

# ANNEX 1

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## **Project proposal:**

### **Intervention Analysis: the Effects of Plain Packaging for Tobacco Products on Smoking Behavior in Australia**

A Quantitative Evaluation Applying Statistical Methods

submitted to

**Philip Morris International (PMI), Lausanne**

on

Wednesday, May 22, 2013

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## A. Background

As mandated in the Plain Packaging Act 2011, tobacco products in Australia have to be sold in plain packaging since December 2012.<sup>1</sup> Australia is thereby the first country to introduce such a regulation. The act is meant to be in line with the National Tobacco Campaign, which aims to reduce smoking rates to 10 percent or less by 2018.<sup>2</sup> According to OECD statistics, the smoking rate in Australia dropped gradually from more than 43% in 1964 to 15% in 2010.<sup>3</sup>

The **stated objectives of the Plain Packaging Act 2011** are the improvement of public health by

- discouraging the taking up of smoking,
- encouraging the giving up of smoking or the use of other tobacco products, and
- reducing people's exposure to smoke from tobacco products.

In addition to the improvement of public health, the Australian government motivates the initiative by its obligations as a member country that signed the WHO Framework Convention of Tobacco Control, a convention signed by 168 states worldwide.<sup>4</sup>

The Plain Packaging Act states clearly that the objectives should be attained by a regulation of the packaging and appearance of tobacco products which is supposed to<sup>5</sup>

- reduce the appeal of tobacco products to consumers,
- increase the effectiveness of health warnings on the retail packaging of tobacco products, and
- reduce the ability of the retail packaging of tobacco products to mislead consumers about the harmful effects of smoking or using tobacco products.

The legislation prohibits branding and prescribes in detail the appearance of cigarette packages, including the material of the pack, the very shape of it and its color. For example, the color was chosen to be Pantone 448 C, a dark green-brownish color reminding of mud, which is supposed to be particularly unattractive to consumers. While trademarks and brand names are allowed, they may only be printed once on the front, top, and bottom surface of the pack. The Australian law includes the prohibition of inserts or onsets, noise or scent, and also any features that might change the appearance posterior to the purchase.

**So far there is no empirical evidence that the measures prescribed by the Plain Packaging Act 2011 are effective in attaining the stated goals of the Australian government.** In fact, there is hitherto not a single research paper that empirically links the introduction of plain packaging in Australia to changes in smoking prevalence, smoking initiation or smoking intensity in Australia.

<sup>1</sup> Tobacco Plain Packaging Act 2011. No 148, 2011.

<http://www.comlaw.gov.au/Details/C2011A00148> (Accessed on 07 May 2013).

<sup>2</sup> <http://www.quitnow.gov.au/internet/quitnow/publishing.nsf/Content/ntc-2009-2013-lp> (Accessed on 07 May 2013).

<sup>3</sup> OECD (2012), "OECD Health Data: Non-medical determinants of health", *OECD Health Statistics* (database). doi: [10.1787/data-00546-en](https://doi.org/10.1787/data-00546-en) (Accessed on 07 May 2013).

<sup>4</sup> [http://www.who.int/fctc/signatories\\_parties/en/index.html](http://www.who.int/fctc/signatories_parties/en/index.html) (Accessed on 07 May 2013).

<sup>5</sup> Tobacco Plain Packaging Act 2011. No 148, 2011.

<http://www.comlaw.gov.au/Details/C2011A00148> (Accessed on 07 May 2013).

## **B. Our Understanding of the Project**

The Australian plain packaging initiative is unprecedented in its approach and scope. Therefore, the scientific evidence on **whether such a drastic measure does prevent individuals from smoking or encourage them to quit is difficult to assess**. Experiments regarding the appearance of the packaging suggest that standardized packages lead people to attribute less positive characteristics to the smoker and to the consumed good (i.e., cigarettes). Whether this perception will actually lead people to reduce cigarette consumption is, however, a blunt and so far unsubstantiated hypothesis. As an example of a comparable though weaker policy measure, mandatory pictorial warnings on cigarette packs have been used for a while in Canada and other countries;<sup>6</sup> but the empirical evidence on their causal effect on falling smoking rates is rather weak.<sup>7</sup> Whether the introduction of standardized (or "plain") packaging has any effect on smoking rates is a priori unclear. However, the measure comes at a very high cost to the tobacco industry and consumers. It is a severe restriction of intellectual property rights related to brands and logos and drastically restricts consumers' freedom of choice. **Whether this policy measure is effective is therefore of major importance. Only the empirical analysis of real-world data can answer this question.**

