

#### [Site Name] ADHOC Consent Form

#### What is ADHOC and what is the purpose of this study?

- ADHOC is a unique, new observational research study and online community that is being created in collaboration with a number of HIV clinics and practices. The project is sponsored by ViiV Healthcare.
- ADHOC stands for Aging with Dignity, Health, Optimism and Community.
- ADHOC collects health information from people living with HIV who are over 50 years of age.
- ADHOC seeks to enable participants to connect with others whose experience most closely matches their own around issues critical to living with HIV.

#### Why are we asking you?

We are asking you to participate because:

- You are living with HIV;
- You are over 50 years of age; and,
- Your healthcare provider is taking part in this ADHOC Study.

#### What are the participation requirements?

This is an on-going study and you can participate for as long as you want or until the study ends.

#### Participation includes:

- **Completing an ADHOC profile** - It reviews your demographic, diagnostic, medical, quality of life, and other health-related information. It will take about 45 minutes to complete and can be accessed immediately after completion of this online consent form.
- **Keeping your ADHOC profile up-to-date** - In order to keep your information current, we ask that you login and update your profile whenever is most convenient for you. This will take as much time as you want to dedicate to it. We anticipate updating your ADHOC profile will take between 5 and 20 minutes.

**Joining the ADHOC Community** - Joining the ADHOC Community gains you access to the following optional features:

- **Share With Your Provider** - Share some or all of your ADHOC profile with your provider, if you choose to do so.
- **Community Summary** - Compare your ADHOC profile to the ADHOC community.
- **Research Briefs** - Learn about current research regarding aspects of aging with HIV most relevant to you.
- **Follow-up Questionnaires** – During your participation in ADHOC, you may be prompted to fill out follow-up profiles or questionnaires. We will notify you of these opportunities via email, phone, US mail, and/or mobile notifications. Details regarding these profiles or questionnaires

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will be included in the notifications. One such follow-up is to complete an annual follow-up of your online profile at least one year after you completed your last profile.

#### Future goals of ADHOC

ADHOC investigators will continue to develop interventions designed specifically for people with HIV over 50 years of age. Currently, two features are being designed and include:

- **Find People Like You:** Using search criteria you select, you will be able to communicate, share experiences, and connect with others whose experiences most closely match your own. Your actual name and contact information will not be revealed to another participant unless both you and that other participant decide to connect with one another.
- **Groups and Forums:** ADHOC may enable you to take part in groups and forums focused on issues of concern to you.

In addition, Mazonson & Santas, Inc. (M&S), the health research firm running the study may contact you by phone, email, push notifications, in-app notifications, text, or US Mail for study-related purposes, or to inform you of possible future projects, studies, or sub-studies that you may be interested in or qualify for, or to inform you of new ADHOC features that are available. New ADHOC features may include updates to the Share With Your Provider summary, new graphs or charts added to the Community Summary, or new Research Briefs. In addition, participants may be contacted when Find People Like You or Groups and Forums have been launched or when information is available related to Find People Like You or Groups and Forums. Correspondence by unsecured email will not contain your personal health information (PHI). Finally, please note that participation is not required to continue seeing your HIV provider, and taking part in the ADHOC study is completely voluntary.

#### What are the risks?

- This study is completely observational.
  - No procedures other than data collection are required.
  - You do NOT need to make any changes to your HIV care.
- As such, the only known potential risk is loss of privacy or confidentiality from accidental disclosure of your personal identifiable medical information. However, we have designed ADHOC to minimize this risk utilizing the following methods:
  - Each profile will be identified by a unique ADHOC Study ID number linked to you. This ID number (not names) will be recorded on your online profile and on a linking list kept by M&S.
  - All study data is stored in a secure, encrypted database. Study records and all study-related documentation will be maintained for at least two years after the completion of the registry.
  - Researchers at M&S with access to individual-level study data will agree to be bound by our security and privacy policy (<http://adhocstudy.com/#/privacy>) and data identifying you as an individual will not be released without your explicit permission. Study data

- may be inspected by the study sponsor, ViiV Healthcare, M&S, regulatory agencies or an Institutional Review Board (IRB) to ensure ADHOC is being properly and ethically run.
- Electronic data will be collected and stored by M&S separate from your contact information. Your name will not be displayed in the database alongside your ADHOC profile. M&S and research collaborators will work together to analyze this data. Publications will show group results and conclusions but will not identify individuals.
  - By joining Groups and Forums or using the Find People Like You feature, you agree to the following rules:
    - No sharing of your log in information, including your username or passwords with anyone within or outside the study.
    - No sharing of other people's personal information such as full name, private phone numbers, email or street address.
    - No use of expletives (swear words).
    - No use of the social network space for urgent medical issues.

