

**Human Subject Studies Privacy Procedure**

Self Assessment Questionnaire

*PH-PCO\_0016 Version 1.02  
 Date: 2015-03-23*

*This “Self Assessment Questionnaire” shall only be used together with the up to date “*[*Guidance”*](https://share-intra.philips.com/sites/ppc/functions/cto/sp/privacy/privacy_compliance/Lists/PCO%20Guidance%20Documents/Attachments/23/PH-PCO_0015%20Human%20Studies%20Privacy%20Procedure.docx) *(PH-PCO\_0015) for this Human Subject Studies Privacy Procedure.*

# Self-Evaluation Checklist

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Study / Survey / Trial name:** | | | | | Study\_Name\_Test | | | |
| **Study Lead:** | | | | | **\*Primary Point of Contact\*** | | | |
| **Project number:** | | | | | SRC-AI-Example-2020-12345 | | | |
| **Responsible Executive:** | | | | |  | | | |
| **Privacy Lead/Officer:** | | | | | Monica Sanches 0.05 | | | |
| **A. Personal Data Processing** | | | | | **Responses** | | **Comments** | |
| **A.1** | Data Subjects? | | | | Employee volunteers  Patients  Consumers / Customers  External volunteers  Other: Click here to enter text. | |  | |
| **A.2** | Type of Data? | | | | Any data about human subjects  Personal Data  Sensitive Data  Financial Data  Biospecimen (e.g., tissue, blood, DNA)  Other? Please specify:  Click here to enter text. | |  | |
| **A.3** | Location of collection? | | | | Single Site  Multiple Site / Single Institution  Single Country / Region  Multiple Countries/Regions  Multiple Site / Multiple Institutions  Single Country / Region  Multiple Countries/Regions | |  | |
| **A.4** | Location of processing? | | | | Philips  In Country/Region of collection  Other Country/Region of collection  Institution  Other 3rd Party  In Country/Region of collection  Other Country/Region of collection | |  | |
| **A.5** | Location of Consent?  (who is maintaining the consent forms) | | | | Philips  Institution | |  | |
| **B. Consent/Authorization for Personal Data Uses and Disclosures** | | | | | **Responses** | | **Comments** | |
| **B.1** | Is there an ICH-E6 / ISO 14155 compliant Informed Consent form that is or will be IRB/ICBE approved? | | | | Yes  No  N/A | |  | |
| **B.1.a** | | | If study is restricted to USA subjects: Is there an IRB waiver of consent? | | Yes  No  N/A | |  | |
| **B.2** | Is there a signed Data Use / Sharing Agreement? | | | | Yes  No  N/A | |  | |
| **B.3** | Are procedures for documentation of informed consent defined? | | | | Yes  No  N/A | |  | |
| **B.4** | Does the Informed Consent form provide: | | | | The purpose of data / biospecimen collection?  Who that data will be shared with?  Description of Personal Data that will be collect?  How Personal Data will be kept confidential (i.e. de-identified, coded, etc)?  Detailed contact information for data subject questions?  Participation conditions (opt-out, stop participation etc.)?  Is the consent process ISO 14155 compliant? | |  | |
| **B.5** | Will the consent be signed? | | | | Yes  No  N/A  If no please describe the consent mechanism used here:  Click here to enter text. | |  | |
| **C. Data Collection (Confidentiality)** | | | | | **Responses** | | **Comments** | |
| Select one of the options below; only if multiple data sets, multiple options possible | | | | | | | | |
| **C.1** | Is it an Anonymized Data Set? | | | | Yes  No  N/A | |  | |
| **C.2** | Is it a De-identified Data Set? | | | | Yes  No  N/A | |  | |
| **C.3** | Is it a Limited Data set? | | | | Yes  No  N/A | |  | |
| **C.3.1** | | If yes, is there a CRA or Data Use / Sharing Agreement in place with the Site? | | | Yes  No  N/A | |  | |
