## QUESTIONNAIRE TO BE COMPLETED BY PI’s FOR ALL PROPOSED PATIENT FOCUSED RESEARCH STUDIES (INCLUDING NON-INTERVENTIONAL STUDIES)

*Please note the purpose of this questionnaire is to ensure there is appropriate* ***insurance cover*** *in place for study subjects, University personnel involved in conducting the patient focused research study and the University itself. Certain responses may be required for onward transmission to the State Claims Agency and/or University’s underwriters for review and/or approval so please try to ensure your responses are comprehensive and provided* ***in lay man’s terms*** *so that they can easily be understood by a bystander who has limited clinical or scientific expertise.*

*(OCLA – January 2018)*

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| Q1 | PLEASE PROVIDE A **BRIEF** SUMMARY OF THE PROPOSED STUDY (INCLUDING DETAILS OF THE STUDY NAME & METHODOLOGY: |
| Q2 | PLEASE LIST **ALL** LOCATIONS WHERE THE STUDY WILL BE CARRIED OUT (IN UNIVERSITY, HOSPITAL LOCATION/S, PRIMARY CARE LOCATIONS ETC): |
| Q3 | PLEASE SPECIFY THE EXPECTED NUMBER OF STUDY/TRIAL PARTICIPANTS: |
| Q4 | PLEASE ADVISE THE NAME OF THE PRINCIPAL INVESTIGTOR/S; AND CLARIFY IF (S)HE IS (a) TCD Employee; (b) HSE Employee or OR (c) JOINT TCD/HSE Employee: |
| Q5 | PLEASE CLARIFY IF THE PROPOSED STUDY REQUIRES CREC APPROVAL?  IF YES, PLEASE ADVISE IF IT HAS BEEN OBTAINED YET? |
| Q6 | PLEASE CLARIFY IF STUDY IS EITHER :-   1. AN INTERVENTIONAL CLINICAL STUDY INVOLVING AN INVESTIGATION MEDICINAL PRODUCT (“IMP”); 2. AN INTERVENTIONAL CLINICAL STUDY INVOLVING A MEDICAL DEVICE 3. AN INVERVENTIONAL STUDY INVOLVING FOOD, EXERCISE, 4. AN OBSERVATIONAL STUDY ONLY   (*See Appendix 1)* |
| Q7 | PLEASE CLARIFY IF THE PROPOSED STUDY REQUIRES REGULATIONS APPROVAL(eg.HPRA)? (*See Appendix 2*)  IF YES, PLEASE CLARIFY HAS IT BEEN OBTAINED YET? |
| Q8 | PLEASE CLARIFY IF FUNDING FOR THIS STUDY HAS BEEN SECURED?  IF YES, PLEASE ADVISE FUNDING SOURCE? |
| Q9 | PLEASE ANSWER THE FOLLOWING QUESTIONS:  **A. Will there be an external/third party providing (financial, in-kind or other) support for the study? If yes, please:**   * Give a brief description of who they are: * Clarify their role (e.g. providing funding support, free products): * Please clarify which party is writing/designing the protocol: * Please clarify which party will assume the role of clinical trial Sponsor of the clinical study: * Please clarify which party shall have the commercialization rights (if any):   **B. Will any TCD employees be collecting any clinical samples?**  If yes, please specify whom, what will be collected, and where**:**  **C**. **Please clarify if any diagnostic investigations other than bloods will be performed as part of the study? If yes, please specify what, by whom and where:**  **D. Does the study involve pregnant women?**  **E. Does the study involve children under 16 years of age?**  **F. Does the study involve subjects with HIV/Hepatitis/vCJD?**  **G. What is the expected start date of the study and expected duration?**  **H. Please specify if the PI wishes for any named person (e.g. department or project manager) to be copied in on correspondence re this study:**  *Please note studies involving pregnant women, children under 16 and/or study subjects with HIV/Hepatitis/vCJD require the* ***prior*** *approval of TCD’s clinical trial insurers* |
| Q10 | Has this proposal been discussed with (a) Dr Martina Hennessy, Director of TCD’s Clinical Research Facility (CRF-C) and/or (b) TCDs Head of Clinical Sponsorships? |
|  | **PLEASE SIGN AND DATE, AND ATTACH (as applicable) COPY OF**  (a) THE PROTOCOL/STUDY PLAN;  (b) PATIENT INFORMATION SHEET; AND  (c) PATIENT CONSENT FORM  SIGNED: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_DATE:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Please return the completed form to** [**insurance@tcd.ie**](mailto:insurance@tcd.ie) **with a copy to** [**rescon@tcd.ie**](mailto:rescon@tcd.ie)

**APPENDIX 1**



(\* e.g. = Food, Software Devices and others interventions not requiring HPRA approval)

**APPENDIX 2:**

**DECISION TREE TO ESTABLISH A WHETHER A TRIAL IS A “CLINICAL TRIAL” OF AN INVESTIGATIONAL MEDICINAL PRODUCT (IMP)**

This algorithm and notes below will help you answer that question. Please start in column A and follow the instructions. Additional information is provided in the notes above the table. If you have doubts about the answer to any of the questions contact the HPRA.

