**ARMMAN’s Ethics Review Board**

**(LETTER HEAD AND DETAILS)**

**(Form 4)**

**FORM FOR APPLICATION FOR ANNUAL REVIEWS (STAGE 1.1, 1.2 AND SO ON)**

TITLE OF THE STUDY: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. NAME OF THE PRINCIPAL INVESTIGATOR with AFFILIATION:

NAME OF THE CO – PRINCIPAL INVESTIGATOR with AFFILIATION:

 (All ERB correspondence will be sent to the PI and Co-PI)

 IF PI AND / OR CO – PI NOT FROM ARMMAN, CITE REASONS:

DATE OF ERB APPROVAL:

DATE OF START OF STUDY (DATA COLLECTION):

1. SHARE THE STATUS OF YOUR STUDY
2. SHARE YOUR EXPERIENCES AND LEARNINGS (FROM AN ETHICS, SCIENTIFIC AND PRAGMATIC POINT OF VIEW)
3. A. SAMPLE SIZE PLANNED AT THE TIME OF STAGE 1 REVIEW:

B. SAMPLE SIZE AT THE TIME OF PRESENT REVIEW:

C. HAVE ANY PARTICIPANTS WITHDRAWN FROM THE STUDY AFTER INITIAL CONSENT? YES / NO

D. STATE SOME COMMONLY CITED BY REASONS PARTICIPANTS:

E. WHAT IS YOURS AND YOUR TEAMS UNDERSTANDING OF THE REASONS FOR THE WITHDRAWL/S:

 F. DO YOU ANTICIPATE THE REDUCED SAMPLE SIZE TO AFFECT THE STUDY IN ANY WAY? YES / NO

 IF YES, SHARE HOW AND MEASURES TO OVERCOME THE SETBACK:

1. DO YOU ANTICIPATE A DELAY IN COMPLETION OF THE STUDY? YES / NO

IF YES, SHARE WHY AND HOW MUCH DO YOU ANTICIPATE:

1. HAVE THERE BEEN ANY ON - FIELD CHANGES TO THE PROTOCOL INCLUDING IN THE INFORMED CONSENT PROCESS? YES / NO

IF YES, SHARE DETAILS

1. IN CASE OF IMPLEMENTATION RESEARCH / SCALING UP INTERVENTIONS: SHARE SOME OF THE ADAPTATIONS MADE IN THE FIELD AND HOW YOU MANAGED TO STICK TO THE CORE PURPOSE, SCIENTIFICALLY AND ETHICALLY. SHARE YOUR EXPERIENCES.

WHAT ARE THE INDICATIONS TOWARDS SUSTAINABILITY AND SCALIBILITY?

ANY ANCILLARY FINDINGS?

(PLEASE ENSURE THESE ASPECTS ARE COVERED IN THE FINAL END OF PROJECT REPORT)

1. HAVE THERE BEEN ANY CHANGES TO RISK – BENEFIT ANALYSIS SINCE THE LAST REVIEW? YES / NO

IF YES, PLEASE SHARE WHAT HAS CHANGED.

1. WERE ANY ETHICS CONSULTATION MEETINGS HELD DURING THIS TIME (V.1.iv)? SHARE DETAILS.
2. THE SOPs REQUIRE YOU TO SEND IN COMMUNCATION REGARDING ETHICAL ISSUES ARISING IN THE FIELD (V.1.iii). DID YOU HAVE ANY SUCH EXPERIENCE? PLEASE ATTACH RELEVANT COMMUNICATION SHARED WITH THE ERB.
3. IS THERE ANYTHING ELSE YOU MIGHT WANT TO SHARE THAT IS PERTINENT AND / OR RELEVANT TO THE REVIEW AND / OR STUDY?

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of the PI Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Co – PI Date