External Assessment Centre Project Specification Form	
Project Number	MT205
Evaluation title	The ReCell Spray-On Skin system for treating skin loss, scarring and depigmentation after burn injury
Synopsis of the technical issue	At its meeting on 21 November 2013, having considered the information in the sponsor's submission, assessment report and assessment report overview, and having received advice from two clinical experts, the Medical Technologies Advisory Committee requested further information before making provisional recommendations for the ReCell Spray-On Skin System. The Committee was disappointed with the lack of economic modelling for patients with full thickness or deep partial thickness burns. It heard from clinical experts that the largest potential value of the ReCell Spray-On Skin System could be for use with wide mesh skin grafting to treat full thickness or deep partial thickness burns. The Committee requested that an economic model for these burns be developed to aid their decision-making in developing recommendations on this technology. The Committee recognised that published data to produce a cost model for patients with full thickness or deep partial thickness burns, which require grafting, are not available. It considered that model parameters could be based on expert opinion similar to the approach used for the sponsor submitted partial thickness burns model but it recommended that a broad range of suitable experts working in the NHS are used. The Committee noted that it is possible that some relevant centre-based audit data may be identified if more experts are contacted The Committee also questioned some of the parameters in the economic model

	for the partial thickness burns patient population, particularly those parameters (length of in-patient stay, time to epithelialisation and requirement for a skin graft) which were based on limited clinical opinion. It requested that broader clinical opinion and any additional data available be collected to confirm that the values for the model parameters were appropriate. The Committee also considered the potential impact of the use on ReCell on improving skin colour match in burns scars. The Committee noted a difference of opinion from the experts about the generalisability of the existing evidence in patients with hypopigmented scars and vitiligo lesions to burns patients. The Committee was aware that the skin colour match in scars is an important patient outcome and agreed that it would like further information from a broad range of experts about this issue.
Objectives for EAC of additional work package	**1. Identification of group of experts to contribute to additional work** • To determine the best method of contacting a wider selection of experts to inform the additional work. These experts should be ratified by their specialist societies using NICE's published processes (Process Guide, section 3.7.2) • To identify and seek agreement to participate from, an appropriate group of experts to provide information for the additional work on the ReCell Spray-on skin evaluation. **2. Economic model for full thickness or deep partial thickness burns which require grafting**

	• To use a suitable process to collect information from experts to populate the economic model. The topic lead team (NICE technical adviser, Committee member, Expert Advisers) should be involved in the development of questions for this process. If possible the uncertainty associated with expert judgments should be characterized so this can be reflected in the economic model. • To collect the information from the identified group of experts. This may involve a questionnaire and follow-up telephone interviews with some experts. • To identify any additional data from local audits or national databases (such as http://www.ibidb.org/) that could be used to inform the model parameters. • To carry out an economic analysis of the cost impact of the ReCell Spray-On Skin System for treating burns which require grafting. This should be considered as two subgroups: a. Large area burns which are judged to need wide mesh grafting These large area burns are likely to involve multiple rounds of surgery and grafting, with ITU or HDU care and with multiple organ support. Such burns are often life-threatening and survival depends

	on wound closure. ◊ Population: Patients with large area full thickness or deep partial thickness burns where wide mesh grafting is needed. ◊ Intervention: Skin mesh graft in combination with ReCell Spray-on skin and possible use of ReCell Spray-on skin at donor site. ◊ Comparator: Skin mesh graft and current donor site treatment ◊ Consider use of cultured cells with skin mesh graft if available. b. <u>Full thickness or deep partial thickness burns which are judged to need skin grafting</u> These burns are anticipated to only require 1 round of surgery and patients would be cared for on a general ward with no organ support. These burns are generally not life threatening. ◊ Population: Patients with full thickness or deep partial thickness burns where grafting is needed. ◊ Intervention: ReCell Spray-on skin alone ReCell Spray-on skin plus skin graft ◊ Comparator: Skin graft alone The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. **3. Hypopigmentation and use of ReCell Spray-on skin**

	• Define questions about use of ReCell Spray-on skin to improve skin colour match in scars. The experts from the lead team should be involved in the development of questions. • Collect information from experts group and analyse responses. • Review any relevant evidence including any patient reported outcomes on the acceptability of scar appearance. **4. Parameters in sponsor's economic model for patients with partial thickness burns (with any revisions made by the EAC described in the assessment report)** • To confirm using expert advice or any relevant data whether the model parameters (length of in-patient stay, time to epithelialisation and requirement for a skin graft) have been accurately estimated in the sponsor's submission. • If more appropriate values are identified the model should be updated and re-run.

External Assessment Centre Project Administration Form	
Project Number	MT205

EAC Project Leader(s)	Sue Peirce and Grace Carolan-Rees
Date form sent to EAC	16th December 2013
NICE contacts • Associate Director • Technical Lead • Technical Adviser • Project manager	 Mark Campbell Caroline Hall Bernice Dillon Phil Pugh
Timelines:	
• Start date	17th December 2013
• Date for delivery of draft report	To be arranged
• Date for delivery of report to Institute	3rd March 2014 The EAC's report will be presented to the Committee without any editing or summarising by NICE and so should be prepared with that in mind, and with appropriate cross-referencing to the submission, AR and ARO. The project objectives should be included as an Appendix.
• Date of Committee meeting for presentation of report	20th March 2014
• Arrangments for EAC/NICE liaison	By regular teleconference, initially weekly