*1 Cf. Article 1 (2) of Directive 2001/83/EC, as amended.*

*2 Substance is any matter irrespective of origin e.g. human, animal, vegetable or chemical that is being administered to a human being*

*3 This does not include derivatives of human whole blood, human blood cells and human plasma that involves a manufacturing process*

*4 Any ingested product which is not a medicine is regarded as a food. A food is unlikely to be classified as a medicine unless it contains one or more ingredients generally regarded as medicinal and indicative of a medicinal purpose.*

*5 The cosmetic Directive 76/768/EC, as amended harmonises the requirements for cosmetics in the Ec. A “cosmetic product “means any substance or preparation intended for placing in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and mucous membranes of the oral cavity with the view exclusively or principally to cleaning them, perfuming them or protecting them in order to keep them in good condition, change their appearance or correct body odours.*

*6 Efficacy is the concept of demonstrating scientifically whether and to what extent a medicine is capable of diagnosing, preventing or treating a disease and derives from EU pharmaceutical legislation.*

*7Assignment of patients to a treatment group by randomisation planned by a trial protocol cannot be considered as current practice.*

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| A | B | C | D | E |
| **A CLINICAL TRIAL OF AN IMP?** | | | | **A NON-INTERVENTIONAL CLINICAL TRIAL?** |
| Is it a medicinal product (MP)? 1 | Is it not a medicinal product? | What effects of the medicine are you looking for? | Why are you looking for those effects? | How are you looking for those effects? |
| 1. If you answer no to all the questions in column A, the activity is not a clinical trial on a MP.   If you answer yes to any of the questions below go to column B | If you answer yes to the question below in column B the activity is not a clinical trial on a MP  If you answer no to this question below to go column C | If you answer no to all the questions in column C the activity is not a clinical trial under the scope of the Directive 2001/20/EC  If you answer yes to any of the questions below go to column D | **I**f you answer no to all the questions in column D the activity is not a clinical trial under the scope of Directive 2001/20/EC  If you answer yes to any of the questions below go to column E | If you answer yes to all these questions the activity is a non-interventional trial which is outside the scope of Directive 2001/20/EC  If your answers in columns A,B,C & D brought you to column E and you answer no to any of these questions the activity is a clinical trial within the  scope of the Directive |

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| A.1.Is is a substance 2 or combination of substances presented as having properties for treating or preventing disease in human beings?  A.2. Does the substance function as a medicine i.e. can it be administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological , immunological or metabolic action or to making a medical diagnosis or is otherwise administered for a medicinal purpose?  A.3 Is it an active substance in a pharmaceutical form? | B.1. Are you only administering any of the following substances?   * Human whole blood3 * Human blood cells * Human plasma * A food product 4(including dietary supplements) not presented as a medicine * A cosmetic product5 * A medical device | C.1. To discover or verify/compare its clinical effects?  C.2. To discover or verify/compare its pharmacological effects e.g. pharmacodynamics  C.3. To identify or verify/compare its adverse reactions?  C.4. To study or verify/compare its pharmacokinetics, e.g. absorption, distribution, metabolism or excretion? | D.1 To ascertain or verify/compare the efficacy6 of the medicine  D.2 To ascertain or verify/compare the safety of the medicine? | E.1 Is this a study of one or more medicinal products, which have a marketing authorisation in the Member State concerned?  E.2. Are the products prescribed in the usual manner in accordance with the terms of that authorisation?  E.3 Does the assignment of any patient involved in the study to a particular therapeutic strategy fall within the current practice and is not decided in advance by a clinical trial protocol?7  E.4 Is the decision to prescribe a particular medicinal product clearly separated from the decision to include the patient in the study?  E.5. Will no diagnostic or monitoring procedures be applied to the patients included in the study, other than those which are applied in the course of current practice?  E.6 Will epidemiological methods be used for the analysis of the data arising from the study? |