# 29th September 2021

# Memo to: National Institutes of Health, Office of Science Policy

**RE**: NOT-OD-21-131: Request for Information on Developing Consent Language for Future Use of Data and Biospecimens

# The Industry Pharmacogenomics Working Group (I-PWG) was established in 2000 and is comprised of functionally diverse members from pharmaceutical and biotechnology companies who engage pre-competitively to address emerging issues related to pharmacogenomics. Our membership is made up of those engaging in regulatory, statistical, technological, genomic and biological research as well as operations. Our mission is to improve patient care through integration of pharmacogenomics in drug development.

# The I-PWG is appreciative for the opportunity to provide the enclosed feedback and recommendations in response to the National Institutes of Health’s Request for Information on Developing Consent Language for Future Use of Data and Biospecimens. In general, the I-PWG makes the following recommendations:

* ***Importance of topics within the Instructions for Use (of the RFI) and General Points to Consider***: We agree with the points raised within the Instructions for Use and the General Points to Consider and encourage including similar points in the final issued guidance, particularly those emphasizing that use of the text is not required and that tailoring it to the specifics of the study may be appropriate.
* ***Value of sharing***: We encourage the NIH to provide example language that clearly explains the value of sharing specimens and data so as to provide additional context for study participants.
* ***Use of clear terminology:***
  + As the word “specimen” is widely used in regulatory documentation, we recommend replacing the term “biospecimen” with the simpler word “specimen” when referring to human biological samples.
  + For scientists, the terms specimen and sample are equivalent, and so the use of the word “sample” in the context of suggested informed consent form (ICF) language may be confusing to some audiences. We therefore recommend the use of “example language” instead of “sample language.”
* ***Clarity on applicability to “storing” vs. “sharing****:”* The current proposed guidance is unclear as to whether it applies to storage only, sharing only, or both storage and sharing of specimens and/or data.

Detailed feedback on specific portions have been provided in the appropriate sections on the submission website.

# In conclusion, we thank you for the opportunity to comment on the example ICF language being developed by the NIH.

# Utility and useability of this resource

We acknowledge the benefits of a standardized informed consent form (ICF) language resource. For clinical trial sponsors, these include efficiencies in creating high quality ICFs; a reduction in redundant work across investigators in multi-institutional studies; and a decrease in investigator, sponsor, and institutional review board (IRB) resources to arrive at mutually acceptable ICF language.

We applaud the NIH for the clear and comprehensive guidance stressing the importance of tailoring the example ICF text as needed. Provision of descriptive example language rather than prescribed example language will facilitate efficient ICF development for industry-sponsored clinical trials.

# Gaps or additional components that should be included

We did not identify any gaps or additional components to include.

# Specific language proposed in the informed consent sample language

Component 1: Introduction- Description

The I-PWG has developed the following language:

<The Sponsor/Company name/We> may make <coded/anonymized/de-identified> specimens and data without personal identifying information from this trial available to external researchers. We will not ask you for any additional permission for this sharing. We will not be able to give you details of the research studies that might be conducted using your specimens, including the purposes of the research. The researchers may perform scientific analyses or conduct more research that can help advance medical science or improve patient care. These uses can maximize the value of the specimens and data provided by trial participants.

We provide this language for illustrative purposes. Like the NIH draft example text, it communicatesthat sharing with other researchers maximizes the value of specimens and data and it describes their potential future use. However, we felt it important to also specify that no specific details about the research would be provided to the participant, nor would the participant be asked to provide additional permission for this research. We recommend that these additional points be considered when developing the final example language.

Secondly, the statement that “researchers must get approval” to gain access to specimens and data does not adequately capture the range of possible appropriate sharing mechanisms. For example, a Material/Data Transfer Agreement may be executed without new ethical board approval if the research to be conducted by the recipient researcher is within the scope of a previous ethical board approval.

Thirdly, the statement “The code key will be kept in a locked location separate from your information”, where “information” refers to identifying information, is not accurate for clinical trials. In clinical trials, the code key links a study participant’s identifying information with the code on the specimens and data and thus contains—rather than is separate from—the identifying information. Furthermore, we recommend that the word “locked” be replaced with “secure” to encompass electronic systems as well as physical file cabinets, etc.

Fourthly, the phrase “until used completely” does not resonate for data. We suggest replacing it with “until used completely or they are no longer needed for research.”

Lastly, the NIH example text includes instruction to indicate the name of the institution at which the study materials will be stored and the storage duration. Given that storage may be for many years, the location may change over time. We suggest either focusing on the entity with oversight of the materials (regardless of their physical location) or including a statement such as “The storage location may change, in which case you will not be notified.”

Component 2: Voluntary Participation

Both options include a sentence about the participant’s ability to change their mind (“You can change your mind later, but researchers may still use your data and biospecimens that have already been shared.”). As Component 3 addresses withdrawal of consent, we suggest this sentence be removed from the Voluntary Participation component.

We suggest that the Considerations for this component acknowledge the differences in levels of identifiability\* (reference below) and that users may need to adjust the example ICF language accordingly. Additionally, we suggest example language be aligned and consistent with the European General Data Protection Regulation to support global research.

(\*International Conference on Harmonisation’s E15 Guideline, *Definitions for genomic biomarkers, pharmacogenomics, pharmacogenetics, genomic data and sample coding categories*, implemented by the FDA in April 2008)

Component 3: Discontinuation/Withdrawal

We recommend that this component be renamed to “Withdrawal.” The term “discontinuation” encompasses many situations in which a study participant ceases taking part in the research without rescinding (withdrawing) their consent.

We recommend removing the sentence “We will do our best to retrieve all your data and biospecimens that have already been shared, but it may not be possible.” This sentence creates an unrealistic perception that complete retrieval is the norm, when in fact the large logistical challenges and, in some cases, impossibility of deleting all copies of data from back-up servers, etc. make complete retrieval a rarity. Also, the phrase “but it may not be possible” is redundant with the last sentence (“… it might not be possible to get them back.”).

Component 4: Risks & Benefits

The potential for overlap between this example language and the “Confidentiality” sections found in most ICFs should be noted to ensure users are mindful to align the messaging in the two sections.

We found the Risk portion of this component to have a negative connotation. Potential risks should be communicated in a balanced, measured fashion as is done in the following text:

We will protect your data and specimens as much as possible during storage and when they are shared. When we share your data and specimens, there is a risk that people may get access to it who are not supposed to and potentially could identify you.

Component 5: Commercial Application

The draft language is clear and concise. However, we feel the last sentence should be worded more conclusively in that participants would not receive compensation in the event of commercialization (e.g. “No payments will be provided to you should this occur.”).

# Hurdles or barriers to wider use of this resource by the community

The proposed language is inconsistent in combining or separating the concepts of sharing and storing, which may cause confusion by end users or study participants. For example, Component 2 addresses sharing, whereas other Components combine both sharing and storing. Storing implies future use, while sharing implies the use of specimens/data by a different party. We suggest that the NIH consider whether it is preferable to consistently combine the two or treat them separately, and then develop proposed language appropriately.

# Other considerations relevant to this resource

The relationship between the NIH’s ICF text and “broad consent” described in the Common Rule is unclear. We recommend alignment between the two and that this topic be addressed in the final NIH product, including whether the NIH ICD text is intended to (partially) fulfill the Common Rule “broad consent” requirements.