H3ABioNet

Pan African Bioinformatics Network for H3Africa

Developing Case Reporting Forms for Genomics Research in Africa

Recommendations from H3Africa Experiences

Acknowledgments

These recommendations were developed by the H3ABioNet Ontology and Structured Vocabulary TaskForce. Members include:

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Introduction

Case Report Forms (CRFs) are used in clinical research projects to collect de-identified patient data (usually clinical phenotypes) that will be included in the project database. Careful design of a project's CRFs to meet the requirements of the protocol will ensure that collected data is captured accurately; efficiently; and consistently, translating into high quality, accurate data that will produce reliable research results.

Due to advances in Genome-Wide Associations Studies (GWAS), there is a need for large-scale phenotypic data which incorporate social, environmental and clinical factors to match the genomic variants. Data pooling and meta-analysis are now central to genetics/genomics to increase statistical power. To encourage harmonization and data sharing, CRFs in biomedical research should use and support common measures; terminology and promote the collection of high quality standardised data.

H3Africa aims to improve human health in Africa by facilitating genomic research in a range of Africa-specific diseases such as cardiovascular, diabetes and infectious diseases. In addition to building capacity in genomic research expertise on the African continent H3Africa's core guiding principles are grounded in promoting data sharing. To facilitate the standardization and cross-study sharing of phenotype data within H3Africa and beyond, H3Africa created the Phenotype Harmonization Working Group (PHWG). The PHWG agreed upon a set of 24 essential questions that should be standardised during data collection (originally based on and incorporating PhenX standards) for inclusion in all H3Africa project CRFs. These essential phenotype questions form a foundation for data sharing across the various H3Africa studies (studies will add to this essential set of phenotypes any additional phenotypes needed as determined by the study). At the time that the PHWG agreed on the 24 variables, most projects had already completed their CRF design and data collection so the implementation of the PHWG recommendations varied across projects. Now there is a need to revisit these recommendations and expand on them based on lessons learnt thus far from the shared CRFs from H3Africa projects and incorporate standardised templates and the agreed 24 core variables into future H3Africa project CRF designs.

In a decision within the H3ABioNet consortium to move towards using RedCap for clinical data collection, consideration needs to be made towards the layout of the paper-based CRFs for a study. RedCap automatically will provide CRFs in pdf format but RedCap's layout and design is not necessarily the ideal design for collecting clinical data on paper both in terms of space usage and flow. We have generated a set of paper-based forms in Microsoft Publisher (which is readily available to users with Office) based on the Standard CRF data elements. These forms can be adapted to suit specific study needs but we

recommend careful attention to data flow and following the RedCap Database design as closely as possible to prevent data capture errors.

After reviewing CRFs from six H3Africa projects, we developed the recommendations proposed in this document. While the proposed recommendations cannot be used for ongoing H3Africa projects which are already in the final data collection phase, lessons learnt thus far can inform future studies within H3Africa and possibly set CRF development standards in African genomics research.

We also propose the following action items for H3Africa to facilitate adoption of these recommendations across genomic studies in Africa:

- These recommendations follow recent ethics committee guidelines created by the H3Africa Ethics Committee. Most ethics committees approve research protocols on the assumption that the protocol will be translated into CRFs which reflect the boundaries outlined in the proposals. In addition, ethics approval usually takes long as committees in Africa are still acquainting themselves to the new research approaches introduced by the genomics field. We therefore propose H3Africa via the Ethics Committee engages the different ethics committees in Africa on the CRF template proposed in this document. A CRF could help ethics committees visualize better how the research will be experienced by the study participants. The proposed CRF template could be used as a benchmark by ethics committees to facilitate quicker reviewing processes and possibly address assumptions.
- Training to be developed for genomics/genetics researchers on CRF design; data collection and data quality assurances. Traditional training in genomics and genetics researches focused mainly on the laboratory skills and not on CRF design and data collection. There is need for genomics experts to be trained in the basics of CRF design, data collection and quality assurances based on recommendations developed in this guideline.
- Engage with bodies which can facilitate the standardization and inclusion of African-specific research measures/protocols or variables into publicly available repositories.

Recommendations

Recommendations 1: Develop CRFs in tandem with protocol

CRFs should be developed during the protocol design and development, not afterward in the rush to meet study initiation dates post ethics approval. CRFs are often developed hastily at the end of the protocol finalisation, as it may be difficult to finalise the forms before protocol is approved and finalised; the design of CRFs may not be viewed as part of the scientific process; there is a general lack of understanding of the benefits to be gained by having good forms prepared carefully and the subsequent common data collection mistakes that could have been avoided (such as confusing results; participant loss; poor quality data; loss of statistical power) with careful CRF design.

Once the protocol is in development, purposes of visits, relevant data to be collected, workflows and types of data can all be identified. This information can all be harnessed to begin the design and development of the study CRFs. Being ahead of the game in the development of the CRFs and study database gives more time to ensure quality data collection; better training and preparation for the study team.

"Given the time and attention usually devoted to protocol development, it is paradoxical that data collection forms are often hastily constructed at the end of that process. – From Data Collection Forms in Clinical Trials, 1991, Raven Press, Spilker and Schoenfelder.

H3Africa studies can utilise the 24 Harmonised Phenotypes template to kickstart their CRF design for their study.

Recommendations 2: Use Established Measures Where Possible

The Phenotypes and eXposures (PhenX) project is a collaboration between the RTI International (Research Triangle Park, North Carolina) and the National Human Genome Research Institute (Bethesda, Maryland). Through Working Groups made of domain experts, PhenX develops consensus measures and units of measurements for phenotypes and exposures for use in biomedical research. The use of the standardised PhenX measures promotes cross-study comparisons and data sharing within the continent and globally. An example of how using PhenX could help standardize measures and units across different studies is illustrated by a smoking example shown in Table 1.

Table 1: Illustration of how using PhenX could help collect comparable data on smoking from two different projects.

Project X	Project Y	PhenX Protocol #030802 SECTION A
How many cigarettes have you smoked in the 5 days?	At most how many cigarettes do you smoke per day?	On average how many cigarettes do you smoke per day?

Some African genomic research studies require measures specific to the African continent, therefore PhenX has limitations due to its development within the United States of America. The 24 phenotypes were assessed at a recent H3Africa Data Catalogue Jamboree in Cape Town in 2017 against the PhenX standardised measures and often minor modifications were necessary when reviewing the questions in an African context. These modifications will be fed back to the PhenX collaboration in order to both promote standards useable in African and to thereafter allow African genomic researchers to realise the full potential of this resource. The limitations of PhenX toolkit will be addressed in a separate report in preparation of exploring a possible collaboration with PhenX.

Recommendation 3: Coding and Numbering

An ideal coding system would include distinctions for project sites (where there are multiple), cases, controls and serial numbers. Using the same participant ID for an individual's samples stored in different platforms will ensure easy traceability and synchronisation of data. Numbering and coding CRFs and questions on the forms clearly and correctly will reduce data collection errors and data filing issues.

In addition, a coding system with sets of consistent codes for standardised answers should be applied to questions. A good coding system presented in a Data Dictionary will make data capturing and data analysis easier and faster. Developing a "universal coding system" within a project and even across H3Africa projects will be very helpful towards promoting larger, shared data platforms for analysis. When sharing data from the 24 harmonised phenotypes template, data will need to be shared with the provided coding recommended to enable true data sharing and reduce time taken to re-format data that has not been collected according to the codes provided.

For example: Yes = 1

No = 2

777 = Other

888 = Don't know

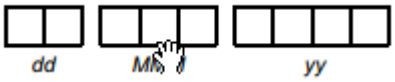
999 = Refused

Recommendation 4: CRF design and completion

Case Report Forms should be developed appropriately depending on the method of data collection. Distinguish between data needed for patient care and data to address the objectives of a study, this enables each item of data collected to be relevant for the study. Of course, in the field of genomics we are not always aware of phenotypic data which may contribute to our understanding of genetics later down the line. Reviewing previous data forms used in other studies and establishing clear principles for guiding the choice of variables to collect is important and weighing up the known costs and benefits of collecting each variable.

Data collected electronically often require a different layout than data collected on paper format. As the majority of H3Africa studies currently collect data on paper forms, the following principles are largely for paper CRF design and development.

Guiding principles:

1. There should never be any identifiers collected on the CRF apart from the study/project unique participant ID. Identifiers in clinical research are any data or combinations of data that could enable someone to identify the participant.
2. Use consistent formats, font styles and sizes throughout a CRF booklet.
3. Use header and footer templates containing version control; unique form name / code; page numbering; study name; organisation name/logo and any other repeating object e.g. staff initials blocks signature space; QC check field etc.
4. It is generally a good idea to stick to portrait versus landscape however whichever layout is used, do not use a combination of portrait and landscape
5. Use clear, concise questions, prompts and instructions. Keep a consistent method for how questions are phrased i.e. will questions be phrased as if directed to participant in person or will data be collected impersonally with simple data prompts of person completing CRF. e.g. 1. What is your age? versus 1. Participant's age:
6. Use visual cues on the CRF such as boxes, arrow indicators etc. to clearly indicate place and format for data to be recorded e.g. date format 

7. Avoid using the option of "circling answers" rather use checkboxes requiring an 'X' and not a tick which can be misinterpreted.

8. Number questions and sub-questions sensibly including clear guidance about skip patterns like what to skip and what not to skip should be mentioned in appropriate places. Keep skip instructions to a minimum to avoid cluttering up the CRFs and creating confusion.
9. Any completion instructions should be bold and italicised but also be minimised and clear and placed appropriately.
10. Make sure boxes and lines for data entry are placed in such a way as to clearly indicate which data should be completed for each question/item on the form.
11. Minimise free text as much as possible. Where lines for free text will have data coded in the database ensure there is sufficient space for entries to be filled in.
12. Avoiding placing too many items/questions on a CRF that will mean it looks cluttered and completing the CRF becomes confusing as this will impact the data quality collected.
13. Page numbering should be consistently places and indicated clearly
14. Indicate number of decimal places to be recorded
15. Use standardised date formats throughout the CRF booklet. It is best to correlate this in your entire study processes to reduce data collection errors. H3Africa has agreed to use the DMY format for consistency sake.
16. Use pre-coded answer sets consistently such as yes / no as mentioned in Recommendation 2.

H3ABioNet is able to support / assist H3Africa data managers in projects making use of RedCap both for paper-based and electronic CRF design. We recommend establishing a study / project CRF look and layout design and then building on the harmonised phenotypes RedCap template already established and available for use.

Refer to **Appendix A** for the H3ABioNet RedCap CRF Completion SOP.

