

Study Proposal

TITLE

Version

Date: 2022-02-08

Principal Investigator:

e-mail:

Study Coordinator:

e-mail:

Proposed start date:

Proposed end date:

# Conflict of interest

## Funding Sources

Note all current, planned or potential funding sources

## Financial or personal interest related to the proposed study

Note all current, planned or potential funding sources

## Interest in intellectual property rights subject of the study

Note all plans for potential monetization, licensing or patents

## Is a drug, device or other investigational product being used or evaluated?

Yes/No

# Study design

## Study type

Please concisely describe the study type: e.,g. Case registry, Retrospective Cohort, Retrospective Case-Series, Prospective Case-Control, Intervention Trial.

## Checklist

If any included, e.g. STROBE, please specify

## Study Outline

Please extensively describe the plans for the study. Topics may include:

* Rationale
* Study design
* Study population (with specific inclusion and exclusion criteria)
* Primary and secondary hypotheses

## Recorded data

E.g. Dermatoscopic images, annotations, surveys, biological specimens, etc.

## Methodology of data collection

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

## Statistical evaluation plan

Note 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.

# Ethics

## Central ethics review already in place?

Please note the respective institutional review board. Studies without a central ethics review will only be accepted for special reasons upon request.

## Informed Consent Form

Written / Waived / Other. Based on recommendation from corresponding Central Ethic Committee/Institutional Review Board.

## Ethics and Data security considerations

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

# Authorship and compensation

## Criteria for co-authorship

E.g. providing at least 10 cases

## Criteria for named contribution

E.g. completing one survey

## Other compensations planned

Any potential financial compensations for participants or patients

## Accessibility of results

Please note how you will make your results available to the community and the IDS, and whether you plan to publish in an Open-Access journal.

## Data availability after publication

Please lay out if and how data will be available for other research groups after conclusion of the study

# Resources

## Requested resources from the IDS

Please note which resources, like the mailing list, or linking from the IDS Website are needed, and why.