Prospero Scoping Review Registration Form

1. **Review title.**
Electronic consent in clinical care: An international scoping review

2. **Original language title**
English

3. **Anticipated or actual start date**
December 15, 2021

4. **Anticipated completion date**
December 15, 2022

5. **Stage of review at time of this submission**
The review has not yet started: Yes

6. **Named contact**
Kemi Gaffney

7. **Named contact email**
Gaffneyk@mskcc.org

8. **Named contact address**

9. **Named contact phone number**
917-327-0412

10. **Organizational affiliation of the review**
MSKCC

11. **Review team members and their organizational affiliations**
Gilad Kuperman, Allison Lipitz-Snyderman, Kemi Gaffney, Susan Chimonas – all MSKCC

12. **Funding sources/sponsors**
This research was funded in part through the NIH/NCI Cancer Center Support Grant.
Grant number(s) P30 CA008748

13. **Conflicts of interest**
None

14. **Collaborators**
n/a
15. **Review question**

What does the research literature say about electronic informed consent for clinical purposes? Specific items of interest include but are not limited to: How is e-consent defined? What are the opportunities and challenges around implementation? What are the outcomes (potential or actual risks, harms, benefits, etc.) for patients, providers, and institutions? What technologies are used to support e-consent?

16. **Searches**

Search databases include PubMed, Scopus, and Embase. Grey literature searching will be done on Google. Searches will be open internationally, provided an English-language translation is available. The publication period has an open-ended start and an end date of 12/31/2021.

17. **URL to search strategy**

TBD

18. **Condition or domain being studied**

The use of electronic consent forms for clinical consent documentation.

19. **Participants/population**

Healthcare institutions, clinicians, administrators, patients. General healthcare as well as oncology-specific.

20. **Intervention(s), exposure(s)**

Use of electronic consent forms in addition to, or in place of, paper-based consent forms in clinical settings (remote or in-person)

21. **Comparator(s)/control**

Paper-based consent processes

22. **Types of study to be included**

**Inclusion criteria:**

We will include qualitative and quantitative experimental and observational studies, including surveys, interviews, case reports, commentaries, research reports and letters, and conference proceedings. We will also include reports by journalists, policymakers, and other investigators publishing in the grey literature. All included studies must investigate clinical e-consent, including for administrative or health information exchange purposes. Abstracts and/or full text must be available.

**Exclusion criteria:**

We will not include opinion pieces/letters or editorials.

23. **Context**

Healthcare
24. **Main outcome(s)**

Adoption/implementation of econsent; Benefits or harms of econsent (to care quality, satisfaction, legal/compliance issues, etc.); feasibility measures; challenges and facilitators (e.g. failure rates, implementation obstacles and/or strategies)

25. **Additional outcome(s)**

Settings (large academic institution, outpatient clinics, community clinics, private practices, etc); disease areas; medical vs. Surgical; clinical procedures vs. Information requests vs. other applications; technical approaches/solutions

26. **Data extraction (selection and coding)**

Title screening independently by two researchers. All studies identified for further review by either researcher move on to abstract and full text review. Studies selected for review will be considered for inclusion based on stated eligibility criteria, jointly by two researchers. Any disagreements will be resolved through consensus, with a third researcher participating as needed.

Data to be extracted: Implementation challenges/experiences (feasibility, etc.); Adoption measures; Quality; Equity; Safety (correct procedure, patient, etc), timeliness of treatment (delay in first procedure), effectiveness of care, efficiency/burden, knowledge/understanding, perceptions of shared decision making; legal/ethical/compliance issues; technology types; publication date; type of publication; authors, journal/source, geography; setting, disease area, type of consent applications; type of procedure/use; oncology vs. Other; funding source

27. **Risk of bias (quality) assessment**

Not applicable for scoping reviews

28. **Strategy for data synthesis**

We will perform a qualitative synthesis of all included studies.

29. **Analysis of subgroups or subsets**

Oncology uses/applications/settings

30. **Type and method of review**

Scoping review

31. **Language**

English (including translations)

32. **Country**

International scoping review

33. **Other registration details**

n/a
34. **Reference and/or URL for published protocol**
No - We do not make this file publicly available until the review is complete

35. **Dissemination plans**
We aim to create a manuscript for publication from the results of this review.

Do you intend to publish the review on completion? Yes

36. **Keywords**
Electronic consent; e-consent; econsent; clinical e-consent; virtual consent; remote consent; telemedicine consent; telehealth consent; health information exchange e-consent; procedural e-consent

37. **Details of any existing review of the same topic by the same authors**
none

38. **Current review status**
Not yet begun

39. **Any additional information**
n/a

40. **Details of final report/publication(s)**
n/a