Recommendation 5: Piloting

After creating a project set of CRFs, we recommend that the researchers pilot the CRFs before the project commences with the staff who will be completing the forms. Testing the forms under actual study conditions before use in the study allows for the CRF set to be adjusted and optimized for use in a real-life setting. Piloting also facilitates training, proof-reading and formatting to make the forms easier to follow and complete. This will help avert errors in CRF completion, poor interpretation of questions and

problems in capture of data to the study database. In addition, other omissions such as space for qualitative answers could be avoided.

In cases where measures are adapted from toolkits such as PhenX, it is important to adapt questions to the African context. As previously mentioned toolkits such as PhenX are mainly based on instruments and measures developed in the first world countries such as the USA. Given the wide-range of cultures and tribes in Africa, it is important to adapt any self-reported questions specifically to the population/community under study without compromising the standardization. Measures and questionnaires implemented in one part of the region might not be optimal for use in another part of Africa and would thus require adjusting and further testing/piloting. There are certain questions which might be culturally unacceptable in different regions or questions which seem clear in one region could be ambiguous in another. Discussing questions with staff working in a patient setting will provide useful insight into best practices to implement and problem areas for data collection can be minimised through training and preparation.

It is also important to consider the international research community when adapting CRF content. While use of local contextual questions is key to getting quality data, it is also important to consider that other international researchers might request use of your CRF or data therefore generic terms could be included in the CRFs, possibly in brackets or as footnotes. After piloting, if the final CRF is drastically different from the version submitted to the ethics committees the CRF would need to be re-submitted for ethical review.

Recommendation 6: Have clear instructions for data entry

CRF completion instructions should be clear and easily accessible to the data collectors. Where possible, face to face training should be provided and a CRF reference manual provided to site personnel to promote accurate data entry. Instructions for fieldworkers should be included in the CRFs, possibly in a font which is distinct eg. italics/bold. Visual cues (e.g. arrows) can also be added to make instructions clearer but keeping the CRF as uncluttered and planned to flow effectively for the reality of data collection is as important to ensuring high quality data is obtained from participants.

Recommendation 7: Screening / Refusal Logs and Exclusion Criteria

Screening or refusal logs should be maintained which can help evaluate the recruitment process and help provide valuable information which can be used by other researchers in the future or help the

researchers to troubleshoot. Ensuring there is a clear process set out for staff with regards to enrolment and assessing inclusion and exclusion criteria will prevent incorrect participant enrolments. See **Appendix B** for examples of screening / refusal logs.

Recommendation 8: Description of the CRF development process

We also recommend that researchers document and describe how their CRFs were developed and make the CRF set available for other researchers to re-use or adapt should they need to. Using the PhenX toolkit can facilitate documentation of the process since each toolkit has a reference number. Translated versions of the CRFs should also be made available to the scientific community**.**

RedCap CRF template for the 24 Harmonised Phenotypes

The proposed RedCap template was split into separate CRF instruments based on the types of data being collected and perceived point at which the data would be obtained from a participant. Cross-sectional (once-off) data should be collected on a separate form from data that will be collected longitudinally (at regular intervals in a study). It should be noted that the inclusion of paediatric participants in a study may require some adaptations to the data collection fields and the PHWG is currently working on a separate Standardised Data Dictionary for paediatric data collection as there are many relevant data elements for paediatric participants that differ from adult participants. Wherever possible the PHWG has attempted to provide standardised data questions that do not require modification as the aim is to make data collection of key variables uniform within the H3Africa consortium.

It should be noted that when paper-based CRFs are utilised for a study, accommodation must be made to ensure the collection of the visit date, date form was filled in (completed) by staff, staff member initials / name, PID, study and site. Electronic CRFs in RedCap will automatically record the date and time of completion and who entered the data.

The complete RedCap CRF template set can be found in **Appendix C**.

Descriptions of each section and tips relevant to that section are included in sections below:

01: Demographics (Essential)

Item	Comments
Key fields	Capture Unique participant ID; visit date is assumed to be date of enrolment. A field is provided to record the visit code or visit name - essentially for any captured clinical study data one should capture: participant identifier; date of data collection (usually this is the visit date); name of visit/event; initials of identification of person completing form or questioning participant; and the date the form was completed if different from the visit date.
1.	Whenever possible participant date or birth should be captured and verified with official documentation. DOB is sometimes considered to be a personal identifier, yet most studies still capture the entire DOB. When reporting it is best to use Year of Birth only to calculate age. In paediatric studies DOB is usually known but when reporting, it may be best to report age in days or months. Age in years is automatically calculated from the Date of Birth in a hidden database field.
1.1.	Approximate age should only be captured if the exact Date of Birth is not known. You should not be entering data in 1.1 unless the checkbox in Item 1 "Don't know" has been checked.
2.	The field collects biological sex of participant, do not confuse it with gender identification. The option "Other" was used as a sensitive manner to identify Intersex participants who may be sensitive due to stigma about their biological sexual status. Avoid using the Refused checkbox whenever possible.
3.	The name of the participant's country of birth should be recorded here (on the electronic form a drop-down list of country names will be available). If unknown, check the "Don't know" box.
4.	The participant's home/native language that they were raised with should be completed here. If the participant has multiple native languages, complete the field with the most commonly used native tongue – the language they consider their home language. If capturing electronically, a dropdown box of African languages will be available in the database, if the language is not on the dropdown list in the database, the data-capturer can enter "Other" and complete the Specify Other field (this is only viewable on the electronic forms on the database with the participant's native language supplied). An African language and ethnicity ontology is still being constructed for H3Africa.
5.	The participant's original ethnic tribal affiliation should be collected here. If the participant identifies with multiple ethnic tribes, either document the primary one first on the form or collect the one the participant first identified with growing up. If capturing electronically, a dropdown box of African ethnic tribal affiliations will be available in the database, if there is not a recognised option in dropdown list in the database, the data-capturer can enter "Other" and complete the Specify Other field only viewable on the electronic forms on the database with the participant's ethnic tribal affiliation. An African language and ethnicity ontology is still being constructed for H3Africa.
6.	The participant's biological father's country of birth should be recorded here. If unknown, check the "Don't know" box. If the participant is adopted or orphaned and unable to supply this information, this should be recorded and it may be worth including a field on the demographics form.
7.	The participant's biological father's home/native language that they were raised with should be completed here. If he has multiple native languages, complete the field with his most commonly used native tongue – the language he considers his home language. If capturing electronically, a dropdown box of African languages will be available in the database, if the language is not on the dropdown list in the database, the data-capturer can enter "Other" and complete the Specify Other field (this is only viewable on the electronic forms on the database with the participant's native language supplied). An African language and ethnicity

	ontology is still being constructed for H3Africa.
8.	The participant's biological father's original ethnic tribal affiliation should be collected here. If he identifies with multiple ethnic tribes, document the most primary one according to the participant's knowledge. If capturing electronically, a dropdown box of African ethnic tribal affiliations will be available in the database, if there is not a recognised option in dropdown list in the database, the data-capturer can enter "Other" and complete the Specify Other field only viewable on the electronic forms on the database with the father's ethnic tribal affiliation. An African language and ethnicity ontology is still being constructed for H3Africa.
9.	The name of the participant's biological mother's country of birth should be recorded here. If unknown, check the "Don't know" box. If the participant is adopted or orphaned and unable to supply this information, this should be recorded and it may be worth including a field on the demographics form.
10.	The participant's biological mother's home/native language that they were raised with should be completed here. If she has multiple native languages, complete the field with the most commonly used native tongue. If capturing electronically, a dropdown box of African languages will be available in the database, if the language is not on the dropdown list in the database, the data-capturer can enter "Other" and complete the Specify Other field only viewable on the electronic forms on the database with the mother's native language supplied An African language and ethnicity ontology is still being constructed for H3Africa.
11.	The participant's biological mother's original ethnic tribal affiliation should be collected here. If she identifies with multiple ethnic tribes, document the most primary one according to the participant first on the form. If capturing electronically, a dropdown box of African ethnic tribal affiliations will be available in the database, if there is not a recognised option in dropdown list in the database, the data-capturer can enter "Other" and complete the Specify Other field only viewable on the electronic forms on the database with the mother's ethnic tribal affiliation. An African language and ethnicity ontology is still being constructed for H3Africa.

02: Smoking Status

Item	Comments
Key fields	Capture Unique participant ID; visit date is assumed to be date of enrolment. A field is provided to record the visit code or visit name - essentially for any captured clinical study data one should capture: participant identifier; date of data collection (usually this is the visit date); name of visit/event; initials of identification of person completing form or questioning participant; and the date the form was completed if different from the visit date.
1.	Participants who have smoked less than 100 cigarettes in their lifetime will respond with "No" to this question and can skip down to item 8 where we ask about use of non-tobacco products. In the instance of a "Don't know" response, prompt the participant further to estimate cigarette usage in their lifetime and help them feel comfortable to continue with smoking questions. If it seems likely there has been or currently is a level of cigarette usage that is fairly regular or daily, and their usage continued or has been continuing for more than 3 months, it is likely the person has smoked up to 100 cigarettes. It is assumed that people who have smoked less than 100 cigarettes in their lifetime do not have a significant smoking status to investigate. This may not be true for children so therefore it may be sensible to include an additional question for children such as "Have you EVER smoked a cigarette?"
2.	Collect age (in years) participant first started smoking daily or fairly regularly (include former smokers). Only if the participant states they have never regularly smoked, complete the age with the age they first smoked part or all of a cigarette. If the participant answers "Don't know", prompt them gently to recall the age they first ever tried a cigarette.
3.	Collect current smoking status of participant. Try to prompt gently and encourage an answer from participant's who want to Refuse to answer or say Don't know.
4.	No matter what their current smoking status is, we want to know if the participant has ever smoked cigarettes daily for 6 or more months. Even if the participant has just smoked one cigarette daily for 6 or more months this would qualify as a "Yes".
5.	This question is to identify how many cigarettes the participant currently smokes on the days that they do smoke. If the participant is no longer smoking (a former smoker), ask them to specify the average number of cigarettes they used to smoke in a day during the height of their regular cigarette usage.
6.	Take note that this question is asking on how many days the participant smokes or used to smoke over the course of a month (30 days). So they are asked NOT the number of cigarettes but on how many days in a month do they smoke. Once again if a former smoker (ask at the height of their regular cigarette usage) to number the days of cigarette use in a month.
7.	This question should be skipped if the participant has not quit smoking (participants identified as EVERY DAY or FAIRLY REGULAR smokers in Item 3). For participants who have completely quit smoking, ask them how long it has been since they last smoked and complete the box with the number of years / months / weeks / days. Do not make calculations to convert to months or years…complete the boxes with what the participant reports. We may need to add a box in case participants report days in the hundreds.
8.	Section 8 examines tobacco use (not in cigarettes) and all participants must complete these questions regardless of cigarette usage. Where participants want to answer Don't know or Refused, encourage and prompt gently for answers without passing judgement.
	We have not asked about the brand or make or form of cigarette smoked – this may be a relevant question to include to truly determine quantity of tobacco smoked. It's assumed that questions 1-7 refer to commercially available whole cigarettes….should handrolled cigarettes be included in this classification?

