A possible structure for a summary page in front of Participant Information Sheets for Human Challenge Studies “key issues” people MUST know)

USE 14 point type: Fit on ONE/MAX TWO pages (if you can)

TITLE of STUDY (recommending use of acronym I.P.O.C. Intervention, Population, Outcome and Comparator)

Invitation and why we are inviting you. [EXPAND AS NECESSARY] “We’d like to invite you to join this study and to help you decide we’ve set aside XXX time for discussion and also provide this Information Sheet.

First we want to highlight key points that we think you must know before making a decision. If you're still interested in joining our study, we'll get into more detail.”

You will get XX infection

What you will need to do [with reasons]

• You must take treatment
• Attend follow up
• Avoid pregnancy ..........

What you mustn’t do

• Give it to others
• ..............

Harms/risks (S/Es) to the participant and others. [EXPAND AS NECESSARY]

Significant, extra interventions (if any) and time commitment (what we will ask you to do)

If you’d like, we can now explain more about the study. After reading the full document and talking it through we feel you should know

• Why we’re doing this study
• What choices you have
• What will happen to you if you join
• A balance of possible benefits and harms if you join
• How we will protect your personal information
• What to do if you have any problems
Where to get more information or make a complaint

SIGNATURE

[You may wish to put a Contents page in index form on the back of this to direct further reading]