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Project Acronym: HappyMums

Project title:

Understanding, predicting, and treating depression in pregnancy to improve mothers and offspring mental health outcomes.

***D1.4 Establishment of the Scientific, Ethical, and
Social Advisory Board***

Research and Innovation Action

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Executive Summary

The *HappyMums* Scientific, Ethical and Social Advisory Board (SESAB) is a consultative body which is formed to ensure and improve the scientific performance, the quality of results of *HappyMums* and to receive feedback about main issues and difficulties of pregnant women with depression during pregnancy. The members of the SESAB will be invited to the annual Consortium meetings in order to monitor the progress of work, to assess the scientific quality and to give feedback to the consortium members, but without a right to vote as opposed to the General Assembly members. The SESAB will also consider and revise any ethical issues or social feedback encountered within the project and reported in each Periodic Report (PR) and support which might require (more) attention in their feedback.

At the moment, the HappyMums project is made up of:

- **Prof. Andreas Reif**, University Hospital Frankfurt, Department of Psychiatry, Psychosomatic Medicine and Psychotherapy
- **Prof. Elisabeth Binder**, Max Planck Institute of Psychiatry, Department of Translational Research
- **Prof. Brenda Penninx**, VU Amsterdam University Medical Center, Department of Psychiatry
- **Prof. Tracy Bale**, University of Maryland, School of Medicine and the Center for Epigenetic Research in Child Health and Brain Development



Acronyms

Abbreviation	Full term
CA	Consortium Agreement
EU	European Union
ECNP	European College of Neuropsychopharmacology
GA	General Assembly
PR	Project Reporting
RIA	Research and Innovation Action
SESAB	Scientific, Ethical and Social Advisory Board
TC	Teleconference
WP	Work Package
WPL	Work package Leader



1. Introduction

The purpose of this deliverable is to describe the *HappyMums* Scientific, Ethical and Social Advisory Board (SESAB) which comprises international experts from different disciplines in the field of mental health and has the aim to provide input about the methods and processes by which the *HappyMums* project is carried out. This input will be used to strengthen the relevance, quality, and attention to ethical considerations of the research carried out within *HappyMums*.

2. The *HappyMums* SESAB

The *HappyMums* SESAB is made up of international experts in field related to perinatal mental health who are not part of the *HappyMums* Consortium and do not work for any of the grant Beneficiaries or Associated Partners, to avoid conflict of interest. Being external to the Consortium, they will take part annually to the Consortium Meetings but will not have the right to vote regarding the decisions to be taken for the project.

SESAB members will critically evaluate project proceedings, give feedback to all the analyses carried out in the different Work Packages (WPs) and will help contextualize results by interpreting them in a meaningful way to other mothers, mother to be, families and stakeholder groups, thus provide an external review of project findings.

Besides that, the SESAB will provide direct contact with several associations, clusters and organisations that can provide further information on perinatal mental health that would be relevant to take into consideration in the project execution. The SESAB will also support outreach activities and promotes the use of the *HappyMums* platform, developed during the project, among its members and network contacts. It will also help the *HappyMums* Consortium promote the engagement activities by disseminating information on events and communication activities. For example, many members of the SESAB are members of leading national and international organizations, such as the European College of Neuropsychopharmacology, ECNP. The ECNP is an independent scientific association whose mission is to advance the science of the brain, promote better treatment and enhance brain health. The annual ECNP Congress attracts some 5,000 scientists and clinicians from across the world to discuss the latest advances in brain research in Europe's largest meeting on brain science. One of the *HappyMums* workshops planned in WP9 (Dissemination & Impact to Society) will be probably organized as satellite event at the annual ECNP Congress. Moreover, it is particularly useful to collaborate with organisations like ECNP to identify which social and clinical need are still unmet, and if there are potential new issues to be addressed or novelties to be taken into consideration in neuroscientific research.

In addition, the *HappyMums* Consortium will also liaise with the members of the SESAB to identify common interests in innovative research areas or common initiatives (such as joint projects or scientific symposia).

2.1 Recruitment and Composition

The selection process of SESAB members was done in 4 steps:

1. Discussion about the ideal composition of the SESAB with respect to its mission during the *HappyMums* Kick off Meeting held in Milan January 12-13, 2023.



2. Shortlisting of candidates to be contacted. On top of the personal biography and insights related to their know-how, we added some meta information on the person and his/her organization to be able to select an integrated SESAB;
3. Initial contacts of the Project Coordinator (PC) with candidates by mail explaining the role and the conditions of participation to the SESAB;
4. Final Approval of possible candidates in the Consortium meeting held in Milan, June 27-29. 2023.

