UNIVERSITY OF PITTSBURGH
Alzheimer's Disease Research Center

ADDENDUM CONSENT – PiB PET Scan Results Disclosure

TITLE: PET Imaging in the ADRC NeuroImaging Core Extension
(ADRC PET Extension Study)

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Who is being invited to take part in this add on to the study?
You are being asked to provide your informed consent to participate in the PiB results disclosure procedures for the ADRC Pet Extension study because you have expressed an interest in learning the results of your research amyloid PiB PET scan. Participants may request their PiB research scan results at any time while the study is active. However, those making the request greater than one year after the scan has been conducted will be advised that findings, particularly negative scan results, may not reflect their current brain amyloid status. It is important to remember that the PiB scan is a research scan and is not done as part of your standard medical care.

What will Happen in the Result Feedback and Follow-Up?
If not done previously by telephone or a Zoom call, participants wishing to receive their results will be screened to determine if they are eligible for results using four questionnaires that ask about mood and feelings. These questionnaires will take approximately 20 minutes. If found to be eligible, participants in the results disclosure portion of the study will undergo a results feedback session. It may be possible for the feedback session to be done at the same visit as when this informed consent is obtained; however, the session may have to be done at a separate visit, depending on scheduling. There will be one or two follow-up interviews done by telephone. The following paragraphs describe the result disclosure procedures.

- **Eligibility Screening Questionnaires** (*if not previous done* -ADRC ~ 20 minutes)
  These four questionnaires are designed to gauge your mood and feelings over the two weeks. The questions ask about feelings of worry and anxiety and also about depression and about thoughts of suicide. There are no right or wrong answers to these questions. In cases where the screening scores show you would not be eligible, you will be informed of your screening assessment results and advised to follow up with your physician.

- **Result feedback session** (ADRC ~ 30 minutes)
  If you have chosen to learn the results of your research PiB PET scan, you will be scheduled to either come back to the ADRC, or attend a video conference for a result feedback session. You are welcome to bring a family member or friend along to hear the results, we just ask you let us know in advance of the appointment. The decision of whether or not to receive your research results is ultimately yours and your wishes will be followed regardless of any requests that your family members may make.
  Should you decide to receive them, your results will be discussed with you by a physician investigator. The feedback session will last approximately 30 minutes.

- **Follow-up interviews** (Telephone, ~ 30 minutes)
  At approximately 1 month and, if needed at 6 months after the results feedback session we will call you for a telephone interview in which we will ask the same questions about your mood and feelings that you completed to determine eligibility. We will also ask a brief additional questionnaire on how the disclosure may have had an impact on you. These telephone interviews will be conducted by trained research staff at mutually agreed upon times. and will last approximately 30 minutes.

What are the possible risks and discomforts of PiB Results Disclosure?

Risks of mood questionnaires

There is a risk that you may experience emotional distress (feelings of sadness or anxiety) during the interview sessions. In addition to emotional distress, answering interview questions may be tiring. In cases where the screening scores show you would not be eligible, you will be informed of their screening assessment results and advised to follow up with a physician. Resources for identifying mental health care providers will also be provided.

Risk of result feedback session

During this session, you may be told about the relationships between this type of brain scan and the likelihood of developing Alzheimer's disease. You may develop emotional distress from learning an unexpected result, for example, that you are at increased or decreased risk for Alzheimer's disease. Risks of such emotional distress are minimized by monitoring you closely for changes in your mood during follow up study interviews.

Risk of breach of confidentiality

There is an infrequent risk of a breach of confidentiality. The research team will attempt to preserve your confidentiality by assigning a special research code number to your research record, and by removing personal identifiers (for example, your name, address, telephone number) from information stored about you for the study. Information linking the research code number to your name and other personal identifiers will be stored in a separate secure location. Access to any identifiable information about you that is contained within your research record will be limited to the Principal Investigator and her research staff.

Will I benefit from taking part in this study?

You may not directly benefit from participating in this portion of the study. Some participants may find the PiB PET scan results helpful.

What are the alternatives to participating in the disclosure procedure?