03: Alcohol Consumption

Item	Comments
Key fields	Capture Unique participant ID; visit date is assumed to be date of enrolment. A field is provided to record the visit code or visit name - essentially for any captured clinical study data one should capture: participant identifier; date of data collection (usually this is the visit date); name of visit/event; initials of identification of person completing form or questioning participant; and the date the form was completed if different from the visit date.
	Be sure to explain to the participant up front what counts as one alcoholic drink based on the instructions at the top of the form.
1.	This question is determining if the participant has drunk at least one alcoholic drink. There is no Don't know of Refused option for the participant to respond with unlike the smoking questions. Interviewers need to be sensitive to the participant's culture and religion and be aware that some participants may be reluctant to answer this question truthfully…participants should be reassured that their answers will be kept confidential, they are only identified by a participant number and the interviewer should restrain from expressing any personal judgement on the participant's answers. If they have never drunk an entire alcoholic drink check No and skip to end of this form.
2.	Asking how old the participant was in years when they started drinking is asking the age at which they drank that first alcoholic drink.
3.	This question is asking for the number of days on which the participant drank in the past 30 days. This means you should not have a number above 30 completed in the boxes provided. If the participant did not drink any alcoholic drinks in the past 30 days then '00' should be completed in the boxes. If the participant has trouble remembering, the interviewer needs to confirm if they actually drank any alcoholic drinks in the past 30 days, if the answer is yes then the participant needs to be encouraged to estimate the number of days on which they drank (NOT the number for drinks in the past 30 days).
4.	This question asks on the days that they drank (as described in Question 3 above), how many drinks were drunk on average each day. An answer to Item 3 is critical to calculate participants alcohol use over the past 30 days e.g. The participant may have said they only drink on weekends; in this case Item 3 would likely have '08' days completed in the boxes provided….and when asked how many drinks in a day, if they said on the days I drank, about 3 drinks….enter '03' in the boxes provided for Item 4.
5.	This question may be confusing to a participant (it does not refer to "in the past 30 days…") so the question is ….What is the most number of alcoholic drinks you have ever drunk in a single day in your lifetime?
	It might be a good idea to include a question asking about what their preferred alcoholic drinks usually are

04: Drug Use

Item	Comments
Key fields	Capture Unique participant ID; visit date is assumed to be date of enrolment. A field is provided to record the visit code or visit name - essentially for any captured clinical study data one should capture: participant identifier; date of data collection (usually this is the visit date); name of visit/event; initials of identification of person completing form or questioning participant; and the date the form was completed if different from the visit date.
	This form is collecting participant's substance use over the past 30 days. Participants may be sensitive to stigma and legal ramifications of revealing their use of some substances, the interviewer therefore needs to remind the participant about their confidentiality in the study and withhold any personal judgement or urge to counsel the participant to alternative behaviour as this is simply a method to collect information on actual substance use.
Note	This is one of the few forms where the order of Yes; No; Don't know has been rearranged simply for ease of form design. The checkboxes asking about substance use are ordered as No; Don't Know; Yes. Where participant's reply "Yes" to substance use in the past 30 days, ask for age of first use in Years and on how many days in the past 30 days they used the substance. If participant's Don't know age of first use or # of days used, complete next the field whatever missing code your project uses to identify unknown data e.g. "NK" can be written next to the field if Not Known.
	It may be helpful for projects to provide training to interviewers on all the different substances listed and provide lists of drug names commonly used in the area/s of research. The Drug Abuse Ontology (DAO) has not yet been finalised …we would like to link an ontology mapping to the mentioned substances.
1.	Sedatives are drugs taken for their calming or sleep-inducing effects.
2.	Tranquilizers are medicinal drugs taken to reduce tension or anxiety.
3.	Painkillers are any drugs created to relieve pain.
4.	Stimulants are drugs that raise levels of physiological or nervous activity in the body, they can increase your heart rate and make you feel more energetic.
5.	Marijuana / hash / HC / grass is hemp / cannabis usually smoked to create a euphoric feeling or "high".
6.	Cocaine is an addictive drug derived from coca or prepared synthetically, used as an illegal stimulant and sometimes medicinally as a local anaesthetic.
7.	Crack cocaine is a free base form of cocaine that can be smoked. Crack offers a short but intense high to smokers.
8.	Hallucinogens e.g. LSD are drugs that cause the person to see hallucinations. These drugs may also include traditional or local forms of drugs that cause the person to hallucinate.
9.	Inhalants or solvents are volatile substances or liquids (even aerosols) that produce chemical vapours that can be inhaled to induce a psychoactive, or mind-altering, effect. These may often be found in many forms and found in households; industrial and medical products.
10.	Heroin is a highly addictive analgesic drug derived from morphine, often used illicitly as a narcotic producing euphoria.
11.	Methamphetamines is a powerful, highly addictive stimulant that affects the central nervous system. Also known as meth, chalk, ice, and crystal, among many other terms, it takes the form of a white, odourless, bitter-tasting crystalline powder that easily dissolves in water or alcohol.
12.	Here the participant should be prompted to describe any other substance/s he or she may be using excessively without a medical justification (not prescribed medication or over the counter medications for specific illnesses/injuries). Details should be entered in 12.1

05: Anthropometrics

Item	Comments
Key fields	Capture Unique participant ID; visit date is assumed to be date of enrolment. A field is provided to record the visit code or visit name - essentially for any captured clinical study data one should capture: participant identifier; date of data collection (usually this is the visit date); name of visit/event; initials of identification of person completing form or questioning participant; and the date the form was completed if different from the visit date.
1.	Height is the distance from the top of the participant's head to the heels of his or her feet (i.e., the vertical length). Three separate height measurements need to be taken in the same session (measured in centimeters) and completed in the #1; #2; #3 boxes provided. Any differing measurements can then be averaged to get an accurate height measurement. These average calculations will be done retrospectively and do not need to be carried out by the interviewer / nurse /doctor taking measurements. **Standing Height Protocol:** https://www.phenxtoolkit.org/index.php?pageLink=browse.protocoldetails&id=20703 Ask the participant to remove hair ornaments, jewelry, buns, or braids from the top of the head that interfere with the measurement. Shoes should be removed. Ask the participant to stand erect against the backboard with the body weight evenly distributed and both feet flat on the stadiometer platform (Exhibit 1). The participant's feet should be positioned with the heels together and toes pointed slightly outward at approximately a 60 degree angle. Check to be sure that the back of the head, shoulder blades, buttocks, and heels make contact with the backboard of the stadiometer. NOTE: Depending on the overall body conformation of the individual, all four contact points - head, shoulders, buttocks, and heels - may or may not touch the stadiometer backboard (Exhibit 2). For example, elderly survey participants may have kyphosis, a forward curvature of the spine that appears as a hump at the upper back. In particular, dowager's hump is a form of kyphosis that creates a hump at the back of the neck. Additionally, some overweight survey participants cannot stand straight while touching all four contact points to the backboard. In such instances it is important to obtain the best measurement possible according to the protocol. Stature measurements are made with the head aligned in the Frankfort horizontal plane (Exhibit 2). The head is in the Frankfort plane when the horizontal line from the ear canal to the lower border of the orbit of the eye is parallel to the floor and perpendicular to the vertical backboard (see Exhibit 2). Many people will assume this position naturally, but for some survey participants the examiner may need to gently tilt the head up or down to achieve the proper alignment. Instruct the survey participant to look straight ahead. If you cannot position the participant such that his or her trunk remains vertical above the waist, that the arms and shoulders are relaxed, and that the head is positioned in the Frankfort plane, be sure to note this in the measurement record. This information might be useful to interpret study findings. In the National Health and Nutrition Examination Study 2007-08, a comment described as "Not Straight" is noted in the stature record. Once positioned, lower the stadiometer headpiece so that it rests firmly on top of the participant's head, with sufficient pressure to compress the hair. Instruct the survey participant to stand as tall as possible, take a deep breath, and hold this position. The act of taking a deep breath helps straighten the spine to yield a more consistent and reproducible stature measurement. Notice that the inhalation will cause the headpiece to rise slightly.

	As soon as the participant inhales, record the measurement. After recording the measurement, tell the participant to relax. Once the measurement is taken, raise the stadiometer headpiece and have the participant step away from the stadiometer. Adjustments for shoes and hair: When participants cannot remove hair braids, buns, and headwear that interferes with the stature measurement, measure the distance from the scalp to the top of the hair with a small ruler to the nearest 0.1 cm. If shoes are worn, measure the height of the shoe heel to the nearest 0.1 cm. A corrected height value can be calculated by subtracting these distances from the original stature measurement, thus yielding an adjusted stature value. **Measuring height in seated position for participants unable to stand:** https://www.phenxtoolkit.org/index.php?pageLink=browse.protocoldetails&id=20701 Knee height was measured on adults 60 years of age and older during National Health and Nutrition Examination Study III, 1988-94. Measurements are taken in the seated position with both legs dangling. The examiner places the fixed blade of the large sliding caliper under the heel of the right leg just below the lateral malleolus of the fibula. From a squatting position, the examiner raises the leg so that the knee and ankle are both at a 90-degree angle (see Exhibit 1). This is best accomplished by resting the participant's foot in the palm of the examiner's hand. The moveable blade of the caliper is placed on the anterior surface of the right thigh, above the condyles of the femur, about two inches above the patella. The shaft of the caliper is held parallel to the shaft of the tibia so that the shaft of the caliper passes over the lateral malleolus of the fibula and just posterior to the head of the fibula. Pressure is applied to compress the tissue. The recorder checks the positioning of the leg and the caliper. Knee height is recorded to the nearest 0.1 cm. Exhibit 1-4. SP position for knee height 
1.1.	Participant's should only be asked to provide their height if measuring is not possible at all. Self-reported height is considered to be less accurate and should only be used if measured height could not be obtained. Skip this item if the 3 height measurements were taken.
2.	Weight is measured using a floor scale. The instrument should be calibrated daily using standardized weights, and a log of calibration results should be maintained. The examiner briefly informs the participant that his/her weight will be measured.