Not following the rules could result in your being asked to leave the study.

Although we have set an expectation with these rules, we cannot promise all participants will follow the rules and that can lead to unexpected risks, such as your identity being known or being exposed to uncomfortable language.

- Your healthcare providers will be required to disclose information required by law. Your provider will also be required to report information to ViiV Healthcare, the study sponsor, related to possible adverse or serious adverse events, only in cases where the information related to those adverse events is disclosed directly to the site investigator(s) by you. If you are experiencing side effects or problems that you think may be related to your HIV medication, please inform your healthcare provider.

#### **Are there costs? Will I be paid?**

- There is no cost to you for participating in ADHOC. You will need to invest your time to complete your initial online profile (approximately 45 minutes) and any other updates you choose to make to your profile.
- To thank you for your effort spent as a participant in ADHOC, we will send you a gift card [Amazon Gift Card OR American Express gift card OR Visa gift card, etc.] valued at \$100 upon completion of your initial profile and related tasks, and after verifying you are a patient at the participating clinic.
- In addition, you will be compensated with a \$75 gift card [Amazon Gift Card or American Express gift card or Visa gift card, etc.] after completing each annual follow-up of your online profile and related tasks.
- Any compensation for participation in additional questionnaires, profiles, studies, or sub-studies will be described in notifications sent to you.

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#### Are there benefits?

- Benefits to you: There are no direct benefits to you by participating in this study. However we expect the following aspects of this study may be helpful to you.
  - Share With Your Provider Summary: After you have completed your ADHOC profile, you will be asked if you would like to share a summary of your online profile with your provider. You will be able to control which section(s) you choose to share and preview the final report before it is sent to your provider. At any time while deciding which sections to share with your provider, you will be able to opt-out of sharing.
    - Your provider will receive a summary containing any new information you provide every 2 – 3 weeks. This is not for reporting medical emergencies. If you are having a medical emergency, please contact your provider or call 911.
  - Receive targeted Research Briefs: You may receive briefs that provide specific information based on your responses in the online profile.
  - Review Community Summary: This report will enable you to compare your responses to those of other anonymized (identifiable information removed) participants in ADHOC.
  - Find People Like You: Beginning in 2019, using search criteria you select, you will be able to communicate, share experiences, and connect with others whose experiences most closely match your own. Your actual name and contact information will not be revealed to another participant unless both you and that other participant decide to connect with one another.
  - Groups and Forums: In the future, ADHOC may enable you to take part in groups and forums focused on issues of concern to you.
- Benefits to others:
  - We hope that the information collected from this study will help improve care for patients over 50 with HIV.

#### Who is available to talk more about ADHOC?

Before, during, and after participation, you should feel free to ask questions and discuss the study with ADHOC personnel.

- If you have any questions or input about your participation or about your rights as a research subject, or if you think you may have been injured as a result of taking part in this study, you may contact:

Principal Investigator: Peter Mazonson, MD, MBA  
Research Managers: Jeff Berko, MPH; Theo Loo, MS  
Phone: (855) 383-0735

- If you have questions or comments you don't feel comfortable asking the Principal Investigator, you may contact the IRB:

Ethical & Independent Review Services (E&I)  
Phone: (800) 472-3241  
Email: [subject@eandireview.com](mailto:subject@eandireview.com)  
Reference E&I study 17130

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#### Study participants have rights.

- Participating in this study is entirely voluntary.
- If you choose not to participate, your relationship with your healthcare provider will remain the same.
- You may choose to discontinue your participation in ADHOC at any time without any penalty or loss of benefits to which you are entitled by notifying the principal investigator, Peter Mazonson, MD, MBA, or research associates Jeff Berko, MPH or Theo Loo, MS; however, any data already provided will remain part of the research study.
- Your alternative to taking part in this study is to refuse without any penalty or loss of benefits to which you are entitled.

#### What do you do next?

- Talk with your healthcare provider or contact ADHOC personnel at (855) 383-0735 if you have any unanswered questions or are uncertain about what participation means;
- When ready, click Agree below to begin.
- If you want a copy of this consent form, please print it out. You will be given another opportunity to print out the consent form once completed.

#### Review and Agree

By agreeing, I confirm that I have read this consent information, all my questions have been answered and that I am voluntarily consenting to participate in the ADHOC study as described.

By agreeing, I do not waive any of my legal rights.

If you agree to be part of this study, type your first and last name below then click agree to continue.

First name	Last name	Date