The PiB PET scan is considered a research scan and uses a non-FDA approved radiotracer. You could undergo a PET scan ordered by your physician for your clinical care that uses one of the three radiotracers which the FDA has approved for use when informing a person about the

presence of amyloid-beta plaques. The three approved radiotracers are: [18F-Florbetaben (Neuraceq), 18F-Florbetapir (Amyvid), and 18F- Flutemetamol (Vizamyl)].

If you have questions about whether to pursue a clinical PET scan involving a different radiotracer you should discuss that with your physician.

Will I be paid if I take part in this research study?
You will not be paid for learning the results of your research brain scan. Parking will be paid for by the study any time that you come to Oakland for study purposes. There are no costs for participating.

Who will have access to the information I provide during this study?
Any information about you obtained from this research study will be kept as confidential as possible. Any information about you obtained from this research kept in locked files at the ADRC. Only authorized study investigators and staff will have access to these files. You will not be identified by name in any publication of research results.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.
If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform the appropriate agencies as required by Pennsylvania law. In addition to the principal investigator and her study team, the following individuals will or may have access to identifiable information related to your participation in this research study:

- Authorized representatives of the University of Pittsburgh Office of Research Protections, the University of Pittsburgh's Human Use Subcommittee (HUSC) of the Radiation Safety Committee and the U.S. Food and Drug Administration may review

your identifiable research information for the purpose of monitoring the appropriate conduct of this research study.

- Authorized representatives of the sponsor of this research study, the National Institute on Aging, may review and/or obtain identifiable information related to your participation in this research study for the purpose of monitoring the accuracy and completeness of the research data.

While the U.S. Food and Drug Administration and National Institute on Aging (as part of the National Institutes of Health) understand the importance of maintaining the confidentiality of your identifiable research and medical information, the UPMC and University of Pittsburgh cannot guarantee the confidentiality of this information after it has been obtained by these agencies.

The investigators may continue to use and disclose, for the purposes described above, identifiable research information related to your participation in this research study for a period of at least seven years after the study ends.

Sharing of De-Identified Research Data: If information regarding the results disclosure procedure is shared with investigators outside of this study, it will be shared without identifiers. The information may be the basis of scientific publications and may be shared in the future with researchers within or outside of the University of Pittsburgh and UPMC who are interested in studying neuroimaging, MCI and Alzheimer's disease or related neuropsychiatric disorders.

Is my participation in this study voluntary?
Your participation in the results disclosure procedures is voluntary. Whether or not you provide your consent for participation in this portion of the study will have no effect on your current or future relationship with the University of Pittsburgh or your current or future medical care at a UPMC hospital or affiliated health care provider. In addition, whether or not you provide consent for participation in this portion of the research study will have no effect on your continued participation in the ADRC.

May I Withdraw?
You may change your mind and decide not to participate in the results disclosure portion of the study.

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VOLUNTARY CONSENT:

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable.

By signing this form, I agree to participate in the results disclosure procedures. A copy of this consent form will be given to me.

_____ _____
Participant's Name (Print) Date

_____
Participant's Signature

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***USE THE FOLLOWING ONLY WHEN APPLICABLE**

The participant (Name)_____ is unable to consent because:

_____

As the participant's legally authorized representative (LAR), I consent to participation for the participant and provide my authorization to share the above-named participant's medical records with the research team.

_____ _____
LAR (Print Name) Relationship to Participant

_____ _____
LAR Signature Date

ASSENT
This research has been explained to me, and I agree to participate.

_____ _____
Signature of Participant Date

_____
Printed Name Participant

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CERTIFICATION OF INFORMED CONSENT

I certify that I have explained the nature and purpose of research study to the above-named individual, and I have discussed the possible risks and potential benefits of participation in the results disclosure portion of the research study. Any questions the individual has about this process have been answered, and the physicians and research staff associated with this study will be available to address future questions as they arise. I further certify that the results disclosure session was not conducted until after this consent form was signed.

_____	_____
Person Obtaining Consent (Print)	Role in Research Study
_____	_____
Person Obtaining Consent (Signature)	Date