	Participants are asked to remove their shoes, heavy clothing such as large jackets or coats and objects such as cell phones, wallets, and toys from their pockets. The health technician directs participants to stand in the center of the scale platform with hands at their sides and looking straight ahead. - Special situations: • Small children: Infants and toddlers who cannot stand alone on the scale will be weighed with an adult, or with an infant's scale. If an adult is holding the child, then the adult guardian or the health technician will stand alone on the scale so the scale can be tared. This sets the scale readout to zero. The child is then handed to the adult and the child's weight is measured. • Note that special consideration may be needed for participants whose weight exceeds the capacity of the study scale. For example, weight can be obtained using two portable scales: o Have the participant stand with one foot on each portable scale. o Add/Combine the two results to approximate the weight and record that as one weight measurement. o If the weight equals the capacity of both portable scales, note that the weight Equals Capacity (EC) of the scales. Record **current** weight in kilograms – Repeat this 3 times and each time record the weight in the 3 separate measurement boxes.
3 & 3.1	Ask if the participant is wearing a cast or medical prosthesis (it may not be noticeable on first inspection). If not, mark "No" and move on to Item 4. If the participant does have a prosthetic or cast, indicate where the cast is located or what the prosthesis is in the next sub-question Item 3.1.
4.	If the participant is wearing a medical/examination gown at the time of weight measurement then "No" should be ticked for street clothes, however if the participant is wearing their usual clothing mark the "Yes" box. Participants should not be wearing shoes when weighed.
5.	This question should be marked N/A if the three weight measurements in Item 2 were obtained. Asking a participant how heavy they are to obtain a weight measurement should only be asked if weighing the participant is not possible.

06: Blood Pressure

Item	Comments
Key fields	Capture Unique participant ID; visit date is assumed to be date of enrolment. A field is provided to record the visit code or visit name - essentially for any captured clinical study data one should capture: participant identifier; date of data collection (usually this is the visit date); name of visit/event; initials of identification of person completing form or questioning participant; and the date the form was completed if different from the visit date.
1.	This question relies on the participant's knowledge and understanding of their medical health history. Healthcare worker describes a doctor or clinician or nurse. If the participant is unsure about whether they have ever been told they have been told they had/have high blood pressure or any type of hypertension confirm with them….usually a participant will remember and be able to say yes or no with regards to being told something important by a medical person. If they are saying Don't know, check that they understand the wording and meaning of high blood pressure and hypertension.
1.1.	Participant's age in years that they were told they had high blood pressure or hypertension, if they cannot recall how old they were at the time mark the Don't know box. The Don't know showing only Do on form.
1.2.	This question is only for female participants. The participant may recognise "gestational hypertension" if they had hypertension during pregnancy only. This question should only be marked Yes if the hypertension occurred ONLY during pregnancy.
2.	If the participant is currently taking prescribed medication for hypertension/high blood pressure then this question should be marked "Yes now". If the participant took medication in the past for high blood pressure then it should be marked "Yes not now". If the participant says no or don't know mark the corresponding box and skip item 2.1 and move to item 3.
2.1.	If the participant is taking or took medication for high blood pressure ask the participant at what age (in years) the began taking medication regularly.
3 – 3.5.	Record the date all three blood pressure measurements were taken – this date may differ from the visit date entered at the top of the form. Record the name and model of the blood pressure instrument such as an aneroid or mercury column sphygmomanometer or an automated device with a manual inflate mode. A chair with arm support for BP measurement, or a chair and table (table must provide for a comfortable resting posture of the arm with the cubital fossa at the level of the 4th intercostal space at heart level). To measure BP, healthcare technicians should: 1. Choose the right equipment: What you will need: 1. A quality stethoscope 2. An appropriately sized blood pressure cuff 3. A blood pressure measurement instrument such as an aneroid or mercury column sphygmomanometer or an automated device with a manual inflate mode. 2. Prepare the patient: Make sure the patient is relaxed by allowing 5 minutes to relax before the first reading. The patient should be seated, legs uncrossed, in a quiet room, with the elbow and forearm resting comfortably on the armrest of the BP measurement chair (or table), with the palm of the hand turned upward. The area

	to which the cuff is to be applied must be bare (free of clothing). Their upper arm should be positioned so it is level with their heart and feet flat on the floor. Patient and healthcare technician should refrain from talking during the reading. 3. Choose the proper BP cuff size and record this in Item 3.2. : Most measurement errors occur by not taking the time to choose the proper cuff size. Wrap the cuff around the patient's arm and use the INDEX line to determine if the patient's arm circumference falls within the RANGE area. Otherwise, choose the appropriate smaller or larger cuff. 4. Locate the brachial artery by palpation and mark the skin with a small dot, using a black pen. (The brachial artery is usually found just medial and superior to the cubital fossa, posterior to the biceps muscle and slightly toward the body.) For brachial artery palpation, fingertips or thumb may be used. Place the BP cuff on the patient's arm and position the BP cuff so that the ARTERY marker points to the brachial artery. Wrap the BP cuff snugly around the arm. 5. Position the stethoscope: On the same arm that you placed the BP cuff, palpate the arm at the antecubical fossa (crease of the arm) to locate the strongest pulse sounds and place the bell of the stethoscope over the brachial artery at this location. 6. Inflate the BP cuff: Begin pumping the cuff bulb as you listen to the pulse sounds. When the BP cuff has inflated enough to stop blood flow you should hear no sounds through the stethoscope. The gauge should read 30 to 40 mmHg above the person's normal BP reading. If this value is unknown you can inflate the cuff to 160 - 180 mmHg. (If pulse sounds are heard right away, inflate to a higher pressure.) 7. Slowly Deflate the BP cuff: Begin deflation. The AHA recommends that the pressure should fall at 2 - 3 mmHg per second, anything faster may likely result in an inaccurate measurement. * 8. Listen for the Systolic Reading: The first occurence of rhythmic sounds heard as blood begins to flow through the artery is the patient's systolic pressure. This may resemble a tapping noise at first. 9. Listen for the Diastolic Reading: Continue to listen as the BP cuff pressure drops and the sounds fade. Note the gauge reading when the rhythmic sounds stop. This will be the diastolic reading. 10. Take readings from both arms and record each reading in Items 3.3; 3.4 and 3.5. **Wait about five minutes between each reading.**

07: Urine Test Results

Item	Comments
Key fields	Capture Unique participant ID; visit date is assumed to be date of enrolment. A field is provided to record the visit code or visit name - essentially for any captured clinical study data one should capture: participant identifier; date of data collection (usually this is the visit date); name of visit/event; initials of identification of person completing form or questioning participant; and the date the form was completed if different from the visit date.
1.	Sample collection date has to be the exact date that the sample is collected from the patient/participant and not the date sample was submitted or banked. Capture date in the precise format given in the form to maintain consistency and sustainability - if transcribing from a set of laboratory results, be careful to be accurate when entering date if date format differs on lab results.
2 - 4.	When filling in numeric results for urinary albumin; urinary creatinine and urinary total protein pre-fill zeros in front of numbers less than four digits e.g. a value of 30 for urinary albumin should be filled in as “0030”.

08: Kidney Disease

Item	Comments
Key fields	Capture Unique participant ID; visit date is assumed to be date of enrolment. A field is provided to record the visit code or visit name - essentially for any captured clinical study data one should capture: participant identifier; date of data collection (usually this is the visit date); name of visit/event; initials of identification of person completing form or questioning participant; and the date the form was completed if different from the visit date.
Note	The questions on this form are questions asked directly to the participant/patient or to the guardian of an underage participant. If you (the interviewer) have access to the participant's medical records/notes the participant should be aware of this and you can corroborate their answers with the medical notes and gently query any discrepancies with the participant/patient. A participant may be uncertain about the terminology used and you can can describe the medical term in plain and simple terms to them using the notes below. If the participant is still unclear you will have to respond with the "Don't know" option.
1.	Kidney failure means you have lost function in one or both kidneys and you have impaired ability to remove waste and balance fluids within the body. Have you ever been told that you have kidney failure? If the answer is No or Don't know then skip Items 1.1 to 1.3 and proceed to Item 2.
1.1	If the participant answered yes to Question 1, then ask them if either of their kidneys are currently working well.
1.2	If the participant answered yes to Question 1, collect the age (in years) a doctor or healthcare worker first told them they had kidney failure.
1.3	Renal dialysis refers to the process of removing excess water, solutes and toxins from the blood using a dialysis machine. If the participant answered yes to Question 1, then ask them if they are currently on dialysis.
2.	Kidney transplant refers to a procedure in which an individual's kidney has been removed and replaced with a donor kidney. It is unlikely that a participant would answer No to Item 1 and Yes to Item 2.
3.	The risk of developing kidney disease is correlated with family history of kidney disease. Kidney disease refers to medical conditions affecting the kidneys and their function. Has anyone in your family had kidney disease or died as a result of kidney disease? It might be worthwhile recording the relationship (level of family connection) for participants answering Yes to Item 3.
3.1	If the participant answered yes to Question 3, then ask them if they know which kidney disease(s) their family member(s) had. If No skip to Item 4.
3.2	If the participant answered yes to Question 3.1, prompt them to specify the kidney disease. Record the type of kidney disease concisely and clearly – do not write a paragraph.
4.	Decreased or low kidney function means that your kidneys are not able to remove the toxins and waste products from your blood as well as someone with normal kidney function. All participants need to answer this question.
5.	Kidney disease refers to medical conditions affecting the kidneys and their function. All participants need to answer this question.

09: Prescribed medication

Item	Comments
Key fields	Capture Unique participant ID; visit date is assumed to be date of enrolment. A field is provided to record the visit code or visit name - essentially for any captured clinical study data one should capture: participant identifier; date of data collection (usually this is the visit date); name of visit/event; initials of identification of person completing form or questioning participant; and the date the form was completed if different from the visit date.
1.	Prescribed medications capture the list of drugs/medications that are prescribed by a doctor/healthcare worker, including self-prescribed over-the-counter medications. This will enable to avoid some common drug-drug interactions. Participants should be asked to bring all their current medications with them at the time of their appointment. For prescribed medications, the interviewer records the following: Name of the medication, write the full name of medication whenever possible. Dosage, check one of the boxes for drug taking frequency: Daily – once a day BID – twice a day TID – three times a day QID – four times a day Noct – once at night Strength, fill in the numeric measure/amount of drug taken at recorded frequency and check off the related unit of measure box mg/ml/tb where tb refers to tablet. Reason for taking the medication Start date of drug Stop date if drug taking not ongoing. E.g. a participant taking Amoxicillin at three times a day would be recorded as: Medication: Amoxicillin 250mg Dosage: TID Strength: 0250 mg Reason: Ear infection Start date: 15 JAN 18 Stop date: 19 JAN 18 For over-the-counter medications (including vitamins and supplements), the interviewer records the name, strength, and actual amount consumed in the previous 2 weeks. Prescribed Medications include pills, liquid medications, skin patches, eye drops, creams, salves, inhalers, and injections, as well as cold or allergy medications, vitamins, herbal remedies, and other supplements. Do we need to include a checkbox under dosage for prn – as needed?