3. Members of the SESAB

For the time being, the *HappyMums* SESAB is made up of 4 members:

The Members of the HappyMums SESAB

NAME	AFFILIATION
Andreas Reif	University Hospital Frankfurt, Department of Psychiatry, Psychosomatic Medicine and Psychotherapy
Elisabeth Binder	Max Planck Institute of Psychiatry, Department of Translational Research
Brenda Pennix	VU Amsterdam University Medical Center, Department of Psychiatry
Tracy Bale	University of Maryland, School of Medicine and the Center for Epigenetic Research in Child Health and Brain Development

Below, a brief description of each members CV and a brief description of their contribution to *HappyMum*.



PROF. ANDREAS REIF, MD

Head of the Department of Psychiatry, Psychosomatic Medicine and Psychotherapy at the University Hospital, Frankfurt.

Andreas Reif studied Medicine from 1993 to 2000 at the University of Würzburg. Having decided that he wanted to work in the field of clinical neuroscience, he obtained his doctorate at the Department of Pharmacology (Supervisor: Prof. Dr. H.H.H.W. Schmidt), working on the catalytic mechanism of nitric oxide synthase type I (NOS1). He subsequently specialized in psychiatry, where - from early on - he complemented clinical work with research projects. During his clinical education at the Department of Psychiatry, University of Würzburg, he joined the research group of Prof. Klaus-Peter Lesch, where he initially focused on the genetic underpinnings of emotions and studied those in animal models. From 2003 onwards, he shifted his focus to adult ADHD, which is still one of his major areas of interest and expertise. In the last 15 years, he has intensively studied the neurobiological basis of this disorder. In doing so, he became a member of a tight network of researchers from many parts of the world, collaborating in the IMpACT consortium and the ECNP Network ADHD across the Lifespan, both of which he co-founded. His second phenotype of interest are mood and anxiety disorders - especially bipolar disorder, depression, and panic disorders. During his work at the University of Würzburg, he got promoted several times up to the level of Vice Chair. In 2014, he moved to Frankfurt am Main, where he took over the Chair position of the Department of Psychiatry, Psychosomatic Medicine and Psychotherapy and established sections on Translational and Experimental Psychiatry. He serves in important positions on the boards of several societies, the most important ones being the DGPPN (German Association for Psychiatry, Psychotherapy and Psychosomatics) and the ENCP for which is s President-elect of the 2022-2025 Executive Committee. He currently coordinates the EU-funded CoCA consortium and is a work package leader in several additional EU-funded consortia. Andreas Reif has published more than 350 papers with a cumulative impact factor > 2.000 and amounting to an h factor of 61.

In *HappyMums*, he will provide clinical expertise regarding mood and anxiety disorders, especially depression for the analyses carried out in WP3 (Multimodal biomarkers for depressive symptoms in pregnancy). Moreover, as a clinician, he will test the *HappyMums* Clinical Dashboard in terms of manageability, user friendliness, content and use of information, etc. His feedback, together with that of other clinicians will be fed into all WP5 (Platform development & Implementation for depression in pregnancy) work and into the improvement of the final Clinical Dashboard.



PROF. DR. ELISABETH BINDER, MD

Director of the Department of Translational Research of the Max Planck Institute of Psychiatry, Munich.

Elisabeth Binder is the Director of the Dept. for Translational Research at the Max Planck Institute of Psychiatry and Full Professor in the Department of Psychiatry and Behavioral Sciences at Emory University School of Medicine (secondary appointment). Elisabeth Binder has studied Medicine at the University of Vienna, Austria and Neuroscience at Emory University in Atlanta, GA, USA. Her main research interests are the identification of molecular moderators of the response to environmental factors, with a focus on early trauma and gene x environment interactions. She studies how such factors influence trajectories to psychiatric disease or well-being to ultimately use this information for novel prevention and treatment strategies.

She has received a number of awards and honors for my research, including the Theodore Reich award of the International Society of Psychiatric Genetics and the Max Hamilton award of the Collegium Internationale Neuropsychopharmacologicum and the Eva King Killiam Research Award for outstanding Translational Research in Neuropsychopharmacology by the American College of Neuropsychopharmacology. She is member of the German National Research Association, the Leopoldina and has received the Carus Medal of this society. Among other functions, she is Executive Committee Member of the ECNP and Advisory Board Member of the Child & Brain Development Program of the Canadian Institute for Advanced Research. She has authored or co-authored over 220 journal articles in the areas of biological psychiatry, psychiatric genetics and epigenetics. Her work is highly cited and she has a Hirsch factor of 65 (Thompson Reuter).

In *HappyMums*, she will provide clinical expertise in WP4 (Biological mediators & environmental moderators of offspring risk and resilience), regarding the identification of mechanisms by which genetic variants and environmental exposure interact to influence stress reactivity and, through these, the risk for negative outcomes development Moreover, due to her expertise on preclinical models, she will also provide feedback in WP6 (Mechanistic Studies in rodents & fish models).



