現有潛在的商業價值，你亦不能分享任何經濟利益。
BENEFITS	**好處**
If you agree to take part in this study, there will be no direct medical benefit to you. However, the information gained from this study will help doctors and scientists learn more about breast cancer, and this may benefit other patients in the future. You may derive satisfaction from the knowledge that you may be benefiting future patients.	同意參加這項研究不會有直接的醫療福利給你。然而，從本研究獲得的訊息將能幫助醫生和科學家更了解乳癌，可能有利於未來的其他患者，造福他們。你可從此得到自滿。
ALTERNATIVES	**其他選擇**
Your alternative is not to participate in this study and still undergo treatment as advised by your doctors.	你可以選擇不參加這項研究而只繼續醫生建議的治療。
DISCLOSURE OF DATA	**披露數據**
Given that most of the tests used in this study are experimental, none of these test results will be disclosed to you. Exceptions to this are standard clinical data (tumor type, stage, grade), which will appear in your medical record, and tests that have	鑑於在研究中的測試都是實驗性的，所以沒有測試結果可以公開給你。例外的是如有出現在你病歷的規範臨床數據（腫瘤類型，階段，等級），和各項已通過美國食品和藥物管理局（FDA）認

been approved by the Food and Drug Administration (FDA).	可的測試。
TREATMENT AND COMPENSATION FOR INJURY If you are injured as a result of being in this study, treatment will be available. The costs of such 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 UCSF Committee on Human Research at (415) 476-1814.	**治療和受傷賠償** 如果因參加本研究而受傷，我們會提供治療。治療費用可能由加州大學負責，但需要從多種因素決定。大學通常不會提供任何其他形式的補償。若要得到更多資訊，您可致電(415) 476−1814 到加州大學舊金山分校人類研究委員部。
CONFIDENTIALITY Participation in a research study may involve loss of privacy. However, the research records will be kept confidential and will be disclosed only with your permission. In order to prevent information from reaching unauthorized individuals, each specimen will be given a code number. When a researcher receives specimens, only the code number will identify them. The code number with personal identification will be kept in a password-protected database. The only people that will have access to your identity within the password-protected database are the data managers who need it to carry out their tasks within the programs of the Cancer Center (data managers).	**保密** 參與研究可能涉及洩露隱私。然而，研究記錄將予以保密，並只會得到你許可才會公開。爲了防止訊息洩露到未經授權的人，每個樣本都會有碼數編號(以代替名)。 當研究人員收到樣本時，只有代號可作識別。個人識別碼將被保存在密碼保護的數據庫。唯一有機會在密碼數據庫中知道你身份的人來自在癌症中心內數據庫中的數據管理員。

At no time and under no circumstances will patient identification information other than the assigned coded number be given to any researcher inside or outside UCSF. If a researcher wishes to obtain follow-up information on specimens he/she will contact the cancer center program that is designed to provide follow-up and will receive this information related to the code number without revealing your identity.	不論在任何時候，任何情況下我們都不會將病人身份資訊（除了代號）給予任何其他加州大學舊金山分校的研究員。如果研究員希望得到樣本的跟進訊息，他/她會聯繫癌症中心。該中心旨在提供跟進服務和讓研究員獲得樣本的代號，但過程中不會揭露你的身份。
By signing this form, you are permitting your research records to be made available as required by state and federal law. Organizations that may look at and/or copy your medical records for quality assurance and data analysis include:	如簽署此表格，即你根據在州和聯邦法律允許下提供研究記錄。可以看/或複製病歷以作質量保證和數據分析的組織包括：
• UCSF's Committee on Human Research	• 加州大學舊金山分校的人類研究委員會
• The National Cancer Institute (NCI) and other government agencies, e.g. the Food and Drug Administration (FDA), involved in keeping research safe for people.	• 美國國家癌症研究所（NCI）和其他政府機構，如：美國食品和藥物管理局（FDA），參與維持研究安全的人。
• Additionally, de-identified medical records may be reviewed by GeneNews (a company that is funding a portion of this study. Representatives from participating biomedical companies and the FDA will receive de-identified specimens for	• 此外，除去身分資料後的病歷可能會被 GeneNews 查看（即部分資助此研究的公司）。參與生物醫學公司的代表，和 FDA 將獲得不暴露你身份的