10: Cardio Vascular Disease

Item	Comments
Key fields	Capture Unique participant ID; visit date is assumed to be date of enrolment. A field is provided to record the visit code or visit name - essentially for any captured clinical study data one should capture: participant identifier; date of data collection (usually this is the visit date); name of visit/event; initials of identification of person completing form or questioning participant; and the date the form was completed if different from the visit date.
	The questions on this form are questions asked directly to the participant/patient or to the guardian of an underage participant. If you (the interviewer) have access to the participant's medical records/notes the patient/participant should be aware of this and you can corroborate their answers with the medical notes and gently query any discrepancies with the participant / patient. Sometimes a participant may be uncertain about the terminology used and you can describe the medical term in plain and simple terms to them using the notes below. If the participant is still unclear you will have to respond with the "Don't know" option.
1.	Atrial fibrillation means there is a problem with the rhythm or rate of your heartbeat. An arrhythmia can be when your heart beats too fast or too slow or in an irregular way (without a steady pattern). Have you been told that you have had an arrhythmia or have atrial fibrillation? If No or Don't know skip to Item 2.
1.1.	If the participant said yes to question 1, then ask them to provide date of first episode. Ask the patient to recall the date they were first had an arrhythmia or have atrial fibrillation - it might be worth asking how they identified a heartbeat irregularity (if they were told by a healthcare worker or self-diagnosed). If the participant can't recall the exact date, prompt them for a month and year. If Day or Month unknown put a diagonal line across the day and/or month field/s and write NK above to represent "Not Known" and be sure to complete the year. If the participant does not know date at all check the Don't know box.
1.2.	The participant may have gone to both a doctor and a hospital, if this is the case, check the box for whichever occurred first. Ask the participant if they went to see a doctor or hospital/clinic when they experienced this first episode of heartbeat irregularity. If they didn't mark No. Try to avoid using the Don't know box as much as possible – it is most unlikely the participant won't recall if they went to see a doctor or hospital/clinic …they may have difficulty being sure of their first episode in which case they would have responded with Don't know to Item 1.1.
2.	This question is required for all participants. Majority of participants would know if they have a permanent pacemaker inserted – you can clarify this by explaining a pacemaker is a small electronic device inserted into the body that keeps the heart beating at a regular pace. It does not mean the participant has had open heart surgery but it would require some surgery for insertion and require regular check-ups.
2.1.	If Yes, record the year (full four digits) that the pacemaker was first inserted.
3.1	This question is asked to all participants regardless of answers to Items 1 and 2. If the participant has no heart problems they may still be taking cardiovascular related medications e.g. participants with blood clotting problems make be taking anticoagulant medications. Describe what anticoagulants are and then indicate if they are taking medication currently with "Yes now" or have taken in the past with "Yes not now"' or not at all with "No". Anticoagulants are medications taken to prevent blood clots, sometimes called blood-thinning medications, these medications are called: Coumadin; Warfarin; Heparin; rivaroxaban (Xarelto); dabigatran (Pradaxa); apixaban

	(Eliquis); edoxaban (Lixiana).
3.2.	Antiarrhythmics also known as cardiac dysrhythmia medications are taken to suppress abnormal rhythms of the heart and have names such as: Fast channel blockers: Quinidine; Ajmaline; Procainamide; Norpace/ Disopyramide Phosphate; Lidocaine; Phenytoin; Mexiletine; Tocainide; Encainide; Flecainide; Propafenone; Moricizine Beta-blockers: Carvedilol; Propranolol; Esmolol; Timolol; Metoprolol; Atenolol; Bisoprolol; Nebivolol; Amiodarone; Sotalol; Ibutilide; Dofetilide; Dronedarone; E-4031; Vernakalant Slow-channel blockers: Verapamil; Diltiazem; Adenosine; Digoxin; Magnesium Sulfate
4.	This question is for all participants, has a doctor ever said participant had rheumatic fever (this is a complication that may arise due to untreated strep throat or scarlet fever and can cause swollen and painful joints, temporary nervous system disorder and lasting heart damage) or has rheumatic heart disease (this is as a result of rheumatic fever when there is lasting heart damage). Inflammatory rheumatism is a general term that covers a number of conditions related to inflamed joints and tissue and muscles. If the participant responds with “No” skip to end of the page. If the participant responds with “Don’t know” confirm their understanding of the terms in question and if they are still unsure, mark “Don’t know” and skip to end of page.
4.1.	It is highly unlikely a participant will answer that they “Don’t know” if they have had rheumatic fever in the past 12 months so avoid using this option as much as possible.
4.2 – 4.2.1	If the participant is currently taking medication for rheumatic fever or rheumatic heart disease, record the name of the medication in the space provided.

11: Stroke History

Item	Comments
Key fields	Capture Unique participant ID; visit date is assumed to be date of enrolment. A field is provided to record the visit code or visit name - essentially for any captured clinical study data one should capture: participant identifier; date of data collection (usually this is the visit date); name of visit/event; initials of identification of person completing form or questioning participant; and the date the form was completed if different from the visit date.
Note	The questions on this form are questions asked directly to the participant/patient or to the guardian of an underage participant. If you (the interviewer) have access to the participant's medical records/notes the participant should be aware of this and you can corroborate their answers with the medical notes and gently query any discrepancies with the participant/patient. A participant may be uncertain about the terminology used and you can can describe the medical term in plain and simple terms to them using the notes below. If the participant is still unclear you will have to respond with the "Don't know" option.
Note	Sudden painless weakness or numbness on either side of the body, as well as sudden loss of vision, ability to understand what other people are saying and (or) the ability to express oneself verbally, are all symptoms of strokes, mini-strokes and silent strokes. Questions 3 to 8 interrogate these symptoms, in order to capture any instances of stroke the participant may not be aware of.
1.	A stroke is a medical emergency which occurs when the blood supply to part of your brain is interrupted or reduced. Have you ever been told that you had a stroke?
2.	A TIA/mini-stroke/transient stroke attack is stroke-like but only lasts a few minutes. Have you ever been told that you had a TIA, mini-stroke or transient stroke attack? If the participant answers "No" or "Don't know" to this question skip to Item 3 to continue confirming any stroke history.
2.1	If the participant answered yes to Question 2; then prompt them to specify how long the attack lasted. There is no "Don't know" option on this question.
3.	This is a required question for every participant to confirm stroke history indicators. Have you ever experienced sudden painless weakness on one whole side of your body?
4.	This is a required question for every participant to confirm stroke history indicators. Have you ever experienced sudden numbness or dead feeling on one whole side of your body?
5.	This is a required question for every participant to confirm stroke history indicators. Have you ever experienced sudden painless loss of vision in one or both eyes?
6.	This is a required question for every participant to confirm stroke history indicators. Have you ever experienced sudden loss of one half of your vision? This question is very similar to Item 5.
7.	This is a required question for every participant to confirm stroke history indicators. Have you ever experienced sudden loss of the ability to understand what other people are saying?
8.	This is a required question for every participant to confirm stroke history indicators. Have you ever experienced sudden loss of the ability to express yourself verbally or in writing?

12: Diabetes History

Item	Comments
Key fields	Capture Unique participant ID; visit date is assumed to be date of enrolment. A field is provided to record the visit code or visit name - essentially for any captured clinical study data one should capture: participant identifier; date of data collection (usually this is the visit date); name of visit/event; initials of identification of person completing form or questioning participant; and the date the form was completed if different from the visit date.
1.	These questions refer to any type of diabetes history. Diabetes is when the body is unable to reduce the amount of sugar in the blood well. If the participant answers "No" or "Don't know" skip to the end of the form.
1.1.	If the participant answered "Yes" to Item 1 then ask what type of diabetes the participant has and indicate their answer accordingly
1.2.	If the participant has diabetes, this questions asks if they are taking any medication for it currently. If No or Don't know skip to Item 2. If the participant is taking medication the following questions ask about insulin.
1.3.	Asks if participant currently taking insulin for their diabetes. If yes, skip to Item 2.
1.3.1.	If No or Don't know to taking medication, this question asks if they are taking any other medication for diabetes. It may be worthwhile to record any medication other than insulin which the participant may be taking.
2.	This question is asked to all participants with diabetes regardless of their responses to Items 1.2 and 1.3. Indicate at what age (years) the participant was first treated for diabetes, they may not currently be on treatment but record the age in years that they first received any form of treatment.
3.	All participants should answer this question, was insulin the first medication you were given for diabetes.
4.	This question is for women only and asking about gestational diabetes, whether their diabetes **ONLY** occurred during pregnancy. Gestational diabetes is not listed as a type of diabetes in Item 1.1.

13: HIV

Item	Comments
Key fields	Capture Unique participant ID; visit date is assumed to be date of enrolment. A field is provided to record the visit code or visit name - essentially for any captured clinical study data one should capture: participant identifier; date of data collection (usually this is the visit date); name of visit/event; initials of identification of person completing form or questioning participant; and the date the form was completed if different from the visit date.
1.	This question asks if the participant has ever been tested for Human Immunodeficiency Virus (HIV). In some regions there is a lot of stigma attached to HIV status, these questions need to be handled with sensitivity and assurance of confidentiality. A refusal to answer indicates the participant does not feel safe to share any HIV related information. If the participant responds with "No"; "Don't know" or "Refused" skip to the end of the form.
2.	Ask the participant to provide the date of their most recent HIV test. If the participant does not recall the exact date cross out the dd boxes of the date and write "NK" (not known) above and record the month and year. If the participant does not remember the month too, then also cross out the MMM boxes and write "NK" above and record the year in the yy boxes. If the participant cannot recall the date at all then check the "Don't know" box.
3.	Record the result of the participant's most recent HIV test. If the study tests for HIV, these results will be available to the study staff to corroborate with the participant's reported result. Record the HIV result.
4.	Item 4 should be asked regardless of HIV result. Perhaps better to ask if participant is on antiretroviral medication? Participant's may have been started on HIV medication as preventative or temporarily due to pregnancy. If "'No", "don't know" or "refused" skip to end of form.
4.1.	If yes to Item 4, record the initiation/start date of the HIV treatment. If the participant does not recall the exact date cross out the dd boxes of the date and write "NK" (not known) above and record the month and year. If the participant does not remember the month too, then also cross out the MMM boxes and write "NK" above and record the year in the yy boxes. If the participant cannot recall the date at all then check the "Don't know" box.

14: Dyslipidemia

Item	Comments
Key fields	Capture Unique participant ID; visit date is assumed to be date of enrolment. A field is provided to record the visit code or visit name - essentially for any captured clinical study data one should capture: participant identifier; date of data collection (usually this is the visit date); name of visit/event; initials of identification of person completing form or questioning participant; and the date the form was completed if different from the visit date.
1.	Dyslipidemia is the medical term for having unhealthy levels of lipids (fats) in the blood. This may mean low levels of HDL; or high levels of LDL; or high triglyceride levels. Ask the participant if they have been told they have dyslipidemia or any abnormal levels of HDL or LDL or triglycerides. If No or Don't know skip to end of form.
1.1.	If Yes, record the age in years that the participant was first told they had dyslipidemia.
1.2.	Check if the participant knows if it was confirmed with a lab result (ask if they had blood drawn to test for dyslipidemia).
1.3.	Ask the participant if they are taking any medication for their unhealthy levels of lipids. If they have taken in the past but are not taking it currently then record "Yes not now". If they are currently on medication for it then record "Yes now" otherwise, record "No" or "Don't know" and skip to end of form.
1.3.1.	If the participant is taking or has taken medication for dyslipidemia then ask them what age they were in years when they started taking medication.