The Australian Plain Packaging Act is a so-called "natural experiment" for empirical researchers. In contrast to laboratory experiments, natural experiments are typically not designed to be analyzed using scientific methods. Legislators in fact mostly simply *assume* that the experiment will produce the desired results. However, every statutory change—often called (policy) *intervention* in the scientific literature—can in principle be evaluated using statistical methods, provided that adequate data are available. A thorough analysis of an intervention based on econometric and/or statistical methods builds on:

- (1) the right research questions,
- (2) high-quality data, and
- (3) an adequate research design.

A combination of economic analysis—taking behavioral reactions of individuals to policy interventions into account—and statistical intervention analysis is best suited to assess such a statutory change.

To evaluate the Australian experiment, it is necessary to examine the effects of the intervention based, most importantly, on original empirical research using real-world data.<sup>8</sup> Going forward, as other researchers may publish research using actual intervention data from Australia, such third party research should also be reviewed and evaluated.

**The main goal of this project is to analyze whether a causal link between the Plain Packaging Act 2011 and smoking behavior (smoking prevalence, initiation, and intensity) in Australia can be established. To do so we apply statistical and econometric methods to real-world data.**

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<sup>6</sup> Canada, Poland, and Thailand were the first countries to require that health warnings must cover at least half of the package's front and back. <http://www.who.int/bulletin/volumes/87/8/09-069559/en/> (Accessed on 07 May 2013).

<sup>7</sup> See Gospodinov and Irvine (2004) for example.

<sup>8</sup> For a more detailed discussion of regulatory intervention analyses and the various techniques involved, please see the presentation attached to this proposal as Annex I.

## C. Outline of Our Suggested Approach

A thorough statistical analysis of the empirical evidence on plain packaging in Australia involves the review of other research, a novel research design, data collection and analysis, and a comprehensive interpretation of the results. Hypotheses and optimal model selection typically develop in the course of the analysis and trigger adaptations in the design of the analysis. Therefore, a **high level of flexibility on our side regarding timing and phases is a prerequisite for a successful project completion**. Also, regular meetings of PMI team members and our team members, regular conference calls, and frequent email communication is inevitable for reaching our project goals. The following four phases sketch the most important steps of our suggested approach.

**Phase 1: Review of databases and check of consistency across the various data streams** (2 months, to be completed by the end of August 2013)

Our analysis will be built on various data sources. In a first step, we suggest to obtain an overview of all relevant data as well as the subset of these data that is available for statistical analysis. This detailed database survey will help us to arrive at a comprehensive assessment of the effects of the plain packaging in Australia. Also, it will enable us to check the consistency of the various data streams and publications based on them.

**Important data sources** are (distinguished according to data type):

1. Market data

Market data are a key data source for our analysis. They serve as a basis for aggregate time series analysis or time series analysis at a more disaggregated level (e.g., using information on different age cohorts). Important data are in-market sales or retail data, e.g., data provided by Aztec, ACNielsen, and PWC (wholesale sales data).

2. Micro (individual-specific) survey data ("Multi-subject data")

Important micro data for a potential statistical analysis are RMR Single Source data, the Woolworth Smoker Panel, and London Economics survey data. Publications and statistics/figures based on government surveys (NDSHS, ASSAD) should also be taken into account, although it seems unlikely that these data will be available for statistical analyses. An important aspect in analyzing the quality of the micro data is an assessment of the applied stratification, weighting, and sampling procedures. The root of inconsistencies across databases—for example in prevalence rates—is likely to be found in differing data collection approaches.

3. Illicit Trade Data

Trends in illicit trade have to be taken into account. We will also critically examine the Deloitte/KPMG methodology for Australia and possibly make suggestions for improving the data quality in the long run.

4. Plain Packaging specific data

There are a few newly built databases that are closely related to evaluating certain aspects of the plain packaging legislation in Australia

(e.g., data compiled by Cancer Council Victoria, the Storyville "focus groups" data, and the "beyond tracker" data). Publications and figures/statistics based on these data will be reviewed and summarized.

