Handling of submitted

IHPBA Trial Proposals

To reach the goal of the IHPBA Research Committee (RC) - to enhance evidence-based medicine in HPB surgery by facilitating large surgical trials - a defined step-by-step process of handling submitted IHPBA Trial Proposal is mandatory. Herewith, a three step approach to maintain transparency in trial selection and in protocol development is proposed to the members of the RC for further discussion.

Step I – Submission of a Trial Proposal and initial assessment

a) Potential study ideas should be submitted to the IHPBA Trial Head Office by IHPBA members via the IHPBA website using a specific Trial Submission Form.

b) Proposals will be evaluated by members of the IHPBA Trial Head Office on clinical relevance, originality, novelty, and financial feasibility; within three months after initial submission, an evaluation report of methodological and clinical relevance will be circulated to the members of the RC to seek a decision on further proceeding or refusal of the trial proposal.

Step II – Preparation of a Study Synopsis

a) A brief study protocol with synopsis, medical problem, design aspects and justification, eligibility criteria, in- and exclusion criteria and a first sample size calculation, and trial management issues should be prepared by the applicant in coordination and close cooperation with members of the IHPBA Trial Head Office.

b) The study synopsis will be again circulated within the members of the RC for evaluation.

Step III – Selection and preparation of a Study Protocol

a) After receiving a positive vote by the majority of the RC and after potential involvement of external experts to obtain further advice, a complete Study Protocol should be prepared according to “Good Clinical Practice” by the applicant, again with strong support by members of the Trial Head Office and the RC. At this time, also sources of financial support should be elaborated. In cases of a refusal of a Study Synopsis, a distinct and detailed report should be prepared.

b) The final Study Protocol should be approved by the RC and the study should receive an official “IHPBA stamp”. All IHPBA Study Units should be informed and asked for participation to establish a network of recruiting centers. Ethical and legislative processes will be supported by the IHPBA Trial Head Office and potential national study coordinating centers.