

IDS Study Proposal

PROJECT TITLE

Version

[to fill in: initial submission, OR revision and revision number]

Date: ......

Principal Investigator:

e-mail:

Study Coordinator:

e-mail:

Proposed start date:

Proposed end date:

**I. STUDY SYNOPSIS**

(2 pages max)

1. Study Background/Rationale

(state briefly what is known and what is the knowledge gap that the study aims to fill)

...................................

 2. Study hypothesis/research question

..........................................

3. Study Objective/Aim

.............................

## **Measurable Study endpoints** (primary/secondary)

 ...........................................................

4. Study Methodology:

* **Study Design** (please mention which applies: retrospective/prospective, case series/cohort/case-control/ survey/ randomized trial etc., observational/interventional, etc.)
* **Study target population:** ........
	+ Inclusion/exclusion criteria
	+ Aimed sample size

## **Type of data to be collected:**

(E.g. Dermatoscopic images, case reports, biological specimens, answer to survey questions etc.)

## **Methodology of data collection**

(E.g. Online Database (e.g. RedCap), printed CRF with provided template attached, Online questionnaire, patients visits, etc.)

## **Statistical evaluation plan**

(give details on the planned analyses such as specific hypotheses, used tests, and correction for multiple testing if applicable. Please include corresponding power calculation for primary hypothesis. If power calculation is not included, please indicate the reason)

## **II. REQUESTED RESOURCES FROM THE IDS**

(Please state which resources from IDS are requested, with brief justification)

# **III. FUNDING & CONFLICT OF INTEREST**

## 1. Relevant funding sources for the proposed study (if applicable)

2. State all potential COI there are with this study

In particular please state if:

i). The work that is planned during the study has received or is planned to recieve financial support from a pharmaceutical company or any company with other commercial interest in the study

 YES/NO

ii) You or your spouse/life partner has any special financial interest in the subject matter discussed in the study. YES/NO

## 3. Interest in intellectual property rights subject of the study

Note all plans for potential monetization, licensing or patents

## 4. Is an unapproved/off label drug or device being used or evaluated for the study?

 Yes/No

# **IV. ETHICS**

## 1. Central ethics review

When reporting experiments on human subjects, indicate whether the procedures followed are in accordance with the ethical standards of the responsible committee on human experimentation (institutional or regional) and with the Helsinki Declaration of 1975, as revised in 1983.

Please state the respective Ethics Committee or Institutional Review Board approval

## 2. Informed Consent Form

Indicate if Patients Informed Consent is required for the study, based on recommendation from the corresponding Central Ethic Committee/Institutional Ethics Review Board.

## 3. Ethics and Data security considerations

Note any potential ethical issues of the study. Please lay out how data will be secured, processed and transferred, especially in regard to data protection regulations.

# **V. AUTHORSHIP AND COMPENSATION**

## 1. Criteria for co-authorship

E.g. providing at least 10 cases

## 2. Criteria for acknowledged contribution

E.g. completing one survey

## 3. Other compensations planned

Any potential financial or other material compensations for participants or patients

**VI PRINCIPAL INVESTIGATOR**

Please include a short CV of the principal investigator- max 2 pages. Include most relevant previous research projects conducted, and up to 5 publications relevant for the topic of the study.