Other survey data (partly qualitative consumer research and retailer surveys) will also be reviewed. They are, however, unlikely to be suitable for a statistical analysis or even to be included in an overall assessment of the effects of plain packaging.

**Main deliverables of Phase 1 (to be submitted by the end of August, 2013)**

The main insights from phase 1 will be summarized in a comprehensive report of about 20 pages. This report will be compiled for PMI internal use only.

Key aspects of this internal report are:

- Insights from an in-depth analysis of the most relevant databases. Which databases can be used for original statistical analysis? Are there important potential inconsistencies in the data and the publications based on them? Which descriptive statistics (e.g., smoking prevalence rates) should be used as a benchmark in our analysis?
- In this report, we also suggest
  - directions for the evolution of the project over the next 6 months (medium-term strategy), and
  - directions for long-term strategic planning of research and data building/collection:
    - Which data should be accessible (made available) in the future?
    - Which databases should be built up in the long run?
    - Which directions for future research are worth pursuing from a PMI point of view?
    - Which developments in the tobacco control research on plain packaging (in Australia) pose a threat to the interest of PMI?

At the end of phase 1, we would ideally identify a first data set, i.e., *one* very promising database, for a statistical analysis. We suggest to first go for an analysis based on *aggregate time series data* on smoking prevalence or cigarette sales volumes (in-market sales). The data should be monthly and it would be necessary to have at least 5 to 6 years of data. 10 years of monthly data would be very satisfactory. From our current knowledge, the necessary data could be built from **Aztec retail scan data**. It would be desirable to consider merging Aztec data and ACNielsen data to extend the time series dimension of the data. RMR single source data would also be interesting to start with (although they are quarterly only). **Ideally, we could already start building pre-implementation trends towards the end of phase 1.**

During phase 1, we would expect the PMI team involved in the project to work on a detailed assessment of regulatory interventions in order to identify significant changes to the regulatory environment in prior years, including tax and price increases, and changes in tobacco control policies. To speed up the data analysis of phase 2, it would also be desirable that the PMI team identify available data from New Zealand and/or Canada as possible comparison countries (e.g., to apply a statistical approach called *difference-in-differences estimation*<sup>9</sup>).

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<sup>9</sup> For an explanation of difference-in-differences estimation, see slides 13, 23-25 of Annex I.

**Phase 2: Internal Data Base Building; Final Assessment of Regulatory Background** (to be completed by the end of November 2013)

During phase 2, we would build on the information of phase 1 about the various databases. The main task in this phase is to prepare the analysis of various data sets using statistical software. Important data therefore have to be collected, adequately cleaned, and built into a database ready for statistical analysis. Also, the joint team should agree on key changes in the regulatory background over the last decade that might affect the assessment of the effects of plain packaging in Australia.

**Australian Data on Smokers and/or Smoking Behavior**

Phase 2 will include a thorough data inspection which starts from checking for coding errors and plausibility, goes over tests on whether there are enough data points and enough information (variables) to answer the relevant questions. In some cases, it will be necessary or beneficial to combine different data sources; for example, individual-based data on smoking behavior with macroeconomic trends, seasons, or the legislation at stake. **Provided that sufficient data is available and the data is well prepared, we could start analyzing pre-implementation and post-implementation trends using time-series regression techniques.**<sup>10</sup>

**Australian Data on Regulation**

It is crucial to thoroughly describe the regulation under consideration and other relevant policy measures in the past. If policy interventions are combined, it is desirable to disentangle the effects of each measure. As part of phase 2 we would therefore—based on PMI material and information—document regulatory interventions in order to **identify significant changes to the regulatory environment in prior years, including tax and price increases as well as changes in tobacco control policies.** These regulatory changes would then be coded in a way that the relevant information can be included in a statistical analysis.

**Data on Potential Reference Countries**

Increasingly restrictive tobacco control legislation can be observed in many countries. Two countries are particularly interesting as reference when analyzing the Australian plain packaging case. *Canada* pioneered the introduction of large-sized pictorial health warnings in 2000.<sup>11</sup> *New Zealand*—being a neighboring country—faces similar economic fluctuations as Australia and has a comparable population in terms of many important consumer characteristics. A comparison between Australia and these two countries could help to disentangle the causal effect of the Australian plain packaging legislation from the trend-based decrease in smoking rates in Australia.