| **C.4** | Is it a Coded Data Set? | | | | Yes  No  N/A | |  | |
| **C.4.1** | | If yes, who is performing the coding? | | | Philips  Institution  3rd Party | |  | |
| **D. Contracts and Agreements** | | | | | **Responses** | | **Comments** | |
| **D.1** | Is there an existing MRA or MCIA? | | | | Yes  No  N/A | |  | |
| **D.1.a** | | Does the MRA or MCIA contain the privacy riders? | | | Yes  No  N/A | |  | |
| **D.1.b** | | Is there a project addendum / exhibit attached for this project? | | | Yes  No  N/A | |  | |
| **D.1.c** | | Is there an appropriate privacy rider in the project addendum / exhibit? | | | Yes  No  N/A | |  | |
| **D.2** | Are there any Third Parties providing services to support the Study? | | | | Yes  No  N/A | |  | |
| **D.2.a** | | Is there a MSA with each of the third parties documenting the agreement between the involved parties? (e.g., Sponsor and CRO, Investigator and CRO) | | | Yes  No  N/A | |  | |
| **D.2.b** | | Are appropriate privacy riders included in the service agreement? | | | Yes  No  N/A | |  | |
| **D.3** | Is there a CRA or Data Use / Sharing Agreement with the site? | | | | Yes  No  N/A | |  | |
| **E. Data Management** | | | | | **Responses** | | **Comments** | |
| **E.1** | Is there a signed CIP / Protocol? | | | | Yes  No  N/A | |  | |
| **E.2** | Is there a sample CRF? | | | | Yes  No  N/A | |  | |
| **E.3** | Are written procedures in place to secure the confidentiality of the data collected? (Consent forms, key codes, etc.) | | | | Yes  No  N/A | |  | |
| **E.4** | Is there a retention period defined? | | | | Yes  No  N/A | |  | |
| **E.4.a** | | Are recordings etc. of interviews deleted after transcription or 6 months whichever comes first? | | | Yes  No  N/A | |  | |
| **E.5** | Are there written procedures for the destruction of records after the defined retention period? | | | | Yes  No  N/A | |  | |
| **F. Additional Documents Supplied** | | | | |  | |  | |
| **F.1** | Clinical Investigation Plan (CIP) / Protocol | | | | Final  Draft  N/A  Click here to enter version/date. | |  | |
| **F.2** | Data Flow Diagram and Data Description (if not already in CIP) | | | | Final  Draft  N/A  Click here to enter version/date. | |  | |
| **F.3** | Case Report Form (CRF) | | | | Final  Draft  N/A  Click here to enter version/date. | |  | |
| **F.4** | Informed Consent | | | | Final  Draft  N/A  Click here to enter version/date. | |  | |
| **F.5** | Master Research Agreement (MRA) and applicable addenda | | | | Final  Draft  N/A  Click here to enter version/date. | |  | |
| **F.6** | Master Service Agreement (MSA) for each Contract Research Organization (CRO) in the trial and applicable exhibits | | | | Final  Draft  N/A  Click here to enter version/date. | |  | |
| **F.7** | Clinical Research Agreement (CRA) with institution | | | | Final  Draft  N/A  Click here to enter version/date. | |  | |
| **F.8** | Master Clinical Investigation Agreement (MCIA) and applicable addenda | | | | Final  Draft  N/A  Click here to enter version/date. | |  | |
| **Privacy Officer Evaluation** | | | | | | | | |
| **Notes:** | | | | | | | | **Acknowledgement:** |
| Click here to enter text. | | | | | | | | Self-assessment OK  Full PIA required |
| **Privacy Officer name:**  (Privacy Officer to acknowledge as delegated by Responsible Executive (RE)) | | | | | | Monica Sanches 0.05 | | |
| **Date:** | | | | Click here to enter text. | **Signature:** |  | | |

Please address additional questions, feedback on this procedure and/or self-assessment checklist to [healthcare.privacy@philips.com](mailto:healthcare.privacy@philips.com).

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