PROF. DR. BRENDA PENNINX, MD

Professor at the Department of Psychiatry, VU University Medical Center, Amsterdam

Brenda W.J.H. Penninx is professor at the department of psychiatry, Amsterdam UMC/VUmc. She is member of the Management Team of the department (research portfolio) and member of the Management Team of Amsterdam Neuroscience.

She studied Health Sciences at the Catholic University of Nijmegen and obtained her PhD in Epidemiology at the VU University in 1996. Afterwards she worked in the USA for several years as Visiting Fellow and Visiting Scientist at the US National Institutes of Health in Bethesda, MD, and as Assistant/Associate Professor at Wake Forest University in North Carolina. In 2004 she returned to the VU University Medical Center in Amsterdam to become the principal investigator of the NESDA study, the Netherlands Study of Depression and Anxiety.

In addition to her leading the NESDA study, she has been involved in several other Dutch and international cohort and intervention studies over the last 20 years. Central themes in her research are understanding psychosocial, environmental, somatic, genetic and neurobiological risk factors and consequences of depression and anxiety disorders and how to intervene on these to improve mental health. Penninx participates e.g. in the EU-funded PRISM, RESPOND, EarlyCause and To_Aition projects. She is also part of the national OPERA project which focuses on the treatment response antidepressants and the efficacy of antidepressant discontinuation.

In *HappyMums*, she will provide clinical expertise regarding the identification of factors associated with response to interventions in pregnancy in WP7 (Preventive strategies: underlying mechanisms & biomarkers). Moreover, as a clinician, she will test the *HappyMums* Clinical Dashboard in terms of manageability, user friendliness, content and use of information, etc. Her feedback, together with that of other clinicians will be fed into all WP5 (Platform development & Implementation for depression in pregnancy) work and into the improvement of the final Clinical Dashboard.



PROF. TRACY L. BALE, PHD

Director at the Center for Epigenetic Research in Child Health and Brain Development, Baltimore

Dr. Tracy Bale is a Professor of Pharmacology at the University of Maryland School of Medicine and Director of the Center for Epigenetic Research in Child Health and Brain Development (CERCH). She obtained her Ph.D. in Neurobiology from the University of Washington, and completed her postdoctoral training with Dr. Wylie Vale and the Salk Institute. Prior to joining UM SOM, Dr. Bale was a Professor of Neuroscience at the University of Pennsylvania, where she also co-directed the Penn Center for the Study of Sex and Gender in Behavioral Health and was the Director of Research for the BIRCWH Faculty Scholars.

Dr. Bale is respected for her research on stress as a risk factor for neurodevelopmental disorders and neuropsychiatric disease. She has been the recipient of several awards including the career development award for early career achievement and promise by the Society for Neuroscience, the Richard E. Weitzman Memorial award as exceptionally promising investigator award by the Endocrine Society, the Medtronic Award from the Society for Women's Health Research for outstanding research that has led to the improvement of women's health, and most recently, the Daniel H. Efron Research Award from the American College of Neuropsychopharmacology.

Dr. Bale's lab has developed mouse models to study vulnerability to stress dysregulation, assessing sex-specificity, developmental timing, and epigenetic mechanisms involved in programming of the brain, placenta, and sperm in response to stress. Her research has provided novel insight into the increased neurodevelopmental risk to males following prenatal insults, such as maternal stress, and the role of placental sex (XX vs. XY) in buffering effects of gestational insult. Her lab identified O-GlcNAc transferase (OGT) expression in the placenta as critical in providing protection to female offspring. Her lab is also making important discoveries linking paternal stress experience to offspring dysregulation through novel epigenetic markers in the sperm.

In *HappyMums*, she will provide feedback regarding the animal experiments in WP6 (Mechanistic Studies in rodents & fish models) and WP7 (Preventive strategies: underlying mechanisms & biomarkers) aimed: to identify the pathological factors and molecular mechanisms that underlie maternal depression and its effects on the offspring and the



causative role of the placenta in mediating the effects (WP6) and to test the impact of pharmacological or non-pharmacological interventions on depressive-like abnormalities in pregnant dams and mal-adaptions in the offspring in (WP7).

4. Conclusions

The next action will be to organize a TC between *HappyMums* Work Package Leaders (WPLs) and SESAB members to inform the SESAB more deeply about *HappyMums*, its mission and objectives, and to refine the mission of the SESAB members and its modus operandi.

The composition of the SESAB might be updated whenever necessary if new areas emerge where external input is needed or if replacement is requested.

As for its set -up, any modification/addition to the SESAB will be discussed within the *HappyMums* Consortium during in-person meetings or, if impossible, during TCs.