**Main deliverables of Phase 2** (to be submitted by the end of November 2013):

The main insights from phase 2 will be summarized in a comprehensive report of about 30 pages. This report will be compiled for PMI internal use only.

Key aspects of this internal report are:

<sup>10</sup> For a more detailed discussion of regression techniques, see slides 29-34 of Annex I.

<sup>11</sup> See Gospodinov and Irvine (2004).

- Insights from the time series data analysis (analysis of pre-implementation and post-implementation trends, possibly already using time-series regression techniques).
- Insights about the data quality regarding our work with the provided micro data.
- Summary of the country comparison analysis and any agreed-upon analyses based on panel data.
- Summary of our assessment of how changes in the regulatory background should be taken into account in the statistical analysis.
- A proposal how to continue in phase 3.

**Phase 3: Statistical Intervention Analysis and Internal Assessment** (to be completed by February 2014)

There are two main tasks to be performed in phase 3. First, we will carry out a statistical intervention analysis on the impact of plain packaging based on time-series data. This step involves model selection, diagnosis and estimation. Key insights for internal use are derived. Based on these insights, a decision on the tasks to be carried out in phase 4 is possible. Second, we will suggest starting the country comparison analysis and any agreed-upon analyses based on panel data. These analyses will be very preliminary in phase 3. However, important insights on a micro level could already emerge (e.g., regarding age-cohort specific).

The key issue of a statistical analysis attempting to link an *intervention* (a policy measure such as plain packaging) to *changes in household behavior* (consumers' smoking behavioral) is **identification**:

*Is the observed effect/trend/behavior actually caused by the intervention or is it only associated with it, but without a causal link?*

**Important approaches to "Intervention Analysis" (or "Program Evaluation")** that could be applied in our setting in phase 3 are:

- Regression Analysis (slides 29-31, Annex I)
- Difference-in-Differences Estimation (slides 13, 23-25, Annex I)
- Matching Methods (slides 26-28, Annex I)
- Regression Discontinuity Design Methods (slides 32-34, Annex I)
- Synthetic Control Methods (slides 35-37, Annex I)

Whether a specific statistical approach is chosen depends on many things; e.g., on the specific research question, data availability, and assumptions under which a certain approach is applicable.

Although the time-series analysis to be carried out in phase 3 is quite clear and only depends on data availability, more uncertainty is involved regarding micro data analysis (based on survey data). **We suggest a high level of flexibility regarding the project work to be done in phase 3 on panel data or other micro data analysis.**

**Main deliverables of Phase 3** (to be submitted by the end of February 2014):

The main insights from phase 3 will be summarized in a comprehensive report of about 30 pages. This report will be compiled for PMI internal use only.

Key aspects of this internal report are:



- Results and insights from the time series-analysis.
- Insights about the data quality regarding our work with the provided micro data.
- Summary of the (presumably preliminary) country comparison analysis and any agreed-upon analyses based on panel data.
- A proposal how to continue in phase 4.

**Phase 4: External Document** (to be completed by the end of June 2014)

The work to be performed in phase 4 will depend on the results of phases 2 and 3, i.e., the availability and quality of data. Depending on the internal assessment of PMI, it will have to be determined whether and in which format the results of the analysis should be presented to a broader audience. In addition, depending on the third party research that may have been published in the meantime and that reports on the impact of plain packaging based on actual intervention data, it will have to be determined to what extent the external document should include a review of such third party research.

**Main deliverables of Phase 4** (to be submitted by the end of May 2014):

The main insights from phase 4 will be summarized in a comprehensive report of about 30 pages. This report will be compiled for PMI internal use only and will be submitted after 11 months.

Key aspects of this internal report are:

- Summary of the progress in the country comparison analysis and any agreed-upon analyses based on panel data.
- Summary of the whole project and results.
- Review of third party research
- Suggestion of directions for the evolution of the project in case of a possible extension.
- Suggestion of directions for long-term strategic planning of research and data.