15: Cancer

Item	Comments
Key fields	Capture Unique participant ID; visit date is assumed to be date of enrolment. A field is provided to record the visit code or visit name - essentially for any captured clinical study data one should capture: participant identifier; date of data collection (usually this is the visit date); name of visit/event; initials of identification of person completing form or questioning participant; and the date the form was completed if different from the visit date.
	This form does not collect different types of cancer that a participant may have experienced without modifications – the questions can be reapplied to every different type of cancer a participant may have experienced but perhaps we need to modify the form to either be continuous collection or able to have repeating instances.
1.	If the participant has never had cancer then skip to end of form. If the participant has had cancer clarify how many different kinds of cancer he/she has had in order to know how many instruments may need to be repeated.
2.	Specify type of cancer and the location/site of the cancer.
2.1.	Record date the participant was clinically diagnosed with this particular cancer. If the participant does not recall the exact date cross out the dd boxes of the date and write “NK” (not known) above and record the month and year. If the participant does not remember the month too, then also cross out the MMM boxes and write “NK” above and record the year in the yy boxes. If the participant cannot recall the date at all then check the “Don’t know” box.
2.2.	Record age in years of the participant when he/she was diagnosed with this cancer. This can be checked against their birthdate and date of diagnosis.
2.3.	If the participant did not have surgery or is unsure, skip Item 2.3.1.
2.3.1.	Provide the name of the surgery procedure. If the participant has undergone multiple surgeries for this cancer, record all procedures in concise form separated by comma’s in the line provided.
2.4.	Indicate any or all the treatments the participant has undergone and collect the completion date for the treatment or if the participant is still undergoing treatment, check the “ongoing” treatment check box.
2.5.	If the participant has suffered a clinically diagnosed recurrence of the same cancer type, select the “Yes” box. If he/she has not had a clinically diagnosed recurrence of the cancer indicate “No” or “Don’t know” if the participant is unsure and skip to end of form. If he/she has experienced a new type of cancer this should be recorded on another Cancer form and not seen as a recurrence.
2.5.1.	If they have suffered a recurrence, collect the date the recurrence was diagnosed.
2.5.2.	Record the location the cancer has recurred at in the space provided.

16: Other Infectious Diseases

Item	Comments
Key fields	Capture Unique participant ID; visit date is assumed to be date of enrolment. A field is provided to record the visit code or visit name - essentially for any captured clinical study data one should capture: participant identifier; date of data collection (usually this is the visit date); name of visit/event; initials of identification of person completing form or questioning participant; and the date the form was completed if different from the visit date.
	This form is simply collecting participant reported information about whether they have had any of the listed infectious disease at any point in their lives.
1.	If the participant has had tuberculosis (TB) of any kind, record this as a Yes; and collect their age in years that they received a clinical diagnosis of TB.
2.	If the participant has had malaria of any kind, record this as a Yes; and collect their age in years that they received a clinical diagnosis of malaria.
3.	If the participant has had sleeping sickness of any kind, record this as a Yes; and collect their age in years that they received a clinical diagnosis of sleeping sickness.
4.	If the participant has had hepatitis A of any kind, record this as a Yes; and collect their age in years that they received a clinical diagnosis of hepatitis A.
5.	If the participant has had hepatitis B of any kind, record this as a Yes; and collect their age in years that they received a clinical diagnosis of hepatitis B.
6.	If the participant has had hepatitis C of any kind, record this as a Yes; and collect their age in years that they received a clinical diagnosis of hepatitis C.

References

Bellary, S., Krishnankutty, B., & Latha, M. S. (2014). Basics of case report form designing in clinical research. *Perspectives in Clinical Research*, *5*(4), 159–66. doi:10.4103/2229-3485.140555

M. Scot Fague (2010) REDCap Best Practicies for Data Collection of Clinical Trials. Washington University School of Medicine, *http://www.biostat.wustl.edu/redcap/?page_id=223*

APPENDIX A

SOP# H3ABioNet_PDM01 Completion of Case Report Forms

This Standard Operating Procedure describes the principles for completing paper-based data collection forms used in clinical data collection. The SOP is designed to be applicable to RedCap Case Report Forms developed in the H3Africa consortium studies but the guiding principles can be applied to completion of all CRFs used in clinical data collection created in any publishing or software program.

This SOP was implemented on the 6 November 2017 and created by Katherine Johnston from the H3ABioNet consortium at the Computational Biology Division at the University of Cape Town, South Africa and all copyright resides with H3ABioNet.

APPROVAL OF STANDARD OPERATING PROCEDURE

Approved by: _____

Signature: _____ **Date:** _____

REVISION HISTORY

None.

I. INTRODUCTION

This SOP developed by the H3ABioNet outlines the essential methods to be used when completing paper-based RedCap Case Report Forms (CRFs). The purpose of the SOP is to standardise the completion of clinical data CRFs, providing guiding principles to the various H3Africa consortium research teams to be adapted and used in various studies collecting clinical phenotypic data.

II. REFERENCES

DAIDS Essential Documents SOP version 2.0, 01 August 2002

DAIDS Source Documentation SOP version 2.0, 01 August 2002

III. DEFINITIONS OF TERMS USED

CRF	Case Report Form
H3ABioNet	Pan African Bioinformatics support network
SDM	Study Data Manager
DMC	Data Management Centre
DAIDS	Division of AIDS
NIH	National Institutes of Health
PID	Participant Identification number
MOP	Manual of Operating Procedures

IV. INSTRUCTIONS AND PROCEDURES

1. Paper CRFs should be filed by participant at study sites and identified only by the PID which is allocated to the participant on entry to the trial. Source documentation for participant containing participant identifiers for clinical care should be stored separately from the CRFs.

2. Required CRF(s) must be completed for each visit and when necessary details taken from the source documentation by the designated person(s) for the study. If CRF checklists for each visit are provided in the CRF file, the checklists should be completed to account for the CRFs that have been completed for that visit.

3. The PID of the CRF must be checked against the PID of the source documentation to ensure that the details entered relates to the correct participant. No personal identifiers such as the participant name or address are to be written on the CRF.

4. Key Identifier information such as visit number/name; PID; date; site and study, staff identifier should be either pre-printed or available on the CRF to enable identification of where, when and whose data has been collected and by whom.

5. All fields should be considered required for completion unless there is a skip pattern, or other instructions given in the study-specific CRF guidelines.

6. Any CRF(s) that are specified in the MOP or protocol as source documentation must have a signature and date at the bottom of the CRF.

7. CRFs are never to be duplicated or rewritten. The original CRF is to be kept in all circumstances regardless of how many corrections are made on it. Do not re-write or copy a CRF unless under the specific guidance of your SDM and always document decisions such as this.

8. **Completion of Questions**
   a. Print in block letters. Print all text in English unless your study has established used of another language for data collection.
   b. All text and explanatory comments should be brief and entered as close to the relevant field as possible.
   c. Answer every question explicitly, do not use ditto marks.
   d. Only enter results in the spaces provided.
   e. If the answer is zero for a required field, do not leave the field blank but write "00"
   f. If the response to a question is unknown, not done or not required, follow your study-specific instructions according to the CRF guidelines for the study.
   g. Mark the choice and check fields with a <u>inside</u> the appropriate box not a tick which can be misinterpreted.

      Example: ☐ Yes ☒ No

   h. Write all numerical values in print and keep the numbers simple as shown below. Where decimal numbers are required use the metric system and a ' . ' to designate a decimal point. Instructions or boxes should be available on the form to indicate expected number formats:

0	1	2	3	4	5	6	7	8	9

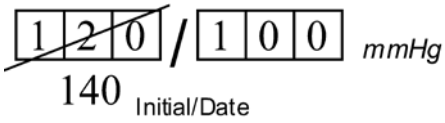
9. **Dates**
   a. All dates are in day/month/year format. Enter the appropriate 2-digit number for each of the day and year (e.g. use 02 for 2002; and 66 for 1966). Enter the first 3 characters of the month's name for the month (e.g. JAN for January, FEB for February)
   b. While every attempt should be made to obtain complete data, enter a '00' for the day and '000' for month, complete the part which is known, and use 00 (zeros) for those which are unknown.

      Examples:

      Date: | 0 | 7 | | J | A | N | | 0 | 2 |
      dd *MMM* *yy*

      Date: | 0 | 0 | | F | E | B | | 0 | 2 |
      dd *MMM* *yy*

10. **Correction of errors**
    a. For any errors, cross through the error with a single straight line
    b. Write the correct value above, below or to the side



    c. Initial and date the correction
    d. Ensure that all corrections are completely clear
    e. Do not use Tippex or any correction fluid; the original entry must be clearly visible

V. DOCUMENTATION

No attachments.

APPENDIX B

Example Screening Log

Study Name: _____ Site: _____ Date: _____

Screening Number	Full Name	Identifier	Date of Birth (DMY)	Sex (M/F/O)	Date Screened (DMY)	Consented ? (Y / N)	Reason Excluded	Staff Initials	PID Allocated
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									

Codes for Reasons for Refusal or Exclusion

1	2	3	4	5	6	7	8	9	10
Study Exclusion Criteria 1	Study Exclusion Criteria 2	Study Exclusion Criteria 3	Study Exclusion Criteria 4	Did not have a good understanding of study	Vulnerable population member	PI decision	Unable to provide informed consent	Unable to comply with visit requirements	Unreliable personal information

APPENDIX C

Microsoft Publisher Standard CRFs

PID: ☐☐☐☐☐☐☐☐☐ Visit Date: ☐☐ dd ☐☐☐ MMM ☐☐ yy

Visit: ☐☐☐☐

DEMOGRAPHICS

---

1. What is your date of birth? ☐☐ dd ☐☐☐ MMM ☐☐ yy ***OR*** ☐ Don't know

   1.1. About how old are you? (**ONLY** If date of birth unknown) ☐☐ ☐ years ☐ months ☐ weeks ☐ days

2. Are you male or female? ☐ male ☐ female ☐ other ☐ refused

3. What is your country of birth? _____ ***OR*** ☐ Don't know

4. What is your native language? _____ ***OR*** ☐ Don't know

5. What is your ethnic or tribal affiliation? _____ ***OR*** ☐ Don't know

The following questions relate to your father:

6. What is your father's country of birth? _____ ***OR*** ☐ Don't know

7. What is your father's native language? _____ ***OR*** ☐ Don't know

8. What is your father's ethnic or tribal affiliation? _____ ***OR*** ☐ Don't know

The following questions relate to your mother:

9. What is your mother's country of birth? _____ ***OR*** ☐ Don't know

10. What is your mother's native language? _____ ***OR*** ☐ Don't know

11. What is your mother's ethnic or tribal affiliation? _____ ***OR*** ☐ Don't know

PID: ☐☐☐☐☐☐☐☐☐ Visit Date: ☐☐ ☐☐☐ ☐☐
dd MMM yy

Visit: ☐☐☐☐

SMOKING STATUS

1. Have you ever smoked at least 100 cigarettes in your entire life?
   ☐ Yes ☐ No ☐ Don't know
   → ***Skip to Item 8.***

2. How old were you when you first started smoking cigarettes?
   ☐☐ years ***OR*** ☐ Don't know

3. What type of smoker would you currently say you are?
   ☐ An EVERY day smoker
   ☐ A FAIRLY REGULAR (some days) smoker
   ☐ A FORMER smoker
   ☐ Don't know
   ☐ Refused

4. Have you <u>EVER</u> smoked cigarettes <u>EVERY DAY</u> for at least 6 months?
   ☐ Yes ☐ No ☐ Don't know

5. On the days that you smoke, on average, how many cigarettes do you smoke?
   <u>OR</u>
   If you are a former smoker, on the days that you smoked, on average, how many cigarettes did you smoke?
   ☐☐ cigarettes ***OR*** ☐ Don't know

6. Over the past 30 days, on how many days did you smoke?
   <u>OR</u>
   If you are a former smoker, on average, on how many days did you smoke in a month?
   ☐☐ days ***OR*** ☐ Don't know

7. (**<u>ONLY</u>** Former smokers) About how long has it been since you completely quit smoking cigarettes?
   ☐☐ ☐ years ***OR*** ☐ Don't know
   ☐ months
   ☐ weeks
   ☐ days

Date Completed: ☐☐ ☐☐☐ ☐☐ Staff Initials: ☐☐☐
dd MMM yy

PID: | | | | | | | | | |

Visit: | | | | |

SMOKING STATUS

TOBACCO (NON-CIGARETTE) - PRODUCT USE

8. In your lifetime, have you….

8.1.	Smoked at least 50 cigars?	☐ Yes	☐ No	☐ Don't know	☐ Refused
8.2.	Smoked a pipe at least 50 times?	☐ Yes	☐ No	☐ Don't know	☐ Refused
8.3.	Used snuff (such as Skoal, Skoal Bandit or Copenhagen) at least 20 times?	☐ Yes	☐ No	☐ Don't know	☐ Refused
8.4.	Used chewing tobacco (such as Redman, Levi Garrett or Beechnut) at least 20 times?	☐ Yes	☐ No	☐ Don't know	☐ Refused

PID: | | | | | | | | | | Visit Date: | | | | | | | | |
dd MMM yy

Visit: | | | |

ALCOHOL CONSUMPTION

Count as a drink a can or bottle of beer; a wine cooler or a glass of wine; champagne or sherry; a shot of liquor or a mixed drink or cocktail.

1. In your entire life, have you had at least 1 drink of any kind of alcohol? (**NOT** counting small tastes or sips.)
   ☐ Yes ☐ No → ***Skip to end of form.***

2. About how old were you when you first started drinking? (**NOT** counting small tastes or sips.)
   | | years ***OR*** ☐ Don't know

3. During the past 30 days, on how many days did you drink one or more drinks of an alcoholic beverage?
   | | days ***OR*** ☐ Don't know
   Enter '00' if you did not drink in the past 30 days

4. On the days that you drank during the past 30 days, how many drinks did you usually have each day?
   | | drinks ***OR*** ☐ Don't know
   Enter '00' if you did not drink in the past 30 days.

5. What was the LARGEST number of drinks that you ever drank in a single day?
   | | drinks ***OR*** ☐ Don't know

Date Completed: | | | | | | | | | Staff Initials: | | |
dd MMM yy

PID: ☐☐☐☐☐☐☐☐☐ Visit Date: ☐☐ ☐☐☐ ☐☐
dd MMM yy

Visit: ☐☐☐☐

DRUG USE

In the last 30 days, have you ever used any of the following substances…

		No	Don't know	Yes	Age of first use	# Days Used (in past 30 days)
1.	Sedatives?	☐	☐	☐ →	☐☐ →	☐☐
2.	Tranquilizers?	☐	☐	☐ →	☐☐ →	☐☐
3.	Painkillers?	☐	☐	☐ →	☐☐ →	☐☐
4.	Stimulants?	☐	☐	☐ →	☐☐ →	☐☐
5.	Marijuana, hash, HC, or grass?	☐	☐	☐ →	☐☐ →	☐☐
6.	Cocaine?	☐	☐	☐ →	☐☐ →	☐☐
7.	Crack cocaine?	☐	☐	☐ →	☐☐ →	☐☐
8.	Hallucinogens e.g. LSD?	☐	☐	☐ →	☐☐ →	☐☐
9.	Inhalents or solvents?	☐	☐	☐ →	☐☐ →	☐☐
10.	Heroin?	☐	☐	☐ →	☐☐ →	☐☐
11.	Methamphetamines?	☐	☐	☐ →	☐☐ →	☐☐
12.	Any other non-prescribed medications / substances?	☐	☐	☐ →	☐☐ →	☐☐

12.1. Specify other: _____

Date Completed: ☐☐ ☐☐☐ ☐☐ Staff Initials: ☐☐☐
dd MMM yy

PID: ☐☐☐☐☐☐☐☐☐ Visit Date: ☐☐ dd ☐☐☐ MMM ☐☐ yy

Visit: ☐☐☐☐

ANTHROPOMETRICS

HEIGHT — *wherever possible direct measurements should be used*

1. Height measurements:
   #1 ☐☐☐ cm
   #2 ☐☐☐ cm
   #3 ☐☐☐ cm

   1.1. How tall are you? (**ONLY** If measuring was not possible) ☐☐☐ cm ***Mark N/A if height measurements taken.***

WEIGHT — *wherever possible direct measurements should be used*

2. Weight measurements:
   #1 ☐☐☐ kg
   #2 ☐☐☐ kg
   #3 ☐☐☐ kg

3. Is the participant wearing a cast or medical prosthesis? ☐ Yes ☐ No → ***Skip to Item 8.***

   3.1. If Yes, specify location of cast or medical prosthesis: _____

4. Is the participant wearing street clothes during the weight measurements? ☐ Yes ☐ No

5. How heavy are you? (**ONLY** If measuring was not possible) ☐☐☐ kg ***Mark N/A if weight measurements taken.***

PID: ☐☐☐☐☐☐☐☐☐ Visit Date: ☐☐ ☐☐☐ ☐☐
dd MMM yy

Visit: ☐☐☐☐ **BLOOD PRESSURE**

HIGH BLOOD PRESSSURE

1. Has a healthcare worker ever said that you have high blood pressure or hypertension? ☐ Yes ☐ No ☐ Don't know → **Skip to Item 3.**

   1.1. If yes, then at what age were you first told this? ☐☐ years ***OR*** ☐ Do

   1.2. ***FOR WOMEN:*** Was this during pregnancy only? ☐ Yes ☐ No

2. Have you ever taken medication for hypertension / high blood pressure? ☐ Yes now ☐ Yes not now ☐ No ☐ Don't know

   Skip to Item 3. (No / Don't know)

   2.1. If yes, then at what age did you begin taking medicine for this? ☐☐ years ***OR*** ☐ Don't know

BLOOD PRESSURE READINGS

3. Date BP measurements taken: ☐☐ ☐☐☐ ☐☐
dd MMM yy

   3.1. For blood pressure measurements, specify Aneroid sphygmomanometers name and model: _____

   3.2. Blood pressure cuffs sizes (S, M, L, XL): ☐ S ☐ M ☐ L ☐ XL

	Systolic	**Diastolic**
3.3. Blood pressure measurement #1:	☐☐☐ /	☐☐☐
3.4. Blood pressure measurement #2:	☐☐☐ /	☐☐☐
3.5. Blood pressure measurement #3:	☐☐☐ /	☐☐☐

Date Completed: ☐☐ ☐☐☐ ☐☐ Staff Initials: ☐☐☐
dd MMM yy

PID: | | | | | | | | | |

Visit: | | | | |

URINE TEST RESULTS

1. Sample collection date: | | | | | | | | | dd MMM yy

2. Urinary albumin: | | | | | mg/L

3. Urinary creatinine: | | | | | mg/L

4. Urinary total protein: | | | | | mg/L

Date Completed: | | | | | | | | dd MMM yy

Staff Initials: | | |

PID: [ ][ ][ ][ ][ ][ ][ ][ ][ ] Visit Date: [ ][ ] [ ][ ][ ] [ ][ ]

dd MMM yy

Visit: [ ][ ][ ][ ]

KIDNEY DISEASE

PERSONAL HISTORY OF KIDNEY FAILURE

1. Has a doctor or healthcare worker ever told you that you had kidney failure? ☐ Yes ☐ No ☐ Don't know → ***Skip to Item 2.***

   1.1. If Yes, are one or both working well now? ☐ Yes ☐ No ☐ Don't know

   1.2. How old were you when you were first told by a medical person that you had kidney failure? [ ][ ] years ***OR*** ☐ Don't know

   1.3. Are you currently on renal dialysis? ☐ Yes ☐ No ☐ Don't know

2. Have you ever had a kidney transplant? ☐ Yes ☐ No ☐ Don't know

3. Has anyone in your family either had kidney disease or died from it? ☐ Yes ☐ No ☐ Don't know → ***Skip to Item 4.***

   3.1. Do you know what type of kidney disease? ☐ Yes ☐ No

   3.2. If Yes, please specify: ______________________________

4. Has a doctor ever told you that your kidneys have low function? ☐ Yes ☐ No ☐ Don't know

5. Has a doctor or healthcare worker told you that you have kidney disease? ☐ Yes ☐ No ☐ Don't know

 Date Completed: [ ][ ] [ ][ ][ ] [ ][ ] Staff Initials: [ ][ ][ ]

dd MMM yy

PID: | | | | | | | | | |

PRESCRIBED MEDICATION

1. Medication: _____ Dosage: ☐ daily ☐ BID ☐ TID ☐ QID ☐ Noct

Strength: | | | | | ☐ mg ☐ ml ☐ tb

Reason: _____

Start date: | | | | | | | | dd MMM yy Stop date: | | | | | | | | dd MMM yy

Staff Initials: _____ Date Completed: _____

2. Medication: _____ Dosage: ☐ daily ☐ BID ☐ TID ☐ QID ☐ Noct

Strength: | | | | | ☐ mg ☐ ml ☐ tb

Reason: _____

Start date: | | | | | | | | dd MMM yy Stop date: | | | | | | | | dd MMM yy

Staff Initials: _____ Date Completed: _____

3. Medication: _____ Dosage: ☐ daily ☐ BID ☐ TID ☐ QID ☐ Noct

Strength: | | | | | ☐ mg ☐ ml ☐ tb

Reason: _____

Start date: | | | | | | | | dd MMM yy Stop date: | | | | | | | | dd MMM yy

Staff Initials: _____ Date Completed: _____

4. Medication: _____ Dosage: ☐ daily ☐ BID ☐ TID ☐ QID ☐ Noct

Strength: | | | | | ☐ mg ☐ ml ☐ tb

Reason: _____

Start date: | | | | | | | | dd MMM yy Stop date: | | | | | | | | dd MMM yy

Staff Initials: _____ Date Completed: _____

PID: ☐☐☐☐☐☐☐☐☐ Visit Date: ☐☐ ☐☐☐ ☐☐
dd MMM yy

Visit: ☐☐☐☐

CARDIO VASCULAR DISEASE

ARRYTHMIA (ATRIAL AND VENTRICULAR)

