## Regulatory Assessment Questionnaire for Principal Investigators of Human Focussed Research Studies in TCD

*Please note the purpose of this questionnaire is to enable TCD to determine the regulatory approval requirements for a clinical research study. The responses to these questions will be reviewed across multiple departments in TCD so please ensure your responses are comprehensive and provided* ***in lay man’s terms*** *so that they can easily be understood by staff in multiple departments.*

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| Q1 | ARE YOU USING HUMAN PARTICIPANTS IN YOUR RESEARCH STUDY? IF THE ANSWER IS YES PLEASE DESCRIBE THE PARTICIPANT GROUP BEING USED (E.G. PATIENTS, HEALTHY VOLUNTEERS, PREGNANT WOMEN, MINORS, ETC). |
| Q2 | DOES YOUR RESEARCH INVOLVE RANDOMISING PARTICIPANTS TO A PARTICULAR INTERVENTION/TREATMENT USING A RESEARCH PROTOCOL? |
| Q3 | ARE YOU ADMINISTERING ANY TEST SUBSTANCES TO YOUR PARTICIPANTS? TEST SUBSTANCES CAN INCLUDE MEDICINES, SUPPLEMENTS, PLACEBOS, HERBAL PRODUCTS, FOOD PRODUCTS, INVESTIGATIONAL PRODUCTS, ETC. IF YES, PLEASE DESCRIBE. |
| Q4 | ARE YOU ADMINISTERING ANY OTHER TYPES OF INTERVENTION TO YOUR PARTICIPANTS? EXAMPLES OF OTHER TYPES OF INTERVETION INCLUDE PRESCRIBED EXERCISE, HEALTH SERVICE STRATEGIES, DIAGNOSTIC TESTS, HEALTH ADVICE, ETC. IF YES, PLEASE DESCRIBE. |
| Q5 | DOES YOUR RESEARCH INVOLVE USING SUBSTANCES, TESTS OR PROCEDURES OUTSIDE OF THE NORMAL STANDARD OF CARE AVAILABLE TO PARTICIPANTS? PLEASE DESCRIBE. |
| Q6 | ARE YOU USING OR INVESTIGATING ANY DEVICE IN YOUR RESEARCH STUDY AND DOES THE DEVICE HAVE A CE MARK? PLEASE ATTACH THE CERTIFICATE. |
| Q7 | IF THE ANSWER IS “YES” TO Q6 PLEASE CONFIRM IF THE DEVICE IS BEING USED WITHIN THE TERMS OF ITS MARKETING AUTHORISATION (CE MARK). IF THE DEVICE IS BEING USED OUTSIDE OF THE TERMS OF ITS AUTHORISATION PLEASE DESCRIBE HOW IT IS BEING USED. |
| **I confirm to the best of my knowledge that the information provided on this form is complete and accurate.**  SIGNED: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ DATE:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  PRINT NAME: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Principal Investigator | |