A second possible deliverable is a first research paper (20-30 pages including appendices). Whether the paper can or should be written depends on the results of the data analysis in phases 3 and 4. A possible decision at the beginning of phase 4 is not to write a research paper but to allocate the free resources to further statistical analyses for internal use. In case it is decided that a research paper is to be written, the paper will present the statistical analysis and the results of one of the data streams (most likely it will be based on aggregate time series data) in a way that it can serve as an external document. Whether the document will eventually be published and in which form shall be decided by PMI.

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## **E. Project Organization and the Project Team**

The project organization from our side will be as follows:

### **Lead Researchers:**

**Michael Wolf, Ph.D.** – Michael Wolf is a full professor of Econometrics and Applied Statistics at the University of Zurich, Switzerland. He holds a Ph.D. in Statistics from Stanford University. Michael Wolf develops statistical methods that allow for precise testing of multiple hypotheses in intervention analysis. His key expertise is in *identifying false findings* (i.e., “evidence” for results which are not there) and *developing better techniques* that allow to establish truly significant results in the presence of “cherry picking”. In a nutshell, he develops methods that allow to separate “skill” from “luck”. His research is published in *leading scientific journals*. Methods that have been developed in Michael’s research are widely applied in economics, finance, medical statistics, and other fields.

**Dr. Ashok Kaul** – Ashok Kaul is a full professor of Economic Policy at Saarland University, Germany. He holds a Ph.D. in Economics from the University of Bonn, Germany. Ashok Kaul works in the areas of public policy, impact assessment and empirical & simulation based policy analysis. He has private-sector and public-sector consulting experience of more than 10 years. He mainly applies program evaluation techniques to real-world problems in his research (examples: car scrappage premium, job training programs, effects of tax policy changes) and in particular in numerous private-sector and public-sector consulting projects.

### **Support Team:**

The support team consists of two highly-qualified postdoctoral researchers. Both hold a Ph.D. in Economics and are specialized in Applied Econometrics. They have extensive experience with practical data analysis and are active researchers in the field of applied program evaluation.

**Dr. Stefan Witte** – Stefan Witte works as a consultant for IPE – Institute for Policy Evaluation, Saarland, and as a postdoctoral researcher at Saarland University, Germany, where he also earned a Ph.D. in Economics with a thesis on program evaluation. He studied economics at the University of Freiburg, Germany, and political sciences at SciencesPo Paris, France. He has worked as a parliamentary assistant in the French National Assembly and as a researcher at the University of Freiburg and at Saarland University. He now works in the field of intervention analysis and policy consulting, mainly focusing on the economic effects of statutory changes.

**Dr. Silke Rath** – Silke Rath works as a consultant for IPE – Institute for Policy Evaluation, Saarland, and as a postdoctoral researcher at Saarland University. She earned a Ph.D. in Economics with a doctoral thesis in Applied Microeconometrics from the University of Mainz, Germany. She studied economics in Mainz and Paris-Nanterre, and has worked as a lecturer and senior lecturer in econometrics and statistics at the University of Mainz, Germany, and Saarland University, Germany. She has consulting experience of about three years.

All team members have worked on joint research/consulting projects. Short bios of all four team members can be found below.

**Professor Michael Wolf, Ph.D.**

Position: Full Professor

Chair of Econometrics and Applied Statistics

Department of Economics

University of Zurich




**Training and Experience**

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<b>Research Interests</b>	Multiple Testing Procedures (avoiding the pitfalls of data snooping) with Applications to Economics, Finance, and Medical Statistics; Evaluation Methods/Intervention Analysis; Nonparametric Inference Methods (Bootstrap und Subsampling).
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<b>Core Competences</b>	Econometrics and Applied Statistics; Simulation Methods
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<b>Selected Consulting Projects</b>	
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<p><b>Dr. Ashok Kaul</b></p> <p>Position: Full Professor</p> <p>Saarland University, Germany</p> <p>Director of IPE – Institute for Policy Evaluation, Saarland</p>	
<p><b>Training and Experience</b></p>	

<p><b>Research Interests</b></p>	<p>Public Policy/Public Finance; Empirical Evaluation of Policy Interventions; Impact Assessment Analysis</p>
<p><b>Core Competencies</b></p>	<p>Policy Evaluation on the Micro Level and Macro Level; Private sector and Public Sector Consulting based on Econometric and Statistical Analyses and Simulation Methods</p>
<p><b>Selected Consulting Projects</b></p>	