1. Have you ever been told you have / had a heart rhythm problem called atrial fibrillation? ☐ Yes ☐ No ☐ Don't know → ***Skip to Item 2.***

   1.1. If Yes, provide date of first episode: ☐☐ ☐☐☐ ☐☐ ***OR*** ☐ Don't know
   dd MMM yy

   1.2. Did you go to a hospital / clinic to see a doctor?
   ☐ Yes, I went to hospital / clinic
   ☐ Yes, I saw a doctor
   ☐ No
   ☐ Don't know

2. Have you got a permanent pacemaker inserted? ☐ Yes ☐ No ☐ Don't know

   2.1. If Yes, what year was it inserted? ☐☐☐☐ ***OR*** ☐ Don't know
   yyyy

3. Have you taken or are you taking any of these cardiovascular medications:

   3.1. Anticoagulants (Coumadin; Warfarin; etc.)
   ☐ Yes, now
   ☐ Yes, not now
   ☐ No
   ☐ Don't know

   3.2. Antiarrhythmics (Quinidine; Procainmide; Norpace; Disopyramide; etc.)
   ☐ Yes, now
   ☐ Yes, not now
   ☐ No
   ☐ Don't know

RHEUMATIC FEVER / RHEUMATIC HEART DISEASE

4. Has a doctor ever said you had rheumatic fever (inflammatory rheumatism)? ☐ Yes ☐ No ☐ Don't know → ***Skip to end of form.***

   4.1. If yes, have you had it in the past 12 months? ☐ Yes ☐ No ☐ Don't know

   4.2. Are you taking any medication for it? ☐ Yes ☐ No ☐ Don't know

   4.2.1. If yes, please specify medication: _____

Date Completed: ☐☐ ☐☐☐ ☐☐ Staff Initials: ☐☐☐
dd MMM yy

PID: ☐☐☐☐☐☐☐☐☐ Visit Date: ☐☐ ☐☐☐ ☐☐

dd MMM yy

Visit: ☐☐☐☐

STROKE HISTORY

ISCHEMATIC INFARCTION AND HAEMORRHAGE

1. Were you ever told by a doctor or healthcare worker that you had a stroke? ☐ Yes ☐ No ☐ Don't know

2. Were you ever told by a doctor or healthcare worker you had a TIA, mini-stroke, or transient ischemic attack? ☐ Yes ☐ No ☐ Don't know → ***Skip to Item 3.***

   2.1. If Yes, how long did the weakness last?
   - ☐ A few minutes
   - ☐ Less than 15 minutes
   - ☐ Less than an hour
   - ☐ A few hours
   - ☐ More than a day

3. Have you ever had a sudden painless weakness on one side of your body? ☐ Yes ☐ No ☐ Don't know

4. Have you ever had a sudden numbness or a dead feeling on one side of your body? ☐ Yes ☐ No ☐ Don't know

5. Have you ever had a sudden painless loss of vision in one or both eyes? ☐ Yes ☐ No ☐ Don't know

6. Have you ever suddenly lost one half of your vision? ☐ Yes ☐ No ☐ Don't know

7. Have you ever suddenly lost the ability to understand what people are saying? ☐ Yes ☐ No ☐ Don't know

8. Have you ever suddenly lost the ability to express yourself verbally or in writing? ☐ Yes ☐ No ☐ Don't know

 Date Completed: ☐☐ ☐☐☐ ☐☐ Staff Initials: ☐☐☐

dd MMM yy

PID: ☐☐☐☐☐☐☐☐☐ Visit Date: ☐☐ dd ☐☐☐ MMM ☐☐ yy

Visit: ☐☐☐☐

DIABETES HISTORY

PERSONAL HISTORY OF TYPE 1 AND TYPE 2 DIABETES

1. Has a doctor or healthcare worker ever told you that you have diabetes (sugar in blood)? ☐ Yes ☐ No ☐ Don't know → ***Skip to end of form.***

   1.1. If Yes, what type of diabetes do you have?
   - ☐ Type 1
   - ☐ Type 2
   - ☐ Type 1 and 2
   - ☐ Don't know

   1.2. If Yes, are you taking medication for it? ☐ Yes ☐ No ☐ Don't know → ***Skip to Item 2.***

   1.3. If Yes, are you taking insulin? ☐ Yes ☐ No ☐ Don't know → ***Skip to Item 2.***

      1.3.1. If you are not taking insulin, are you taking other medication? ☐ Yes ☐ No ☐ Don't know

2. At what age was your diabetes first treated? ☐☐ years ***OR*** ☐ Don't know

3. Was insulin your first diabetes medicine? ☐ Yes ☐ No ☐ Don't know

4. ***FOR WOMEN ONLY:*** Did diabetes occur <u>only</u> during pregnancy? ☐ Yes ☐ No ☐ Don't know

PID: ☐☐☐☐☐☐☐☐☐ Visit Date: ☐☐ ☐☐☐ ☐☐
dd MMM yy

Visit: ☐☐☐☐ **SELF REPORT HIV**

SELF-REPORT OF HUMAN IMMUNODIFICIENCY VIRUS (HIV) TESTING

1. Have you ever been tested for HIV? ☐ Yes ☐ No ☐ Don't know ☐ Refused
   → ***Skip to end of form.***

2. When did you have your most recent HIV test? ☐☐ ☐☐☐ ☐☐ ***OR*** ☐ Don't know
   dd MMM yy

3. What was the result of your most recent HIV test?
   - ☐ Positive
   - ☐ Negative
   - ☐ Indeterminate
   - ☐ Never obtained results
   - ☐ Don't know
   - ☐ Refused to answer

4. Are you on HIV treatment? ☐ Yes ☐ No ☐ Don't know ☐ Refused
   → ***Skip to end of form.***

   4.1. If Yes, when did you initiate (start) HIV treatment? ☐☐ ☐☐☐ ☐☐ ***OR*** ☐ Don't know
   dd MMM yy

PID: ☐☐☐☐☐☐☐☐☐ Visit Date: ☐☐ ☐☐☐ ☐☐
dd MMM yy

Visit: ☐☐☐☐

DYSLIPIDEMIA

1. Has a doctor or healthcare worker ever told you that you have dyslipidemia? ☐ Yes ☐ No ☐ Don't know
   → ***Skip to end of form.***

   1.1. If Yes, at what age were you first told this? ☐☐ years ***OR*** ☐ Don't know

   1.2. Was it confirmed by a laboratory test? ☐ Yes ☐ No ☐ Don't know

   1.3. Have you ever taken medication for dyslipidemia?
   ☐ Yes, now
   ☐ Yes, not now
   ☐ No
   ☐ Don't know
   ← ***Skip to end of form.***

   1.3.1. If yes, then at what age did you begin taking medicine for this? ☐☐ years ***OR*** ☐ Don't know

Date Completed: ☐☐ ☐☐☐ ☐☐ Staff Initials: ☐☐☐
dd MMM yy

PID: ☐☐☐☐☐☐☐☐☐ Visit Date: ☐☐ ☐☐☐ ☐☐
dd MMM yy

Visit: ☐☐☐☐ **CANCER**

---

1. Have you ever had cancer? ☐ Yes ☐ No → ***Skip to end of form.***

2. If Yes, please specify cancer type and site: _____

_____

2.1. Date of diagnosis for this cancer: ☐☐ ☐☐☐ ☐☐
dd MMM yy

2.2. Age at diagnosis for this cancer: ☐☐ years ***OR*** ☐ Don't know

2.3. Did you have surgery for this cancer? ☐ Yes ☐ No ☐ Don't know

2.3.1. If yes, name of procedure: _____

2.4. Indicate what treatment/s you had and the dates of treatment completion:

	dd	MMM	yy	
☐ Chemotherapy →	☐☐	☐☐☐	☐☐	***OR*** ☐ Ongoing
☐ Hormonal therapy →	☐☐	☐☐☐	☐☐	***OR*** ☐ Ongoing
☐ Radiotherapy →	☐☐	☐☐☐	☐☐	***OR*** ☐ Ongoing
☐ Other therapy →	☐☐	☐☐☐	☐☐	***OR*** ☐ Ongoing

If other, specify: _____

2.5. Have you had a recurrence of this cancer? ☐ Yes ☐ No ☐ Don't know
→ ***Skip to end of form.***

2.5.1. If yes, date of recurrence: ☐☐ ☐☐☐ ☐☐
dd MMM yy

2.5.2. Where did cancer recur? _____

PID: ☐☐☐☐☐☐☐☐☐ Visit Date: ☐☐ dd ☐☐☐ MMM ☐☐ yy

Visit: ☐☐☐☐

OTHER INFECTIOUS DISEASES

SELF-REPORT OF OTHER INFECTIOUS DISEASE HISTORY

Has a doctor or healthcare worker ever told you that you had any of the following conditions:

1. Tuberculosis? ☐ Yes → ☐☐ Age diagnosed (years)
   ☐ No
   ☐ Don't know
   ☐ Refused

2. Malaria? ☐ Yes → ☐☐ Age diagnosed (years)
   ☐ No
   ☐ Don't know
   ☐ Refused

3. Sleeping sickness? ☐ Yes → ☐☐ Age diagnosed (years)
   ☐ No
   ☐ Don't know
   ☐ Refused

4. Hepatitis A? ☐ Yes → ☐☐ Age diagnosed (years)
   ☐ No
   ☐ Don't know
   ☐ Refused

5. Hepatitis B? ☐ Yes → ☐☐ Age diagnosed (years)
   ☐ No
   ☐ Don't know
   ☐ Refused

6. Hepatitis C? ☐ Yes → ☐☐ Age diagnosed (years)
   ☐ No
   ☐ Don't know
   ☐ Refused

Date Completed: ☐☐ dd ☐☐☐ MMM ☐☐ yy Staff Initials: ☐☐☐