analysis purposes but will not have access to identifiable personal health information. Clinical information (gender, age, tumor marker status, tumor stage, surgical and breast biopsy pathology reports, etc.) that does not identify you may be released and shared with collaborating research groups and companies. Your name will not be used in any published reports about this study.	樣本作分析用途，但他們無法獲得可識別的個人健康訊息。無法識別你個人身份的臨床訊息（性別、年齡、腫瘤標誌狀態、腫瘤分期、手術和乳房活檢的病理報告等）可能被公開與合作研究機構和公司分享。但你的名字不會出現在被關於這項研究發表的任何報告。
QUESTIONS Dr. _____ who can be reached at the telephone number , has discussed this study with you, and you have been given the opportunity to ask questions. If you have any further questions about this study or if you experience a research-related injury, you should contact Dr. John W. Park, or Dr. Laura J. Esserman at (415) 885-3700. Study Coordinator, Erin Bowlby, may also be contacted for questions at (415) 885-7638.	**如有問題：** _____醫生曾與你討論過這項研究，而你亦有機會發問你的問題。如果你對這項研究仍有任何疑問或者你因參加研究遇到傷害，你應該致電（415）885−3700 聯繫 Dr. John W. Park 或者 Dr. Laura J. Esserman。也可以聯繫研究協調員，Erin Bowlby，（415）885−7638。

CONSENT

Participation in research is voluntary. I have the right to withdraw from the study at any time. Withdrawing will not affect my relationship with my doctors or jeopardize my future medical care. My participation may be ended at any time with or without my consent. If I wish to participate, I should sign below. I have been given a signed copy of this document and a copy of the Experimental Subject's Bill of Rights to keep. I will be asked to sign a separate form authorizing access, use or creation or disclosure of health information about me.

同意書

參與研究是自願的。我在任何時間都有退出研究的權利。
退出並不會影響我與我的醫生的關係或不會危及我未來的醫療。我的參與可能在任何時間得到或沒有得到我的同意就結束。如果我想參加，我會在下方簽名。我得到了這簽署文件的副本和一份參與調查研究權利的法案作保存 。我會被要求簽署另外一份表格作授權、使用、創造或披露關於我的健康訊息。

Yes 是 ☐ No 不是 ☐	I agree to allow a sample of blood to be taken for the study, portions of which may be kept for future cancer research purposes. 我同意允許抽取我的血液樣本作研究用途，它們可被保留作未來癌症研究。
Yes 是 ☐ No 不是 ☐	I agree to allow a sample of blood to be withdrawn from my bone (bone marrow sample) while I am in the operating room. Portions of my bone marrow, particularly isolated cells, may be saved for future cancer research purposes. 我同意當我在手術室時，從我的骨取血液樣本（骨髓樣本）。我的部分骨髓，尤其是分離的細胞，它們可被保留作未來癌症研究目的。
	_____ _____ Signature of Patient 病人簽署 Date 日期
	_____ _____ Signature of Physician/Person Obtaining Consent 醫生/同意人的簽署 Date 日期
	_____ _____ Signature of Interpreter 翻釋員簽署 Date 日期
	_____ _____ Signature of Witness 見證人簽署 Date 日期