<p><b>Dr. Stefan Witte</b></p> <p>Position: Consultant and postdoctoral researcher</p> <p>IPE – Institute for Policy Evaluation, Saarland Chair of Public Policy, Saarland University</p>	
<p><b>Training and Experience</b></p>	

<p><b>Research Interests</b></p>	
<p>Empirical Public Finance; Applied Econometrics with a focus on Program Evaluation Methods</p>	
<p><b>Core Competencies</b></p>	<p>Impacts of Policy Changes on Economic Outcomes</p>
<p><b>Selected Research Projects</b></p>	
<p><b>Selected Publications</b></p>	<p>Economic Effects of Cash for Clunkers-Germany's Scrappage Scheme and its Effects on the Market and Prices, 2013, Berlin: Wissenschaftlicher Verlag Berlin (Ph.D. Thesis).</p> <p>Transport, Welfare and Externalities. Replacing the Polluter Pays Principle with the Cheapest Cost Avoider Principle, (joint with D. Schmidtchen, C. Koboldt, J. Helstroffer, B. Will und G. Haas), 2009, London: Edward Elgar.</p>

<p><b>Dr. Silke Rath</b></p> <p>Position: Consultant and postdoctoral researcher</p> <p>IPE – Institute for Policy Evaluation, Saarland Chair of Public Policy, Saarland University</p>	
<b>Training and Experience</b>	

<b>Research Interests</b>	Empirical Public Finance; Applied Microeconometrics
<b>Core Competencies</b>	Analyses of Large Microdata; Impact Assessment of Tax and Transfers System Reforms; Distributional Effects of Labor Market and Tax Policies
<b>Selected Consulting Projects</b>	2009/2010, German Federal Ministry of Finance: Empirical Analysis of the Impact of VAT Reform Options in Germany 2012, Thuringian State Ministry of Economics (TMWAT), Empirical study on the past development and the future prospects of the East German economy
<b>Selected Publications</b>	Rath (2012): Taxation and Income Distribution – Analysis of Income Tax and Value Added Tax (Ph.D. Thesis).



## **F. Cost and Billing, Non-Disclosure Agreement**

The fee budget for the project is **CHF 340,800 for one year (CHF 28,400 per month) excluding incidentals and VAT**. We will undertake this project for a fixed professional fee, plus incidental expenses (e.g., printing, travelling to joint meetings as well as travelling of team members to our offices in various cities in Germany and Zurich, Switzerland) *as incurred*. Incidental expenses shall be paid subject to terms and conditions to be determined according to the guidelines of PMI.

The budget of CHF 28,400 per month would be split as follows between the two involved contractors, IPE – Institute for Policy Evaluation, Saarland, Germany, and the University of Zurich, Switzerland:

IPE – Institute for Policy Evaluation, Saarland: CHF 18,500 per month.

University of Zurich: CHF 9,000 per month plus 10 percent university overhead (CHF 900 per month) = CHF 9,900 per month.

If PMI accepts our proposal, we would start the project on July 1, 2013. We would have to set up a separate contract (University Services Contract on Statistical Consulting Services) with the University of Zurich (UZH). From our experience we know that this may take around four weeks; however, this would leave our staffing and project work unaffected. The UZH contract has a minimum duration (minimum initial term) of six months, i.e., a minimum payment of CHF 59,400 is agreed upon if this proposal is accepted *and* a contract with UZH is signed.

No minimum initial term is part of the contract based on this proposal between IPE and PMI. PMI retains the right to terminate any element of the services or this agreement forthwith upon notice to Ashok Kaul, or representatives of IPE involved in this project, entirely at its convenience and discretion, with or without cause.

UZH undertakes upon execution of this agreement to sign a non-disclosure agreement on substantially the same terms as are contained in the non-disclosure agreement Ashok Kaul and Michael Wolf have already signed. The same is true for the other team members listed in this proposal or other team members who may join in while the project is running.

In the unlikely event that UZH is not willing to contract with PMI, IPE will take over all services described in this proposal. The staffing and project work as well as the total fee budget would be unaffected in this case.