

Implementation – Required Participant Questions

Purpose

This document defines the minimum required participant-facing questions for implementation, strictly aligned with the locked study protocol (15 clinical conditions × 3 imaging stages). The study is non-diagnostic and appearance-based, focused on agreement between application and physician determinations.

Study Context

- Observational, non-diagnostic study
- 15 visible facial conditions
- 3 imaging stages per condition
- 45 determinations per rater (App + Doctors)
- Participant questions are limited to scan validity and assessability only

Required Questions (Mandatory)

1. Product / Makeup Use

Have you applied any makeup or facial products today?

Options:

- No products applied
- Skincare only (cleanser / moisturizer)
- Treatment products (serums, actives)
- Makeup (foundation, concealer, etc.)

Rule: If makeup is selected, the scan should be excluded or rescheduled.

2. Recent Appearance-Altering Activity

In the last 2 hours, have you done anything that could temporarily change your facial appearance (exercise, sun exposure, crying, facial massage, hot/cold exposure)?

Options: Yes / No

Use: Metadata only. Not shown to doctors. Not used for diagnosis.

3. Lighting Condition Confirmation

What best describes the lighting during photo capture?

Options:

- Bright, even natural light
- Indoor artificial light
- Mixed lighting
- Poor or uneven lighting

4. Scan Compliance Confirmation

Are you currently wearing no makeup and following all scan instructions?

Options: Yes / No

Rule: If No, block submission.

Questions Explicitly Not Required

The following should not be implemented unless study scope changes:

- Sleep quality questions
- Hydration / water intake questions
- Skin concern or wellness checklists
- Free-text comments

Important Clarification

Participants do not answer 45 questions. The 45 determinations are generated by the application and physician reviewers during evaluation. Participant inputs exist only to ensure clean, assessable scans.

Status

This question set is locked for implementation and is defensible for IRB/IEC review. Downstream CRFs and reviewer manuals will be derived from the study protocol.