Yes 是 ☐ No 不是 ☐	I agree to allow portions of my tissue (that remain after the pathologist has evaluated all tissue) to be saved for future cancer research purposes. 我同意我的部分組織（病理學家已經評估了所有組織的剩餘部分）可作爲今後的癌症研究目的。
Yes 是 ☐ No 不是 ☐	I agree to be contacted about future clinical research trials based on the results of this study. 我同意可因有關這項研究的結果而被再次聯繫參加將來的臨床研究。
Yes 是 ☐ No 不是 ☐	If I am receiving chemotherapy before surgery and the timing of my enrollment in the study permits, I agree to allow a sample of blood to be taken for the study prior to the start of chemotherapy, portions of which may be kept for future cancer research purposes. 如果我在手術和得到參加研究的允許前接受化療，我同意進行化療前開始抽取血液樣本作研究，其中部分血液它們可被保留作未來癌症研究目的。
Yes 是 ☐ No 不是 ☐	OPTIONAL: I am willing to undergo a bone marrow aspiration under local anesthesia prior to neoadjuvant chemotherapy in order to donate a bone marrow sample for the study. Portions of my bone marrow, particularly isolated cells, may be saved for future cancer research purposes. 可選：在局部麻醉下，新輔助化療前，。我願意經過骨髓穿刺捐出骨髓樣本作研究用途。部分的骨髓，尤其是分離的細胞，可被保留作未來癌症研究目的。
	_____ _____ Signature of Patient 病人簽署 Date 日期
	_____ _____ Signature of Physician/Person Obtaining Consent 醫生/同意人的簽署 Date 日期
	_____ _____ Signature of Interpreter 翻釋員簽署 Date 日期
	_____ _____ Signature of Witness 見證人簽署 Date 日期

Yes 是 ☐ No 不是 ☐	**For patients receiving chemotherapy AFTER surgery only,** 只供手術後才接受化療的患者閱讀： If I am receiving chemotherapy after surgery, I agree to allow a sample of blood to be taken upon completion of chemotherapy, portions of which may be kept for future cancer research purposes. 如果我手術後接受化療，我同意讓化療完成後抽取血液樣本，其中部分可被保留作未來癌症研究目的。 _____ _____ Signature of Patient 病人簽署 Date 日期 _____ _____ Signature of Physician/Person Obtaining Consent 醫生/同意人的簽署 Date 日期 _____ _____ Signature of Interpreter 翻釋員簽署 Date 日期 _____ _____ Signature of Witness 見證人簽署 Date 日期

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

三藩市加利福尼亞大學

研究參加者權利法案

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:	下面提及的權利是每個參加研究者的權利。作爲實驗對象我有以下權利：
I) To be told what the study is trying to find out,	1) 被告知研究試圖找出甚麼
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,	2) 被告知甚麼事會發生在我身上以及研究的程序、藥物或裝置是與規範的做法有甚麼不同
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,	3) 被告知我會因爲參加研究而有的高危風險、重要副作用或不適及其次數
4) To be told if I can expect any benefit from participating, and, if so, what the benefit might be,	4) 被告知如果我參加後可能有任何益處，並且如果有，益處是甚麼
5) To be told of the other choices I have and how they may be better or worse than being in the study,	5) 被告知我可以有的其他選擇，和比起研究，它們有甚麼好處或壞處
6) To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study,	6) 不論在研究之前或過程中都可以問關於研究的任何問題
7) To be told what sort of medical treatment is available if any complications arise,	7) 被告知如果有任何併發症出現，甚麼醫療服務會爲我提供
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,	8) 如果拒絕參與研究或在研究開始了後才改變主意，這決定不會影響我醫療服務應受有權利
9) To receive a copy of the signed and dated consent form,	9) 已收到簽了名並註明日期的同意書副本
10) To be free of pressure when considering whether I wish to agree to be in the study.	10) 我在考慮是否願意參與研究項目時是不會有壓力
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.	如果我有其他問題，我應該問研究員或研究助理。此外，我可聯繫人類研究委員會，這是一個關懷保護參與研究志願者的委員會。我可每逢星期一至五早上八時至下午五時致電(415) 476−1814 或者寫信至 the Committee on Human Research, Box 0962, University of California, San Francisco, CA 94143.
Call 476-1814 for information on translations.	如需翻譯服務，請致電 476−1814。
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